Proposed regulatory framework for unpasteurised milk products

NZFSA Public Discussion Paper No 02/09

May 2009

ISBN number 978-0-478-32274-3 (Print)
ISBN number 978-0-478-32275-0 (Online)

ISSN number 1174-961X (Print)
ISSN number 1177-7478 (Online)

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1 Executive summary

This discussion paper provides details of a regulatory framework, being proposed by the New Zealand Food Safety Authority (NZFSA), which would further facilitate the New Zealand manufacture, domestic sale, and export of unpasteurised milk products for human consumption, and the importation of a similar range of such products.

This is the second discussion paper that NZFSA has released on unpasteurised milk products. An earlier discussion paper was released in August 2008 and can be viewed at: http://www.nzfsa.govt.nz/dairy/publications/consultation/discussion-raw-milk/discussion-doc/discussion-document-on-raw-milk-products-final-aug-2008.pdf.

Currently, only a small variety of unpasteurised milk products are available in New Zealand. These products consist of a few cheese varieties imported into New Zealand under the Food (Milk and Milk Products Processing) Standard 2007, and limited farm gate sales of liquid raw milk permitted under section 11A of the Food Act 1981 (the Food Act).

Otherwise, all New Zealand dairy products are made from pasteurised milk, except for some cheeses that are subjected to alternative treatments to pasteurisation during manufacture. These alternative treatments have been approved by NZFSA and combine processing and product compositional factors which contribute to pathogen death and result in processes with an equivalent food safety outcome to pasteurisation.

New Zealand processors of dairy products are able to apply to NZFSA to manufacture unpasteurised milk products under a risk management programme (RMP) under the Animal Products Act 1999 (APA) or a food safety programme (FSP) under the Food Act. However, until now, no technical criteria or guidance material for operators have been developed to assist with the development, evaluation, assessment for registration or approval, and verification or auditing of such programmes. Emphasis has instead been given to facilitating production of, and trade in, pasteurised milk products.

In recent years NZFSA has received requests that it should both permit a wider range of unpasteurised milk products to be imported into New Zealand, and develop the technical criteria and guidance material that would enable the local manufacture, sale and export of a similar range of such products. These requests have come from consumers, the food and retail trade, local manufacturers, importers, and overseas trading partners. In part, they reflect the fact that unpasteurised milk products are already produced and consumed safely in many other parts of the world. The international food safety standard setting agency, the Codex Alimentarius Commission, provides for the manufacture of such products in its *Code of Hygienic Practice for Milk and Milk Products* and Australian authorities are

also considering making changes to allow more unpasteurised milk products on to the Australian market.

In response to these developments, NZFSA is proposing the introduction of a regulatory framework that covers all unpasteurised milk products, and would allow those that can be produced to an acceptable level of safety (that is, that pose a low level of risk to the general population) to be produced, sold, exported and imported.

The framework acknowledges that unpasteurised milk products pose varying levels of hazards to human health. There is potential for pathogens present in raw milk (such as *Listeria monocytogenes*, *Campylobacter spp.* and *Escherichia coli*) to multiply in some unpasteurised milk products to levels in excess of acceptable food safety criteria. However, many other unpasteurised milk products have intrinsic compositional characteristics and/or undergo processing steps which ensure that pathogens are either eliminated from the end products, or are unable to multiply to levels in excess of food safety criteria.

The framework proposed by NZFSA, and outlined in this discussion paper, consists of:

- processes to group unpasteurised milk products according to the hazards they pose;
- requirements relating to on-farm and processing techniques, with which producers of some unpasteurised milk products would need to comply;
- proposed new specifications, to be issued under the APA, that would apply to some unpasteurised milk products;
- revised import standards relating to unpasteurised milk products;
- risk communications and educative material targeted at vulnerable consumers; and
- labelling to indicate products contain unpasteurised milk.

This discussion paper also provides information about the research and risk profiling that NZFSA has undertaken or commissioned to inform the development of the proposed framework, and provides an overview of the risks associated with unpasteurised milk products.

NZFSA is responsible for administering the APA and Food Act, and would implement the proposed new framework for unpasteurised milk and raw milk products. NZFSA would develop guidance materials to familiarise industry operators, importers, third party agencies and other interested parties with the relevant technical and legal requirements for manufacturing and importing unpasteurised milk products. NZFSA would also run information and training workshops about these requirements.

NZFSA's risk communications strategy would evolve to include resources to educate consumers about unpasteurised milk products.

A second round of public consultation on the framework will be initiated by the release of this discussion paper. During the consultation period for this paper, NZFSA will host workshops in regional centres to familiarise stakeholders with the proposal and to seek feedback. Submissions on the discussion paper are invited from all interested parties.

Dependent on the results of consultation and decisions by government, the proposed regulatory framework could be introduced in the latter part of 2009.

2 Introduction

This discussion paper provides details of a proposed regulatory framework that would facilitate the New Zealand manufacture, domestic sale, and export of unpasteurised milk products for human consumption, and the importation of a similar range of such products.

This is the second public discussion paper which the New Zealand Food Safety Authority (NZFSA) has released on unpasteurised milk products. An earlier discussion paper, *Proposed framework for the manufacture, importation and sale of raw milk products*: NZFSA Public Discussion Paper No 04/08 (referred to below as 'the first discussion paper'), was released in August 2008. In releasing this first discussion paper, NZFSA had the objective of gauging public reaction towards a proposal that a wider range of unpasteurised milk products should be made available in New Zealand. The first discussion paper also provided an analysis of various options relating to the future availability of such products in New Zealand, and supplied preliminary details about how a New Zealand regulatory framework for such products might operate.

The great majority of persons who made a submission on the first discussion paper supported a wider range of unpasteurised milk products being made available in New Zealand. As a result, NZFSA has subsequently continued to develop the framework which would facilitate this objective, and the results are outlined in this paper.

Matters covered by this second NZFSA discussion paper on unpasteurised milk products include:

- defining unpasteurised milk products for New Zealand regulatory purposes;
- the results of the research and risk profiling that NZFSA has undertaken or commissioned relating to the proposed regulatory framework;
- requirements, relating both to on-farm practices and processing techniques, that would need to be satisfied by producers of those unpasteurised milk products that would be able to be sold under the proposed regulatory framework;
- how imported unpasteurised milk products will fit into the regulatory framework;
- the legal instruments that would be needed to enact the regulatory framework; and
- information about how the regulatory framework would be implemented, also proposals for a risk communications programme for consumers, labelling of products, and training and familiarisation for industry.

The first discussion document described what is meant by 'raw milk products' for the purposes of outlining the scope of the proposed framework, i.e. raw milk products were defined as including all milk products, except those produced from milk that has been pasteurised or thermised. The consumer market research survey commissioned by NZFSA (see section 4.7 for an outline of the survey and summary of results) identified 'unpasteurised' as a term that is more familiar to New Zealand consumers. As a result, the proposed regulatory framework has been described as it applies to unpasteurised milk products.

NZFSA has now developed a proposed New Zealand legal definition for a raw milk product (refer to the draft specifications in Appendix 1 for this definition). This definition better defines which products will need to be produced subject to regulatory measures which are being proposed in addition to current regulatory measures. NZFSA proposes that a raw milk product will be legally defined as a product made from milk which has not been pasteurised or made using an equivalent process to pasteurisation. Raw milk products, would therefore, form a defined sub group of unpasteurised milk products. The proposed regulatory framework and terminology is explained further in section 6.

Both this paper and the first discussion paper released in August 2008 are designed to be stand-alone and read independently. However, readers may find it helpful to consult the first discussion paper for background information. The first discussion paper can be accessed on the NZFSA web site at:

http://www.nzfsa.govt.nz/dairy/publications/consultation/discussion-raw-milk/discussion-doc/index.htm.

3 Submissions

NZFSA seeks submissions on any aspect of this discussion paper from all interested parties, including consumers, industry, importers, trading partners, and public health specialists.

3.1 Requirements for submissions on this paper

Submissions are invited from any interested person, whether representing an organisation or acting as an individual. When sent on behalf of an organisation, the submission should indicate the position in the organisation of the person signing the submission and the extent of internal consultation undertaken in preparing the submission. All submission formats will be accepted, but the following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section of the paper. All major sections are numbered and these numbers should be used to link comments to the paper.
- Comments should be to the point and, where possible, supporting reasons and data are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.
- Please include the following information in your submissions:
    - the title of the discussion paper
    - your name and title (if applicable)
    - your organisation's name (if applicable); and
    - your address.

A suggested guide to the format of submissions is provided in Section 11, but submitters are welcome to comment on any additional matter relating to the proposal.

3.2 Address for submissions

Please send your submission on this discussion paper to:

Technical Standards and Systems Team

New Zealand Standards Group

New Zealand Food Safety Authority

PO Box 2835

Wellington – New Zealand

Fax: (04) 894 2643

Email: TSS@nzfsa.govt.nz

3.3 Closing date for submissions

The closing date for submissions is 5pm on 3 July 2009.

3.4 Official Information Act

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

3.5 Process after submissions

After the closing date, submissions will be analysed by NZFSA and a summary will be published. Submissions will be taken into consideration when providing advice to the Minister for Food Safety.

4 Background

4.1 Current availability of unpasteurised milk products in New Zealand

4.1.1 Manufacturing in New Zealand

Currently, dairy products manufactured in New Zealand are made from pasteurised[1] milk, other than some cheeses that have been subjected to an alternative treatment to pasteurisation during manufacture. The alternative treatments have been approved by NZFSA and combine processing and product compositional factors which contribute to pathogen death, and thus result in a process with an equivalent food safety outcome to pasteurisation. These approved alternative treatments include thermisation of the milk, long storage times during the cheese ripening stage, and low moisture content.

New Zealand processors of dairy products are able to apply to NZFSA to manufacture unpasteurised milk products, which have not been subjected to the approved alternative treatments, under a risk management programme (RMP) under the Animal Products Act 1999 (APA) or a food safety programme (FSP) under the Food Act 1981 (the Food Act). However, no technical criteria or guidance material are in place to assist with the development, evaluation, assessment for registration or approval, and verification or auditing of such programmes. This has contributed to the fact that, up until now, no New Zealand producer has progressed an application to register either an RMP or an FSP for unpasteurised milk products that have not been subjected to approved alternative treatments.

4.1.2 Sale of liquid raw milk

The only exception to the requirement for pasteurisation, or an approved alternative treatment for dairy products made in New Zealand, relates to farm gate sales of liquid raw milk. Section 11A of the Food Act 1981 (the Food Act) allows for producers to sell up to five litres of raw milk at any one time from their farm gates to people who intend to consume it themselves, or to provide it to their families. Such producers must, however, harvest the milk under an RMP that has been approved for this purpose under the APA. New Zealand law has allowed limited sales of raw milk at the farm gate for several decades.

[1] Please refer to the Glossary in section 12 for further explanation of technical terms such as pasteurisation, thermisation and raw milk products.

4.1.3 Importation of unpasteurised milk cheeses

A small range of unpasteurised milk cheeses can be imported into New Zealand under the Food (Milk and Milk Products Processing) Standard 2007, issued pursuant to the Food Act. These are: Emmental, Gruyere and Sbrinz – three hard and very hard Swiss cheeses; various extra-hard grating cheeses, including Grana Padano, Parmigiano Reggiano, Romano, Asiago and Montasio; and Roquefort – the French semi-hard blue-veined cheese.

Permission for these cheeses to be imported into New Zealand was granted by the Minister for Food Safety in 2002 (for the Swiss cheeses) and 2007 (for the Italian and Roquefort cheeses). In each case, permission was granted only after risk assessments had been carried out on the individual cheeses, either by Food Standards Australia New Zealand (FSANZ)[2] or by NZFSA.

The need for risk assessments of the imported unpasteurised milk cheeses is linked to the potential for some unpasteurised milk products to pose inherently higher food safety risks than products that have been produced with pasteurised milk or by an approved alternative, equivalent method. For further details on the possible hazards and risks associated with unpasteurised milk products, refer to Section 5.1 below.

It should be noted that the approval to import specific unpasteurised milk cheeses may be granted on the basis of these cheeses being produced according to specific controls imposed by the country of origin. In the case of the Swiss cheeses this is 'The Ordinance on Quality Assurance in the Dairy Industry of the Swiss Federal Council of 18 October 1995', and for Roquefort compliance with five ministerial orders. These documents include a variety of conditions to be met during processing. It should be noted that the type of process control used to produce Roquefort is fundamentally the same as is being proposed by NZFSA under the proposed new specification for raw milk products (see Section 6.2.2 below for an explanation).

4.2 Requests for New Zealand restrictions on unpasteurised milk products to be lifted

In recent years NZFSA has received a number of requests that it should both permit a wider range of unpasteurised milk products to be imported into New Zealand, and develop the technical criteria and guidance material that would enable the local manufacture, sale and export of a similar range of such products. These requests have come from sources including consumers, New Zealand producers,

[2] FSANZ is responsible for developing joint food compositional and labelling standards for both New Zealand and Australia.

importers, and trading partners. In developing the proposal for a regulatory framework for unpasteurised milk products, NZFSA is responding to these requests.

A variety of other developments have also prompted NZFSA to review the policy relating to unpasteurised milk products. These developments include evidence that some unpasteurised milk products, which are not currently permitted for sale in New Zealand but are freely available in other countries, are safe for consumption by most, if not all, groups in the population. The Codex Alimentarius Commission (Codex), of which New Zealand is a member, also provides for the production of unpasteurised milk products (with the specific exclusion of unpasteurised drinking milk) under appropriate hygienic conditions in its *Code of Hygienic Practice for Milk and Milk Products*. In addition, Australia is considering developing standards to allow the production and importation of a wider range of unpasteurised milk products, and any such Australian standards would have implications for New Zealand in terms of the Trans-Tasman Mutual Recognition Arrangement and our relationship with FSANZ. NZFSA also recognises that if, in the absence of any future regulatory framework, it was to continue to assess overseas-made unpasteurised milk products on a case-by-case basis when requested by overseas trading partners (as occurred with the three Swiss cheeses, extra hard grating cheeses and Roquefort cheese), this would be resource intensive and could set up inconsistencies between the treatment of New Zealand producers and importers, and between different imported products.

4.3 Options for a regulatory framework for unpasteurised milk products

In 2007, NZFSA announced it would begin developing a regulatory framework for unpasteurised milk products.

To determine the form this regulatory framework should take, NZFSA considered several options. These options ranged from maintaining the status quo and only allowing a small range of imported unpasteurised milk products to be sold in New Zealand, through to allowing all unpasteurised milk products to be made in, and imported into, New Zealand.

Following analysis, NZFSA developed a preferred option which balances public health considerations against the drivers for freeing up access for unpasteurised milk products (drivers such as demand by New Zealand consumers for a wider range of unpasteurised milk products, and the facilitation of business diversification and new export market opportunities). The NZFSA preferred option involves developing a regulatory framework which is based on hazards to consumers and enables the domestic production, export, importation and domestic sale of some, but not all, unpasteurised milk products while maintaining an acceptable level of protection for consumers.

A detailed analysis of the potential positive and negative impacts of both the NZFSA preferred option, and other options considered by NZFSA, can be found in the first discussion paper. The Regulatory Impact Statement in Section 10 also outlines some of these impacts.

4.4 Proposed regulatory framework as described in the first discussion paper

The regulatory framework for unpasteurised milk products, as proposed by NZFSA in the first discussion paper, consisted of the following key elements:

- three risk categories for unpasteurised milk products;
- processes to categorise such products;
- some preliminary information about how import standards would be revised to reflect the category approach;
- extension of the NZFSA education programme for vulnerable consumers (pregnant women and very young, the frail elderly and those with weakened immune systems (YOPIs)) to cover all available unpasteurised milk products; and
- labelling of such products.

4.5 Developments since the release of the first discussion paper

Since the first discussion paper was released, several developments have occurred which have had a bearing on the proposed regulatory framework for unpasteurised milk products. These developments are summarised below.

4.5.1 Submissions received on the first discussion paper

A wide range of interested parties were notified in August 2008 of the release of the first discussion paper. These interested parties included consumers and groups representing consumers, dairy processors, importers, stakeholder groups, and trading partners.

Forty-three submissions were received by the closing date of 30 September 2008, comprising 26 submissions from consumers; 13 from industry (for example, cheese makers and dairy industry groups); three from persons/groups with academic affiliations; and one submission from a trading partner. The great majority – 40 out of the 43 submitters – were in favour of unpasteurised milk

products becoming more widely available in some form. Those in favour included all submitters from the dairy industry and all consumers and consumer groups. Supporters of greater access to such products cited factors such as improved consumer choice; appreciation of the flavour, texture and perceived nutritional qualities of such products; a desire for local manufacturers to be able to make the same range of products as could be imported; and better business opportunities, including export opportunities, for the dairy industry.

Where those in support of the wider availability of unpasteurised milk products gave an opinion on the framework and categories for unpasteurised milk products proposed by NZFSA, most were also in favour of the NZFSA approach. Many of the industry submitters considered appropriate regulatory controls would be necessary to ensure the safety of such products, and that these would be provided by the framework. Three industry submitters indicated they would need further access to details before providing an opinion on the proposed framework. Some consumers favoured a more liberal approach, which would see all unpasteurised milk products, including raw drinking milk, being made available.

Three submitters stated opposition to unpasteurised milk products becoming more widely available. These submitters raised food safety and public health concerns, particularly for vulnerable consumers.

Further details of the submissions on the first discussion paper can be found in a published summary on the NZFSA website at: http://www.nzfsa.govt.nz/dairy/publications/consultation/rm-summary-of-responces.htm.

4.5.2 Decision to continue work on the proposed framework

Whilst noting the concerns of the few submitters on the discussion paper who opposed the proposal, NZFSA announced early in 2009 that it would continue to develop the technical and legal aspects of the framework. This decision acknowledged the support expressed by the great majority of submitters for a wider range of unpasteurised milk products to be made available in New Zealand.

4.6 Results of research

To inform the development of the proposed framework for unpasteurised milk products, and the associated technical and legal requirements and risk communication strategy, NZFSA has undertaken and commissioned literature reviews and risk profiles relating to the public health issues associated with the consumption of raw drinking milk and unpasteurised milk products. The term ‘raw milk’ has been used here as this is the terminology that was used in these scientific documents.

The results of a number of these studies are outlined below.

4.6.1 Systematic review of the human disease evidence associated with the consumption of raw milk and raw milk cheese

NZFSA commissioned Massey University to undertake a review of the available human morbidity and mortality evidence associated with the consumption of raw milk and raw milk cheeses, and an agreed list of pathogens.

The appraisal process utilised standard systematic review approaches. It focussed on publications reporting human illness linked to raw milk, raw milk cheeses and other untreated products and by-products of raw milk of bovine, goat, sheep or buffalo origin contaminated with pathogens such as *Bacillus cereus*, *Brucella spp.*., *Campylobacter spp.* (*Campylobacter)*, *Coxiella. burnetii*, *Escherichia coli* (*E.coli*), *Listeria monocytogenes* (*L. monocytogenes*), *Mycobacterium bovis* (*M. bovis*), *Salmonella serovars* (*Salmonella*), *Shigell spp*., *Staphylococcus aureus*, *Streptococus spp*., *Yersinia spp*., and *Toxoplasma spp.*

The authors expressed a concern about the overall lack of studies, in particular the lack of studies with good internal validity.

Based on the evidence collected, it was not possible to determine a 'strong' causal link between consumption of raw milk, or dairy products made from raw milk, and any of the pathogens reviewed. However, the review did demonstrate 'moderate' evidence supporting a causal link between consumption of raw milk and raw milk products and the following pathogens: *Campylobacter spp*., *E. coli spp*., *L. monocytogenes*, and *Salmonella serovars*. However in the case of *Campylobacter* the majority (17/18) reports were related to the consumption of raw milk with only one report linking infection to soft cheeses made from raw milk. There was also 'some evidence, albeit weak', to support a causal link between infection with *Brucella spp*. and the consumption of raw milk products.

It was not possible to objectively evaluate if there was a causal link between exposure to raw milk and products made from raw milk and the following pathogens/diseases: *Coxiella burnetii; M. bovis; Shigell spp.; Staphylococcus aureus; Streptococcus spp.; Yersinia spp.*; cancer; Crohn's disease; and *Cryptosporidium*. There was insufficient information to prove any causal association between *Toxoplasma* infections in humans and consumption of raw milk/raw milk products. No literature was found for *Bacillus cereus* reporting human disease in association with the consumption of raw milk and/or raw milk products. The findings of this report were taken into account when developing the draft specifications in Appendix 1.

A summary of the Massey University review can be accessed at: http://www.nzfsa.govt.nz/science/research-projects/final-report-rawmilk.pdf.

4.6.2 Report on on-farm provisions for raw milk production

The Animal Health Centre in Morrinsville was commissioned by NZFSA to undertake a report entitled *Consideration of on farm provisions for raw milk production*. The Animal Health Centre has expertise in areas including general preventative dairy herd health and disease control. The report aimed to identify known, or potential, milk-borne pathogens in raw milk in New Zealand using published literature (including international literature). The report also reviewed potential risk factors for bacteria in milk, and made recommendations about on farm control measures that could be introduced to minimise or reduce these risks. A copy of the report can be viewed at: http://www.nzfsa.govt.nz/dairy/publications/reports/index.htm

The Animal Health Centre report concluded that increased health risks would arise if raw milk products were to be made and sold in New Zealand using milk produced under current management practices and systems. New on-farm management procedures and monitoring regimes, designed specifically to take account of the New Zealand environment and systems, were therefore recommended as necessary in order to mitigate these risks. The findings of this report have been taken into consideration by NZFSA when developing the proposed technical requirements that will apply to raw milk products relating to the harvesting of milk and processing.

4.6.3 Pathogens in raw milk

A survey was carried out by Fonterra, in collaboration with NZFSA, to quantify the levels of key non-spore forming pathogens in raw milk.

The survey included *Campylobacter, E. coli* (total, O157:H7 and O157:non H7), *Listeria (L.monocytogenes and L. innocua)*, *Salmonella* and *Staphylococcus aureus*.

The samples were taken from raw milk tanks on individual dairy farms nation-wide.

Neither *Salmonella* nor *E. coli* O157:H7 were recovered from any of the samples (total 294, 296 samples respectively). However, three samples did contain *E. coli* O157 non-H7 (from a total of 296 samples).

There was only one positive *Campylobacter* sample (total 296 samples). The species in the sample was not identified.

Thirteen samples contained *L. innocua* (generally considered to be non-pathogenic*)* and three contained *L. monocytogenes.* One other sample contained a *Listeria* species which was not typed further (total 295 samples).

Seventy seven percent of the samples contained *Staphylococcus aureus.*

The frequency and level of all the pathogens included in the raw milk survey is consistent with other international studies.

It should be noted that this survey was undertaken using milk samples harvested under current dairy requirements and was intended for manufacture of pasteurised dairy products.

4.6.4 Risk profiles on the risks associated with milk products

Various microbiological risk profiles have been prepared for NZFSA by Environmental Science and Research (ESR) on the risks associated with pasteurised and unpasteurised milk products. These can be viewed at: http://www.nzfsa.govt.nz/science/risk-profiles/index.htm.

NZFSA has also undertaken an assessment of the food safety risks posed by the consumption of Roquefort cheese, and a copy of the summary assessment can be viewed at: http://www.nzfsa.govt.nz/imported-food/imports-portfolio/risk-management-roquefort/riskmanagementdecision_roquefort.pdf

4.7 Survey of consumer awareness and understanding of unpasteurised milk products

NZFSA commissioned a market research survey to gain information about public understanding of unpasteurised milk products. This was intended to assist the design of the framework for unpasteurised milk products, especially suitable risk management tools.

The objectives of the survey were to determine:

- awareness of any risks associated with consuming unpasteurised milk products;
- understanding of associated terminology;
- helpful labelling for unpasteurised milk products;
- the effectiveness of the measures that NZFSA has put in place to date to educate consumers about unpasteurised milk products, and to gather opinion about education strategies that could be introduced in future; and
- consumption profiles for unpasteurised milk products.

Four specific surveys made up the wider survey, focussing on the general public; consumers of unpasteurised milk products; trade (wholesale, retail and restaurant outlets) and health professionals;

and focus groups (targeting consumers who may be more vulnerable to hazards present in some foods).

The findings of the survey, following an initial analysis of the results, include:

- two-thirds of the general public surveyed understood the term 'raw milk' to mean unpasteurised or uncooked milk. However nearly one-third of the general public thought that that term 'raw milk' meant 'fresh milk' or milk in general;
- for the purposes of consumer education and labelling, 'unpasteurised' was identified as a more useful and meaningful term than 'raw milk';
- whilst many people were aware of messages that have been communicated about the safety of unpasteurised milk products, almost a third of the public thought that unpasteurised milk cheeses/products were as safe to consume as pasteurised milk products, and this included some vulnerable consumers most at risk from such products;
- whilst a low number of people surveyed were aware of NZFSA educational material on unpasteurised milk products (perhaps because many of these people were not interested in consuming such products), there was quite high awareness of educational material available both on general food safety and for vulnerable groups on the dangers of certain foods;
- for most people, the greatest source of information about unpasteurised milk and unpasteurised milk products was the general news media; and
- effective means of communicating information about unpasteurised milk products were identified as: labelling and/or packaging, and a multi-faceted education programme using one or more brochures as a centrepiece.

The data generated by the consumer survey is being taken into account by NZFSA as it designs strategies for risk communications for unpasteurised milk products.

4.8 Collaboration between NZFSA and FSANZ

Australian legislative requirements for the production of dairy products are set out in the Australia New Zealand Food Standards Code (the Code) which is developed and administered by FSANZ. The Code requires that milk and liquid milk products made in Australia must be pasteurised (or undergo an equivalent treatment) 'unless an applicable law of a State or Territory otherwise expressly provides' (as occurs in New South Wales, Queensland, South Australia and Western Australia where the sale of raw goat milk is permitted). For further details of the Australian requirements for dairy products, refer to the first NZFSA discussion paper.

Like NZFSA, FSANZ has commenced work on developing a framework that would allow the production and importation of a wider range of unpasteurised milk products in Australia. In August 2008, FSANZ released a Discussion Paper: *Proposal P1007 Primary Production & Processing Requirements For Raw Milk Products* seeking public comment on the possible future sale in Australia of a wider range of such products. This Discussion Paper can be viewed at: http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp1007primary3953.cfm

FSANZ has since continued with a consultation process which has involved engaging with stakeholders including state regulators, consumer groups, cheese makers, and importers.

NZFSA and FSANZ have recognised that both are proposing to take a similar approach to unpasteurised milk products and have therefore been working collaboratively on the development of a technical framework for such products. Matters on which collaboration has occurred include technical discussions to facilitate consistency in the proposed on-farm and processing requirements for raw milk products to be introduced in New Zealand and Australia; and labelling of some unpasteurised milk products.

5 Risk management

5.1 An overview of the risks associated with unpasteurised milk products

5.1.1 Milk as a source of pathogens

Milk that is raw (that is, has not been subjected to pasteurisation or an alternative treatment method) may contain pathogenic bacteria. Pathogens can contaminate the milk either directly, for example if an animal has an infection such as mastitis (clinical or sub-clinical), or through unhygienic practices employed during milk harvesting, milk collection and transport.

Historically, a wide range of pathogens have been associated with milk. For example, the systematic review of evidence undertaken by Massey University and summarised in section 4.6.1 above identified moderate evidence of a casual link between consumption of raw milk (and raw milk products) and *Campylobacter spp*., *E.coli spp.*, *L. monocytogenes*, and *Salmonella serovars*. The level at which such pathogens will be present in raw milk may vary from low to high. On occasions, such levels may lead to overt disease in vulnerable members of the population (such as the very young, pregnant women, the frail elderly and those with weakened immune systems), even though they would not cause clinical illness in healthy individuals.

5.1.2 Reducing the levels of pathogens in milk

As scientific knowledge has advanced and it has been understood that liquid milk can transmit illness, strategies to reduce the incidence of pathogens in milk have been introduced. Such strategies have included improved animal health practices, such as bovine tuberculosis control programmes, somatic cell count monitoring, and more effective sanitation of milking machines. However, even when such strategies are employed, they do not guarantee the elimination of all pathogens from milk. As a result, it is now standard health practice to ensure that liquid milk destined for drinking, especially by vulnerable consumers, is heat treated, for example by pasteurisation, ultra heat treatment or scalding[3]. Pasteurisation removes most pathogens of concern and reduces the number of spoilage organisms present. Pasteurised milk will still spoil even under refrigeration, due to the growth of any spoilage

[3] It should be noted that this proposal does not put forward any alternative to this standard health practice for raw milk intended for drinking and, apart from the very limited farm gate sales of raw milk already permitted under the Food Act, there is no intention to allow raw drinking milk to be sold in New Zealand.

organisms remaining after heat treatment, unless it is subjected to a process such as ultra heat treatment and aseptic packaging.

5.1.3 Extending the shelf life of milk by converting it into dairy products

Traditionally, milk has been converted into cheeses and other fermented products to extend its shelf life. For most of these milk products, processing commences with the addition of specific cultures which cause the milk to ferment. Dependent on the type of product being made, the shelf life of milk can in this way be extended from weeks (as occurs with yoghurt), to months or even years (as in the case of hard cheeses). The length by which the shelf life is extended is dependent on the intrinsic characteristics of the product, the processing techniques employed, and the inhibiting effect which these have on the growth of micro-organisms that cause spoilage. For example, characteristics such as acidity, low moisture content, and antimicrobial factors produced by the fermenting organisms all result in the elimination or growth inhibition of both micro-organisms that cause spoilage and of pathogens that were in the milk. The final spoilage patterns that result are due to the final product characteristics brought about by all of these factors. For example, the shelf life of a dry, hard cheese such as parmesan is longer than that of a very moist product such as yoghurt.

5.1.4 Raw milk in cheese making

Cheeses that are made from poor quality milk may display flavour and quality defects due to the presence of contaminating micro-organisms. As bacteria are present in raw milk and can grow rapidly, the quality of raw milk can soon deteriorate unless it is processed soon after collection. Cheeses made from raw milk can show varying characteristics from day to day, due to the different micro-organisms that can be present. Many cheese makers prefer to pasteurise milk before they produce cheese as this can result in a more consistent product and reduce the potential for production batches to fail requirements for flavour, quality and food safety. However, other cheese makers value the flavour, texture and quality characteristics which they consider the use of raw milk can produce in a cheese.

During the early stages (warm and moist) of cheese making, any pathogenic and spoilage bacteria present may multiply unless a preliminary heating step has destroyed them. However as the starter culture grows and starts to increase acidity in conjunction with the release of inhibitory factors, then the growth of the pathogens present will be slowed. In the next stage of cheese making – curd making – the growth of pathogens will in most cases have ceased. Whilst at the beginning of this stage a greater number of pathogens may now be present than were in the incoming milk, the process of producing curd, reducing the moisture content, salting, and ripening will usually result in pathogen numbers decreasing to low levels. However, this expected die-off of pathogens takes time and may not occur if the cheese making process does not include a lengthy ripening stage of at least several

weeks duration (an example of products not subject to lengthy ripening are the Mexican-style unripened soft cheeses), or if the factors that are inhibitory to pathogens are reversed, such as occurs when the acidity of a product decreases.

The inhibitory effects during cheese making have been studied and some examples of this scientific evidence are described below:

- Certain soft cheeses, such as Camembert (where the pH is almost back to neutral at the end of the ripening phase), and Quesco Blanco and Quesco Fresca (which have a high moisture content and a neutral pH) will support the growth of *L. monocytogenes.* Quesco Blanco and Quesco Fresca have been associated with outbreaks of listeriosis (CDC 2001[4]; Linnan et al 1989)[5].

- Hard cheeses such as Cheddar and Parmesan have acid pHs and low water activity and do not support the growth of listeria. They show a marked decline in live bacteria during ripening (Yousef AE and Marth, EH 1990[6]).

- While pathogen population levels may not decline to undetectable levels in hard cheeses during aging, pathogen survival is strongly influenced by the moisture content and pH levels, and there have been no recorded outbreaks of illness associated with cheeses aged for a minimum of 60 days (ILSI, 2005[7]).

- In the United States of America, 11 events between 2000 and 2005 (five relating to *L. monocytogenes*, two to *Salmonella* and two to *M. bovis*), have been linked to the consumption of cheeses made from unpasteurised or raw milk. However, ten of these events were linked to Mexican-style soft cheeses, which in most cases were purchased from street vendors rather than retail stores, meaning that it is not clear whether the products were made following Good Hygiene Practice (Quoted by the US FDA).

5.1.5 Risk assessments of unpasteurised milk products

A full quantitative risk assessment of milk products requires the availability of extensive data relevant to each stage of manufacture to allow modelling of the impact of changes in parameters such as pH,

[4] CDC (2001) *Outbreaks of listeriosis associated with homemade Mexican-style cheese*. Morbidity and Mortality Weekly Report 50, 560-562.

[5] Linnan, MJL et al (1989) *Epidemic listeriosis associated with homemade Mexican-style cheese,* New England Journal of Medicine, 319, 823-828.

[6] Yousef AE and Marth EH (1990) *Fate of Listeria monocytogenes during the manufacture and ripening of Parmesan cheese.* Journal of Dairy Science 73, 3351-3356.

[7] ILSI (2005), *Achieving continuous improvement in reductions in foodborne listeriosis – a risk-based approach.* Journal of Food Protection 68, 1932-1994.

the likelihood of the survival of contaminating micro-organisms, and the subsequent potential of products to cause illness. However, in general, there is a scarcity of such data and, for this reason, very few full quantitative risk assessments have been undertaken for individual cheeses either in New Zealand or overseas. One assessment that has been done was undertaken by NZFSA to support the risk management decision taken with regards to the importation of the French unpasteurised sheep milk cheese, Roquefort, refer to: http://www.nzfsa.govt.nz/imported-food/imports-portfolio/risk-management-roquefort/riskmanagementdecision_roquefort.pdf

As there are many types of cheeses, probably several thousand, each of which has its unique processing parameters, it is not possible to complete a general risk assessment that includes all unpasteurised milk cheeses or other types of unpasteurised milk products. However, it is possible to group dairy products according to some key characteristics, although the boundaries between the groups may not always be clear-cut. For example, several national and international agencies have conducted risk assessments on the association of groups of dairy products with *L. monocytogenes*, and the outcome of one such assessment by the US FDA is described in Section 5.1.6 below.

5.1.6 What we do know about the risks associated with milk products

Despite the limitations outlined above, it is possible to identify three general levels of risks for milk products (and other dairy products), using evidence collected from challenge studies and outbreaks of illness associated with the consumption of dairy products.

Assuming that milk may on occasion contain pathogens, then the potential risk to general members of the public of illness from consumption of milk and milk products will be:

- extremely low if the milk is pasteurised or subjected to an equivalent treatment;
- low if the milk is treated in a way that results in a combination of extrinsic and intrinsic factors that minimise the survival and growth of the pathogens; or
- moderate to high if there are no factors or limited factors (either extrinsic or intrinsic) that inhibit the survival and growth of the pathogens.

The regulatory framework for unpasteurised milk products developed by NZFSA, including the three descriptions of unpasteurised milk products outlined in Section 6.1, is based on these three general levels of risk.

Risk assessments which support the proposed NZFSA regulatory framework include those undertaken by the US FDA in 2003 relating to listeria in ready to eat foods. These ranked unpasteurised fluid milk as high risk, soft unripened cheeses as moderate risk, and other cheeses as low risk, with hard

cheese being ranked the lowest risk to the general population of all the products in the 23 categories of ready to eat foods studied.

Outbreaks of illness have rarely been associated with unpasteurised milk cheeses, but nevertheless the potential for such events exist (as the Massey University systematic review of evidence demonstrates). It is therefore necessary to endeavour to ensure that there is minimal pathogen contamination of raw milk used in such products, and that the subsequent processing of the milk ensures that the growth and survival of any pathogens that may be present is minimised by stringent control of the manufacturing process. This means that the manufacture of unpasteurised milk products needs to be subject to rigorous controls and that all those involved understand the specific hazards and risks, and how to control them.

In the draft specifications in Appendix 1, controls and requirements proposed by NZFSA for raw milk products are outlined. In developing these, NZFSA has taken account of the work undertaken by Codex and published in the Codex *Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004.* This *Code* contains specific additional provisions for raw milk products. Particular emphasis is given to on-farm practices to ensure the quality of the raw milk, and to strict controls during processing to ensure factors essential for the manufacture of a safe product are monitored and managed effectively. The Codex *Code* can be accessed at:

http://www.codexalimentarius.net/download/standards/10087/CXP_057e.pdf

5.2 Managing the hazards associated with unpasteurised milk products

The framework that NZFSA proposes utilises Good Hygienic Practice (GHP) and hazard-based controls to ensure that, at the end of manufacturing, unpasteurised milk products comply with specific food safety criteria. It is proposed that there will be specifications which contain requirements for the production of some unpasteurised milk products in New Zealand. Standards under the Food Act will allow for the importation of an equivalent range of products and the import requirements that apply. NZFSA will develop guidance to aid producers, evaluators, verifiers and importers to determine which requirements apply.

NZFSA will also develop a risk communication strategy to manage public understanding of the higher likelihood of the presence of hazards in unpasteurised milk products. Unlike some overseas countries, New Zealand does not have a culinary tradition of consuming unpasteurised milk products. As a result the New Zealand public's awareness of the hazards associated with the consumption of such products is limited. This is borne out by the survey of consumers commissioned by NZFSA, which found that almost a third of the general public surveyed considered that raw or unpasteurised milk cheeses/products were, as a general group, as safe as pasteurised milk products. The NZFSA future risk communication strategy will be targeted at those consumers most likely to be vulnerable to

any hazards associated with the unpasteurised milk products that would be available in New Zealand – namely the young, frail elderly, pregnant and immune-compromised (sometimes referred to as 'YOPIs').

To support the risk communication strategy and assist consumer recognition of unpasteurised milk products, such products would also need to be labelled as containing raw or unpasteurised milk.

5.2.1 Risk communication

Risk communication is an important component of managing risk. Risk communication involves providing people with information about a risk or hazard (including putting that risk or hazard into context) and allowing them to make an informed decision about their actions in relation to that risk or hazard. It can be described as 'alerting' and 'reassuring'.

NZFSA runs a substantial programme of informing consumers about risks and hazards from food. This includes a range of information brochures, fact sheets, a comprehensive web site, and working with public health and industry organisations via the Foodsafe partnership. Brochures are distributed to the public through health professionals, public health units, territorial authorities, and directly from NZFSA.

Some of NZFSA's information brochures target specific audiences and some are issue-based. Examples of brochures for audiences with specific food safety needs include *Food safety when you have a low immunity* aimed at the very young, frail elderly, pregnant and immune-compromised groups; *Food safety in pregnancy*; and *Good food/Safe food for older people*. Issue-based publications include *Meet the Bug* (which describes foodborne pathogens) and *Agricultural compounds in food*. A full list of NZFSA consumer information brochures is available on the NZFSA web site at: http://www.nzfsa.govt.nz/consumers/index.htm.

When NZFSA updates its advice on a topic, or when a new food safety risk or hazard is communicated to New Zealand consumers, relevant new information is added immediately to the web site and to existing publications when they are next reviewed. Depending on the specific risk or hazard, a new publication might be developed.

5.2.2 Risk communication for unpasteurised milk products

In 2007 New Zealand's food laws were changed to allow the direct importation of some unpasteurised milk cheeses not previously available (i.e. Roquefort and some Italian hard grating cheeses). Part of the risk management plan developed at the time by NZFSA included the design of a point-of-sale flyer for Roquefort and a more general flyer about raw milk products for distribution to medical offices. The

term ‘raw milk’ has been used here for information produced to date as this is the terminology that was used in these publications.

Two new publications for at-risk groups were also released at that time which included new information alerting them to the need to avoid eating products made from raw milk.

Since 2007, NZFSA’s brochure for pregnant women has been updated to include the raw milk message. The NZFSA brochure for YOPI groups is also currently being updated.

If this proposal proceeds, and a wider range of unpasteurised milk products become available on the New Zealand market, then NZFSA will further develop its risk communication strategy for such products. Details of the type of adjustments that would be made to the strategy are given in Section 9.3.

5.2.3 Labelling

In the first discussion paper, NZFSA identified labelling of unpasteurised milk products as a possible tool that could be used to mitigate any hazards associated with such products.

The labelling requirements for all food sold in New Zealand (including dairy products) are set out in the Code. Among other things, the Code requires that the label on a package of food for retail sale includes the name of the food and a list of its ingredients. Standard 1.2.4 of the Code requires that ingredients must be declared using the common name of the ingredient, or a name that describes the true nature of the ingredient, or if applicable a generic name. This requirement means that in relation to products made from raw or unpasteurised milk, the ingredient declaration would need to include a statement that the milk is ‘raw’ or ‘unpasteurised’. In the case of products made other than from cows’ milk, labels would also need to include the common name of the species from which the milk is sourced.

Feedback received on the first discussion paper indicated that submitters supported labelling of unpasteurised milk products as an effective means of helping consumers to recognise such products. The NZFSA survey of consumer awareness of unpasteurised milk products also identified labelling as a valuable mechanism for ensuring consumers are made aware when they are buying products made from raw or unpasteurised milk. Some consumers surveyed also considered that an explanation and/or warning of any hazards associated with unpasteurised milk products should be included on labelling.

The Code does allow for mandatory advisory statements to be used when consumption of a food exposes the general population, or a population subgroup, to a health and safety risk, or where guidance about a food is needed to maintain public health and safety. Such mandatory advisory

statements are included separately, and in addition to, ingredient lists. The list of foods that are currently required by the Code to have a mandatory advisory statement includes unpasteurised milk and liquid milk products, but not unpasteurised milk cheeses or other unpasteurised milk products. This means that the labelling on unpasteurised milk and liquid milk products (which are available in some Australian states) must include an advisory statement 'to the effect that the product has not been pasteurised', but that no such mandatory advisory statements nor any other warnings are currently required on the labels of unpasteurised milk cheeses or other unpasteurised milk products.

Like New Zealand, Australia is considering liberalising its regulatory environment for unpasteurised milk products. While the likely outcome is an Australian only processing standard, labelling matters will be addressed and, under the terms of the *Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Food Treaty), any changes to labelling are to apply jointly in Australia and New Zealand. NZFSA will therefore continue to collaborate and consult with FSANZ to ensure that the needs of New Zealanders are addressed. NZFSA's preferred option is that all (i.e. not just liquid) raw milk products that are subject to the proposed new specifications (see Section 6.1. below) should be labelled with a mandatory advisory statement to the effect that they contain 'unpasteurised milk'.

If agreed, any such mandatory advisory statement would be introduced jointly in New Zealand and Australia at an appropriate future time that would equate with FSANZ's timeline for completing its work on unpasteurised milk products (gazettal of any new Australian requirements is currently set for February 2011[8]). NZFSA favours the use of the term 'unpasteurised milk' rather than 'raw milk' in any future mandatory advisory statement because this reflects submissions on the first NZFSA discussion document, and the market research commissioned by NZFSA to determine consumer understanding of commonly used terms relating to raw or unpasteurised milk products.

If adopted in future, such a mandatory advisory statement would also apply to raw milk products that are not required to bear a label, for example those made and packaged on the premises from which they are sold, as the statement would need to be displayed on, or in conjunction with, the display for the food concerned, or provided to the purchaser on request.

In the meantime, producers of unpasteurised milk products may wish to voluntarily label their products with a mandatory advisory statement. Recommendations relating to labelling will be incorporated in the Code of Practice relating to raw milk products that NZFSA proposes to develop for industry operators (refer Section 6.2.2.).

[8] For further information about the FSANZ work plan, visit:
http://www.foodstandards.govt.nz/_srcfiles/Work%20Plan%20LATEST4.pdf

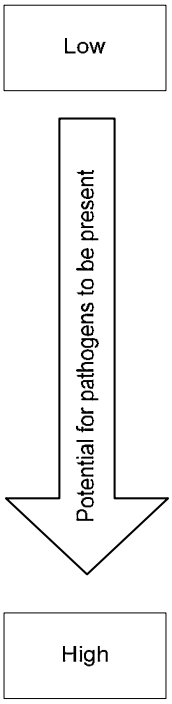
6 Proposed regulatory framework

6.1 Definitions of milk product categories

The first discussion paper introduced three categories (categories 1-3) for what was referred to as raw milk products, with the categories being based on the likely presence of pathogens and the potential risk to human health that such products pose to consumers. This risk is determined by the effect that the processing techniques and the intrinsic characteristics of the final products have on pathogen survival and growth. Intrinsic characteristics can include: water activity, moisture content and acidity; and processing factors can include: curd cooking time, acidity and salt concentrations.

Since the release of the first discussion paper, NZFSA has refined the definitions of the different types of milk products, and clarified terms such as raw milk product. It is now proposed that the term 'raw milk product' will refer to a specific defined sub-group of products made from unpasteurised milk. The description of the three groups of products now provides a clear link to the regulatory requirements that currently apply and are proposed to apply in future.

Table 1: Milk products made from milk that has not been pasteurised

Unpasteurised milk products able to be produced under existing dairy regulatory requirements Products where intrinsic characteristics and/or processing techniques have been approved as able to eliminate pathogens that may have been present in the raw milk (previously Category 1 in the first discussion document). **Raw milk products able to be produced under the proposed specifications** A processed dairy product that has not received a defined pathogen elimination step or steps, and excluding raw drinking milk and colostrum products, where intrinsic product characteristics and/or processing techniques may allow the survival of pathogens that may be present in raw milk but which have been demonstrated not to support the growth of pathogens to levels in excess of food safety criteria (previously Category 2). **Unpasteurised milk products not able to be produced in New Zealand** Unpasteurised milk products with an unacceptable or unknown level of risk (Category 3).	

For the purposes of these definitions, the following meanings are attributed to terms:

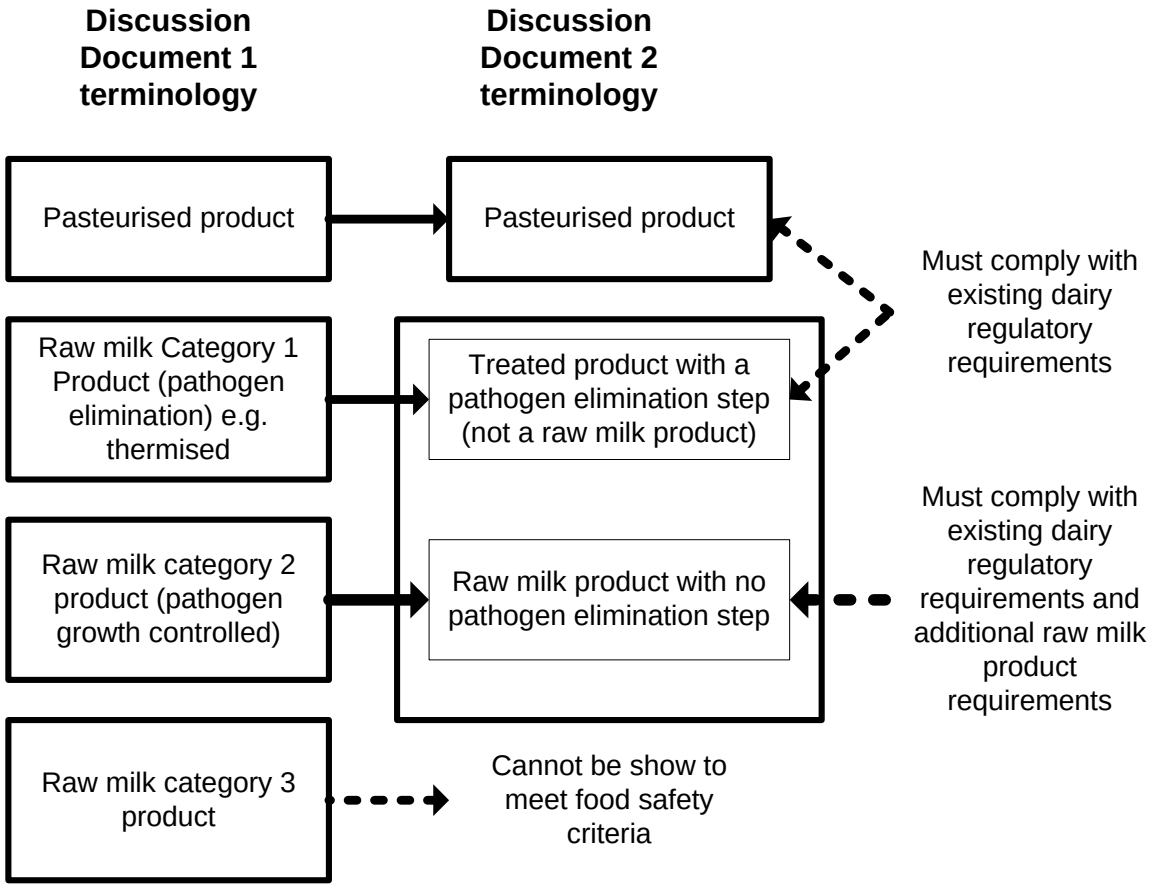
- 'eliminate' means the use of a process or processes that will achieve an overall reduction of the specified pathogens of at least 5 log;
- the specified 'pathogens' are likely to include *L. monocytogenes* and *Salmonella spp*.;
- 'food safety criteria' is as defined by the proposed Draft Animal Products (Raw Milk Products Specifications) Notice 2009 (refer Appendix 1); and
- 'proposed specifications' means the proposed Draft Animal Products (Raw Milk Products Specifications) Notice 2009 (refer Appendix 1).

The unpasteurised milk products able to be produced under existing dairy regulatory requirements will (whether produced in New Zealand or imported) not be subject to any additional control measures over and above those already stipulated. Parmesan style extra hard grating cheeses would be an example of the type of product that would fall into this group.

For 'raw milk products' that will be able to be produced under the proposed draft specifications, NZFSA has developed additional technical requirements covering both on-farm and processing techniques. Providing that compliance with these requirements, or equivalent requirements, can be demonstrated, products in this category will be able to be produced in New Zealand or imported.

Those unpasteurised products which fall outside the two categories above will not be able to be produced or imported, given the level of safety currently seen as acceptable for New Zealanders. It is proposed that these products include raw drinking milk and colostrum. (The only exception will be the small scale farm gate sales of raw liquid milk which are permitted under Section 11A of the Food Act if the milk is harvested under an approved RMP, as referred to in Section 3.1.2).

The diagram below demonstrates how the product definitions and regulatory requirements interrelate. The proposed rules and framework for imported unpasteurised milk products, including raw milk products, are covered in the following sections.



6.2 Requirements for unpasteurised milk products

6.2.1 Products that can be produced under existing dairy regulatory requirements

An unpasteurised milk product can be made under existing regulatory requirements if it meets one of the following:

1. the milk or cream from which a cheese, or cheese product, is being made is held at a temperature of no less than 62 degrees Celsius (C) for a period of no less than 15 seconds, and the cheese or cheese product is stored at a temperature of no less than 2 degrees C for a period of 90 days from the date of processing; or

2. during cheese-making the curd is heated to a temperature of no less than 48 degrees C, and the resulting cheese or cheese product has a moisture content of less than 39 percent after being stored at a temperature of no less than 10 degrees C for a period of no less than six months from the date of processing; or

3. manufacture includes a validated process that can be shown through scientific evidence to eliminate pathogens of concern e.g. Gruyere, Emmental, Sbrinz.

6.2.2 Raw Milk Products that can be produced under the proposed specifications

Raw milk products that cannot be produced under existing dairy requirements may be able to be made under the proposed specifications detailed in Appendix 1 if they can be shown to satisfy the food safety criteria and process hygiene criteria specified. For example the product or process maybe shown to be suitable through various means such as:

1. ensuring products cannot support the growth of *Listeria monocytogenes* (i.e. products with a water activity of less than 0.92, a pH of less than 4.4[9], or sodium chloride (salt) content of greater than 10%)[10]; or

2. the production process has been validated as capable of meeting microbiological food safety criteria; or

3. the product has a combination of other inhibitory growth factors that through scientific evidence (for example mathematical analysis or modelling of reliable scientific data that can predict the fate of any pathogens present) can be shown to meet food safety criteria; or

4. following a code of practice or RMP template approved by NZFSA.

6.2.2.1 Requirements in the proposed specifications for raw milk products

Manufacturers of products that can be produced under the proposed specifications must ensure that product:

a. is produced from milk specifically intended and suitable for the manufacture of raw milk products; and

b. is manufactured using an approved or validated process that contributes to product safety through appropriate monitoring and management of operator defined process measures. Operator defined process measures are discreet process steps applied during the manufacture of the product that

[9] Reference for water activity and pH parameters: ICMSF (1996) Micro-organisms in Foods 5. Microbiological Specifications of Food Pathogens. International Commission on Microbiological Specifications for Foods (ICMSF). London: Blackie Academic and Professional.

[10] Reference for salt: http://www.nzfsa.govt.nz/science/data-sheets/listeria-monocytogenes.pdf

are integral to achieving food safety outcomes. They include parameters such as cooking time and temperature, acidification and pH, maturation time and temperature, water activity and salt concentration; and

c. is labelled in the ingredients with a statement that the product is made from raw or unpasteurised milk and, in the case of cheese made other than from cow's milk, should also include the common name of the species from which the milk is sourced.

6.3 Approval processes for unpasteurised products

For raw milk products and other unpasteurised products the procedure for developing and validating a programme, and submitting this to NZFSA for evaluation (where necessary) and approval or registration is expected to be the same as the procedure for existing dairy RMPs. The RMP operator will be expected to provide sufficient information to give confidence that the proposed processing steps and the nature of the product will deliver a product that meets the applicable microbiological criteria.

For raw milk products the operator may be able to confirm the validity of the RMP or FSP by various means as set out under section 6.2.2.

For other unpasteurised products intended to be processed under the existing dairy requirements the operator will need to provide evidence that it meets the requirements under section 6.2.1.

To assist recognised evaluators and processors who elect to undertake or commission validation studies, NZFSA will develop a guidance paper on the design of validation studies. This will be based on the Codex *Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 – 2008)*. Effective validation studies are likely to involve the raw milk (from which end products are made) being inoculated with a specified number of micro-organisms, and this then being compared with the number of micro-organisms present at the end of the process to demonstrate that no increase has occurred. Such a validation study would probably be undertaken at a pilot plant. This plant would need to recreate the normal operating range for the equipment and facility where the actual commercial production would occur, to ensure that an acceptable and faithful reproduction of the actual process is represented by the study. Validation studies would need to be funded by producers. The results generated from these validation studies would be submitted to NZFSA in order that a determination could be made as to whether the product/s concerned could be produced in New Zealand.

Producers could elect to work together, including when commissioning validation studies or providing alternative evidence to justify production. It would however be essential for those working jointly to demonstrate that generic, transferable processes would be involved. It would be advisable for producers who want to combine efforts to discuss this with NZFSA in advance. Producers of

unpasteurised milk products operating under RMPs or FSPs would also need to subsequently have their RMPs or FSPs individually evaluated (if required), registered or approved, and verified or audited.

6.4 The use of a predictive mathematical model to assist operators

As signalled in the first discussion paper, NZFSA is working on the development of a mathematical model as a tool to predict the suitability of a product based on its characteristics. This model could assist both evaluators and manufacturers in assessing whether a raw milk product could be expected to consistently meet applicable microbiological criteria. The NZFSA model will take account of models and studies that are available internationally and use a combination of parameters (such as moisture, salt, pH and water activity) to determine the likely fate of the specified pathogens of interest. The model in this way could help to assess the likely degree of pathogen control in a product with specific processing steps and conditions.

Other predictive mathematical models may also be available, or will become available in future, and would be accepted by NZFSA where they can be shown to be suitable.

There are major limitations, however, in the development of the NZFSA model as it relies on the existence of extensive and robust data for a wide variety of cheeses and for key pathogens. Unfortunately, only limited reliable data is currently available and then only for some pathogens and some parameters. In spite of the potential limitations, a model may assist operators by identifying which pathogens may require validation studies to confirm suitability.

NZFSA is also investigating new science work with which it hopes to undertake validation studies concerning specific unpasteurised cheese types that may be produced domestically. This will assist in both developing the necessary studies to demonstrate a safe production process, as well as generating important data to assist the development of the planned model to help predict the food safety outcomes of other similar cheese production processes. Such work will be dependant on research resources being available and is being given a high level of priority within NZFSA.

6.5 Application to imported products

Unpasteurised products (including raw milk products) will only be able to be imported once the exporting country's human health standards and production requirements have been assessed and recognised as complying with the New Zealand standards, or as producing an equivalent food safety outcome. Unpasteurised milk products (excluding raw milk products) will be required to be manufactured according to one of the processes outlined above in section 6.2.1 and to be produced under exporting country requirements that have been assessed as meeting, or being equivalent to,

current New Zealand dairy requirements. An exporting country's systems for production of raw milk products will be assessed against the requirements and processes outlined in section 6.2.2 and the proposed specifications (see Appendix 1).

Unpasteurised and raw milk products will only be able to be imported into New Zealand once the exporting country's programme has been assessed and recognised, and a pre-clearance arrangement between NZFSA and the competent authority of the exporting country is in place. Such products will be required to be accompanied by recognised certification from the relevant competent authority, as agreed under each pre-clearance arrangement.

7 Technical requirements and controls for raw milk products

7.1 Current regulatory requirements for dairy products made in New Zealand

In New Zealand processing requirements for milk and milk products are regulated under the APA and the Food Act.

The APA covers all dairy processing and requires most dairy processors to operate under a registered RMP. The dairy processing requirements issued under the APA cover a wide scope of activities, from on farm practices through to processing, and retail or export of end products.

An exclusion under the APA allows processors of dairy products who supply only the domestic or Australian markets to choose to operate under an FSP under the Food Act, instead of an RMP. This exclusion applies to all dairy processors except for farm dairy operators (that is, harvesters of milk). Farm dairy operators harvesting milk for human consumption must operate under an RMP, regardless of whether the milk is intended for domestic or export sale.

The Animal Products (Exemptions and Inclusions) Order 2000 also provides for an exemption from the requirement to have an RMP or FSP for dairy products that are sold and then totally consumed on the manufacturing premises (such as ice cream made and consumed in a restaurant).

Both RMPs and FSPs are designed to identify, control and minimise hazards and other risk factors relating to the production and processing of dairy products, in order to ensure that the resulting products are 'fit for intended purpose'.

7.2 Technical requirements proposed

7.2.1 Processors of unpasteurised milk products able to be produced under existing regulatory requirements

The unpasteurised milk products currently produced under the existing regulatory requirements have been assessed and determined to result in pathogen elimination that is at least equivalent to that provided by pasteurisation. As such NZFSA considers they are as safe for human consumption as

products made from milk that has been pasteurised and therefore it is appropriate that existing regulatory requirements continue to apply. As a result, it is proposed that processors of these unpasteurised milk products should operate under registered RMPs or approved FSPs which meet the same base requirements under the APA and Food Act that apply to all processors of dairy products. No additional control measures will be required over and above these usual requirements.

The existing regulatory requirements would also apply for any new product or process that is shown, through validation studies, to provide pathogen elimination to a level at least equivalent to pasteurisation.

7.2.2 Processors of raw milk products that can be produced under the proposed specifications

New Zealand processors of raw milk products that can be produced under the proposed specifications will be required to operate under registered RMPs or approved FSPs which meet both the base requirements set under the APA and Food Act and additional on-farm and processing requirements. It is proposed that these additional requirements will be set out in primarily outcomes-based specifications, to be issued pursuant to the APA (refer Section 8.1 for more detail), with further guidance being provided in a Code of Practice. The additional requirements acknowledge that these products require additional controls at the milk harvesting and processing stages due to the absence of a pathogen elimination step(s), even though the intrinsic characteristics and/or processing techniques of such products would not support the growth of these pathogens to levels in excess of food safety criteria.

The proposed additional requirements for these products are a combination of Good Hygiene Practice (GHP) and hazard-based management interventions that take into account the recommended 'additional provisions for raw milk products' identified in the Codex *Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004*. These 'additional provisions' are designed to minimise pathogen contamination of the milk and/or dairy product (and include, for example, provisions relating to animal health and milking hygiene), and to minimise pathogen growth in the milk and/or dairy product (an example of such a provision would be appropriately controlled cooling).

The draft specifications are attached as Appendix 1.

Section 8.2 covers proposed amendments to the Food (Milk and Milk Processing) Standard 2007, which permits the importation into New Zealand of unpasteurised milk products.

NZFSA proposes to issue one or more Codes of Practice, or to add supplementary information to existing Codes of Practice, to guide operators on how to satisfy the requirements in the proposed

specifications. The Code(s) of Practice will elaborate on these requirements and how NZFSA expects them to be met, and will provide assistance for operators developing an RMP or FSP.

The Code(s) of Practice would have benefits for operators such as:

- if the Code of Practice is followed, then the relevant regulatory requirements could be demonstrated as having been met without the need for additional validation; and
- the evaluation (where required), registration or approval, and external verification or auditing of RMPs or FSPs based on the Codes of Practice, are likely to be more straightforward than otherwise.

8 Legal issues

In 1995, New Zealand and Australia agreed to establish a joint food standards setting system under an *Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Food Treaty). As a result, the Australia New Zealand Food Standards Code (the Code) was introduced. The Code covers the content, limits for food chemical and microbiological contaminants and additives, and labelling for food sold in New Zealand and Australia. However the Food Treaty does not apply to requirements for food safety, agricultural compounds, or third country trade and instead, in these areas, each country operates under its own legislation.

In New Zealand, processing requirements for milk and milk products are regulated under the APA and Food Act. Facilitating the domestic production, sale and export of a wider range of unpasteurised and raw milk products, and the importation of a similar range of such products, will require changes to be made to New Zealand law, namely the introduction of a proposed Animal Products (Raw Milk Products Specifications) Notice 2009 (the Notice), and the amendment of the Food (Milk and Milk Products Processing) Standard 2007 and the Food (Prescribed Foods) Standard 2007.

8.1 Proposed Animal Products (Raw Milk Products Specifications) Notice 2009

It is proposed that the Chief Executive of NZFSA will issue specifications under the APA, to be known as the 'Animal Products (Raw Milk Products Specifications) Notice 2009' (the Notice). The Notice will set out mandatory requirements to be met by producers of those raw milk products which fall under the following definition (as opposed to all unpasteurised milk products):

'raw milk product means a processed dairy product-

(a) that has not received a pathogen elimination step; and

(b) in which as a result of its nature and the manner in which it is processed, may allow the survival of pathogens, but in the case of pathogens specified in the food safety criteria, will not support their growth or allow their survival, to levels that exceed those specified in the food safety criteria; and

(c) that is not raw drinking milk; and

(d) that is not made from colostrum.'

The proposed Notice will be issued pursuant to section 167(1)(h) of the APA which provides for the Chief Executive of NZFSA 'setting specifications and providing for matters of detail in relation to animal product standards in accordance with section 45'.

Section 45 of the APA provides for the Chief Executive of NZFSA to set specifications and other detailed requirements that 'are specified or contemplated by or necessary to give effect to any standard prescribed under section 44 and are necessary or desirable to amplify the manner in which any such standard may or must be achieved'. In this case, the Chief Executive would issue specifications in the proposed Notice to give effect, in relation to raw milk products, to the Animal Products (Dairy) Regulations 2005.

As the proposed Notice will set out mandatory requirements for raw milk products, rather than only matters or items that must be included in an RMP, it will apply regardless of whether such products are made under an RMP under the APA or an FSP under the Food Act.

A draft of the proposed Notice is attached as Appendix 1.

8.2 Amendment to the Food (Milk and Milk Products Processing) Standard 2007

The Food (Milk and Milk Products Processing) Standard 2007 (the Standard), issued pursuant to section 11C of the Food Act, is the legal instrument which permits the importation into New Zealand of a small range of unpasteurised milk cheeses that have been produced according to permitted methods of processing. These cheeses are: three hard and very hard Swiss unpasteurised milk cheeses; extra-hard unpasteurised milk Parmesan style grating cheeses, and Roquefort cheese.

NZFSA proposes that the Standard be replaced by the Food (Imported Milk and Milk Products) Standard 2009 to allow for the importation of unpasteurised milk products that meet current dairy requirements and raw milk products that meet the requirements proposed in the 'Animal Products (Raw Milk Products Specifications) Notice 2009'.

NZFSA proposes that the Imported Milk and Milk Products Standard allow unpasteurised milk products produced under an overseas processing standard to be imported, where the food safety outcome will be at least an equivalent level of safety for consumers as that which is achieved by the domestic New Zealand milk and milk products processing requirements. The Chief Executive will be given the authority to approve such overseas process standards and products following an assessment by NZFSA.

The current references to the three named hard and very hard Swiss unpasteurised milk cheeses, extra-hard unpasteurised milk Parmesan style grating cheeses, and Roquefort cheese will remain in the Standard with their associated permitted methods of processing. Existing pre-clearance arrangements in place with exporting countries such as the European Union are recognised in the Standard. A draft of the Food (Imported Milk and Milk Products) Standard is attached as Appendix 2.

8.3 Amendment to the Food (Prescribed Foods) Standard 2007

The Food (Prescribed Foods) Standard 2007 allows for unpasteurised milk cheeses that have not undergone pasteurisation or cheese treatment (as defined in the Food (Milk and Milk Processing) Standard 2007) to be monitored for the presence of pathogenic organisms. This is because there are hazards that need to be managed during the production of unpasteurised milk cheeses that make some products of regulatory interest. Unpasteurised milk cheeses were added to the prescribed food list to allow for the importation of Roquefort cheese following an NZFSA risk assessment.

Replacing the Food (Milk and Milk Products Processing) Standard 2007 (as described in Section 8.2 above) with the Food (Imported Milk and Milk Products) Standard will broaden the scope of unpasteurised milk products that can be imported. NZFSA proposes to expand the prescribed food standard to take into account the new Imported Milk and Milk Products Standard by amending the current reference to raw milk cheese.

A draft of the amended Food (Prescribed Foods) Standard 2007 is attached as Appendix 3.

8.4 Other legal requirements for New Zealand producers and retailers of unpasteurised milk products

8.4.1 Farm gate sales of unpasteurised drinking milk

Section 11A of the Food Act contains a provision allowing raw milk to be sold at a producer's dairy premises in a quantity not exceeding five litres at any one time to a person intending the milk for personal consumption, or for consumption by their family. Such milk must have been harvested in accordance with an approved RMP under the APA. No change is currently proposed to this section of the Food Act.

NZFSA has undertaken a Domestic Food Review and, as a result, has designed and consulted on a proposed new domestic food regime. If the new food regime is progressed, it is intended that farm gate sales of raw milk would continue.

8.4.2 Evaluation, auditing and verification requirements

New Zealand processors of unpasteurised and raw milk products will be required to operate under registered RMPs under the APA or approved FSPs under the Food Act. As such, they will be subject to the legal requirements relating to evaluation, auditing and verification set by the APA and Food Act.

Under the APA, an RMP for dairy processing must be evaluated by an evaluator recognised for this purpose by NZFSA. The evaluator recommends registration of the RMP to NZFSA once all regulatory requirements have been addressed in the RMP. If this proposal progresses, for raw milk products covered by the proposed Notice, the RMP will need to take account of the requirements set out in the Notice. An RMP must be verified by an agency recognised for this purpose by NZFSA, using a performance-based verification system. The recognised agency also has responsibility for reporting any critical non-compliance to NZFSA.

Under the Food Act, an FSP covering the manufacture of dairy products must be audited annually by a dairy FSP auditor approved by NZFSA. The auditor recommends approval of the dairy FSP to NZFSA and the auditor has a responsibility to inform NZFSA if any critical non-compliance is identified. If this proposal progresses, any FSP for raw milk products covered by the proposed Notice would again, prior to approval, need to take account of the requirements for 'raw milk products' set by the Notice.

8.4.3 The Australia New Zealand Food Standards Code (the Code) and labelling

8.4.3.1 Compliance with the Code

All unpasteurised products (i.e. including raw milk products) sold in New Zealand will be required to comply with Chapters 1 and 2 of the Code which cover General Food Standards and Food Production Standards. NZFSA is responsible for administering the Code in New Zealand.

NZFSA is in the process of seeking a review of the microbiological limits applying to food contained in the Code (Section 1.61 of the Code) with FSANZ.

8.4.3.2 Labelling

The labelling requirements for all food (including dairy products) sold in New Zealand are set out in the Code. Among other things, the Code requires that the label on a package of food for retail sale must include the name of the food and a list of its ingredients.

Standard 1.2.4 of the Code further requires that ingredients must be declared using the common name of the ingredient, or a name that describes the true nature of the ingredient, or if applicable a generic name. This requirement means that in relation to products made from raw or unpasteurised milk, the ingredient declaration should include a statement that the milk is 'raw' or 'unpasteurised'. In the case of products made other than from cows' milk, labels should also include the common name of the species from which the milk is sourced.

It is also proposed that the new Notice (referred to under section 8.1 above) will include a section on labelling, that will require 'the use of raw milk as an ingredient to be declared in the statement of ingredients in accordance with clause 4 paragraph (b) of 1.2.4 of the Food Standards Code.'

As described in section 5.2.3 above, NZFSA intends to continue to collaborate and consult with FSANZ about the possibility of introducing a requirement for a mandatory advisory statement that would apply to raw milk products covered by the proposed new Notice under the APA and be issued under the Code. Any such requirement, if agreed, would not be introduced until FSANZ has finalised its future policy on unpasteurised milk products.

8.5 Importation of unpasteurised milk products

8.5.1 Legal requirements

The importation into New Zealand of the extra hard grating, Swiss and Roquefort unpasteurised milk cheeses is currently managed by the Food Act and two food standards issued under the Act: the Food (Milk and Milk Products Processing) Standard 2007 and the Food (Prescribed Foods) Standard 2007. Amendments are proposed to both these standards to allow for a wider range of unpasteurised milk products to be imported and for these products to be monitored according to their level of risk.

Prescribed foods are imported into New Zealand in accordance with notified Imported Food Requirements (IFR) which specify the conditions under which these products can be imported. Currently a limited range of unpasteurised milk products can only be imported from an exporting country that operates a production programme that has been assessed and recognised as complying with New Zealand standards, or that has been recognised as meeting an equivalent outcome. NZFSA proposes that the same approach be applied to a wider range of unpasteurised milk products proposed for import under this framework.

Countries that are interested in exporting unpasteurised milk products to New Zealand will need to apply to NZFSA for recognition of their public health production programme. NZFSA is the lead agency for assessment of human health risks of the exporting country. When undertaking its food safety assessment, NZFSA will take into account the Ministry of Agriculture and Forestry Biosecurity New Zealand (MAFBNZ) assessment of the animal health risks and any resulting import health standards (see section 8.5.2 below).

The recognition of compliance or equivalence, and any associated pre-clearance conditions, is formalised in country-to-country arrangements between New Zealand and the competent authority of the recognised exporting country. Each arrangement is specific in terms of scope and import conditions.

8.5.2 Biosecurity Import Health Standards

In order for a wider range of unpasteurised milk products to be introduced, animal and human health risks other than food safety also need to be managed. MAFBNZ is responsible for ensuring New Zealanders, our natural resources, our plants and animals are all kept safe and secure from damaging pests and diseases. It is the lead organisation for the assessment of animal health risks of the exporting country. Currently, MAFBNZ has import health standards that allow for the importation of Roquefort, extra hard grating cheeses and the three Swiss hard and extra hard cheeses.

Countries that are interested in exporting unpasteurised milk products to New Zealand will need to have their animal health risk and control programmes assessed by MAFBNZ against New Zealand's animal outcomes before NZFSA public health assessment and import can take place. MAFBNZ, in accordance with their standards development process, will develop the necessary standards for animal health.

8.6 Export of unpasteurised milk products

If this proposal is progressed, New Zealand producers of unpasteurised milk products may take advantage of new export market opportunities, since until now all dairy products exported from New Zealand have been pasteurised. Whilst it is not possible to precisely quantify the volumes and values of any such future exports of unpasteurised milk products, it is likely that such trade would initially be quite limited but could have the potential to expand substantially over time. The benefits that could arise from any future export trade in New Zealand unpasteurised milk products do, however, need to be balanced against the need to ensure that the current significant New Zealand export trade in pasteurised dairy products is safe guarded. A damaging food safety incident related to an exported unpasteurised milk product could possibly have the potential to impact not only on unpasteurised milk product exports, but on all New Zealand dairy exports. However, NZFSA does not believe there would be any difference in impact between a damaging food safety incident related to a pasteurised dairy product and one related to an unpasteurised product.

Food products exported from New Zealand must be produced in accordance with New Zealand legislative requirements. Export products must also meet the legislative requirements of the importing country.

Details of Codex standards, and some overseas country standards and requirements for unpasteurised milk products are attached as Appendix 4[11].

[11] Appendix 4 is drawn largely from information released in the first discussion paper.

Any future exported unpasteurised milk products would need to be manufactured in compliance with the proposed Animal Products (Raw Milk Products Specifications) Notice 2009. In addition, the development of general export standards for unpasteurised milk products may be necessary. Any additional export requirements would most likely relate to verification activities from farm through to export, the separation and identification of raw milk products post manufacture, labelling, and official certification. However, it is likely that any such additional general export requirements would be minimal.

Labelling is one area where additional requirements may be required for all unpasteurised milk export product compared to product sold in New Zealand. Product exported in bulk does not have the same labelling requirements as consumer packs. The product must be labelled with a product designation and an ingredient list, including 'unpasteurised milk', does not need to be included. If product is exported in consumer packs, these packs will be labelled according to the national legislation of the market country, and the consumer packs will be packaged in an outer package for shipping. As interested overseas authorities and importers have to date been told that all New Zealand dairy products are pasteurised, it may be prudent to provide clear information on the labels of all exported unpasteurised milk products to make this change clear to importing countries unaware of the revised New Zealand policy towards unpasteurised milk products.

NZFSA notifies exporters of certain legislative requirements made by or agreed with importing countries, or requirements deemed necessary, through Export Requirement Notices. When an importing country requires that raw milk or unpasteurised products are labelled as such, this will be included in the country specific Export Requirement Notice.

Export Requirement Notices usually specify whether or not dairy products must be pasteurised and, for numerous countries, the requirement for pasteurisation has been established for many years. Such Export Requirement Notices will make reference to export certificate declarations associated with heat treatment of milk and milk products, such as pasteurisation, where such declarations form part of the requirements set by importing countries. Subsequent to a New Zealand producer stating their intention of manufacturing unpasteurised milk product/s, NZFSA will review export certification templates for dairy products to ensure declarations are compatible with the certification of both unpasteurised milk and pasteurised products processed in New Zealand.

NZFSA liaises with competent authorities in export markets. For the potentially important export markets of the European Union, the United States of America and Canada, this would include obtaining an understanding of import requirements for unpasteurised milk products. This information will facilitate the potential review of Export Requirement Notices for these markets if a New Zealand producer of unpasteurised milk products expresses an intention to export to these markets.

Export Requirement Notices for unpasteurised milk products would be reviewed on a country by country basis, on request from New Zealand producers prior to export, and the relevant Notice amended accordingly. Future exporters of unpasteurised milk products need to be aware that negotiations with importing country authorities, and the establishment of export requirements for unpasteurised milk products, may be a lengthy process. Export requirements for unpasteurised milk products are likely to be part of a package of requirements relating to a wider range of export products, and negotiation of any new requirements for unpasteurised milk products should also take into account more general dairy industry strategies. As such, appropriate allowances for these activities should be made in any timelines for the development of export markets.

9 Implementation of the framework for unpasteurised milk products

9.1 Familiarisation for industry, importers and third parties

9.1.1 Guidance material

NZFSA proposes to provide guidance to industry operators, importers, third party agencies and other interested parties to assist them to become familiar with the processes for manufacturing and importing unpasteurised milk products.

Guidance materials will be developed and made available to stakeholders to assist them to understand any relevant technical requirements, and these materials would include:

- information about the technical requirements for raw milk products, including the content of the proposed Animal Products (Raw Milk Products Specifications) Notice 2009;
- validation – guidance on the evidence and supporting information that will be required from operators if they are undertaking studies to validate their programmes in order to help determine whether their products can be classified as ‘unpasteurised milk products’ or ‘raw milk products’;
- qualifications and training that may be available to manufacturers of unpasteurised milk products and other interested parties;
- the process for development, evaluation (where required), registration, auditing and verification of risk based management plans for unpasteurised and raw milk products; and
- information for importers on the process to be followed when importing such products.

NZFSA would welcome feedback on any other forms of material that may be useful.

9.1.2 Workshops

During the consultation period for this paper, NZFSA will undertake workshops in Auckland, Hamilton and Christchurch for all stakeholders with an interest in unpasteurised milk and raw milk processing, including people who intend to manufacture such products, importers, evaluators and verifiers of RMPs, auditors of FSPs, and staff from public health units.

The workshops will provide an opportunity for stakeholders to become familiar with, and to discuss, the proposal outlined in this paper. The workshops will be timed to ensure that, following attendance, stakeholders have sufficient time to make a written submission on the discussion paper prior to the consultation period closing. Participants will also be able to request that comments they make at the workshops are included in the summary of submissions.

Stakeholders will be asked to indicate which workshop they wish to attend by a set date to allow time for arrangements to be made.

Providing this proposal progresses, NZFSA will also provide training workshops for attendance by auditors of FSPs, evaluators and verifiers of RMPs, the NZFSA Compliance and Investigation Group, staff from public health units and accreditation bodies. These would occur once the technical and legal requirements relating to this proposal have been finalised.

9.2 Costs

Costs incurred in the process of manufacturing, importing or exporting unpasteurised and raw milk products will need to be met by the operator concerned. Such costs may for example be incurred when assessing intrinsic characteristics and/or processes in order to determine the regulatory requirements that will apply; developing and obtaining registration or approval of an RMP or FSP for unpasteurised or raw milk products; getting RMPs or FSPs evaluated, verified or audited; and seeking registration as an exporter.

In future when NZFSA provides services related to unpasteurised and raw milk products at the request of an operator of an RMP or FSP, or any other processor or person, NZFSA will charge at the appropriate hourly rate as prescribed in regulations under the relevant legislation, plus the costs of any actual and reasonable expenses incurred. For example, NZFSA currently recovers for the time applied to dairy approvals at a rate of $137.25 inclusive of GST per hour.

The work that NZFSA could be requested to undertake by operators could include: assessing data provided in conjunction with an application to register a RMP or approve a FSP and determining the regulatory requirements that would apply (for example by making a determination using the results of a validation study). Where possible and appropriate, NZFSA will work over time to train third parties to undertake tasks associated with the assessment of unpasteurised milk product processes.

NZFSA would welcome comment from submitters about the costs which they may incur when satisfying the regulatory requirements described in this paper.

9.3 Risk communication and consumer education

Implementing the outcomes of this proposal would also involve communicating the right messages to the right consumer audiences in a timely way.

NZFSA's current risk communication strategies for vulnerable consumers, and for the limited range of unpasteurised milk products that are currently available, are described in sections 5.2.1. and 5.2.2. above. In light of the market research survey into the effectiveness of NZFSA's previous unpasteurised milk products education campaign (referred to as raw milk products) and the public's level of awareness of the hazards that may be associated with some unpasteurised milk products, the strategy for unpasteurised milk products is now being updated.

New initiatives to reach affected people are being added. These include working with government and non-government groups to inform their members/constituency about unpasteurised milk products. Proposals include providing website information or links to targeted information; supplying copy for publications on food safety issues, and making presentations or supplying brochures for their meetings or resource centres. NZFSA's consumer resources will also be updated to ensure they use terminology that consumers understand.

NZFSA's risk communications strategy for unpasteurised milk products will continue to evolve as the outcomes of the proposal are finalised. The objective will be to ensure not only that all sectors of industry have the information they need to meet their legal obligations, but also that consumers are made aware of any hazards associated with unpasteurised milk products.

10 Regulatory impact statement

Executive summary and proposal

Currently only a very small variety of unpasteurised milk products are available in New Zealand. These products consist of a few imported cheeses, and very limited sales of raw drinking milk which can be made at farm gates to consumers for their own personal or family consumption. Otherwise, all dairy products made in New Zealand use milk that has been subject to pasteurisation, or an equivalent alternative treatment approved by the New Zealand Food Safety Authority (NZFSA).

In recent years there has been growing demand for a wider range of unpasteurised milk products to be made available in New Zealand. This demand has come from consumers, the food and retail trade, local manufacturers, importers, and overseas trading partners.

Some unpasteurised milk products pose health hazards to consumers because of the potential for pathogens[12] that are present in the raw milk to survive and multiply in end products, and to then cause illness in those who consume them. However, other unpasteurised milk products can be consumed safely by most if not all of the population; as they have intrinsic characteristics or undergo processing steps that ensure pathogens do not multiply to unacceptable levels in end products.

Until now, no technical criteria has been developed in New Zealand that takes account of the variation in the hazards posed by unpasteurised milk products, or which defines the controls that need to be in place at the milk harvesting and processing stages to ensure unpasteurised milk products satisfy acceptable food safety criteria.

NZFSA is now proposing the introduction of a regulatory framework that recognises the variation in the health hazards that different unpasteurised milk products pose to consumers. NZFSA proposes grouping unpasteurised milk products according to the hazards they pose, and where necessary setting technical requirements relating to on-farm and processing steps. The framework would facilitate the local manufacture, importation, export and domestic sale of those unpasteurised milk products that can be produced to an acceptable level of safety (i.e. can be safely consumed by all, or most of the population).

[12] Pathogens that can be present in raw or untreated milk include *Listeria monocytogenes, Campylobacter spp., Salmonella serovars* and *Escherichia coli spp.*

The proposed framework for unpasteurised milk products would open up new market opportunities for manufacturers, facilitate imports and exports of unpasteurised milk products, provide for greater consumer choice, and be consistent with developments internationally; whilst still ensuring an acceptable level of consumer protection.

Status quo and problem

All dairy products currently manufactured in New Zealand are made from milk that has been subject to pasteurisation, or an alternative equivalent treatment method approved by NZFSA. The one exception relates to farm gate sales of raw milk. Section 11A of the Food Act 1981 (the Food Act) permits up to five litres of raw milk to be sold at any one time from farm gates to those buying the milk for personal or family consumption.

A small range of overseas-made unpasteurised milk cheeses[13] can be imported under the Food (Milk and Milk Products Processing) Standard 2007, issued pursuant to the Food Act. Permission for these imports has only been granted upon application to NZFSA from overseas trading partners and after case-by-case assessments of the health hazards that the individual cheeses pose to consumers. Such case-by-case assessments are resource intensive and costly for NZFSA to undertake. They also set up the potential for inequity in the treatment of imported and locally made products.

It is, in theory, possible for New Zealand producers to apply to NZFSA to make unpasteurised milk products under a Risk Management Programme (RMP) under the Animal Products Act 1999 (APA) or a Food Safety Programme (FSP) under the Food Act. However, no technical criteria or guidance material for operators are in place to assist with this process. This makes it difficult for industry operators to develop such RMPs or FSPs; or to get such programmes evaluated, verified or audited, and approved or registered with NZFSA. As a result, the absence of technical criteria and guidance material has contributed to the fact that no New Zealand producer has to date progressed an RMP or an FSP for unpasteurised milk products.

There are several reasons why technical criteria and guidance material for unpasteurised milk products have not been developed. These include that both the New Zealand dairy industry and current and former regulators have, until now, given priority to the development of pasteurised dairy products. In the past, there has also been limited demand for unpasteurised milk products.

[13] These cheeses are Emmental, Gruyere and Sbrinz – three hard and very hard Swiss cheeses; various extra-hard grating cheeses including Grana Padano, Parmigiano Reggiano, Romano, Asiago and Montasio; and Roquefort – the French semi-hard blue-veined cheese.

A number of developments have now prompted NZFSA to develop the proposed regulatory framework (which would include technical criteria and guidance material) for unpasteurised milk products. These developments include that:

- there is now demand for an increased range of unpasteurised milk products amongst some New Zealand consumers and the food retail and hospitality sectors;
- local manufacturers seek equity with importers. They seek to be able to make the same range of unpasteurised milk products as can be imported; and some wish to expand this range and to develop new domestic and export markets for such products;
- importers and overseas trading partners have requested that New Zealand allow a greater range of unpasteurised milk products to be imported;
- many unpasteurised milk products are produced and consumed safely in other parts of the world, and the Codex Alimentarius Commission provides for the production of unpasteurised milk products (except for raw drinking milk), under appropriate hygienic conditions in its *Code of Hygienic Practice for Milk and Milk Products*; and
- Food Standards Australia New Zealand in Australia (FSANZ) is consulting on developing standards to allow for a wider range of unpasteurised milk products in Australia. This has implications for New Zealand under the Trans-Tasman Mutual Recognition Arrangement.

In light of these developments, problems that could arise if changes are not made to the status quo (which does not readily facilitate the production, sale, export and importation of unpasteurised milk products) include:

- loss of opportunity for local manufacturers and importers to develop markets for such products, including potential export markets;
- that the status quo could be identified as an impediment to trade; and
- limited choice for consumers and the food sector.

A benefit of maintaining the status quo would be that, as unpasteurised milk products would not be widely available, any hazards that they may pose to consumers (especially vulnerable consumers) would be limited or non-existent. However NZFSA considers that the proposed regulatory framework would mitigate any such hazards.

Objective

The central objective of the NZFSA proposal is to develop and implement an effective regulatory framework to cover all unpasteurised milk products that could potentially be manufactured, sold, exported, and imported into New Zealand.

Preferred option

NZFSA's preferred option is to develop a regulatory framework that covers all unpasteurised milk products, and would allow those that can be produced to an acceptable level of safety (that is, that pose a low level of risk to the general population) to be produced, sold, exported and imported.

Some unpasteurised milk products pose hazards to human health because there is potential for pathogens present in the milk to multiply in end products to levels in excess of acceptable food safety criteria. However, the hazards that unpasteurised milk products pose vary from product to product. Some are as safe to eat as pasteurised products. Others are safe for consumption by the general population, but should be avoided by vulnerable consumers (such as infants, pregnant women, the frail elderly and the immune-compromised). At the other end of the spectrum, some unpasteurised milk products have the potential to cause foodborne illness to the general public[14].

The proposed framework would categorise unpasteurised milk products into three groups. One group could be made under existing dairy regulations, because their characteristics and/or the processing steps they undergo ensure the elimination of pathogens (that could cause illness) in the end products. A second group of products would be subject to proposed new specifications, designed to control the harvesting of milk and processing techniques, to ensure that any pathogens present in the raw milk do not multiply in end products to levels in excess of acceptable food safety criteria. This second group of products could be safety consumed by the general public, but could pose hazards to vulnerable consumers, who would be encouraged to avoid eating them, just as they are encouraged to avoid other "risky" foods, such as shellfish. The third group of unpasteurised milk products would be unable to be made or imported, because they do not undergo processing steps or have any intrinsic characteristics which prevent pathogens multiplying to unacceptable levels in the end products.

The proposed framework would consist of:

- processes to group unpasteurised milk products for regulatory purposes;

[14] Foodborne illness has a significant negative impact on the New Zealand economy. A recent ESR study estimated that the cost of lost productivity from foodborne illness, associated with people temporarily or permanently removed from the workforce, equates to $83 million annually. This figure does not take into account hospital or medical costs incurred in the treatment of foodborne illness.

- technical requirements relating to on-farm and processing steps, with which producers of some unpasteurised milk products would need to comply;
- new specifications that would apply to some unpasteurised milk products and revised import standards;
- education targeted at vulnerable consumers; and
- labelling to indicate products contain unpasteurised milk.

The framework would be enacted by specifications issued by the Chief Executive of NZFSA pursuant to section 45 of the APA, and likely to be known as the 'Animal Products (Raw Milk Products Specifications) Notice 2009'. Amendments would also be made to the Food (Milk and Milk Products Processing) Standard 2007 and the Food (Prescribed Foods) Standard 2007, issued pursuant to the Food Act.

Under the Australia New Zealand Food Standards Code, labels on unpasteurised milk products sold in New Zealand would need to include ingredient declarations that the milk used is raw or unpasteurised. Over time, and depending on the results of consultation about extending the range of unpasteurised milk products available in Australia, NZFSA would also work with FSANZ on the development of a joint New Zealand-Australian food standard for labelling unpasteurised milk products.

The benefits of this option include that it would facilitate trade in unpasteurised milk products at the same time as managing the hazards associated with some such products. Although it is not possible to precisely quantify the value of any future trade in unpasteurised milk products, New Zealand producers and importers would have the opportunity to further develop the domestic market for such products. New Zealand producers could also develop new export markets for unpasteurised milk products.

The hazards associated with some unpasteurised milk products would be managed by: the most hazardous unpasteurised milk products being prohibited from sale or manufacture; proposed new specifications covering on-farm practices and processing steps; the use of risk communications to educate vulnerable consumers and encourage them to avoid consumption of unpasteurised milk products; and such products being labelled as containing unpasteurised milk.

Producers and importers would incur costs as they work through the steps required to determine the regulatory requirements that would apply to their unpasteurised milk products. For example, where validation studies would be needed to determine whether unpasteurised products would be subject to proposed new specifications or could be made under existing dairy regulations, these would be undertaken at the expense of those making or selling the product. The costs of such studies would vary depending upon the pathogens and parameters requiring validation. However, NZFSA has

progressed criteria to remove the need for validation studies where feasible, and is working on developing additional tools which may in future further reduce the requirement for, and associated costs of, validation studies. Industry members could work together and share costs where production processes are transferable. NZFSA would also develop guidance material to assist operators in commissioning validation studies. Operators would be free to choose who undertakes their validation studies, with NZFSA's interest being centred on the outcome of the validation. Costs incurred during this process would be one-off, rather than ongoing.

Producers and exporters of unpasteurised milk products would be subject to the usual ongoing compliance costs associated with making products under RMPs under the APA, or FSPs under the Food Act. Such costs include those related to evaluation (where required), registration or approval, and verification or auditing of plans. Examples of these costs are from $10,000 to $20,000 to develop and register an FSP and from $900 to $5.000 to get an FSP audited (depending on the complexity of the operation).

The ingredient lists on labels for raw milk products would need to indicate the use of unpasteurised milk. However, for any new product, a label including an ingredient list must be developed. If a Joint Food Standard was to be subsequently introduced and require a mandatory advisory statement on packaging for unpasteurised milk products, the cost of this additional requirement is not expected to be significant. It is normal practice to allow a transition time before new requirements apply, so that any new labelling requirements could be introduced in line with usual production timetables.

The proposed framework includes provision for education of consumers about the hazards associated with some unpasteurised milk products. The responsibility for this risk communication would fall to NZFSA, and would be incorporated into NZFSA's existing risk communications programme.

Alternative options

Two alternatives to the status quo and NZFSA's preferred option were analysed in detail in an earlier NZFSA discussion paper: *Proposed framework for the manufacture, importation and sale of raw milk products,* released in August 2008.

One alternative option would involve allowing all unpasteurised milk products to be made and sold in New Zealand, regardless of the hazards they may pose to human health. The benefits of this option include that it would not limit consumer choice in any way, and would allow local producers and importers to make and sell whichever such products they chose. However, there could also be significant costs. As some unpasteurised milk products do pose health hazards to the general population, this option could have public health consequences. A damaging food safety incident relating to unpasteurised milk products made in New Zealand might adversely impact on New Zealand's international reputation as a safe producer and trader of food. This option would also not

align with government policy on food safety, which requires that risk factors are identified, controlled and/or eliminated.

The other option considered involved both maintaining the current regulatory environment which does not facilitate the local manufacture of unpasteurised milk products, and not considering any future applications for case-by-case assessments that would enable importation of overseas made raw milk products not already available in New Zealand. However, this option would be inconsistent with New Zealand's obligations under the World Trade Organization Sanitary and Phytosanitary Agreement.

Implementation and review

NZFSA is responsible for administering the APA and Food Act, and would implement the proposed regulatory framework. NZFSA would develop guidance materials to familiarise industry operators, importers, third party agencies and other interested parties with the relevant technical and legal requirements. NZFSA would also run information and training workshops on these requirements. NZFSA's risk communications strategy would evolve to include resources to educate consumers about unpasteurised milk products.

Dependent on the results of consultation and decisions by government, the proposed regulatory framework could be introduced as early as the latter part of 2009.

Compliance with RMPs and FSPs for raw milk products, developed to take account of the proposed new 'Animal Products (Raw Milk Products Specifications) Notice 2009', would be regularly verified or audited by third parties recognised or approved for this purpose by NZFSA. The Compliance and Investigation Group of NZFSA would manage any corrective actions and sanctions required as a result of significant non-compliance, and provide feedback to the NZFSA Standards Group.

Consultation

Consultation on the proposed framework was initiated by an NZFSA public discussion paper released in August 2008. The great majority of submitters – 40 out of 43 – supported unpasteurised milk products becoming more widely available. Where submitters gave an opinion on the proposed framework, most also favoured the NZFSA approach. As a result, NZFSA has since continued to develop the framework.

Further public consultation on the framework will be initiated by the release of the attached discussion paper. During the consultation period for this paper, NZFSA will host regional workshops to familiarise stakeholders with the proposal and seek feedback.

Throughout the process of developing the framework, NZFSA has kept key players in the dairy industry informed, including the Dairy Product Safety Advisory Council.

The following government agencies were consulted on the August 2008 discussion paper, and will be made aware of this second discussion paper: the Ministries of Agriculture and Forestry (including Biosecurity New Zealand), Consumer Affairs, Economic Development, Foreign Affairs and Trade, and Health, also the Department of the Prime Minister and Cabinet, the Treasury and Food Standards Australia New Zealand.

Adequacy statement

NZFSA has prepared this regulatory impact statement for the purposes of public consultation.

NZFSA acknowledges that, for a number of reasons, it is not possible to precisely quantify the hazards that all individual unpasteurised milk products pose to all consumers. These reasons include that: there are a very large variety of milk products each with its own unique manufacturing process; there is a scarcity of relevant data internationally about the processes used to make both pasteurised and unpasteurised milk products; and some consumers may be more vulnerable to hazards than others. However, using evidence collected from challenge studies and outbreaks of illness associated with dairy products, it is possible to identify broad levels of hazards that unpasteurised milk products pose to general members of the public[15]. The NZFSA proposed regulatory framework for unpasteurised milk products is based on these levels of hazards.

NZFSA is unable to precisely quantify the volume of new sales and exports that manufacturers of unpasteurised milk products and importers of such products could achieve under the proposed framework. NZFSA is asking submitters on the discussion paper to provide estimates of potential new sales of such products, where possible.

Some compliance costs associated with the future production and importation of unpasteurised milk products are unable to be precisely calculated. Many such costs will vary according to the individual product concerned and the regulatory requirements that will apply. For example, some programmes will require validation studies in order to demonstrate it produces products that meet the relevant regulatory requirements. The cost of such studies will vary depending on the parameters and pathogens being studied. Other products will not require such studies prior to manufacture and sale. NZFSA is asking submitters to comment on the likely costs they may incur in producing or importing unpasteurised milk products, should the proposed framework be implemented.

[15] These levels are: (i) low if the milk is treated in a way that results in a combination of extrinsic and intrinsic factors minimising the survival and growth of pathogens; and (ii) moderate to high if there are no factors that inhibit the survival and growth of pathogens.

11 Questions and submission example

NZFSA seeks your views on the proposal in this paper. The form below is provided to assist you in making a submission, but comments in other formats will be welcome.

If you have queries about this paper and the NZFSA proposal, please contact NZFSA's Technical Standards and Systems Team on 04 894 2467 or TSS@nzfsa.govt.nz.

Name:

Organisation's Name (if applicable):

Contact details (including phone, email if available):

Headings under which you may wish to comment include:

- the consultation process;
- developments since the first NZFSA discussion document on unpasteurised milk products;
- the proposed process for determining regulatory options for such products;
- the proposed technical requirements for raw milk products;
- the intended legal mechanisms for implementing the proposed framework;
- the plans for implementing the framework, and particularly ideas you may have on guidance material and other assistance that may help stakeholders become familiar with the framework;
- the proposals for risk communications and labelling relating to unpasteurised milk products;
- the impact that the proposed new framework would have on your business or other interests, for example: new business (domestic and/or export) and marketing opportunities that you may pursue if the proposal progresses; and the costs that you expect to incur (e.g. relating to the categorisation process, the new technical requirements, or import standards);
- if you plan to export unpasteurised or raw milk products, comment on suitable labelling for exports; and
- whether you support the proposal in the discussion document, either in full or in part.

12 Glossary

Australia New Zealand Food Standards Code (the Code): A collection of individual food standards developed by FSANZ (see below). As a result of an *Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Food Treaty), signed in 1995, New Zealand and Australia have a joint food standards setting system which resulted in the Australia New Zealand Food Standards Code (The Code). The Code covers the content and labelling of food sold in New Zealand and Australia. However, the Food Treaty does not apply to requirements for food safety, maximum residue levels, or third country trade; in these areas each country operates under its own legislation and therefore the Code's Standards relating to food safety (Chapters 3 and 4, and Standard 1.6.2) do not apply in New Zealand.

Aw: Water activity or Aw is defined as the amount of water available for microbial (bacteria, yeast and mould) growth. Water activity is based on a scale of 0 to 1.0, with pure water having a water activity of 1.00.

Extra hard grating cheeses: These cheeses can be referred to as extra hard Parmesan style grating cheeses as they are so hard they require grating to serve. The treatment required to produce these cheeses is defined in the Food (Milk and Milk Products Processing) Standard 2007 as:

'Method B:

i. The heating of the curd to a temperature of not less than 48 degrees Celsius; and

ii. The cheese or cheese product is stored at a temperature of not less than 10 degrees Celsius for a period of no less than 6 months from the date of manufacture.'

Food safety programme: A programme as required by Section 4A of the Food Act 1981,

designed to identify and control food safety risk factors in order to establish and maintain food safety.

Food Standards Australia New Zealand (FSANZ): An independent statutory agency, established by

the Food Standards Australia New Zealand Act 1991 (Australian Commonwealth legislation), which sets food standards covering the composition and labelling of food, for both countries (see Australia New Zealand Food Standards Code).

Operator defined process measures: Discreet process steps applied during the manufacture of the product that are integral to achieving food safety outcomes. They include parameters such as cooking time and temperature, acidification and pH, maturation time and temperature, water activity and salt concentration.

Pasteurisation: The term 'pasteurisation' for milk or a milk product is defined in the Food (Milk and Milk Products Processing) Standard 2007 as treatment according to one of the following methods –

i. The holding method, by which the milk or milk product is rapidly heated to a temperature of not less than 63 degrees Celsius and not more than 66 degrees Celsius, retained at that temperature for not less than 30 minutes, and then -(a) immediately and rapidly reduced to 5 degrees Celsius or less in the case of milk or milk products other than cream, or to 7 degrees Celsius or less in the case of cream; and (b) maintained at or below that temperature until the milk or milk product is removed from the premises for delivery;

ii. The high-temperature short-time method, by which the milk or milk product is rapidly heated to a temperature of not less than 72 degrees Celsius, retained at that temperature for not less than 15 seconds, and then treated in accordance with subparagraphs (a) and (b) of the method in paragraph (i);

iii. Any other heat treatment method that is as effective in terms of bacterial reduction as methods (i) and (ii).

Pathogenic and Non-pathogenic organisms (Pathogens): Pathogenic organisms (pathogens) include bacteria, viruses or cysts, which are capable of causing diseases (for example, typhoid, cholera, dysentery) in a host (such as a person). Non-pathogenic organisms do not cause disease.

pH: a measure of acidity or alkalinity in which the pH of pure water is 7, with lower numbers indicating acidity and higher numbers indicating alkalinity.

Raw milk product: The first discussion document described what is meant by "raw milk products" for the purposes of outlining the scope of the proposed framework, i.e. raw milk products were defined as including all milk products, except those that have been produced from milk that has been pasteurised or thermised.

NZFSA has now developed a proposed New Zealand legal definition for raw milk products. In arriving at the definition of raw milk products NZFSA recognises that there are a variety of technical definitions for raw milk products in use internationally, including a definition set by the Codex Alimentarius Commission (Codex) in its *Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004*. However the proposed definition is most appropriate for the proposed regulatory framework as it defines which milk products will need to be produced subject to the proposed additional regulatory measures (referred to as Category 2 in the first discussion document). NZFSA proposes that for the purpose of regulating their production, import, export and sale, raw milk products will be legally defined as those products made from milk which has not been pasteurised or made using an equivalent process to pasteurisation (refer to the draft specifications in Appendix 1 for this definition).

Section 5.1 discusses more fully the definition of raw milk products and how this relates to the category approach outlined in the first discussion document and the proposed regulatory framework.

Risk management programme: A programme as defined by Section 12 of the Animal Products Act 1999, designed to identify, control, manage and eliminate or minimise, hazards and risk factors in relation to the production and processing of animal material and animal product in order to ensure that the resulting animal product is fit for intended purpose.

Thermisation is a heat treatment and is included in the definition of cheese treatment method A defined in the Food (Milk and Milk Products Processing) Standard 2007. The Standard states:

'Method A:

i. The rapid heating of milk or a milk product to be used in the manufacture of cheese to a temperature of not less than 64.5 degrees Celsius, retaining it at that temperature for not less than 16 seconds; and

ii. Storing the cheese prior to sale at a temperature of not less than 7 degrees Celsius for not less than 90 days from the date of commencement of manufacture.'

Subsection (i) is thermisation and (ii) is the storage requirement that must occur in conjunction with this treatment. Cheeses that have been treated and stored as per this requirement are known as thermised cheeses.

The Trans-Tasman Mutual Recognition Arrangement (TTMRA): A non-treaty arrangement between the New Zealand and Australian governments that aims to remove regulatory barriers to the movement of goods and thus facilitate trade between the two countries. Goods that may legally be sold in New Zealand may be sold in Australia and vice versa, regardless of any differences in standards or other sales-related regulatory requirements. Goods need only comply with the standards or regulations applying in the jurisdiction in which they are produced or through which they are imported before they can be sold in another participating jurisdiction. There are limited exemptions to these provisions Implemented in New Zealand by the Trans-Tasman Mutual Recognition Act 1997.

YOPI group: term used to describe a sub group of consumers comprising the young, frail elderly, pregnant and immune-compromised.

Appendix 1: Draft Animal Products (Raw Milk Products Specifications) Notice 2009

See below.

Contents

Notice

1 Title

This notice is the Animal Products (Raw Milk Products Specifications) Notice 2009.

2 Commencement

This notice comes into force on [day month] 2009.

Part 1
Preliminary Provisions

3 Purpose and application

(1) The purpose of this notice is to set additional requirements that apply to-
  (a) the production and processing of raw milk and dairy material to be used for the manufacture of raw milk products intended for human consumption; and
  (b) the production and processing of raw milk products intended for human consumption.

(2) By way of explanation, the requirements set out in this notice are in addition to any other applicable requirements set out in the Act or the Food Act 1981, or any regulations, notices, or standards made pursuant to those Acts.

4 Interpretation

(1) In this notice, unless the context otherwise requires,-

Act means the Animal Products Act 1999

approved auditor has the meaning given to it in the Food Act 1981

critical non-compliance has the meaning given to it in the Animal Products (Dairy Specifications) Notice 2006

diseased means the clinical and/or pathological manifestation of infection

farm dairy assessor means a competent person responsible to the programme operator for assessing dairy processing activities at farm dairies

farm dairy assessment means a systematic, independent review and examination of the design and operation of a farm dairy and includes the construction, facilities, equipment, services, and activities and records to confirm that milk processing is in compliance with the registered risk management programme and regulatory requirements under the Act and that the milk supplied is expected to be fit for its intended purpose

food safety criteria means the criteria contained in clause 23

infection means the entry and development or multiplication of an infectious agent in the body of humans or animals.

lot means a quantity of dairy material or product manufactured during a discrete period of time, typically not exceeding 24 hours, in one continuous process

milk harvester means a person involved in the milking of animals at a farm dairy

milking means the extraction of milk from a milking animal

milking herd means the milking animals kept and milked for the purpose of making raw milk products, including but not limited to, cows, sheep, goats, and buffalo.

milking plant means equipment used for the-
(a) extraction, filtering, cooling, or storing of milk; and

(b) cleaning, sanitising, or similar activities
at a farm dairy

national Tb eradication scheme means the National Operational Plan for the National Bovine Tuberculosis Pest Management Strategy (NBTPMS), prepared pursuant to section 85 of Biosecurity Act 1993, to give effect to the Biosecurity (National Bovine Tuberculosis Pest Management Strategy) Order 1998 and its amendments of 30 September 2004, and any subsequent amendments or replacements

operator defined process measure means a discrete process step or set of process steps applied during the manufacture of the raw milk product that-

(a) contributes to achieving the food safety criteria; and

(b) is documented in the operators' programme,

including but not limited to, cooking time and temperature, acidification and pH reduction, maturation time and temperature, water activity and salt concentration

pathogen means a disease causing organism

pathogen elimination step means a processing step, or a combination of processing steps, that effect a 5-log reduction in the number of pathogens of human health significance in raw milk

pest mean a harmful, destructive, or unwanted organism which may adversely affect the animals in the milking herd, the suitability of the environment, or the raw milk, including but not limited to birds, mice, vermin, pigs, poultry, and cats.

programme means a registered risk management programme, or a food safety programme to the extent that the law allows

programme operator means an operator of a registered risk management programme or, to the extent that the law allows, a food safety programme

raw milk means milk produced in accordance with a registered risk management programme and that has not been subjected to any processing intended to alter the quality or composition characteristics of the milk

raw milk product means a processed dairy product-

(a) that has not received a pathogen elimination step; and

(b) in which as a result of its nature and the manner in which it is processed, may allow the survival of pathogens, but in the case of pathogens specified in the food safety criteria, will not support their growth or allow their survival, to levels that exceed those specified in the food safety criteria; and

(c) that is not raw drinking milk; and

(d) that is not made from colostrum

season means the period from the 1st of June to the 31st of May of the following calendar year

starter culture means a preparation of micro-organisms that is free of pathogens, and prepared for the purpose of modifying the characteristics of the dairy material.

Tb clear means achieving a rating of "C5" through to "C10" under the national Tb eradication scheme

verifier means a recognised risk management programme verifier or an approved auditor

(2) Any term or expression that is defined in the Animal Products Act 1999, and used but not defined in this notice has the same meaning as in that Act.

Part 2
Farm dairy requirements

5 Identification of farm dairies

Farm dairy operators intending to supply milk for the manufacture of raw milk products must be identified within their programme covering those operations.

6 Milking animal identification

(1) Farm dairy operators must implement an identification system to ensure each animal in the milking herd is uniquely identifiable.

(2) Records must be kept that enable the farm dairy operator to identify which animals are part of the milking herd.

(3) The records referred to in subclause (2) must:
- (a) legible; and
- (b) held for four years; and
- (c) stored in a manner which protects the records from damage, deterioration or loss.

7 Animal health

(1) Farm dairy operators must ensure that all animals in the milking herd are subject to a veterinary inspection twice each season, one being in the period from 1 August to 30 November and one being in the period from 1 February to 31May.

(2) Farm dairy operators must ensure that all animals in the milking herd are:
- (a) classified as Tb clear; and
- (b) tested for Tuberculosis each season.

(3) Any animal in the milking herd that has been-
- (a) identified as Tb standard test positive in accordance with the national Tb eradication scheme; or
- (b) identified as a Tb reactor in accordance with the national Tb eradication scheme; or
- (c) directed to slaughter by a veterinarian or person authorised to do so under the national Tb eradication scheme,

must be isolated from the other animals in the milking herd and, for the purposes of this notice, have all milk withheld regardless of whether the result is subject to confirmation testing under the national Tb eradication scheme

8 Water and feed for animals in the milking herd

Farm dairy operators must ensure that water and feed made available to animals in the milking herd must be of suitable quality and must not be a vector for pathogens.

9 Milk cooling and storage

(1) Raw milk must be—
- (a) cooled in accordance with the Animal Products (Dairy Processing Specifications) Notice 2006 if collected daily; and
- (b) cooled to 6°C or below within 2 hours from the completion of milking if collected every other day, unless manufacture commences within 2 hours from the completion of milking.

(2) Raw milk stored at the farm dairy must be held at the temperature applicable in subclause (1) until it is removed from the farm bulk milk tank or until the next milking.

10 Milk harvesting

(1) All teats used for milk harvesting must be-
- (a) clean and dry; and
- (b) washed and dried with a single service towel when used for bovine animals; and
- (c) wiped when used for caprine animals.

(2) Milk harvesters must-
- (a) strip and observe the foremilk from each teat immediately prior to each milking; and
- (b) withhold all the milk from any animal found to have abnormal milk from any teat.

(3) Farm dairy operators must take all reasonable steps to avoid raw milk intended for the manufacture of raw milk products being mixed with, or contaminated by, any milk not intended for the manufacture of raw milk products.

11 Operator monitoring of farm milk supply

The programme operator must specify in the programme the manner in which the raw milk supply will be monitored, including but not limited to-
- (a) the parameters to be monitored; and
- (b) the frequency at which they are to be monitored; and
- (c) the acceptable limits; and
- (d) the actions to be taken if those limits are exceeded.

12 Disposal of non-conforming raw milk

(1) Raw milk that has not been harvested in accordance with this notice, or is otherwise not fit for the manufacture of raw milk products, must be withheld and either:
- (a) disposed of appropriately; or
- (b) redirected to be supplied for processing into a heat treated product.

(2) The use or disposal of the withheld milk must be recorded.

(3) The records referred to in subclause (2) must be-
  (a) legible; and
  (b) held for four years; and
  (c) stored in a manner which protects the records from damage, deterioration or loss.

13 Farm dairy assessment

(1) The programme operator must ensure that a farm dairy assessment is carried out in each of the following periods-
  (a) in the period from 1 August to 30 November; and
  (b) in the period from 1 February to 31 May.

(2) The farm dairy assessments referred to in subclause (1) must be undertaken by a suitably qualified person while the milking herd is in lactation.

(3) If the farm dairy operations are not able to be confirmed as suitable for the harvesting of milk for the manufacture raw milk products, or any situation where a critical non-compliance is identified-
  (a) the farm dairy assessor is to advise the farm dairy operator and programme operator immediately; and
  (b) no raw milk harvested at the farm dairy is to be used for the manufacture of raw milk products until the situation has been resolved; and
  (c) any affected raw milk already supplied must be identified and reported in accordance with clause 14.

14 Reporting findings

The programme operator must ensure that-
  (a) the farm dairy operator is advised of unsatisfactory raw milk collection temperatures and unsatisfactory results from sampling and testing of the farm dairy milk supply; and
  (b) for any non-conforming milk or any activity not in compliance with the programme affecting the status of the milk supplied-
    (i) dairy processors in receipt of the milk are advised without delay; and
    (ii) the verifier is advised without delay.

Part 3
Transport

15 Transfer to processing premises

(1) Raw milk intended for the manufacture of raw milk products must be segregated from milk not intended for the manufacture of raw milk products.

(2) A programme covering the transport and storage of raw milk and raw dairy material intended for the manufacture of raw milk products must ensure that equipment, facilities, and storage areas protect the raw milk and dairy material from contamination.

(3) The raw milk temperature must not exceed 8°C at any point from collection at the farm dairy through to commencement of the manufacturing process.

Part 4
Manufacturing requirements

16 General requirements applicable at all stages of raw milk product processing

Raw milk products must be manufactured-

(a) from raw milk that:
  (i) is suitable for the nature of the intended raw milk product; and
  (ii) has been harvested and handled in accordance with this notice; and

(b) using procedures and equipment of a design that do not permit cross contamination.

17 Milk acceptance and storage

The raw milk used for the manufacture of raw milk products must-

(a) be held at or below 8°C prior to manufacture; and

(b) be no older than 48 hours at the commencement of manufacture; and

(c) be monitored at the commencement of manufacture according to a documented plan in the programme at sufficient frequency to ensure that process hygiene criteria and food safety criteria will be met.

18 Operator defined process measures

The programme operator must document-

(a) the operator defined process measures to be applied during the manufacture of the raw milk product that alone, or in combination, ensure the food safety criteria is met; and

(b) the manner in which the operator defined process measures will be monitored; and

(c) the actions to be taken should any operator defined process measures fail to be applied as intended.

Processing controls and restrictions

19 Milk treatment and preparation

The temperature of raw milk and dairy material must be controlled to minimise the opportunity for growth of pathogens.

20 Starter cultures

(1) Any starter culture used as part of an operator defined process measure must be capable of achieving any required acidification within the time allowed

(2) Whey or material derived from previous dairy product manufacture must not be added as a starter culture.

Managing raw milk product conformance

21 Monitoring dairy product conformance

(1) The programme operator must ensure that raw milk products-

(a) are monitored for relevant pathogens at a frequency appropriate to the nature of the raw milk product and process; and

(b) satisfy the process hygiene criteria requirements contained in clause 22; and
(c) meet the food safety criteria.

(2) Any raw milk product that fails to meet the food safety criteria is non-conforming and must be managed in accordance with regulation 5 of the Animal Products (Dairy) Regulations 2005.

22 Process hygiene criteria

(1) The raw milk or raw milk products listed in column 2 of table 1 must comply with the microbiological limits listed in column 3 set in relation to the applicable micro-organisms contained in column 1 at the time the criterion listed in column 4 applies.

(2) If a raw milk or raw milk product listed column 2 of table 1 does not meet the microbiological limit contained in column 3 set in relation to that raw milk product then the programme operator must take the corrective action specified in column 5.

Table 1

Column 1	Column 2	Column 3	Column 4	Column 5
Micro-organisms	**Raw milk or Raw milk product**	**Microbiological limits**	**Criterion applies**	**Corrective action required**
Coagulase Positive Staphylococci	All	100 cfu/g	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improve production hygiene and monitoring of raw milk supply.
Aerobic Plate Count at 30°C	Raw milk	300,000 cfu/ml	Raw milk immediately prior to the commencement of manufacture	Improve production hygiene and monitoring of individual raw milk supplies

23 Food safety criteria

The raw milk products listed in column 2 of table 2 must comply with the limits set in column 3 set in relation to the relevant micro-organism listed in column 1.

Table 2

Column 1	Column 2	Column 3
Micro-organism	**Raw milk Product**	**Limits**
Salmonella	All	Absence in five 25 g samples taken over the lot
Listeria monocytogenes	All	Absence in five 25 g samples taken over the lot while under the control of the manufacturing processor

24 Operator defined process measure failures

Dairy material and raw milk product are deemed to be non-conforming if there is a failure to apply any operator defined process measure as set out in the programme.

25 Non-conforming dairy material and dairy product

(1) Any raw milk, dairy material, or raw milk product that has not been harvested, transported, stored, manufactured, or otherwise processed in accordance with this notice, must be managed as non-conforming dairy material in accordance with regulation 5 of the Animal Products (Dairy) Regulations 2005.

(2) Notwithstanding subclause (1), raw milk or dairy material that is identified as not suitable for the intended raw milk product may be redirected for further processing with a heat treatment provided the procedure for managing and tracing the dairy material is set out in the programme.

Labelling

26 Labelling

By way of explanation,-

(a) (a)clause 4 of Standard 1.2.4 of the food standards code requires ingredients to be declared using the common name of the ingredient, or a name that describes the true nature of the ingredient, or if applicable a generic name; and

(b) (b)this requirement means that in relation to food made from raw milk, the ingredient declaration should include a statement that the milk is raw or unpasteurised

Issued under sections 45 and 167(1)(h) of the Animal Products Act 1999.
Date of notification in Gazette: [ ]
This notice is administered in the New Zealand Food Safety Authority.

Appendix 2: Draft Food (Imported Milk and Milk Products) Standard 2009

See below.

Contents

Standard

1 Title

This standard is the Food (Imported Milk and Milk Products) Standard 2009.

2 Commencement

This standard comes into force 28 days after the date of its notification in the gazette

3 Revocation

Under section 11L of the Food Act 1981, the Food (Milk and Milk Products Processing) Standard 2007, issued by the Minister for Food Safety on 30 July 1007 are revoked.

Part 1
Preliminary Provisions

4 Purpose

This standard sets out requirements for all milk and milk products imported into New Zealand.

5 Interpretation

(1) In this standard, unless the context otherwise requires, -

commercially sterile means the absence of viable micro-organisms or spores capable of growing in UHT treated product at normal non refrigerated conditions at which the UHT treated product is likely to be held during manufacture, distribution and storage.

ice cream treatment means heat treatment of an ice cream mix to be used in ice cream by retaining the ice cream mix –

(a) at a temperature of not less than 69 °C for not less than 20 minutes; or
(b) at a temperature of not less than 74 °C for not less than 10 minutes; or
(c) at a temperature of not less than 79.5 °C for not less than 15 seconds; or
(d) at a temperature of not less than 85.5 °C for not less than 10 seconds; or
(e) at another temperature for a time which achieves an equivalent result to the treatments in paragraphs (a) to (d),

and then freezing the ice cream mix

milk means the mammary secretion of milking animals

pasteurisation means treatment according to one of the following methods-

(a) the holding method, by which the milk or milk product is:
    (a) rapidly heated to a temperature of not less than 63 °C and not more than 66 °C; and
    (b) retained at that temperature for not less than 30 minutes; or
(b) the high-temperature short-time method, by which the milk or milk product is:
    (a) rapidly heated to a temperature of not less than 72 °C; and
    (b) retained at that temperature for not less than 15 seconds; or
(c) any other heat treatment method that is as effective in terms of bacterial reduction as the methods referred to in (a) and (b).

ultra high temperature treatment (UHT) means for milk or liquid dairy material -

(a) the application of heat to a continuously flowing milk or liquid dairy material using such high temperatures for such time that renders the product commercially sterile at the time of processing; and
(b) when the UHT treatment is combined with aseptic packaging, it results in a commercially sterile dairy product; and
(c) is sufficient to ensure that the product remains microbiologically stable after incubating for 15 days at 30 °C in closed containers or for seven days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.
(d) Any term or expression that is defined in the Food Act 1981, or regulations made under the Food Act 1981 and used, but not defined, in this standard has the same meaning as in those Acts or regulations.

Part 2
Import requirements for milk and milk products

6 Import requirements for milk and milk products

Milk and milk products may be imported into New Zealand if they have been-

(a) processed in accordance with part 3; or

(b) manufactured in accordance with part 4.

Part 3
Permitted processing methods for milk and milk products

7 Permitted processing methods for milk and milk products

Subject to clause 8, milk and milk products listed in column 1 of table 1 may be imported into New Zealand if they have been processed in accordance with an applicable permitted processing method specified in column 2 of table 1.

Table 1

Column 1	Column 2
Milk or milk product	**Permitted processing method**
All milk and milk products	1. Pasteurisation; or 2. UHT
Ice-cream	Ice-cream treatment

8 Alternative processing methods

(1) In addition to the permitted processing methods specified in clause 7, milk and milk products may be imported into New Zealand if they have been processed in accordance with a processing method that has been approved by the Director-General in accordance with subclause (2).

(2) For the purposes of subclause (1), the Director-General may approve a processing method for milk or a milk product if he or she is satisfied that the method will ensure that the processed milk or milk product achieves at least an equivalent level of safety protection for consumers as that which is achieved by the permitted processing methods listed in column 2 of table 1 in clause 7.

9 List of alternative processing methods

(1) The Director-General must keep a list of all alternative processing methods approved in accordance with clause 8.

(2) The list referred to in subclause (1) must be maintained and published on the New Zealand Food Safety Authority web site: http://www.nzfsa.govt.nz, and must be made available.

Part 4
Recognised sanitary standards for the manufacture of milk and milk products

10 Recognised equivalent overseas sanitary standards

Subject to clause 11, a milk or milk product listed in column 1 of table 2 may be imported into New Zealand if it has been manufactured-

(a) in accordance with the applicable sanitary standard listed in column 2 of table 2; and

(b) in the applicable country or geographical region listed in column 3.

Table 2

Column 1	Column 2	Column 3
Milk and milk products	**Sanitary standard**	**Country or geographical region in which processing must occur**
Emmental cheese; and Gruyere cheese; and Sbrinz cheese	Ordinance on Quality Assurance in the Dairy Industry of the Swiss Federal Council of 18 October 1995, and any subsequent ordinance or amendment that replaces or amends that ordinance.	Switzerland
Milk and milk products for human consumption listed in annex V section 3 part 8 of Council Decision 97/132/EC which have been determined equivalent; and Roquefort cheese; and Extra hard grating cheese.	European Commission (EC) Regulation No 852/2004, and any subsequent regulation or amendment that replaces or amends that regulation; and European Commission (EC) Regulation No 853/2004, and any subsequent regulation or amendment that replaces or amends that regulation; and European Commission (EC) Regulation No 854/2004; and any subsequent regulation or amendment that replaces or amends that regulation.	In a member state of the European Union

11 Alternative overseas sanitary standards

(1) In addition to the permitted overseas sanitary standards specified in clause 10, milk and milk products may be imported into New Zealand if they have been manufactured in accordance with an overseas sanitary standard that has been approved by the Director-General in accordance with subclause (2).

(2) For the purposes of subclause (1), the Director-General may approve an overseas sanitary standard for a milk and milk product if he or she is satisfied that the standard will ensure that the manufactured milk or milk product achieves at least an equivalent level of safety protection for consumers as that which is achieved under New Zealand law.

12 List of alternative overseas sanitary standards

(1) The Director-General must keep a list of all alternative overseas sanitary standards approved in accordance with clause 11.

(2) The list referred to in subclause (1) must be maintained and published on the New Zealand Food Safety Authority web site: http://www.nzfsa.govt.nz, and must be made available.

Issued under section 11C of the Food Act 1981.

Date of notification in Gazette: [ ]

This standard is administered by the New Zealand Food Safety Authority.

Explanatory Note

This note is not part of the standard and has been included to explain its general effect.

This standard provides requirements for all importers of milk and milk products for sale.

By way of explanation, a person who imports any milk and milk products for the purposes of sale without complying with this standard commits an offence in accordance with section 11O and 11Q of the Food Act 1981.

Guidance material in relation to operational information on this standard can be viewed at: www.nzfsa.govt.nz

Food standards subject to Regulations (Disallowance) Act 1989

Food standards, including this amendment, are subject to the Regulations (Disallowance) Act 1989. Any person has the right to make a complaint about a food standard to the Regulations Review Committee.

Availability of food Law

An outline of New Zealand food law, and further advisory information on this amendment, can be viewed on the New Zealand Food Safety Authority (NZFSA) web site: http://www.nzfsa.govt.nz or can be obtained from the NZFSA, Policy Group, PO Box 2835, Wellington.

Copies of all New Zealand food law, including food standards, can be viewed free of charge at NZFSA, 86 Jervois Quay, Wellington, or purchased from:

- Bennetts, Massey University Albany Campus, New Teaching Block, Gate 1, Albany, Auckland, Ph: (09) 443 9707, Fax: (09) 443 9708, Email: aku@bennetts.co.nz
- Bennetts, Auckland University of Technology Akoranga Campus, Gate 1 Akoranga Drive, Northcote, Ph: (09) 921 9803, Fax: (09) 921 9967, Email: aau@bennetts.co.nz
- Bennetts, Auckland University of Technology, Student Plaza Gate 2, Wellesley Street, Auckland City, Ph: (09) 921 9801, Fax: (09) 921 9986, Email: wau@bennetts.co.nz

- Bennetts, Manukau Institute of Technology, Gate 11, NP Block, Otara Road, Manukau, Ph: (09) 274 8627, Fax: (09) 274 8830, Email: mkp@bennetts.co.nz
- Bennetts, The University of Waikato, Gate 5, Hillcrest Road, Hamilton, Ph: (07) 856 6813, Fax: (07) 856 2255, Email: wku@bennetts.co.nz
- Bennetts, Waikato Institute of Technology, Gate 5, Tristram Street, Hamilton, Ph: (07) 839 0003, Fax: (07) 834 1291, Email: wkp@bennetts.co.nz
- Bennetts, Massey University - Turitea Campus, Student Centre, Palmerston North, Ph: (06) 354 6020, Fax: (06) 354 6716, Email: massey@bennetts.co.nz
- Bennetts, Massey University Wellington, Gate E Tasman Street, Wellington, Ph: (04) 384 1407, Fax: (04) 384 1408, Email: wgp@bennetts.co.nz
- Bennetts, Corner Lambton Quay & Bowen Street, Wellington, Ph: (04) 499 3433, Fax: (04) 499 3375, Email: gbs@bennetts.co.nz
- Bennetts, Whitcoulls, Bush Inn Shopping Centre, Riccarton Road, Christchurch, Ph: (03) 343 0304, Fax: (03) 343 0316, Email: bun@whitcoulls.co.nz
- Bennetts, Christchurch Polytechnic Institute of Technology, Madras Street, Christchurch, Ph: (03) 365 1394, Fax: (03) 365 7314, Email: chp@bennetts.co.nz

The Food Standards Code can be viewed on the Food Standards Australia New Zealand website: http://www.foodstandards.govt.nz or can be viewed free of charge at NZFSA, 86 Jervois Quay, Wellington. Copies of the Code, or Amendments to the Code, can be purchased by subscription from: ANSTAT, PO Box 447, South Melbourne, VIC 3205, Australia, http://www.anstat.com.au, Email foodcode@anstat.com.au, or Phone +61 3 9278 1144.

Appendix 3: Draft Amended Food (Prescribed Foods) Standard 2009

See below.

Contents

1 Title

This standard is the Food (Prescribed Foods Standard 2007) Amendment Standard 2009.

2 Commencement

This standard comes into force 28 days after the date of its notification in the gazette

Part 1
Preliminary Provisions

3 Purpose

This purpose of this standard is to amend the Food (Prescribed Foods) Standard 2007.

4 Interpretation

(1) In this standard, unless the context otherwise requires, -

principal standard means the Food (Prescribed Foods) Standard 2007

(2) Any term or expression that is defined in the Food Act 1981 and used but not defined in this standard has the same meaning as in that Act.

Part 2
Amendment

5 Prescribed food

The item in the table contained in clause 6 of part 2 of the principal notice relating to raw milk cheese is revoked and the following item substituted:

Raw milk products (being milk products that have not undergone pasteurisation, ice-	The presence of pathogenic organisms.

cream treatment, or ultra high temperature treatment as those terms are defined in the Food (Imported Milk and Milk Products) Standard 2009)	

Issued under section 11C of the Food Act 1981.

Date of notification in Gazette: [ ]

This standard is administered by the New Zealand Food Safety Authority.

Food standards subject to Regulations (Disallowance) Act 1989

Food standards, including this amendment, are subject to the Regulations (Disallowance) Act 1989. Any person has the right to make a complaint about a food standard to the Regulations Review Committee.

Availability of food Law

An outline of New Zealand food law, and further advisory information on this amendment, can be viewed on the New Zealand Food Safety Authority (NZFSA) web site: http://www.nzfsa.govt.nz or can be obtained from the NZFSA, Policy Group, PO Box 2835, Wellington.

Copies of all New Zealand food law, including food standards, can be viewed free of charge at NZFSA, 86 Jervois Quay, Wellington, or purchased from:

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- Bennetts, Auckland University of Technology Akoranga Campus, Gate 1 Akoranga Drive, Northcote, Ph: (09) 921 9803, Fax: (09) 921 9967, Email: aau@bennetts.co.nz
- Bennetts, Auckland University of Technology, Student Plaza Gate 2, Wellesley Street, Auckland City, Ph: (09) 921 9801, Fax: (09) 921 9986, Email: wau@bennetts.co.nz
- Bennetts, Manukau Institute of Technology, Gate 11, NP Block, Otara Road, Manukau, Ph: (09) 274 8627, Fax: (09) 274 8830, Email: mkp@bennetts.co.nz
- Bennetts, The University of Waikato, Gate 5, Hillcrest Road, Hamilton, Ph: (07) 856 6813, Fax: (07) 856 2255, Email: wku@bennetts.co.nz
- Bennetts, Waikato Institute of Technology, Gate 5, Tristram Street, Hamilton, Ph: (07) 839 0003, Fax: (07) 834 1291, Email: wkp@bennetts.co.nz
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The Food Standards Code can be viewed on the Food Standards Australia New Zealand website: http://www.foodstandards.govt.nz or can be viewed free of charge at NZFSA, 86 Jervois Quay, Wellington. Copies of the Code, or Amendments to the Code, can be purchased by subscription from: ANSTAT, PO Box 447, South Melbourne, VIC 3205, Australia, http://www.anstat.com.au, Email foodcode@anstat.com.au, or Phone +61 3 9278 1144.

Appendix 4: Standards and requirements for unpasteurised and raw milk products set by a selection of overseas countries and international bodies

Codex Alimentarius Commission

The Codex Alimentarius Commission (Codex) develops standards that are designed to protect the health of consumers and promote fair practices in food trade and that may be used as a base for national legislation by all of its member nations (New Zealand has been a member of Codex since 1964).

Provisions for raw milk products, with the specific exclusion of raw drinking milk, are included in the Commission's *Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004*). Raw milk is defined in the Commission's Code as milk that has not been heated beyond 40 degrees Celsius or undergone any treatment that has an equivalent effect. The Commission's Code emphasises strict hygiene conditions for the harvesting of milk and on-farm activities to ensure that, in combination with control measures during processing, raw milk products are safe and suitable for human consumption. The Commission's Code also contains a requirement for the labelling of the product to make it clear that the milk has not been heat-treated.

European Union

The European Union (EU) is a political and economic community of twenty-seven member states. The EU has developed a single market through a standardised system of laws which apply in all member states, guaranteeing the freedom of movement of people, goods, services and capital. EU legislation is set by the European Community (EC).

Many European countries have a tradition of producing a wide range of unpasteurised and raw milk products (particularly cheeses)[16] and these products are permitted for sale in the EU. EC legislation sets out microbiological, food safety and process hygiene criteria governing the production and labelling requirements for raw milk products. Specific provisions for raw milk production include: animal health requirements; hygiene of milking; storing and collection operations; and health and

[16] Defined as products made from milk that has not been treated beyond 40 degrees Celsius or undergone any treatment that has an equivalent effect.

hygiene of personnel. Where the manufacturing process does not include any heat treatment, or physical or chemical treatment, products made with raw milk must be clearly labelled with the words 'made with raw milk'.

The European Union (EU) permits the sale of raw milk products subject to the following EC sanitary and food hygiene regulations:

- Regulation (EC) 852/2004 on the hygiene of foodstuffs (lays down the hygiene requirements for all food business operators);
- Regulation (EC) 853/2004: specific hygiene rules for food of animal origin (lays down specific requirements for food businesses dealing with foods of animal origin); and
- Regulation (EC) 854/2004: specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Following publication of the consolidated EC Food Hygiene Regulations in 2004, a number of implementing regulations and transitional measures that support the application of the EC regulations have also been published, including Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

New Zealand and the EC have a Treaty level Sanitary Agreement which recognises EC sanitary measures (including food controls) for almost all animals and animal products as equivalent to New Zealand requirements. The Agreement includes almost all animal products and the Annexes describe the conditions that apply to each product.

United States of America

In the United States of America (USA), the production of raw milk products is regulated by individual states, some of which allow for their manufacture and sale. For example, the sale of raw drinking milk is legal in 26 of the 50 states in the USA. The raw milk regulations differ between states but can contain requirements for warning labels; licensing; restriction of sales to the farm gate or to individuals who have a signed prescription from a physician; and limits on the period that raw milk can be sold from the time when a farmer fills a milk container.

Federal law bans the movement between states of all locally manufactured or imported raw milk products, except for certain cheeses which must be aged for a minimum of 60 days at a set temperature.

Canada

The sale of raw drinking milk is strictly prohibited under Canadian Food and Drug Regulations. However, like the USA, some Canadian provinces permit the sale of some raw milk cheeses that have been stored for at least 60 days at a set temperature. There is also an agreement between the Canadian Food Inspection Agency and French authorities which allows for the importation of raw milk soft and semi-soft cheeses and exempts these French products from having to satisfy the requirement for 60 days storage.

Canada has recently attempted tighter regulatory control with respect to soft and semi-soft cheeses. For this purpose, a Code of Hygienic Practice, developed by Health Canada, has been distributed for comment amongst provincial and territorial governments.

Canada has also developed education campaigns that attempt to raise awareness of the potential hazards associated with raw milk cheeses.

The province of Quebec recently gazetted regulations (July 2008) containing provisions applying to the preparation of raw milk or unpasteurised soft or semi-soft cheeses sold without a minimum 60-day ripening period at a set temperature.