



Proposed framework for the manufacture, importation and sale of raw milk products

Consultation Process and Invitation for Public Comment
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1 Executive summary

1.1 Purpose of this document

The purpose of this discussion document is to provide information and seek submissions on a proposed framework (the framework) developed by the New Zealand Food Safety Authority (NZFSA) that, if progressed, would facilitate the manufacture and domestic sale or export of some raw milk products for human consumption, and the importation and sale of a similar range of raw milk products.

Submissions on this discussion document are invited to be made to NZFSA by 30 September 2008. All submissions received will be analysed and a decision then taken about whether to progress the proposed framework for raw milk products.

Should the framework be progressed, then a second round of consultation would be initiated in 2009 on the specific detail of the various elements that would be necessary to implement the framework. These elements would likely include:

- the additional technical requirements that would apply to any raw milk products able to be produced in New Zealand;
- how the requirements would be implemented in New Zealand food legislation;
- the interface with the implementation of the Imported Food Review, including the proposed high, medium and low regulatory interest categories of imported foods and the possible need to review any applicable biosecurity import health standards; and
- measures that would be introduced to mitigate potential risks that raw milk products can pose to vulnerable consumers eg labelling, and education programmes.

This document refers to some technical terms and readers should refer to the glossary in Section 9 for definitions.

1.2 Raw milk products and the scope of this proposal

All foods have the potential to cause foodborne illness and milk and milk products are no exception. Dairy animals may carry human pathogens (organisms which can cause a foodborne illness) that can be present in the milk used to produce dairy products. The composition of some dairy products (eg

soft cheeses) means that they provide a good environment for the growth of any pathogens that may have been present in the milk used to produce them.

Some heat treatments such as pasteurisation raise the temperature of the milk used to produce dairy products to a degree that is sufficient to kill or inactivate pathogens, making these products low risk¹. However, other dairy products are made from milk that has not undergone such a heat treatment. Broadly speaking these products are generally referred to as raw milk products, but it is important to note that there is no universally agreed definition of raw milk products, with several technical definitions in use internationally, including one used by the Codex Alimentarius, which is the international food standards setting body (see Section 3.2.5.1).

This document does not propose a definition for raw milk products for New Zealand purposes (this would instead be developed as part of the more specific technical work that could follow if a decision is taken to adopt the framework). However, this document does outline what is meant by raw milk products in order to explain the scope of the framework that is proposed. Raw milk products are defined for the purposes of this document as products that have been produced from milk that has not been pasteurised or thermised in accordance with the Food (Milk and Milk Products Processing) Standard 2007. The framework proposed in this document would cover products for human consumption that have been manufactured from the raw milk of a number of milking animals including cow, goat, sheep, buffalo, horse and camel. These products would include cheeses and yogurts. The proposal does not, however, make any change to the existing allowance under Section 11A of the Food Act 1981 for up to five litres of raw milk to be purchased for personal consumption from the farm gate.

Some raw milk products can be made in such a way that pathogens that may have been present in the raw milk used to produce them are eliminated or have their growth inhibited. As a result, raw milk products such as cheeses present a range of food safety risks, from those that are as safe as cheese made from pasteurised milk (such as certain hard and very hard raw milk cheeses), to those that pose a higher risk to all consumers (such as soft unripened raw milk cheeses).

NZFSA believes it is possible to allow the importation of a wider range of raw milk products than is currently provided for, and to enable the production of equivalent products in New Zealand, by ensuring they are made from milk produced under particularly stringent conditions of animal health, and by following appropriate processing hygiene and controls. The types of products permitted under the proposed NZFSA framework would therefore be those that achieve an acceptable level of microbial safety for the general population.

¹ This does not preclude contamination during processing or post processing which is a risk for all dairy products.

Some vulnerable groups in the population can potentially face greater risks (serious or life-threatening illness) from eating raw milk products, just as they face similar risks from eating some other commonly available foods, such as raw shellfish. These vulnerable groups consist of babies and toddlers, expectant mothers, the frail elderly, and anyone whose immune system may be compromised because of a chronic illness, long term medication or a recent operation. For example, these groups are highly susceptible to some microbiological hazards (eg *Listeria*, *Salmonella*, *Escherichia coli*) that may be present in raw milk products. The NZFSA proposal set out in this discussion document is based upon mitigating the risks to vulnerable consumers by educating them about the risks associated with those raw milk products that pose a higher risk than pasteurised and thermised products, and by labelling such products so vulnerable consumers can avoid them.

It is also possible that many raw milk products would have a niche market status (ie made or imported in limited quantities and be highly priced). As such the availability of these products, and therefore the exposure of the majority of the New Zealand population to them, would be limited, thus also limiting the probability of any impact occurring from any risk the products may pose.

1.3 Background to this proposal

1.3.1 Current availability of raw milk products in New Zealand

Currently all dairy products manufactured in New Zealand are made from pasteurised or thermised milk.² The only exception to this is the “Five-Litre” Rule, which is provided for in Section 11A of the Food Act and allows producers to sell up to five litres of raw milk at any one time from their farm gate to people who intend to consume it themselves or provide it to their family. The only raw milk products that can legally be imported and sold in New Zealand are a limited variety of cheeses, following case-by-case assessments of the risks that the particular cheeses pose to consumers and attestation that any relevant import health standards can be attained.

Domestic dairy producers can apply to NZFSA for approval to manufacture raw milk products under a Risk Management Programme (RMP) under the Animal Products Act 1999 or a Food Safety Programme (FSP) under the Food Act 1981. However, there are no technical criteria or other guidance material in place to assist with the development, evaluation, assessment for registration and subsequent verification of such a programme. This has contributed to the fact that no manufacturer has applied to NZFSA for registration of a programme to cover the manufacture of raw milk products in New Zealand.

² For an explanation of this and other technical terms, refer to the Glossary in Section 9.

New Zealand food legislation currently permits the importation and sale of the following raw milk cheeses: three named hard and very hard Swiss cheeses, extra-hard Parmesan style grating cheeses, and Roquefort cheese. The hard, very hard and extra-hard grating cheeses were only allowed to be sold in New Zealand (and Australia) following risk assessments carried out by Food Standards Australia New Zealand (FSANZ)³. These cheeses have low moisture content and a very long storage period and are not considered to pose a risk to consumers. As a semi-hard raw milk cheese, Roquefort has different properties than the hard and extra-hard cheeses and, therefore, NZFSA conducted its own risk assessment of Roquefort, prior to recommending its direct importation and sale in New Zealand. The NZFSA risk assessment of Roquefort indicated that consumption would constitute a low risk to most New Zealand consumers but a higher risk to vulnerable groups. These vulnerable groups are highly susceptible to some microbiological hazards (particularly *Listeria*) that may be present in raw milk products. Risk management measures, including a consumer education programme, have been introduced to mitigate the risks to these vulnerable groups.

1.3.2 The impetus for change

In some parts of the world there is a culinary tradition of raw milk products (particularly cheeses), and such products are widely available. In recent years there has been increasing interest in the availability of raw milk products within New Zealand. Requests have been made to NZFSA to allow more raw milk products (particularly cheeses) to be imported, and to develop the relevant technical criteria and other guidance material that would allow for the domestic manufacture and sale of raw milk products.

This interest in raw milk products comes from consumers, importers and domestic manufacturers. Some consumers want a wider range of products to be available in New Zealand as they are in other countries, and may consider that raw milk products are superior in flavour and texture, as well as offering health benefits. Importers see potential business opportunities, for example to supply gourmet speciality cheeses, and are concerned about the restrictions imposed by the current regulatory regime. New Zealand dairy manufacturers, including smaller specialist cheese makers, are concerned about the inequity of the current situation whereby importation of some raw milk cheeses is allowed, but no provision for the manufacture of similar cheeses in New Zealand has been made. Such manufacturers have expressed an interest in producing raw milk cheeses and see this as a business opportunity, both in terms of sales in the domestic market and possibly in export markets.

³ FSANZ is responsible for developing food standards for both New Zealand and Australia (see Section 3.2.1.1. for more information).

In relation to imported products, NZFSA must also ensure that import standards and requirements meet the World Trade Organization (WTO) Sanitary Phytosanitary Agreement and obligations under the European Commission/New Zealand Sanitary Agreement. New Zealand's current import requirements have allowed some raw milk products to be imported on the basis of individual risk assessments (including Roquefort cheese), but not others (see Section 3.2.1.2 for the background to these decisions). Some of New Zealand's trading partners have questioned why this is the case. Completing the individual risk assessments for these imported cheeses has also been resource intensive and has resulted in decisions being made on a case-by-case basis.

Australia is also considering new legislation to allow the production and importation of a wider range of raw milk products. Under the Trans-Tasman Mutual Recognition Agreement (TTMRA) food produced in New Zealand or imported into New Zealand that meets New Zealand's legal requirements, may also be sold in Australia and vice versa. There are some exceptions, however, with for example, high-risk foods listed in either country requiring certification or testing before being permitted entry. The limited range of raw milk cheeses currently able to be imported into New Zealand is included on the high risk list.

As a result of all these factors, NZFSA has been investigating ways of expanding the regulatory framework, should a decision be taken to allow a wider range of raw milk products to be manufactured in, and imported into, New Zealand.

In developing this framework and now providing an opportunity for a consultation process, NZFSA does however acknowledge that some New Zealanders may not support raw milk products becoming more widely available in New Zealand.

1.4 NZFSA proposal

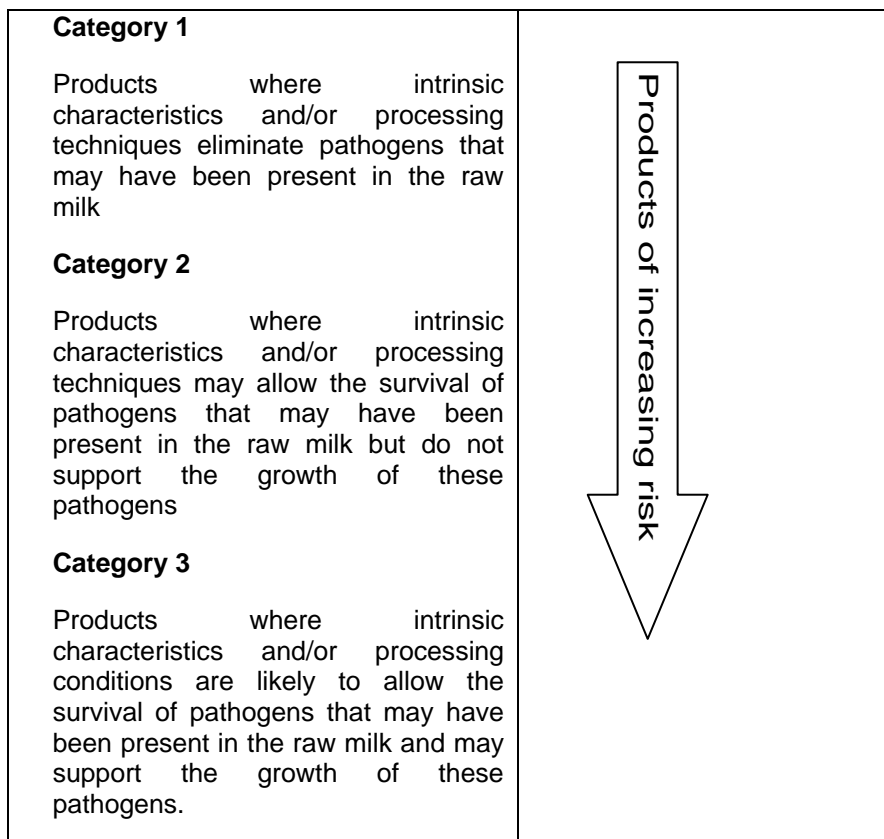
NZFSA commenced consideration of a range of options relating to the domestic production and importation of raw milk products following the 2007 risk assessment and risk management decision for Roquefort cheese. These options are outlined in detail in Section 6 of this document. NZFSA's preferred option is to develop an appropriate regulatory framework that would allow for both New Zealand production of some raw milk products and the importation of a similar range of raw milk products, without the need for full individual risk assessments on a product-by-product basis, while maintaining an acceptable level of consumer protection.

To support the development and analysis of options related to raw milk production and importation, NZFSA is undertaking a portfolio of risk assessment work concerned with the public health risks associated with the consumption of raw milk and raw milk products. Further details about this work are provided in Section 5.1.1.

NZFSA is working in collaboration with Australia on a proposed framework based on a 'category approach'. Instead of case-by-case assessments, raw milk products would be placed in one of three categories according to their food safety risk to human health. The categories would be used as the basis for determining the additional requirements, if any, necessary to produce raw milk products with a low or acceptable food safety risk. Under this framework, it is expected that some types of raw milk products would still not be able to be imported or made in New Zealand.

The categories are defined depending on the effect that production and processing techniques, and the intrinsic characteristics of the final products, have on the survival and growth of pathogens that may be present in the raw milk. Raw milk products which allow for the survival and/or growth of pathogens pose a greater food safety risk, compared to products where pathogen growth and survival is less likely.

The potential food safety risk associated with each Category increases from Category 1 to Category 3 as illustrated below:



The category approach would assist NZFSA with developing risk management measures; for example such measures would be more comprehensive for Category 2 products than for Category 1 products.

It is considered that Category 1 products would be able to be safely produced or imported without additional control measures being required.

The focus of regulatory control would be on Category 2 products, with regulatory measures expected to be developed relating to the harvesting of raw milk on farms and the processing into the resulting products.

Category 3 products would not be able to be produced or imported into New Zealand, given the level of safety currently seen as acceptable for New Zealanders. These products would include raw drinking milk.

Further details of this framework, including examples of products likely to fall under each Category, are provided in Section 5.

NZFSA considers it important that, if this category approach is adopted, it is introduced simultaneously with a range of strategies designed to mitigate the risks that the consumption of some raw milk products (likely to be those products in Category 2), would pose to vulnerable groups of consumers. These strategies would include the broadening of NZFSA's consumer education programme and the commissioning of a consumer survey to inform educative material and to provide input into decisions about appropriate labelling for raw milk products.

2 Consultation

Comments and suggestions on the proposal outlined in this document are invited from industry, consumers, importers, key trading partners, public health specialists and other interested parties.

2.1 Requirements for submissions

Submissions are invited from any interested party, whether representing an organisation or acting as an individual. When sent on behalf of an organisation, the submission should include 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. A guide to the content of submissions is provided in Section 8, but you are welcome to comment on any additional matter relating to the proposal.

2.2 Address for submissions

Please send your submission on this proposal to:

Technical Standards and Systems Team
New Zealand Standards Group
New Zealand Food Safety Authority
PO Box 2835
Wellington – New Zealand

Facsimile: (04) 894 2643
Email: TSS@nzfsa.govt.nz

2.3 Closing date for submissions

The closing date for submissions is 30 September 2008.

2.4 Official Information Act

The Official Information Act 1982 (OIA) states that information is to be made available unless there are grounds for withholding it. Grounds for withholding information are in the OIA. Submitters may wish to indicate 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.

2.5 Process after submissions

After the closing date, submissions received will be analysed and taken into account when providing advice to the Minister for Food Safety and in making any subsequent recommendations to the Government. NZFSA will publish a summary of the submissions received on this document.

3 Background

Many of New Zealand's trading partners, particularly European countries, have a long culinary tradition of producing and consuming raw milk products, especially cheeses, and such products are widely available in these countries. However, in New Zealand, all dairy products manufactured and sold domestically or exported, and most imported dairy products, are made from pasteurised or thermised milk. While legislation allows the domestic manufacture and sale of raw milk products under a registered Risk Management Programme (RMP) or an approved Food Safety Programme (FSP), there are currently no approved technical criteria or other guidance material that can be used by producers or processors to develop an FSP or RMP and against which such programmes could be evaluated, assessed for registration and verified. This has contributed to the fact that no manufacturer has applied to NZFSA for registration of a programme to cover the manufacture of raw milk products in New Zealand.

Only limited varieties of cheeses made from raw milk can be imported and sold in New Zealand, following case-by-case assessments of the risks that the particular products pose to consumers and attestation that any relevant import health standards have been attained.

3.1 General information

3.1.1 Pasteurisation and other heat treatments

Pasteurisation is a well established and highly effective process for assuring the safety of milk and milk products. It involves heating milk to a specified temperature for a specified period of time - usually a high temperature for a short period of time - to kill or inactivate foodborne microbiological pathogens.

The pasteurisation of milk has been progressively introduced in New Zealand since the 1890s for public health reasons, so that today it is the predominant heat treatment method used for processing dairy products.

Some hard cheeses manufactured in New Zealand are also allowed to be produced using thermisation (heating the milk to lower temperatures than pasteurisation) provided the cheese is stored at a specified temperature for not less than 90 days. This combination of control measures for these types of cheeses are considered to provide an equivalent level of safety to pasteurisation.

3.1.2 Arguments made to NZFSA in support of raw milk cheese

Raw milk cheese is made from milk that has not been pasteurised or thermised⁴ and some people maintain that raw milk cheese has a particular flavour and/or texture. While pasteurisation destroys potentially harmful pathogens, raw milk cheese enthusiasts contend that heat treatment also alters the natural composition and microflora of the milk (including the natural defences of the milk) and ultimately the flavour and health properties of the cheese. There is also the contention that, while pasteurisation eliminates the pathogens that may be present in the raw milk, it does not guarantee a safe cheese as post-pasteurisation contamination⁵ can occur.⁶

However, these views need to be considered in conjunction with the information about microbiological hazards and risk factors outlined below.

3.1.3 Microbiological hazards

Pathogenic bacteria have been identified as the major hazard in raw milk. As raw milk products are made from milk that has not been pasteurised or undergone any treatment that has an equivalent effect, they have a higher likelihood than pasteurised products of containing pathogens that may have been present in the raw milk such as *Listeria monocytogenes*, *Salmonella*, *Escherichia coli* and the tubercule bacillus (causative agent of tuberculosis).

These pathogens can cause serious illnesses and can be life-threatening for vulnerable population groups – namely babies and toddlers, expectant mothers, the frail elderly, and anyone whose immune system may be compromised because of a chronic illness, long term medication or a recent operation. While no food can ever be considered 100 percent safe, heating milk in the pasteurisation process destroys the harmful pathogens and eliminates many of these hazards.

⁴ Note discussion on description of scope of this proposal and raw milk products in Section 1.2.

⁵ Manufacturers in New Zealand and many overseas countries are, however, very aware of the possibility of contamination of dairy products and apply strict hygiene practices to ensure this does not occur. Scientific evidence shows that pasteurised dairy products are very safe to consume.

⁶ This view does not necessarily represent the views of NZFSA. Please note NZFSA's purpose in this paragraph is to describe views held by those who advocate wider availability of raw milk products.

3.1.4 Risk factors

In recent years, many nations have improved animal health and milk harvesting practices, and this development has increased the safety of the resulting raw milk products (although many raw milk products still pose higher risks than equivalent pasteurised products).

A variety of factors can affect the safety of raw milk and the products manufactured from it. Risk factors that may introduce pathogens into raw milk and/or allow them to multiply include poor animal health, faecal contamination, environmental contamination, and inadequate temperature control during production, processing, storage and transport.

Once pathogenic bacteria are present in raw milk, they may then contaminate the products made from it. The extent to which they then survive and grow is influenced by the manufacturing process and intrinsic properties of the product—for example, moisture content, pH (acidity) and salt concentration—and conditions during maturation and ripening, especially storage times and temperatures.

While processing conditions for some products can prevent survival and growth of pathogenic bacteria, conditions associated with other products may facilitate survival and/or possible growth of pathogenic bacteria. For example, the high moisture content and high pH of soft unripened raw milk cheeses may allow bacteria to survive and grow and such products are, therefore, likely to pose a higher risk to consumers than hard raw milk cheeses, which have lower moisture content and lower pH. Longer storage times during maturation and ripening may also assist in controlling pathogen levels, as harmful bacteria may die off because of such factors as increasing acidity and salt content.

3.1.5 An acceptable level of safety

While some raw milk products do pose inherently higher food safety risks than products that have been produced with pasteurised or thermised milk (due to the survival of pathogens from the raw milk), there is evidence that some can be manufactured so as to provide an acceptable level of protection for consumers.

NZFSA proposes that it would be acceptable for raw milk products, including cheeses, manufactured in New Zealand or imported into New Zealand to, at most, either:

- pose only a minimal or low risk to the entire population, including vulnerable groups; or
- pose only a low risk to the general population but a higher risk to vulnerable populations (similar to other foods commonly available in New Zealand such as raw shellfish.) In such cases, it is essential that the presence in the market of such products be accompanied by strategies to mitigate the risks to vulnerable consumers, eg education programmes and labelling that would

enable vulnerable consumers to avoid consumption of such products. It was on this basis that NZFSA recommended, and obtained Government agreement, to the importation into New Zealand of the semi-hard cheese Roquefort.

Other raw milk products which pose greater health risks to the general population would not be permitted in New Zealand under the proposed framework.

3.2 Current legislative requirements

3.2.1 New Zealand

3.2.1.1 Overview

Under 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, which is developed and published by FSANZ, covers the content, limits for food chemical and microbiological contaminants and additives, and labelling of 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; 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.

As a result, in New Zealand, processing requirements for milk and milk products are regulated under the Animal Products Act 1999 (APA) and the Food Act 1981. The APA covers all dairy processing in New Zealand and requires most dairy processors to operate under a registered Risk Management Programme (RMP). The dairy processing requirements issued under the APA cover a wide scope of activities – from farm through to export or the point of sale. However, an exclusion under the APA also allows dairy processors supplying only the domestic market and Australia to operate under an approved Food Safety Programme (FSP) under the Food Act 1981. This exclusion applies to all dairy processors except for farm dairy operators (ie milk harvesters). Farm dairy operators harvesting milk for human consumption must operate under an RMP, regardless of whether the milk is intended for the domestic market or export. An exemption from the requirement to have an FSP and an RMP is also available for dairy products sold and totally consumed on the manufacturing premises (eg cheese made in a restaurant) under the Animal Products (Exemptions and Inclusions) Order 2000.

The Food (Milk and Milk Products Processing) Standard 2007 under the Food Act requires dairy products manufactured in New Zealand to be made from pasteurised milk; from milk which complies

with the requirements for “cheese treatment” (two treatments are specified: thermisation and the treatment used to produce extra-hard grating cheeses); or under a registered RMP or approved FSP as noted above. The only exception to this is the “Five-Litre” Rule, which, under Section 11A of the Food Act 1981, allows producers to sell up to five litres of raw milk (which has been harvested under an appropriate RMP) at any one time from their farm gate to people that intend to consume it themselves or provide it to their family – this provision is being considered in the Domestic Food Review and is outside the scope of this proposal.

Both RMPs and FSPs are risk-based management programmes designed to identify and control hazards and other risk factors relating to the production and processing of dairy products, other animal products, and food products in order to ensure that the resulting products are safe and suitable. RMPs and FSPs are either developed by individual producers to meet their specific requirements, or are based on templates and codes of practices approved by NZFSA. RMPs developed by the individual operator must be independently evaluated before registration is granted. In all cases, once a programme is registered or approved and is operating, it is subject to verification on a regular basis.

Although domestic dairy producers can apply to NZFSA for approval to manufacture raw milk products under an RMP or FSP, there are no technical criteria or other guidance material in place to assist with the development, evaluation, assessment for registration and subsequent verification of such a programme. This has contributed to the fact that no such RMP or FSP applications have been received by NZFSA and so there have been no approvals of such programmes.

3.2.1.2 Imported raw milk products

Currently, only limited varieties of cheeses made from raw milk can be imported and sold in New Zealand, following case-by-case assessments of the risk that the particular products pose to consumers. All other imported dairy products are made from pasteurised or thermised milk.

The requirements for importers relating to pasteurisation and other heat treatments are set out in the Food (Milk and Milk Products Processing) Standard 2007 issued under the Food Act.

Until July 2007, the only raw milk cheeses that were able to be legally imported into New Zealand were three specific hard and very hard Swiss cheeses—Emmental, Gruyere and Sbrinz. These cheeses have low moisture content and a very long storage period, which means NZFSA views them as similar in risk to cheeses made from pasteurised milk.

In 2007, following consultation, NZFSA amended the New Zealand (Milk and Milk Processing) Food Standard 2007 and the Food (Prescribed Foods) Standard 2007 to permit the import of Roquefort and extra-hard raw milk grating cheeses into New Zealand. NZFSA conducted its own risk assessment of Roquefort prior to recommending the direct importation and sale of this cheese in New Zealand. The

assessment was prompted in part by a request in 2004 from the French Government, following a decision by the Australian Government to allow the importation of Roquefort into Australia.

The hard and very hard Swiss raw milk cheeses and extra-hard grating raw milk cheeses are manufactured by heating the curd and have very low moisture content and long maturation/ripening periods. Risk assessments conducted by FSANZ concluded that cheeses manufactured to these criteria, using good hygienic and manufacturing practices, pose a low food safety risk because the cooking of the curd and the long storage periods control/destroy bacterial pathogens and the low moisture content inhibits their subsequent growth. As a result, these specific varieties of hard and extra-hard raw milk cheeses are considered to have a similar level of microbiological safety to products derived from pasteurised milk. It was on this basis that a change was made to allow for their importation and sale into New Zealand.

The importation and sale of Roquefort was allowed on the basis that it should be accompanied by appropriate risk mitigation measures, including an education campaign for vulnerable consumers on the possibility of foodborne risks associated with the consumption of Roquefort. NZFSA noted during consultation that, while the risk assessment indicated that appropriate risk management measures applied to the production of Roquefort cheese would minimise risks to the general New Zealand consumer to a level similar to other higher risk food types such as raw shellfish, a low (unquantified) level of foodborne risk remained.

As a semi-hard raw milk cheese, Roquefort carries a higher risk for some consumers. Softer raw milk cheeses are of higher risk than hard raw milk cheeses as their additional moisture content can allow pathogens to more readily survive and possibly grow.

The NZFSA risk assessment of Roquefort indicated that consumption would constitute a low risk to most New Zealand consumers but a higher risk to vulnerable consumers. Although production methods for Roquefort minimise the risks, they are not lowered to the same level as pasteurised dairy products.

NZFSA is not aware that the subsequent presence on the New Zealand market of Roquefort has provoked any rise in related foodborne illness.

3.2.1.3 Raw milk products for animal consumption

The framework proposed in this document addresses raw milk products for human consumption only. Requirements for the processing and sale or export of dairy products intended for animal consumption are already addressed by the Animal Products Act 1999 and the Agricultural Compounds and Veterinary Medicines Act 1997.

Processors of dairy material intended for animal consumption are required to operate under an independently evaluated and NZFSA registered RMP unless exempt. Section 8B(2) of the Animal Products (Exemptions and Inclusions) Order 2000 provides an exemption for processors of dairy material for animal consumption from the requirement to operate under a RMP provided that no other operations at the same place require an RMP and the product is for sale in New Zealand or Australia. However, regardless of any exemption, the requirements or duties set out in the Animal Products (Dairy) Regulations 2005 and, for use within New Zealand, the Agricultural Compounds and Veterinary Medicines Regulations 2001 apply.

Currently, the most common trade of raw dairy material for animal consumption is thought to relate to raw colostrum for calf rearing and raw milk or unpasteurised products for pigs. Any change to enable the manufacture of raw milk products in New Zealand is not expected to have any impact on the manufacture of animal feeds.

3.2.2 Australia

Like New Zealand, Australia does not currently allow production of raw milk products, with the exception of the production for sale of raw goat milk which is permitted in New South Wales, Queensland, South Australia and Western Australia. Australia does permit the importation of the same raw milk cheeses as New Zealand—namely three specific Swiss hard cheeses, extra-hard Parmesan-style grating cheeses and the French semi-hard cheese Roquefort.

Australian legislative requirements for the production of dairy products are set out in the Australia New Zealand Food Standards Code (the Code). The Code requires that milk and liquid milk products in Australia must be pasteurised (or undergo an equivalent treatment), “unless an applicable law of a State or Territory otherwise expressly provides”. As a result, States or Territories are responsible for giving permission to produce and sell raw milk and the production of raw drinking goat milk for sale for human consumption is permitted in four States.

FSANZ has developed a number of national standards through its work on primary production and processing standards for identified primary industry sectors. The Primary Production and Processing Standard for Dairy Products, Standard 4.2.4, was gazetted in the Code on 5 October 2006 and comes into effect in Australia on 5 October 2008. Standard 4.2.4 contains measures to address food safety in the dairy industry from production of milk through to processing, including the manufacture of specified dairy products. These measures include pasteurisation or an equivalent process. Standard 4.2.4A in the Code applies to Australia only and allows the importation and sale of Roquefort cheese and the same three raw milk Swiss cheeses allowed to be imported and sold in New Zealand.

FSANZ has recently commenced work on developing a framework that would allow the production and importation of a wider range of raw milk products in Australia. This proposal (Proposal P1007) includes addressing: public health and safety issues; existing applications that FSANZ has received to allow the production/import and sale of raw milk products; and regulatory inconsistencies. FSANZ is currently consulting on Proposal P1007.

3.2.3 Collaboration with Australia

As noted in Section 1.3.2, under TTMRA food that can be legally sold in one country may be legally sold in the other. There are some exceptions, however, with for example, high-risk foods listed in either country requiring certification or testing before being permitted entry. Australia and New Zealand are committed to removing regulatory barriers to the movement of goods and service providers between Australia and New Zealand and so facilitate trade between the two countries. To this end NZFSA and FSANZ have been cooperating in the area of high-risk foods to allow the removal of 'risk-goods' from the exemption schedule of the TTMRA.

Australia is facing similar issues to New Zealand in that there is domestic demand for raw milk products, but legal restrictions on the production and importation of such products. NZFSA and FSANZ have recognised that both are proposing to take a similar approach to raw milk products and have therefore been working collaboratively on the development of a technical framework for raw milk products.

Although there is potential for differences in approach, FSANZ and NZFSA will continue to consult and collaborate on a technical level, recognizing that risk management measures may be enacted differently in the respective countries.

3.2.4 Imports from other countries

NZFSA is in the process of implementing the outcome of the Imported Food Review. This includes the categorisation of foods into those of High, Medium and Low interest. Should the proposals set out in the discussion paper proceed, then NZFSA will need to consider the interface with the imported foods categorisation. Many foods imported to New Zealand must also comply with Import Health Standards set by the Ministry of Agriculture and Forestry (MAF) Biosecurity New Zealand. Implementation of these proposals, should they proceed, will also therefore need to include consideration of whether any Import Health Standards need to be developed or reviewed and the timeframe that needs to be allowed for this work to occur (refer also to Section 5.4).

3.2.5 Relevant national and international standards

3.2.5.1 Codex Alimentarius

The Codex Alimentarius (Latin for 'food code' or 'food book') is an international food standards code developed and maintained by the Codex Alimentarius Commission. The Commission was established and is jointly run by the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO). The Commission 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.

3.2.5.2 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 raw milk products⁷ (particularly cheeses) 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 hygiene of personnel. Member

⁷ Defined as products made from milk that has not been heated beyond 40 degrees Celsius or undergone any treatment that has an equivalent effect.

states then develop their own laws, regulations and administrative provisions, which must comply with the EC regulations. 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:

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

These regulations took effect in member countries on 1 January 2006.

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 animals and animal products as equivalent to New Zealand requirements. Once a product or class of products is acknowledged as being included under this Agreement, that product or class of product can be imported to New Zealand.

3.2.5.3 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.

3.2.5.4 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.

4 The reasons for the development of the proposed framework for raw milk products

There has been increasing interest in the availability in New Zealand of raw milk products, particularly cheeses, with requests being made to NZFSA that it allow for the domestic manufacture, sale and export of raw milk products and for the importation of a similar range of products. The requests have come from several sources:

- Some New Zealand consumers consider raw milk products to be superior in taste, texture and quality than pasteurised dairy products. Others believe it is their right to have access to the same choice of foods as is available overseas. A further group of consumers consider that there are health benefits to be derived from consuming raw milk products, including improvements in the symptoms of arthritis, asthma and eczema, and boosting of the immune system. Some in the gourmet food sector would also welcome access to raw milk products for use in their food products.
- Some New Zealand dairy manufacturers, especially specialist cheese makers, have indicated an interest in producing raw milk cheeses. They have expressed concern about the inequity and inconsistency of the current situation whereby some raw milk cheeses can be imported but may not be manufactured in New Zealand, and are interested in developing markets for raw milk products, both in New Zealand and overseas.
- Importers are concerned about the restrictions imposed by the current regulatory regime and would like to bring other types of raw milk cheeses into New Zealand in order to satisfy demand for gourmet foods, without the need for the individual assessment of such products.
- A number of EU member countries are interested in exporting raw milk cheeses to New Zealand, and the decision to allow French Roquefort cheese to be imported in 2007 has increased this interest.

Other factors that have supported a review of the availability of raw milk products in New Zealand include that:

- There is evidence that some raw milk products, other than those already available on the New Zealand market, are safe for human consumption, either because of their intrinsic characteristics, or because of steps that are followed during their production process.
 - Current New Zealand legislation does allow for domestic dairy producers to apply to NZFSA for approval to manufacture raw milk products under an RMP or FSP. However, because there are
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no technical criteria or other guidance material in place to assist with the development, evaluation, assessment for registration and subsequent verification of such programmes, New Zealand manufacturers have not applied to NZFSA for the registration of programmes for the manufacture of raw milk products.

- The production of raw milk products (with the specific exclusion of raw drinking milk), under appropriate hygienic conditions, is recognised in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products. New Zealand is a member of the Codex Alimentarius Commission.
- The New Zealand/European Community (EC) Sanitary Agreement recognises EC sanitary measures (including food controls) for animals and animal products as equivalent to New Zealand requirements. This is relevant because, should a framework to allow wider importation of raw milk products be introduced, it is likely that many of the new types of raw milk products that would be imported into New Zealand would originate from Europe.
- Australian legislation allows the importation of the same raw milk cheeses that can be imported into New Zealand. However in response to domestic demand, Australia is considering developing standards to allow the production and importation of a wider range of raw milk products. Under the TTMRA, food that can be legally sold in Australia can be legally sold in New Zealand, and vice versa. There are some exceptions, however, with for example high-risk foods listed in either country requiring certification or testing before being permitted entry. Australia and New Zealand are committed to removing regulatory barriers to the movement of goods and service providers between Australia and New Zealand and so facilitate trade between the two countries. To this end, NZFSA and FSANZ have been co-operating in the area of high-risk foods.
- Continuing to assess on a case-by-case basis whether raw milk products manufactured overseas are suitable for import into New Zealand, as has been done for Roquefort and the hard and very hard Swiss cheeses and extra-hard grating cheeses, is not practical. It is resource intensive and allows for potential inconsistencies between the treatment of imported and domestic products, and between different imported products.

5 Proposed framework for raw milk products

NZFSA is proposing to introduce a framework (the framework) that would allow for raw milk products to be assessed as to whether they can be safely produced, imported, exported and sold in New Zealand, and to identify the specific requirements that would apply to such products. While the framework would cover all raw milk products, only those that could be produced to an acceptable level of safety (that is, present a low food safety risk to the general human population) would be able to be legally produced and imported.

If, following the consultation initiated by this discussion document, a decision is taken to advance the proposed framework, then a second round of public consultation would be initiated providing further details of the framework (for example the criteria for categorising raw milk products) and the draft technical and legal requirements necessary to implement the framework. The framework would apply to products that fall under the Animal Products Act 1999, the Food Act 1981 and the proposed new Food Bill.

5.1 Proposed framework for raw milk products

The proposed framework is based on a 'category approach', with raw milk products being grouped into one of three categories according to their food safety risk. The proposed framework includes the following elements:

- three risk categories for raw milk products;
- processes to categorise products into these three categories;
- education of vulnerable consumers;
- labelling of raw milk products that pose a higher risk to vulnerable consumers; and
- revised import standards reflecting the category approach.

5.1.1 Risk assessment

To inform the development of the proposed framework, NZFSA is undertaking a portfolio of risk assessment work concerned with public health risks associated with the consumption of raw milk and milk products. This includes:

- various Risk Profiles including; *Listeria monocytogenes* in low moisture cheese, *Listeria monocytogenes* in soft cheeses, *Mycobacterium bovis* in milk and Shiga toxin-producing *Escherichia coli* (STEC) in raw milk;
- a review of the science supporting the current dairy pasteurisation time and temperature parameters;
- a qualitative risk assessment of the risk to New Zealand consumers from the consumption of Roquefort cheese;
- a Quantitative Risk Assessment (QRA) to assess the risk to New Zealand consumers from the consumption of raw milk and raw milk products (see 5.1.4. for further information);
- scientific studies relating to heat inactivation of pathogens in raw milk (in partnership with Fonterra) from which data was generated to provide parameters for the Quantitative Risk Assessment; and
- Systematic Review of the human disease evidence associated with the consumption of raw milk and raw milk cheese.

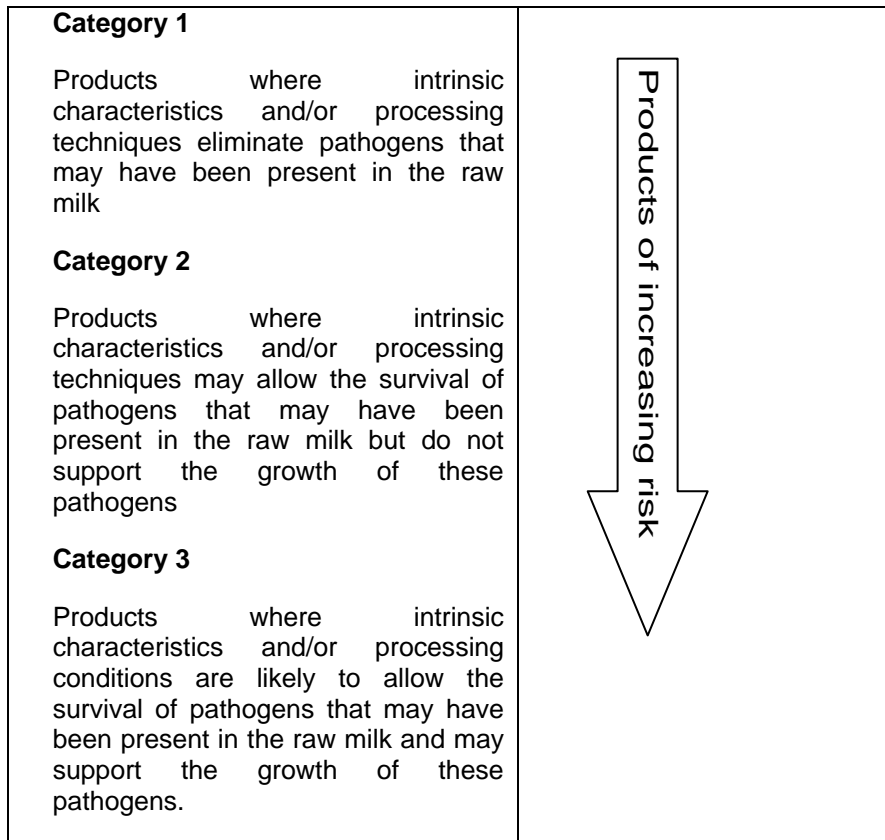
FSANZ is also undertaking microbiological risk and social science assessments relating to the consumption of raw milk and some raw milk cheeses, and NZFSA will be closely monitoring the results of this work.

5.1.2 Proposed category approach

The proposed category approach for raw milk products has been developed after consideration of:

- the existing legal requirements for raw milk cheeses currently able to be sold in New Zealand and Australia, and the risk assessment advice used to determine these requirements, which examined production factors and the intrinsic properties of selected dairy products; and
- FSANZ and EU assessments available for other European-style raw milk cheeses.

Raw milk products would be categorised into one of three categories on the basis of food safety risk to human health. This is determined by the effect that the production methods and the intrinsic characteristics of the final products have on pathogen survival and growth. Processing factors include: curd cooking temperature, acidification and storage time. Intrinsic characteristics include: water activity, moisture content, acidity and salt concentrations. As illustrated below, the potential food safety risk associated with the products in each category would increase from Category 1 to Category 3, with Category 1 products having the lowest risk to human health and Category 3 the highest.



Risk management options for each category would vary and be more comprehensive for higher risk products. The category approach would assist NZFSA to develop risk management options for groups or categories of raw milk products, removing the need for resource intensive and ad hoc case-by-case assessments of individual processes and products.

Prior to the importation of any overseas-made raw milk products not already available in New Zealand, MAF Biosecurity New Zealand would also need to be involved in any necessary revision and/or development of biosecurity import health standards.

5.1.3 Description of categories

The proposed three categories for raw milk products are described below. The descriptions in bold apply to products at the end of the manufacturing process—this includes any maturation of the products as is, for example, required for many cheeses. Also included are some examples of products that could be included in each of the categories and some indication of the risk management options that could apply.

5.1.3.1 Category 1

Category 1 products are defined as those products where intrinsic characteristics and/or processing techniques eliminate pathogens that may have been present in the raw milk.

Examples of products in Category 1 would include the extra hard grating cheeses, which are made from raw milk by heating the curd and have a long maturation/ripening period. These steps result in the death of pathogens and mean that these cheeses have an equivalent level of safety to pasteurised products.

Category 1 raw milk products would pose a low risk (similar to pasteurised and thermised products) to all New Zealand consumers, including vulnerable populations. As a result, they would be able to be produced and imported safely, without additional control measures being required.

5.1.3.2 Category 2

Category 2 products are defined as those products where intrinsic characteristics and/or processing techniques may allow the survival of pathogens that may have been present in the raw milk but do not support the growth of these pathogens.

This Category would apply to products where there is possible survival, but not growth of micro-organisms such as *Salmonella*, *Listeria monocytogenes*, *Campylobacter* or *Staphylococcus aureus*. A combination of control measures and verification procedures (including of on farm practices) additional to those currently applied to dairy products, would be applied to the production of Category 2 products to provide an acceptable level of microbial safety for consumption by the general public.

Based on the previous risk assessments of imported Roquefort cheese, this could be an example of a Category 2 product.

The focus of NZFSA regulatory control would be on allowing the safe production and importation of products in Category 2 (see Section 5.2). Some raw milk products would be assigned to Category 2 with the development of technical criteria to assist in the design, evaluation and verification of FSPs and RMPs for these products.

Products in Category 2 would pose a low food safety risk to the general population, but would potentially be of higher risk to vulnerable groups. The introduction of such products would need to coincide with risk mitigation strategies including education and labelling, to ensure that vulnerable consumers can identify raw milk products in this Category and are aware of the risks posed by their consumption.

5.1.3.3 Category 3

Category 3 products are defined as those products where intrinsic characteristics and/or processing techniques are likely to allow the survival of pathogens that may have been present in the raw milk and may support the growth of these pathogens.

Category 3 products are those that are not subject to any control measures that would reduce pathogens to an acceptable level. In general, if pathogens are present, they would be expected to multiply during any processing, maturation or storage steps and in the final product. This Category would include products such as raw drinking milk and would be likely to include high moisture content cheeses, such as unripened cheeses.

Category 3 products would not be able to be legally produced in New Zealand or imported because there are no appropriate processing techniques that could ensure such products are safe for consumption by the general New Zealand population, given the level of safety currently seen as acceptable to New Zealanders.

5.1.4 Categorisation of raw milk products

NZFSA proposes to develop tools to assist with categorisation of raw milk products.

It is proposed initial categorisation of products into Category 1 be determined by a filter based on processing factors and product characteristics (e.g. pH, salt level, moisture). Raw milk products that did not meet the criteria of Category 1 would fall into either Category 2 or Category 3. A second filter will be necessary to categorise many of the raw milk products into either Category 2 or Category 3.

The second filter will include a Quantitative Risk Assessment (QRA) that has been developed in order to assess the risk to New Zealand consumers from the consumption of raw milk and raw milk cheeses. The QRA takes a farm-to-fork approach from primary production, through milk processing, product manufacture, sale and consumption. The results from the QRA will then aid the categorisation of the product into either Category 2 or Category 3.

However, for some products manufacturers or importers will need to provide NZFSA with additional evidence to demonstrate that processing factors and the intrinsic characteristic of a product/category of product can provide for an acceptable level of safety.

Raw milk products that are placed in Category 3 would not be able to be produced or imported given the level of safety currently seen as acceptable for New Zealanders. Those wanting to manufacture or import a product in Category 3 would be required to specify additional processing steps that would be introduced to increase the safety of the product and show how these steps would be validated. If NZFSA accepts that the product could be produced to an acceptable level of safety with these

additional controls, then it would be moved into Category 2. If not, the product would remain in Category 3.

It is likely that ongoing monitoring will be required to confirm that particular products have been categorised correctly and that these categories remain valid.

5.2 Preliminary risk management options for categories

Raw milk products that can be produced safely without additional control measures would fall into Category 1, whilst Category 3 products would not be able to be manufactured or imported for sale. As a result, the regulatory framework would focus on Category 2 products and the additional control measures or requirements that would be necessary to produce Category 2 products to an acceptable level of safety. It is likely that measures relating to Category 2 milk harvesting and milk processing would also require closer monitoring and control throughout the production life cycle, compared to Category 1.

5.2.1 Category 2

NZFSA has undertaken some preliminary work to consider what additional measures or requirements might be necessary to ensure that Category 2 raw milk products have an acceptable level of safety (whilst acknowledging that these measure would only need to be introduced if the framework is agreed). NZFSA has split the process into two stages: milk harvesting and milk processing. The following is an indication of what NZFSA may propose.

Milk Harvesting:

At present, requirements related to the harvesting of milk on the farm are set out under the Animal Products Act 1999. If the proposed framework is agreed, there would need to be additional requirements for the harvesting of the milk used to produce raw milk products.

Current milk harvesting requirements are based on the assumption that the milk will be pasteurised, which kills or inactivates foodborne pathogens. As raw milk products are not subjected to this processing step, it is crucial that the levels of pathogens in raw milk are kept as low as possible. The areas that would need to be considered when determining the requirements for raw milk production are still to be finalised, but would include animal health, feeding, transport and storage times, temperature control and registration of farm dairies.

The requirements for raw milk harvesting would be based on the guidelines established for raw milk products by the Codex Alimentarius Commission. This approach is considered appropriate due to:

- the clear and existing guidance on risk management options for raw milk products provided in the Codex Code of Hygienic Practice for Milk and Milk Products;
- the large number of milk harvesting operations in New Zealand, which require a detailed approach to ensure the methods that are used to achieve food safety are consistent and effective; and
- the proposed approach needing to be consistent with the current mandate of the Animal Products Act, because milk harvesting does not fall within the scope of the Food Act.

Milk Processing:

The proposed processing requirements for the manufacture of raw milk products would most likely be more outcome based and less detailed than the requirements applied at the milk harvesting stage. NZFSA considers that this is appropriate due to the diversity of processing conditions that are potentially available and that could be used to safely produce raw milk products.

Processing controls that may be required could include: the use of starter cultures in fermented products; acid production including target pH values and the time for acid development; salting procedures and salt levels; and curing or ripening conditions.

Should the proposed framework for raw milk products be agreed, NZFSA would need to consider how these processing requirements would be implemented under both the Animal Products Act and the Food Act.

5.3 Other risk mitigation considerations

As part of the proposed framework, NZFSA has been undertaking preliminary consideration of ways of helping to mitigate the risks associated with consumption of raw milk products. Raw milk products can contain harmful pathogens that may cause serious illnesses and be life-threatening to vulnerable groups. In countries where raw milk cheeses are part of the culture, the longstanding culinary tradition means there is widespread awareness of the risks of consuming raw milk products. However, as these products are new to New Zealand, raising public awareness of the risks involved in their consumption by vulnerable groups is very important.

5.3.1 Consumer education programme

NZFSA operates an education programme for vulnerable groups to communicate information about public food safety risks to both vulnerable groups (the young, frail elderly, expectant mothers and the immune-compromised), and other members of the community.

In 2007 NZFSA broadened its education programme to include the raw milk cheese Roquefort, following amendments to the legislation that allowed the direct importation and sale of this product. Activities included articles in NZFSA publications and consumer magazines, media releases, and flyers displayed at points-of-sale. In addition, NZFSA specifically targeted at-risk groups by distributing information to every medical centre and midwife in New Zealand.

Should the framework for raw milk products be agreed, NZFSA would further utilise its education programme for vulnerable groups to communicate the risks associated with raw milk products generally in order to ensure consumers make informed choices. NZFSA is currently reviewing the effectiveness of the education programme for Roquefort cheese. This will assist in determining if any changes or additions to the programme may be required in future.

As part of the consultation process initiated by this discussion document, NZFSA would welcome feedback on effective and equitable strategies to communicate with vulnerable groups.

5.3.2 Consumer survey

To enhance the design and effectiveness of its education programme and to gain more information on New Zealand consumers' understanding of raw milk products, NZFSA is commissioning a survey of consumers, the hospitality and retail trade, and health professionals.

The primary objectives of the NZFSA consumer survey are to determine public awareness and understanding:

- of terms such as 'raw milk', 'un-pasteurised milk', 'pasteurised milk' and 'raw milk cheese';
- of the risks associated with the consumption of raw milk products; and
- that raw milk products pose relatively greater risks to some vulnerable population groups.

The survey will also ask participants about their current and expected future consumption of raw milk products, and their expectations about labelling and the content and placement of information material.

In association with the survey, NZFSA will also use small focus groups to discuss labelling options, including the need for advisory statements, wording for labelling and the effectiveness of NZFSA's education materials for vulnerable consumers.

FSANZ is also commissioning research into Australian consumer behaviours and motivations in respect of raw milk products, and NZFSA will be taking an interest in the findings of the FSANZ research with the view to better informing New Zealand education strategies.

5.3.3 Labelling

The labelling requirements for all food (including dairy products) sold in New Zealand are set out in the Australia New Zealand Food Standards Code (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. In the case of raw milk products, the list of ingredients would include raw (or unpasteurised) milk.

Mandatory advisory statements are used when consumption of a food exposes the general population or a population subgroup to a health and safety risk, or where guidance about a food is needed to maintain public health and safety. The list of foods that are required by the Code to have a mandatory advisory statement includes unpasteurised milk and liquid milk products, but does not currently include raw milk cheeses or other raw milk products. This means that the labelling on unpasteurised milk and liquid milk products 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 required on the labels of raw milk cheeses or other raw milk products.

The consumer survey being commissioned by NZFSA will provide data about New Zealand consumers' understanding of raw milk products. Combined with the feedback received in response to this discussion document, this is expected to assist with determining whether the current labelling requirements for raw milk products are considered sufficient, or whether these requirements should be strengthened and if so how this may be achieved. One possibility is the use of mandatory advisory statements to more clearly differentiate raw milk products.

The need for any change to the current labelling requirements is also an area in which NZFSA will continue to collaborate and consult with FSANZ.

5.4 Imported food standard for raw milk products

Raw milk cheeses are currently included in the Food (Prescribed Foods) Standard 2007 as they are considered a high risk food. This recognises that some foods, because of their nature or the way in which they are handled, can pose an increased risk of illness to consumers. The Prescribed Food Standard details which foods are prescribed and also the hazards for which they can be monitored.

New Zealand legislation permits the importation and sale of three named hard and very hard Swiss raw milk cheeses, extra-hard raw milk Parmesan style grating cheeses, and Roquefort cheese. These cheeses are listed in the Food (Milk and Milk Products Processing) Standard 2007. Raw milk cheeses can only be imported from an exporting country that operates a production programme that has been

assessed and recognised as equivalent to, or complying with, New Zealand's standards, through a country-to-country arrangement.

Development of a future import standard for raw milk products would be based on the outcome of any New Zealand processing standard for raw milk products, with the same category approach (as outlined in Section 5.1) being applied. Under the new Imported Food Regime, which is currently in the process of being implemented, many raw milk products are likely to be classed as high regulatory interest foods. This means such products would only be able to be imported from countries with which New Zealand has a country-to-country arrangement. This would provide a high level of food safety assurance prior to these products entering New Zealand.

MAF Biosecurity New Zealand (MAFBNZ) is responsible for ensuring all New Zealanders, our natural resources, plants and animals are protected from the potential introduction of pests and diseases. MAFBNZ develops Import Health Standards which are issued under the Biosecurity Act 1993. They state the requirements that must be met before goods identified as a risk to our biosecurity can be imported into New Zealand. In order for a wider range of raw milk products to be introduced, MAFBNZ would need to develop Import Health Standards for these products and the development of such Import Health Standards would need to be prioritised against other projects on the MAFBNZ work programme.

5.5 Exports

If permitted, the New Zealand manufacture and export of raw milk products could potentially open new export market opportunities, since previously all dairy products exported from New Zealand have been pasteurised. The possible future volumes/value of exports of raw milk products are not able to be precisely quantified at this time by NZFSA. Initially such trade is likely to be small, but potentially it could grow considerably. Balanced against this benefit there is, however, a need to ensure that the current significant export trade in pasteurised products is protected, as a damaging food safety incident relating to an exported raw milk product could impact not only on raw milk product exports, but on all New Zealand dairy exports.

All food products exported from New Zealand must be produced in accordance with New Zealand legislative requirements and also meet the legislative requirements of the importing country. Should the proposal outlined in this discussion document proceed, the development of general export standards for raw milk products may be necessary but would be dependent on the outcome of the New Zealand standard for such products. 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, and official certification. However, it is likely that any additional general export requirements would be minimal.

NZFSA is also undertaking initial review of other elements that could impact on any future export of raw milk products including:

- Labelling: Since all dairy products exported from New Zealand have, to date, been pasteurised, it may be prudent to provide clear information on the label of all unpasteurised export dairy products to prevent misconception by importing countries unaware of the change in New Zealand policy. This would also ensure that foreign consumers are made aware of any risks posed by the consumption of New Zealand raw milk products.
- Export certificates: NZFSA is reviewing export certificate templates for dairy products to ensure declarations would be compatible with the certification of both raw milk and pasteurised products processed in New Zealand.
- Export requirement notices: These generally specify whether or not dairy products must be pasteurised, and for many countries, this requirement has been established for many years. NZFSA is obtaining updated information on the import requirements for raw milk products in potentially important export markets such as the EU, the USA and Canada. Requirements for other markets would be established or reviewed on a country by country basis, on request from exporters prior to export, and the relevant export requirement notice amended accordingly.

5.6 Cost recovery

If a decision is taken to facilitate the local production of raw milk products and the importation of a similar range of such products, NZFSA would apply its cost recovery policy and framework to determine which of the associated activities need to be funded privately or through industry, rather than through Crown funding. Further information about any fees, charges or levies relating to raw milk products would be discussed during the second round of consultation, should this proceed.⁸

⁸ For further details on the NZFSA cost recovery policy and framework, see the NZFSA Background Paper No 06/04: Cost Recovery Policy and Framework at <http://www.nzfisa.govt.nz/policy-law/publications/reports/cost-recovery/index.htm>

6 Possible options considered by NZFSA and analysis of their impacts

In considering the approach to take with regard to the New Zealand production and importation of raw milk products, NZFSA considered four possible options:

- Option 1: To maintain the status quo;
- Option 2: To maintain the status quo and, in addition, not consider any further applications for case-by-case assessments that could allow importation of raw milk products not already available New Zealand;
- Option 3: To develop a framework, based on risk to consumers, which would allow both New Zealand production of some raw milk products and the importation of a similar range of raw milk products while maintaining an acceptable level of protection for consumers; and
- Option 4: To allow all types of raw milk products to be both made in New Zealand and imported into New Zealand, regardless of the risk they pose to consumers.

The potential positive and negative impacts of each of these options are analysed below.

The preferred option of NZFSA is Option 3.

6.1 Analysis of options

6.1.1 Option 1: To maintain the status quo

Potential positive impacts of Option 1 include:

- A small range of raw milk cheeses would continue to be available in New Zealand, maintaining some limited access to raw milk products for New Zealand consumers.
- There would be no need for resources to be devoted to developing either a framework for raw milk products, or the necessary standards to implement this framework.

Potential negative impacts of Option 1 include:

- The restrictions on the range of raw milk products available would be unpopular with those who advocate consumer choice, or those who consider raw milk products have desirable flavour, quality or health properties.
- New Zealand legislation would continue to allow for domestic dairy producers to apply to NZFSA for approval to manufacture raw milk products under an RMP or FSP, but in practice there would still be no technical criteria or other guidance material to assist with the development, evaluation, assessment for registration and subsequent verification of such a programme. This would be likely to deter local production, as has been the case in the past, and to prevent local manufacturers from diversifying into new market niches, both in New Zealand and overseas.
- NZFSA would continue to assess, on a case-by-case basis, any additional raw milk products which importers might apply to bring into New Zealand. This is a slow, resource intensive process that can potentially result in inconsistencies between the treatment of imported and domestic products, and between different imported products.
- Overseas suppliers wishing to export raw milk products to New Zealand (other than those varieties approved by case-by-case assessments) would be unable to do so.
- Australia is considering developing a regulatory framework which, if approved, would allow for the production and importation of a wider range of raw milk products in Australia. Should this occur, NZFSA and FSANZ would need to work to facilitate trade of these products. This would exacerbate the anomalous situation for those interested in manufacturing raw milk products in New Zealand, or create an anomaly for those interested in importing such products directly from markets other than Australia.
- The EC and some EU member states have expressed interest in New Zealand allowing a wider range of raw milk products to be more readily imported; but this option would not facilitate such trade.

6.1.2 Option 2: To maintain the status quo and, in addition, not consider any further applications for case-by-case assessments that could allow importation of raw milk products not already available in New Zealand

Potential positive impacts of Option 2 include:

As for Option 1 above, but would also include that:

- Some local manufacturers may consider this Option more equitable than Option 1. This is because no further varieties of raw milk products, other than those already on the New Zealand market, could be imported in the future.
- Those that consider that raw milk products pose significant health risks to vulnerable consumers (despite proposed risk mitigation strategies) may welcome this Option as it would prevent wider importation and production of raw milk products.

Potential negative impacts of Option 2

As for Option 1 above, but would also include that:

- Some commentators could consider this Option to be inconsistent with New Zealand's obligations under the World Trade Organization Sanitary and Phytosanitary Agreement.
- Under this Option, no further case-by-case assessments of overseas made raw milk products would be undertaken. Whilst this would remove the potential for inconsistencies to arise between the treatment of imported and domestic raw milk products, it would also mean that New Zealand consumers would not have access to any other types of overseas raw milk products, other than those varieties already available.

6.1.3 Option 3: To develop a framework, based on risk to consumers, which would facilitate both New Zealand production of some raw milk products and the importation of a similar range of raw milk products, while maintaining an acceptable level of consumer protection for New Zealanders

This is NZFSA's preferred option.

Potential positive impacts of Option 3 include:

- New Zealand consumers would have access to a wider range of raw milk products. This would be welcomed by those who advocate consumer choice and those who consider that raw milk products have desirable flavour, quality and/or health properties.
- New Zealand manufacturers could produce some raw milk products. This could allow local manufacturers to take advantage of new business opportunities both in domestic and export markets, and would ensure there is no inequity between the treatments of overseas and locally made raw milk products.
- The framework proposed by this Option would categorise raw milk products according to the level of risk that their consumption poses to human health. As a result, those raw milk products that pose higher levels of risk to New Zealand consumers would be unable to be made in, or imported into, New Zealand unless manufacturers or importers could demonstrate that processing steps could be followed to ensure products were produced to an acceptable level of safety. The framework proposed by this Option includes risk mitigation strategies (for example, consumer education and labelling), which would offer protection for public health.
- New Zealand importers could import a wider range of raw milk products directly from their countries of origin (once any Import Health Standards have been reviewed or developed by MAF Biosecurity New Zealand, as may be required).
- NZFSA would assess the risks posed by imported raw milk products according to the new framework, instead of the current case-by-case basis. The current case-by-case system is resource intensive and allows for potential inconsistencies to arise between the treatment of imported and domestic products, and between different imported products.
- This Option would remove the potential for an anomaly to be created if a local manufacturer was to apply to have an RMP registered or an FSP approved for raw milk products, only to find that no technical criteria exist against which such a programme could be evaluated, assessed or verified.

- If Australia proceeds with plans to allow for the production and importation of a wider range of raw milk products, then New Zealand and Australian rules for the importation and manufacture of raw milk products would remain similar.
- New Zealand trading partners may welcome this Option.

Potential negative impacts of Option 3 include:

- Those who may consider that raw milk products pose significant health risks to vulnerable consumers (despite the proposed risk framework and risk mitigation strategies) may be concerned that an increased variety of raw milk products would be available in New Zealand.
- Raw milk products classified under NZFSA's proposed new framework as Category 3, or high risk products, would be unable to be manufactured or imported (see Section 5.1.3 for a description of these categories). Whilst some may consider this to be an advantage, others, such as local manufacturers and those who contend that all raw milk products can provide health benefits to consumers may oppose this restriction.
- This Option would require resources to be devoted to developing the risk management framework, developing the standards necessary to implement the framework, and to educating consumers about raw milk products.
- Manufacturers and importers of raw milk products would have to follow technical criteria, and/or demonstrate that these have been met, and would need to commit resources to this process.
- This Option would require that agencies and persons are available, or can be trained, to provide verification and related services for raw milk products.

6.1.4 Option 4: To allow for all types of raw milk products to be both made in New Zealand and imported into New Zealand, regardless of risk

Potential positive impacts of Option 4 include:

- New Zealand consumers would have access to a full range of raw milk products. This could be welcomed by those who advocate consumer choice and those who consider that raw milk products have desirable flavour, quality and/or health properties.
- New Zealand manufacturers could produce raw milk products without any restriction and there would be no inequity between the treatment of overseas and locally made raw milk products.

- New Zealand importers could import the full range of raw milk products directly from their countries of origin.

Potential negative impacts of Option 4 include:

- In the absence of a framework based on risk, all types of raw milk products could be manufactured, and imported into New Zealand, regardless of the risks that they pose to public health. As some types of raw milk products do pose high risks, this could result in serious health consequences for the New Zealand population.
- An outbreak of illness associated with consumption of raw milk products could damage New Zealand's reputation as a reliable and trusted supplier of safe and suitable food.
- If raw milk products that pose high risks to consumers were to be exported from New Zealand, a negative incident related to any such products could have a substantial and damaging impact on New Zealand's reputation as an international exporter of food, and especially as an exporter of milk products. The success of the New Zealand dairy industry is linked to its reputation as a high quality and safe provider of products, both to export markets and to the New Zealand domestic market.
- RMPs and FSPs require that food safety risk factors are identified and controlled and/or eliminated. Allowing all types of raw milk products to be available in New Zealand, regardless of the risks that they pose, would therefore be out of step with current food safety policy and would require amendment to, or exemption from, existing legislation.
- This proposal is out of step with government policy and the approach taken in other food related legislation. Some raw milk products are a threat to public health, as evidenced by outbreaks in other countries. To knowingly allow these products to be manufactured or imported into New Zealand would expose NZFSA, and possibly the government, to a charge of relinquishing responsibility.
- New Zealand does not operate a 'buyer beware' approach to food – therefore importers and/or manufacturers of products that were identified as causing illness or death would be open to prosecution unless the relevant legislation (the Food Act and Animal Products Act) was amended to remove such a liability.

The scale and significance of the potential negative impacts of Option 4 calls into question the viability of this Option.

7 Conclusion

NZFSA's preferred option is to enable the manufacture and sale (both within New Zealand and for export) of some raw milk products, and allow for the importation and sale of a similar range of raw milk products, while maintaining an acceptable level of consumer protection.

NZFSA is proposing to introduce a framework that would allow for the assessment and identification of those raw milk products that could be safely produced, imported and sold in New Zealand, and any specific requirements that would need to apply to these products. While the framework would cover all raw milk products for human consumption, only those that could be produced safely (that is, present a low food safety risk to the general population) would be able to be legally produced and imported. If the proposed framework was to be progressed, regulations and associated guidance information would then be introduced to enable its implementation. The framework would include provision for consumer education and informative labelling of raw milk products.

The proposed framework is based on a 'category approach' with raw milk products being placed in one of three categories according to their food safety risk. The category approach has been developed after consideration of the FSANZ and NZFSA risk assessments of raw milk cheeses currently able to be sold in New Zealand and Australia, and EU assessments for other European-style raw milk cheeses. It has also been informed by other NZFSA risk assessment work on the public health risks associated with the consumption of raw milk and raw milk products. The category approach would assist NZFSA to develop risk management options for each of the categories, removing the need for case-by-case assessments of some individual processes and products. It is likely that technical criteria would not be initially developed for all raw milk products categories, with priority instead being given to raw milk cheeses.

If, following the consultation initiated by this discussion document, a decision is taken to advance the proposed framework for raw milk products, a second round of public consultation would be initiated on the draft technical and legal requirements necessary to implement the framework outlined in this document. The proposed regulatory framework would apply to products that fall under the Animal Products Act 1999, the Food Act 1981 and the proposed new Food Bill. Associated implementation matters including the interface with the Imported Food Review, MAF Biosecurity Import Health Standards, and any monitoring programmes needed, along with a regulatory impact assessment on any proposed regulations, would also be considered in the preparation for any further public consultation.

8 Questions and submission example

NZFSA seeks your views on the proposal in this document. The following form has been provided to assist you in making a submission, but comments in other formats will also be welcome.

If you have any queries about the NZFSA proposal or other information in this document, please contact the 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):

Please comment under any or all of the following headings:

1. The consultation process
2. Support for and against raw milk products:
 - Consumers may wish to provide information on matters such as whether:
 - you perceive a demand for raw milk products in your community;
 - you currently consume such products;
 - you would consume such products if they were more widely available;
 - such products appeal to you; and
 - you have a greater demand for some raw milk products (such as cheeses) than others.
 - Industry may wish to provide information on matters such as whether:
 - you support the proposed new framework for raw milk products;
 - you wish to make or import raw milk products and if so what type(s); and
 - the proposed framework would have an impact on your business.

3. Proposed framework:

Please provide comments on the NZFSA proposal, including:

- the suggested framework and categories for raw milk products;
- the preliminary risk management options for categories and
- other risk mitigation considerations, including suggestions on:
 - how best to communicate with vulnerable groups, and
 - effective labelling for raw milk products (for example is a warning statement needed on raw milk products? What is the best term to use to describe such products?)

4. Alternative options:

- Are there other feasible options that have not been canvassed?
- Do you have any comments to add to the analysis of the options?

5. Please provide any other comments or information that could supplement the analysis in this discussion document.

9 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.

Extra hard grating cheeses: These cheeses are often 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 (FSP): 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 content of labelling of food, for both countries (see Australia New Zealand Food Standards Code).

New Zealand Food Safety Authority (NZFSA): The government department with a role of protecting and promoting public health and facilitating access to markets for New Zealand's food and food related exports.

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: 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.

Risk Management Programme (RMP): A programme as defined by Section 12 of the Animal Products Act 1999, designed to identify, and control, manage and eliminate or minimise, hazards and other 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. 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.