FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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PROPOSAL P1007
PRIMARY PRODUCTION & PROCESSING REQUIREMENTS FOR RAW MILK PRODUCTS (Australia Only)

DISCUSSION PAPER

Executive Summary

This Discussion Paper provides the first opportunity for the public to comment on Proposal P1007 and, if possible, assist Food Standards Australia New Zealand (FSANZ) with information and data to assist in its assessment.

Purpose

Proposal P1007 will address issues in relation to production and sale of raw milk products in Australia arising from inconsistent legislation currently applying to dairy products, Applications to FSANZ to permit raw milk products and any public health and safety issues from consumption of raw milk products. Raw milk products may be derived from a number of milking animals including cow, goat, sheep, buffalo, horse and camel.

Introduction

Since June 2002, FSANZ has had responsibility for developing national food safety requirements that cover all parts of the food supply chain – an integrated paddock-to-plate approach. The Primary Production and Processing Standard for Dairy Products, Standard 4.2.4 (Australia only) was gazetted in the *Australia New Zealand Food Standards Code* (the Code) on 5 October 2006 and comes into effect on 5 October 2008. Standard 4.2.4 establishes through chain requirements for milk and milk products to be pasteurised (or equivalent process).

Issues

FSANZ is now addressing raw milk products issues through Proposal P1007. These issues include:

- national consistency - the Code currently allows for the States and Territories to individually permit the production for sale of unpasteurised milk and milk products (excluding cheese);
- inconsistent requirements for domestic and imported products - the Code currently allows the sale of specific imported cheeses but not for the equivalent domestic production;
- reference to legislation of other countries - permissions for imported cheeses refers to legislation of other countries;
- Applications received by FSANZ to allow the import and sale of raw milk products; and
- risks to public health and safety.

Objectives

The heat treatment of milk and milk products is mandated by the Code as an important public health measure to destroy potential microbiological hazards that may be present in milk and has provided the benchmark public health and safety measure for dairy foods in this country.

Specifically, this Proposal will consider whether the Code should be amended to address:

- providing nationally applicable Standards rather than State-based provisions for raw milk products;
- replacing the current references to the legislation of other countries with specific control measures; and
- the applications (current and potential future) for extended permissions in the Code for raw milk products.

Overriding the issues outlined above is the assessment of the risks to public health and safety and how these are, or could be, managed if the status quo was changed. In regard to this work, protection of public health and safety and the provision of adequate information relating to food to enable consumers to make informed choices are the key objectives.

Approach for achieving the objectives

FSANZ has developed a framework in which to consider the various products that could be considered within the scope of this Proposal. This Category Framework Approach and the description of the categories have been developed taking into consideration previous risk assessment advice used to determine the existing requirements for raw milk products in the Code. This framework also considers the preliminary findings of the risk assessment work currently underway on raw goat milk, raw cow milk and raw milk cheese.

The categories are defined depending on the effect production methods and intrinsic characteristics of the final products have on pathogen survival and growth. If the survival and growth of pathogens is more likely in some products, then these

products present a greater food safety risk compared to products where pathogen survival and growth is less likely. The potential food safety risk associated with each category increases from Category 1 to Category 3.

	Raw milk products
Category 1	Products in which pathogens are eliminated
Category 2	Products where pathogens may survive but do not grow
Category 3	Products where pathogens survive and grow

Increasing Risk

This Proposal will examine all activities associated with the production of raw milk products from on-farm milk production through to retail sale and the consumer. While cheese is the major commercial raw milk product being considered, the framework approach will endeavour to achieve outcomes that are applicable to all products including cultured milk, yoghurt, butter, ice cream etc.

Scientific assessments

Microbiological risk assessments

The risk assessments will qualitatively and/or quantitatively examine microbiological hazards and epidemiological and other data to determine whether these hazards have presented, or are likely to present, a public health risk through the consumption of raw goat milk, raw cow milk and some raw milk cheeses. The risk assessments will also identify where in the supply chain these hazards may be introduced. This includes information and data on:

- potential food safety hazards associated with animal disease and animal treatments;
- and on-farm inputs (e.g. feed, water, veterinary interventions);
- the likelihood of any contamination of raw milk and raw milk products with specific hazards at all points along the production/supply chain, and the levels and extent of any such contamination;
- the incidence of foodborne disease arising from consumption of raw milk products will be examined in the risk assessment; and
- food consumption patterns to assist in determining exposure to a particular hazard.

As part of the information gathering process, FSANZ is seeking Australian epidemiological data on the extent and cases of human disease associated with the consumption of raw milk products information on consumption frequency and quantities of raw cow milk and raw goat milk.

Consumer research

It is important that risk management decisions are not based on implicit or untested assumptions about consumer behaviours or motivations. Anecdotal evidence

suggests that some individuals consume raw drinking milk and may have perceptions of food risks inconsistent with scientific risk assessments. To better understand raw milk consumers' behaviour, risk perceptions and motivations, FSANZ commissioned an exploratory study of raw milk consumers.

The study is currently being finalised and collected data through in-depth interviews regarding:

- motivations for consumption to identify any value and behaviour based consumer segments;
- knowledge about raw milk; their sources of information; and the benefits and risks associated with raw milk consumption;
- consumption behaviour such as the frequency, quantity, storage and treatment of raw milk; and
- a socio-demographic profile of the consumers interviewed.

In addition to providing evidence to support risk management options, the information obtained from the survey will help inform areas such as labelling, consumer information and education and help to target food safety strategies.

Risk management

FSANZ will use the outcomes of the scientific assessment to assess whether the nature of the hazards and the level of risk warrant permissions within the categories for the production of raw milk products for sale. This would involve a variation to current regulatory requirements for the production of milk and dairy products in the Code.

Applying the category approach will enable FSANZ to assess whether through chain control measures and verification procedures can be applied to provide an acceptable level of microbial safety to the general population. Currently, the Code includes control measures and verification activities for some products that would potentially fall within Category 1 (for example very hard grating cheeses) and Category 2 (Roquefort cheese). However, currently the Code does not permit Category 3 products.

Assessing the Proposal

In assessing the Proposal, FSANZ has regard to the following matters prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a regulatory measure developed or varied as a result of this Proposal outweigh the direct and indirect benefits to the community, government or industry that arise from the development or variation of the regulatory measure;
- whether other measures (available to FSANZ) would be more cost effective than a food regulatory measure developed or varied as a result of the Proposal;
- any relevant New Zealand standards ; and

- any other relevant matters.

Consultation

This Discussion Paper provides the first opportunity for the public to comment on the Proposal and, if possible, assist FSANZ with information and data to assist in its assessment.

A Standards Development Committee, consisting of representatives from the dairy industry, consumers and jurisdictions, is advising FSANZ on this work to deliver a comprehensive and a nationally consistent through chain approach to the management of raw milk products in Australia.

In addition, FSANZ has established a Dairy Scientific Advisory Panel to provide technical assistance and advice to FSANZ during the preparation of the microbiological risk assessment. The Panel consists of experts from industry and government.

Invitation for Submissions

Written submissions are invited from interested individuals and organisations to assist FSANZ in assessing this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 17 September 2008

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

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INTRODUCTION

Since June 2002, Food Standards Australia New Zealand (FSANZ) has had responsibility for developing national food safety requirements that cover all parts of the food supply chain – an integrated paddock-to-plate approach. To this effect, FSANZ has been developing primary production and processing standards for identified primary industry sectors for inclusion in the *Australia New Zealand Food Standards Code* (the Code). To date FSANZ has developed primary production and processing standards for seafood and some dairy products, including milk for processing, and is currently developing standards for poultry meat and eggs. These standards do not apply in New Zealand.

The Primary Production and Processing Standard for Dairy Products, Standard 4.2.4, was gazetted on 5 October 2006 and comes into effect on 5 October 2008. Standard 4.2.4 contains measures to address food safety for the dairy industry from production of milk through to processing, including manufacture of specified dairy products. These measures include pasteurisation or an equivalent process.

During the initial stages in the development of Standard 4.2.4, consideration was given to developing risk management measures for raw milk products. This work was deferred until completion of the national dairy standard, which establishes through chain requirements for milk and milk products to be pasteurised (or equivalent process). Now that the national dairy standard is completed, FSANZ has commenced work on addressing raw milk products issues through Proposal P1007. This includes addressing some public health and safety issues, existing applications and regulatory inconsistencies.

Raw milk is not defined in the Code but is defined for the purpose of this Proposal as milk that has not been treated in accordance with the processing requirements of the Code[1]. The use of the term 'raw milk' rather than 'unpasteurised milk' recognises that there are processes other than pasteurisation currently permitted (e.g. thermisation for cheesemaking) and that other non-thermal processing treatments may be applied.

Historically in Australia the drinking of raw milk and consuming of raw milk products such as raw milk cheese has been considered by governments to present an unacceptable level of health risk to the population. The heat treatment[2] of milk and milk products has therefore been mandated via the Code as an important public health measure to destroy microbiological hazards that may be present in milk and has provided the benchmark public health and safety measure for dairy foods in this country.

Within this Proposal, FSANZ will assess the risks associated with raw milk products including raw milk intended for drinking and other products made from raw milk that

[1] Internationally, the use of the term raw milk may differ. For example the Codex *Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004* defines raw milk as 'milk which has not been heated beyond 40°C or undergone any treatment that has an equivalent effect'.

[2] Heat treatment includes pasteurisation or thermisation processes whereby microbiological hazards are eliminated from the milk.

undergo further processing such as cheese. Raw milk products may be derived from a number of milking animals including cow, goat, sheep, buffalo, horse and camel. FSANZ will determine if there is a scientific basis to develop appropriate measures to manage any risk to public health and safety. This will deliver a comprehensive and a nationally consistent through chain approach to the management of raw milk products in Australia.

A Standard Development Committee has been established by FSANZ to assist and advise with this Proposal. The Standard Development Committee consists of representatives from the dairy industry, consumers and jurisdictions who are recognised for their skills and knowledge of dairy processing, on-farm practices and veterinary practices.

1. The Issues

There are a number of issues to be addressed by this Proposal. These relate to legislation currently applying to dairy products, applications to FSANZ to permit raw milk products, and public health and safety. Additional background information is provided in Attachment 1.

1.1 National consistency

The Code requires that milk and liquid milk products must be pasteurised (or an equivalent treatment), 'unless an applicable law of a State or Territory otherwise expressly provides'. Therefore the permission for the production and sale of raw milk is a State or Territory based provision and currently the production of raw goat milk for sale for human consumption is permitted in four States. FSANZ now has responsibility for developing national standards through its work on primary production and processing standards.

Current State Regulations relating to the sale of some raw goat milk are summarised at Attachment 2.

1.2 Inconsistent requirements for domestic and imported products

The Code allows the sale of French Roquefort cheese and three raw milk Swiss cheeses through specific permissions under conditions specified in Standard 4.2.4A. These include production of these cheeses in accordance with French Ministerial Orders and Swiss Ordinances.

The approach taken to permit specific Swiss cheeses and French Roquefort in Standard 4.2.4A has, in effect, allowed for the importation and sale of these cheeses in Australia but does not allow for the domestic production of the same styles of cheese. This has raised the issue of a non-level playing field for Australian producers and that the current approach is discriminatory.

1.3 Reference to legislation of other countries

In general, reference to the legislation of other countries in the Code is undesirable because FSANZ has no say in review of amendment to these documents. These documents may change over time and differ to the version at the time of gazettal into the Code.

In relation to raw milk cheese, the Code makes reference to Swiss Ordinances and French Ministerial Orders. These regulations cover through chain[3] control measures, including requirements for HACCP based food safety systems which, at the time of amendment, the Code did not provide for in the case of Australian manufacturers. Such measures can now be reflected through primary production and processing requirements for dairy products in Chapter 4 of the Code.

Current international regulations relating to the sale of some raw milk products are summarised at Attachment 2.

1.4 Applications received by FSANZ

FSANZ currently has three applications on its Work Plan in relation to raw milk products:

- Application A514 Raw cows milk – this Application seeks an amendment to the Code to permit the sale of unpasteurised milk to the public. This application was made by a member of the public who has a preference for unpasteurised milk because of perceived health benefits.

- Application A530 Cheddar cheeses – this Application seeks an amendment to the Code to permit the sale of the raw milk cheeses KEENS FARM CHEDDAR and MONTGOMERY CHEDDAR (products of Britain), produced according to the evaluation report and HACCP management system that sets out production requirements. This application was made by a cheese trading company.

- Application A531 Raw milk in cheese – this Application seeks to amend the Code to enable the production and sale of any cheese type made from unpasteurised milk, provided that the cheese meets European Union or Codex microbiological, physical and chemical standards of identity. This Application was made by a cheese trading company.

These Applications will remain on the Work Plan while work proceeds on this Proposal.

1.5 Public health and safety

Overriding the issues outlined above is the assessment of the risks to public health and safety and how these are or could be managed if the status quo was changed.

[3] Through chain control measures include control measures from on farm through to processing

2. Current Standards

2.1 Standard 1.6.2 and Standard 4.2.4A

Processing requirements for milk and liquid milk products and for cheese and cheese products are specified in Standard 1.6.2 - Processing Requirements[4] and Standard 4.2.4A - Primary Production and Processing Standard for Specific Cheeses.

Standard 1.6.2 currently requires that milk and liquid milk products must be pasteurised by holding at 72°C for 15 seconds, or equivalent heat treatment, unless an applicable law of a State or Territory expressly provides for the sale of milk or liquid milk products that have not undergone these heat treatment requirements.

In relation to cheese and cheese products, Standard 1.6.2 requires that milk and milk products used in cheese manufacture are pasteurised or thermised5. In addition it allows for an exemption from these heat treatment provisions for:

- very hard grating cheeses that have undergone a curd cooking step at temperatures of 48°C and above, have a moisture content of less than 36% and have been stored at a temperature of no less than 10 degrees for a period of no less than 6 months from the date of manufacture

- cheeses manufactured in accordance with clause 1 of Standard 4.2.4A.

Standard 4.2.4A currently allows for the manufacture of Emmental, Gruyere and Sbrinz raw milk cheese according to Swiss regulations: Ordinance on Quality Assurance in the Dairy Industry. Raw milk Roquefort cheese is also permitted according to French Ministerial Orders and with three conditions specified:

- pH, salt and moisture are monitored and recorded during cheese manufacture;

- milk used for cheese production should have no detected levels of Listeria monocytogenes in 25 ml of milk per tanker; and

- the cheese must be stored for no less than 90 days from the date of manufacture.

2.2 Standard 1.6.1 Microbiological limits

Microbiological standards for unpasteurised milk, butter made from unpasteurised milk and for raw milk cheeses are contained in Standard 1.6.1 - Microbiological Limits for Food as follows:

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[4] The processing requirements for milk, milk products and cheese specified in Standard 1.6.2 have been carried across into Standard 4.2.4 - Primary Production and Processing Requirements for Dairy Products which will come into effect on 5 October 2008. At that time, the provisions relating to dairy products in Standard 1.6.2 will be repealed.

[5] Pasteurisation and thermisation are discussed further under section 2.4.2 Heat treatment requirements.

- limits for *Campylobacter*, coliforms, *Escherichia coli*, *Listeria monocytogenes*, *Salmonella* and Standard Plate Count are specified for unpasteurised milk;

- a limit for *Campylobacter* is specified for raw milk unripened cheeses (moisture content >50% with pH >5.0);

- limits for *Listeria monocytogenes* and *Salmonella* are specified for all raw milk cheese;

- a limit for *Escherichia coli* is specified for all cheese (including raw milk cheese); and

- limits for *Campylobacter*, Coagulase positive staphylococci, coliforms, *Escherichia coli*, *Listeria monocytogenes*, *Salmonella* and Standard Plate Count are specified for butter made from unpasteurised milk.

2.3 Standard 1.2.3

Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, requires unpasteurised milk and liquid milk products to be labelled with an advisory statement to the effect that the product has not been pasteurised.

2.4 Standard 1.2.4

Clause 4 of Standard 1.2.4 – Labelling of Ingredients requires ingredients to be declared using the common name of the ingredient, or a name that describes the true nature of the ingredient, or if applicable a generic name. This requirement means that in relation to cheese made from unpasteurised milk, the ingredient declaration should include a statement that the milk is unpasteurised, and in the case of cheese made other than from cows milk, should also include the common name of the species from which the milk is sourced.

There are no other specific labelling requirements for raw milk products.

3. Objectives

The objective of Proposal P1007 is to resolve the issues outlined above through the development of regulatory and/or non-regulatory measures.

Specifically this Proposal will consider whether the Code should be amended to address:

- providing nationally applicable standards rather than State-based provisions for raw milk products;

- replacing the current references to the legislation of other countries with specific control measures; and

- the Applications (current and potential future) for extended permissions in the Code for raw milk products.

FSANZ must consider whether such changes to the Code will meet the three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In regard to this work, protection of public health and safety and the provision of adequate information relating to food to enable consumers to make informed choices are the key objectives.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food
- any written policy guidelines formulated by the Ministerial Council
- Australia's rights and obligations under the World Trade Organization.

4. Approach for Achieving the Objectives

During the initial stages in the development of Standard 4.2.4, consideration was given to developing risk management measures for raw milk products. Preliminary consultations arising from that work raised concerns around the range and types of raw milk products that would be considered in this Proposal. As a result, FSANZ has developed a framework in which to consider the various products that could be considered within the scope of this Proposal. This Category Framework Approach and the description of the categories has been developed taking into consideration previous risk assessment advice used to determine the existing requirements for raw milk products in the Code and consideration of preliminary findings of the risk assessment work currently underway on raw goat milk, raw cow milk and raw milk cheese.

The categories are defined depending on the effect production methods and intrinsic characteristics[6] of the final products have on pathogen survival and growth. If the survival and growth of pathogens is more likely in some products then these products present 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.

	Raw milk products
Category 1	Products in which pathogens are eliminated
Category 2	Products where pathogens may survive but do not grow
Category 3	Products where pathogens survive and grow

Increasing Risk

While cheese is the major commercial raw milk product being considered, the framework approach will endeavour to achieve outcomes that are applicable to all products including cultured milk, yoghurt, butter, ice cream etc. Therefore, this Proposal will examine all activities associated with the production of raw milk products from on-farm milk production through to retail sale and the consumer.

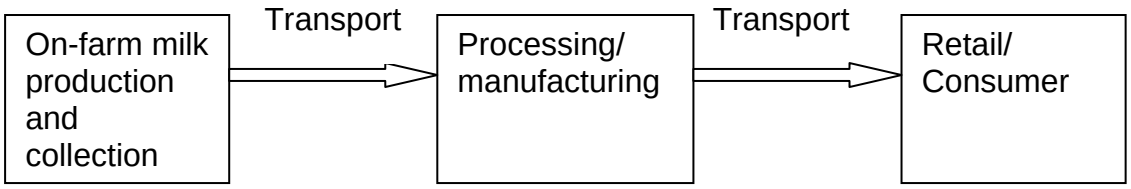

Figure 1: *Through chain stages for raw milk products to be considered by Proposal P1007*

SCIENTIFIC ASSESSMENT

FSANZ uses an internationally agreed risk analysis approach embodied in the FSANZ Act to inform its decision- making process. This approach incorporates the process endorsed by Codex of risk assessment, risk management and risk communication.

5. Microbiological Risk Assessment

FSANZ has commenced microbiological risk assessments on raw goat milk, raw cow milk and selected raw milk cheeses to examine the microbiological hazards associated with these products and the risks they pose to public health and safety.

These risk assessments will qualitatively and/or quantitatively examine microbiological hazards and epidemiological and other data to determine whether these hazards have presented, or are likely to present, a public health risk through the consumption of raw goat milk, raw cow milk and some raw milk cheeses. The risk assessments will also identify where in the supply chain these hazards may be

[6] Intrinsic characteristics include combinations of factors such as moisture, acidity, salt concentration

introduced. The findings of the risk assessments may subsequently be applied to the primary production of raw milk intended for further processing of other raw milk products. Further information on the risk assessment process is at Attachment 3.

Access to relevant and accurate information, including data, is essential for the assessment of risks to public health and safety, as the risk assessor requires a good understanding of the entire production chain (paddock-to-plate) and knowledge of the various factors that may impact on the safety of raw milk and raw milk products. This includes information and data on:

- potential food safety hazards associated with animal disease and treatments and on-farm inputs (e.g. feed, water, veterinary interventions);

- the likelihood of any contamination of raw milk and raw milk products with specific hazards at all points along the production/supply chain, and the levels and extent of any such contamination;

- the incidence of foodborne disease arising from consumption of raw milk products will be examined in the risk assessment; and

- food consumption to assist in determining exposure to a particular hazard.

Australian epidemiological data on the extent and cases of human disease associated with the consumption of raw milk products are being sought. In regard to consumption data, at this stage, the available information indicates that with the exception of raw goat milk and selected raw milk cheeses, raw milk products are rarely consumed in Australia. However there is some evidence suggesting that some individuals do consume raw milk products. As part of the information gathering process FSANZ is seeking further information on consumption frequency and quantities of raw cow milk and raw goat milk.

Animal health issues other than those that specifically impact upon human health via foodborne transmission are not part of FSANZ's responsibility and will not be considered in this assessment.

The outcome of the microbiological risk assessment will include the probability and severity of an adverse health effect due to the consumption of raw milk products examined in the risk assessment. The scientific assessment will also, if possible from the information available, identify where in the production chain controls over hazards will have the greatest impact on minimising risk i.e. informing risk managers where an intervention will be most effective. This information will be provided in Assessment reports for this Proposal.

FSANZ is working closely with the dairy industry and other appropriate agencies to ensure that as much relevant Australian data as possible can be incorporated into its assessment of risks to public health and safety.

6. Consumer Research

Consumer knowledge and understanding of the risks associated with consuming raw milk products will influence their food safety and consumption behaviours with respect to these products. The operation of existing markets for some raw milk cheeses and for raw goat milk confirm the demand for raw milk products, while anecdotal evidence regarding the consumption of other raw milk products suggest consumers seek and access products not currently for sale for human consumption. While these markets and demands exist there is little evidence regarding consumers knowledge and understanding and how this influences food safety and consumption behaviours. Changes in food safety and consumption behaviours of raw milk products has the potential to influence short and long term public health outcomes. To develop, and assess the impact of, potential changes to any risk management measures for these products we need to understand consumers risk perceptions and food safety behaviours to these products.

Decisions in the development of primary production and processing standards must be based on reliable evidence. This is particularly important when it comes to current and future human behaviour, where decisions should not be based on implicit or untested assumptions about consumer behaviours or motivations.

As noted anecdotal evidence suggests that some individuals consume raw drinking milk. Additionally it is suggested that some consumers may have perceptions of food risks inconsistent with scientific risk assessments. To better understand raw milk consumers' behaviour, risk perceptions and motivations FSANZ commissioned an exploratory study of raw milk consumers. The study is currently being finalised and collected data through in-depth interviews regarding:

- motivations for consumption to identify any value and behaviour based consumer segments;
- knowledge about raw milk; their sources of information; and the benefits and risks associated with raw milk consumption;
- consumption behaviour such as the frequency, quantity, storage and treatment of raw milk; and
- a socio-demographic profile of the consumers interviewed.

In addition to providing evidence to support risk management options, the information obtained from the survey will help inform areas such as labelling, consumer information and education and help to target food safety strategies.

The results of this research, following peer review, will be included in Assessment reports for this Proposal.

RISK MANAGEMENT

7. Category Framework Approach

The development of the Category Framework Approach has been based on preliminary results of microbiological risk assessments currently being undertaken by FSANZ which have examined production factors and intrinsic properties of selected dairy products. Processing factors include curd cooking temperature, acidification and storage time. Intrinsic factors include moisture content, acidity and salt concentrations.

7.1 Category 1

Products in this category 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 this Category would include the extra hard grating cheeses. The extra hard grating cheeses are made from raw milk by heating the curd to greater than 48°C, have low moisture content (<36%) and 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.

These parameters are already included in the Code, in Standard 1.6.2 (and will be carried across into Standard 4.2.4 when it comes into effect).

7.2 Category 2

Products in this category 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 survival, but not growth of pathogens that may have been present in the raw milk. In this case, control measures would need to ensure that the raw milk used to produce products is of an appropriate microbiological quality and that processing steps would achieve the necessary critical limits to control pathogens.

To produce these products, potentially a combination of control measures and verification activities will need to be applied to provide an acceptable level of microbial safety for consumption by the general population.

Based on the previous assessments of Roquefort cheese, (Application A499) this could be an example of a Category 2 product.

7.3 Category 3

Products in this category are defined as those products where:

- intrinsic characteristics and / or
- processing conditions

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 where the processing step(s) that are applied would not reduce pathogens to an acceptable level. In general, if pathogens are present, they would be expected to multiply during manufacture. This category would include products such as raw drinking milk including raw goat's milk. This category is likely to include high moisture content cheeses.

7.4 Application of Category Framework Approach

Following the completion of the risk assessment and consumer research FSANZ will use the outcomes to assess whether the nature of the hazards and the level of risk warrant permissions within the categories for the production of raw milk products for sale. This would involve a variation to current regulatory requirements for the production of milk and dairy products in the Code and other industry management interventions. The appropriate control measures underpinning any permission will be presented in Assessments reports to this Proposal.

8. Options

There are generic management options which could be used singularly or in combination to resolve the issues described in Section 1. FSANZ may propose that no changes are made to the Code or that the Code is amended or varied. The amendments or variations could be to include or replace processing requirements with new requirements, or to amend or vary other requirements such as those for labelling. In deciding options for amending the Code if required, there are varying levels of intervention that can be implemented throughout the production chain.

Implementation and enforcement is the responsibility of the State and Territory government and the Australian Quarantine and Inspection Service (AQIS) for imported foods. FSANZ may recommend to the implementation authorities that specific guidance material be available to industry outlining the stringency of compliance and enforcement of any requirements in the Code.

Depending on the outcomes of this Proposal, specific education and/or information strategies on the nature of these products for the general population and for vulnerable sectors of the population and/or labelling provisions advising the product has not been pasteurised may be considered.

FSANZ will discuss its proposed options for addressing the issues in Assessment reports to this Proposal, which will be released for public comment.

9. Impact Analysis

The Assessment reports on this Proposal will provide information to meet the Council of Australian Governments (COAG) requirements for regulatory impact analysis. FSANZ will seek advice from the Australian Government's Office of Best Practice Regulation on how to comply with the COAG requirements. FSANZ has identified and described a regulatory issue / problem with the current requirements in the Code and examined the background to the problem.

The options developed for raw milk products will be based on an analysis that considers:

- the microbiological risk assessments;
- the social science assessment including the outcomes of consumer and behaviour research;
- technical feasibility of control measures;
- the ability to validate and verify potential control measures or other interventions;
- the costs associated with the interventions to industry, governments and consumers compared with the benefits they achieve; and
- Australia's rights and obligations under the WTO.

FSANZ, with advice from the Standards Development Committee and taking into account submissions made on this report, will examine the options in terms of the protection they provide to public health and safety and will also take into account their social and economic implications. FSANZ will propose a preferred option to manage risks that generates the greatest net benefit for the community taking into account all the impacts on affected parties.

FSANZ will present the options, the analysis and the preferred option in the Assessment reports to this Proposal.

9.1 Affected Parties

9.1.1 Consumers

Preliminary work on consumer preferences in regard to milk and milk products indicates that there is a demand in Australia for raw milk products. This demand falls largely into four areas:

- proponents of raw drinking milk and associated products because of perceived health benefits or philosophical reasons;
- individuals who opportunistically consumer raw milk due to ease of access, for example farming families and farm workers;
- advocates of raw milk cheeses that explain their choice in terms of superior flavours and textures that are not found in products made from heat treated milk; and
- ethnic groups now residing in Australia have a cultural tradition of using raw milk to produce traditional foods.

In regard to the last dot point, anecdotal information suggests that this practice is wide spread with people producing these products on farm or in their homes for family use. The raw milk may be obtained from producers licensed to sell packaged raw goat milk in their State or Territory or from their own sources of raw milk.

Consumers who demand raw drinking milk generally claim that there are health benefits associated with raw milk. Claims include strengthening of the immune system and improving symptoms of asthma, eczema and arthritis. Additionally there may be particular value sets associated with this preference such as for whole foods produced through small scale traditional production techniques rather than large industrial processes. The consumer and social research being undertaken by FSANZ will assist in understanding consumer motivations and help inform risk management options.

Currently consumers are able to purchase raw goat milk in several states however there is anecdotal evidence that most demand for raw milk, particularly cow milk, is being met through unlicensed sources such as cow share schemes and the purchase of ‘pet milk’ and ‘bath milk’.

Discussion around access to raw milk cheeses has been raised in Australia in recent years, particularly by high profile chefs and restaurateurs. This was evident during the assessment of raw milk French Roquefort cheese with many media articles and submissions advocating raw milk cheeses as gourmet foods that should be available to Australian consumers as they are in Europe and elsewhere.

Potentially all consumers of dairy products are affected by this Proposal. The following are indicative of the issues that may affect consumers:

- some consumers may consider that they may benefit as a result of a new range of raw milk products becoming available;

- there may be confusion as to the safety of these products and whether this affects all or some sectors of the population such as those with an increased susceptibility to food borne illness;
- should the Proposal result in a limitation of products that are available, consumers may consider they have lost freedom to make their own decisions about the foods they purchase; and
- there may be increases in the price of raw milk products currently available to cover costs to businesses of implementing any new requirements.

9.1.2 Industry

The domestic dairy industry ranges from large production units to small, family businesses producing specialty or 'boutique' products. The Australian dairy industry produces dairy products of a high level of safety. The implementation of through chain control measures together with pasteurisation has been integral to this. There has been concern raised from the industry that the sale of raw milk products may impact on consumer confidence in the safety of dairy foods, particularly if there are outbreaks of food borne illness in Australia associated with them.

There is interest, particularly from some specialty cheese manufacturers, in being able to produce raw milk cheeses in Australia. In previous assessments of raw milk cheese, particularly of Roquefort cheese, industry raised that permissions for specific imported cheeses in the Code created an unlevel playing field as domestic producers were unable to manufacture similar products.

Where raw milk cheese production is permitted internationally, particularly in Europe where there is a long history of production, systems and controls have been established to support the production and sale of raw milk cheese. It has been raised in previous submissions to FSANZ that Australia may not, however, currently have the necessary systems and controls required for such products.

Importers are also likely to be affected by this Proposal as there is the potential for imports of additional raw milk products. There is interest from importers of specialty cheeses in being able to import a wider range of raw milk cheeses to satisfy an increasing demand for gourmet specialty cheeses. The food service industry may also have increased opportunities to use domestic and imported raw milk products in their food.

9.1.3 Government

State and Territory governments, through Dairy Authorities, Departments of Health or local government, are responsible for implementation and enforcement of Primary Production and Processing Standards and therefore there will be impacts on them resulting from any changes to requirements for raw milk products in the Code.

Changes to the Code may also impact on opportunities for trade; exports and imports. Also, there may be changes in the Code that impact on requirements for imported product at the border.

Therefore, Australian government agencies such as the Department of Foreign Affairs and Trade and the Department of Agriculture, Fisheries and Forestry including AQIS may be parties affected by this Proposal.

9.2 Information to assist the impact analysis

At this stage FSANZ is seeking information from consumers, industry and governments on how this Proposal could affect them.

Consumers may wish to provide information on matters such as:
What raw milk products do you consume, why, and how much?
Do you perceive much demand for raw milk products in your community?
Is there a demand for some products in particular for example, domestically produced raw milk cheese?

Industry may wish to provide information on:
Whether you produce or retail raw milk products, which ones and in what volume?
Are raw milk products a minor or major part of your business?
If a new standard supported production of raw milk products, would / how would that affect you and your industry?

Governments may like to provide information on implementation costs of the possible options and of any benefits in regards to this Proposal.

COMMUNICATION AND CONSULTATION STRATEGY

10. Communication

Risk communication is the two-way flow of information and opinion throughout all stages of the risk analysis process. FSANZ, throughout the assessment of this Proposal, will endeavour to identify all stakeholders and provide for an open and transparent process of consultation and information exchange.

As the standard development work proceeds, FSANZ will report progress on our website at www.foodstandards.gov.au. FSANZ will use its normal communication channels of website, media releases and newspaper advertisement to alert people to the public consultation processes. Organisations or individuals with an interest in this Proposal can seek to have their names listed as an interested party for this Proposal by emailing the Standards management officer at standards.management@foodstandards.gov.au .

11. Consultation

11.1 Consultation on this Proposal

FSANZ, in accordance with the FSANZ Act, will continue to engage in public consultation during the assessment stages of Proposal P1007.

FSANZ encourages interested individuals and organisations to make written submissions in response to this Discussion Paper and subsequent Assessment reports. This is to ensure they have an input into the Proposal development process and to assist FSANZ to produce an outcome that will most effectively address the objectives of this Proposal. Issues raised through public submissions will be considered in subsequent Assessment reports to this Proposal.

In addition to the FSANZ statutory consultation processes, FSANZ will engage with regulators, industry and consumers on an ongoing basis through the Standard Development Committee (discussed below) and through targeted consultations. For example, FSANZ staff have made on-site visits with raw goat milk producers and met with specialty cheese manufacturers, who have raised an interest in manufacturing raw milk cheeses, in order to identify drivers for stakeholder positions and attitudes. Because raw milk products are not generally available in Australia, assessing the likely attitudes and behaviours of Australian consumers with respect to these products presents a challenge. The results of a study of consumers of raw milk, discussed in Section 7 of this report, will therefore help inform our communication strategies.

11.2 Public Consultation on Proposal P296

The Initial Assessment Report for Proposal P296 Primary Production and Processing Standard for Dairy raised the issue of developing a management framework for raw milk products and invited submissions on this matter. The comments received in response to the Initial Assessment Report for P296 will be taken into consideration in conjunction with submissions received on this Discussion Paper.

11.3 Standard Development Committee

FSANZ established a Dairy Standard Development Committee (SDC) in 2004 to provide input into Proposal P296 - Primary Production & Processing Standard for Dairy Products. The Committee consisted of representatives from industry, consumers and jurisdictions who have broad knowledge of the dairy industry, understanding of food management systems, understanding of the food regulatory framework and the capacity to contribute effectively to a national standard process. In May 2007, the FSANZ Board appointed members of this Committee to continue the work on raw milk products under Proposal P1007 as well as increasing membership by adding additional expertise in raw milk issues. A list of members of the Dairy SDC (Raw Milk) is provided at Attachment 4. This representation of the dairy industry, government and consumers is expected to provide a useful communication conduit to people in their constituencies.

In addition to the overarching SDC a smaller Communication Sub - Committee comprising of volunteer members from the SDC has been formed to assist with addressing communication issues for the Proposal. This Sub - Committee will participate in the development and review of the Proposal communication strategy, communication materials, communication activities and assist in the implementation of the communication plan and activities.

The Communication Sub Committee will report on communication issues and activities at each meeting of the Standard Development Committee. The mode of operation for the Sub - Committee will include correspondence by email and teleconference discussions as and when required.

11.4 Collaboration and consultation with New Zealand Food Safety Authority

The 'Trans Tasman Mutual Recognition Arrangement' was made between the Commonwealth, States and Territories of Australia and the Government of New Zealand to remove regulatory barriers to the movement of goods and service providers between Australia and New Zealand to thereby facilitate trade between the two countries. This is intended to enhance the international competitiveness of Australian and New Zealand enterprises, increase the level of transparency in trading arrangements, encourage innovation and reduce compliance costs for business. In regard to food, it ensures that food that may be legally sold in one country can be sold in the other.

The Chapter 4 Standards in the Code and the current processing requirements for milk do not apply in New Zealand. Therefore, any amendments made as a result of this Proposal will also not apply. However, New Zealand is facing similar issues to Australia in that there is a demand for raw milk products and there are legal restrictions on production. Therefore, New Zealand has been interested in the approach FSANZ is taking to this work and a similar interest exists on our side.

The SDC has a representative from the New Zealand Food Safety Authority to take advantage of the expertise on milk production in New Zealand. The SDC has been advised of current New Zealand work to consider production controls for raw milk products. New Zealand, through the New Zealand Food Safety Authority, and Australia, through FSANZ, have built on this link to share information and participate in joint expert meetings on raw milk products characteristics and production methods; the aim being to cooperatively develop options for risk management that would where possible be similar in each country.

Although there is a potential for digression, FSANZ and the NZFSA will continue to consult and cooperate in developing risk management measures applicable to the specific circumstances of their respective countries.

11.5 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

This issue will be fully considered during the assessment of the Proposal and, if necessary, notification will be recommended to the agency is responsible in accordance with Australia's obligations under the WTO technical barrier to trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements.

This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact upon them

CONCLUSION

12. Conclusion

This Discussion Paper provides an opportunity for stakeholders to comment on and supply information and/or data to FSANZ in regard to Proposal P1007.

FSANZ welcomes and encourages stakeholder input. The comments, information and data provided during this consultation will be considered in combination with the scientific risk assessment and impact analysis during the assessment stages of the Proposal to address the issues identified.

ATTACHMENTS

1. Background

2. Australian State and International Regulations

3. Microbiological Risk Assessment Information

4. Standard Development Committee Membership

Attachment 1: Background

1. Historical background

1.1 Pasteurisation

Pasteurisation is a heat treatment process applied to a food which is, primarily, designed to destroy vegetative cells of pathogenic microorganisms. Spoilage organisms may also be eliminated during the process, increasing the stability and shelf life of the product.

The criteria for pasteurisation of milk was historically based on the destruction of Mycobacterium bovis, the causative agent of bovine tuberculosis which, in the past, was also responsible for causing tuberculosis infections in humans. Current time temperature requirements for milk pasteurisation are based on the destruction of Coxiella burnetii, the causative agent of Q fever in humans and the most heat resistant vegetative pathogen found in milk. High temperature short time pasteurisation (HTST) of milk at 72ºC for 15 seconds has been shown to be effective in eliminating this organism and is accepted internationally as the standard process for milk pasteurisation. Other time and temperature conditions of equivalent effect are also permitted in the Code.

The Code requires pasteurisation of milk and milk products, however it also allows for State and Territory legislation to permit the production and sale of raw milk products (excluding cheese). This reference to State and Territory legislation has been in place historically to allow for jurisdictions to take into account accessibility issues in rural and remote locations and to manage milk from minor species (such as goat). Where raw milk production and sale is permitted, additional control measures have been implemented by the State jurisdictions to address potential risks.

1.2 Thermisation

The Code permits a time-temperature process of milk for cheese production that is less rigorous than pasteurisation (62ºC for 15 seconds), providing that the cheese is stored for at least 90 days from the date of manufacture. This heat treatment is generally referred to as thermisation.

While thermisation kills psychrotrophs (microorganisms active at lower temperatures), it may not destroy all pathogenic microorganisms that may be present. This heat treatment, however, may not be sufficient to destroy all pathogenic microorganisms that may be present and so a further safeguard is required and the cheese produced must be stored for at least 90 days at a temperature greater than 2ºC. During this time, depending on the physical and chemical characteristic of the cheese such as pH, water activity and salt content, it is expected that pathogenic bacteria present will die off. Thermisation is normally limited to harder cheese types as soft and semi soft cheeses are generally ripened for less than 90 days.

2. Previous cheese assessments

The Code currently allows for the sale of several imported raw milk cheeses as a result of applications requesting specific cheese permissions:

Raw milk Emmental, Gruyere and Sbrinz cheeses were permitted following the assessment of an Application (A357) from the Swiss Federal Veterinary Office, received in 1998. The assessment process for this Application concluded that these hard cheeses could meet an appropriate level of safety and, therefore, the Code was amended in to specifically permit them. Part of this permission was to include reference in the Code to a number of Swiss Ordinances (regulations) relating to milk and cheese production, including the requirement for HACCP plans based on Codex principles and verification and approval processes by Swiss regulatory authorities.

Raw milk Roquefort cheese was permitted following an Application (A499) received from the French Government (Ministry of Agriculture, Food, Fisheries and Rural Affairs) in 2004. The assessment of the safety of Roquefort cheese concluded that the sale of this cheese would pose a low risk to the public health and safety of Australian consumers. This conclusion was supported by an assessment of the cheese-making process and an examination of the regulatory and industry management framework for the safe production of Roquefort cheese, verified through an on-site audit in France. The Code was amended to specifically permit Roquefort cheese in accordance with French regulations (Ministerial Orders).

In addition, FSANZ prepared a Proposal P263 in 2002 to assess the safety of extra hard grating cheeses made from raw milk. A scientific evaluation of the manufacture of extra hard grating cheeses supported the exemption of this category of cheese from the milk heat treatment requirements of Standard 1.6.2 on the basis that these cheeses can achieve an equivalent level of safety as cheeses using heat treated milk and do not pose any significant public health and safety risk. Standard 1.6.2 was amended to permit the manufacture of extra hard grating cheeses using milk that has not been heat treated, under specified conditions i.e. the final cheese contained <36% moisture, had been stored for >6 months, and was prepared using a curd cooking temperature of at least 48°C.

Except for extra hard grating cheeses, the assessment of raw milk cheeses has generally been done on a case-by-case basis as a result of an application being made to FSANZ. The Applications to date have related to a specific type of imported cheese and have not allowed for a more general safety assessment that could apply to both imported and domestically produced cheeses.

3. Domestic production and imports of raw milk products

3.1 Domestic production of raw drinking milk

The only milk permitted for sale in Australia as raw milk for human consumption is raw goat milk.

As of 2006, approximately 65 commercial dairy goat farms were in operation Australia wide, carrying close to 11,000 goats.

The majority of milk produced is further processed (e.g. for cheese making), either directly by the dairy farmers or on-sold to other processors. Of the 5.4 million litres of goat milk produced annually, it is estimated that only 300,000 litres is sold as raw drinking milk.

NSW currently has 16 goat milk producers licensed to produce raw milk. Approximately two-thirds of the entire volume of goat milk sold in New South Wales is marketed as raw milk. This is estimated to be approximately 270,000 litres per year.

In the other States there are a very small number of farms producing raw goat milk for sale. In 2007, South Australia had five commercial goat milk producers licensed by the Dairy Authority of South Australia, with only three producers selling raw goat milk direct to the public. At this time the estimated production volume of raw milk was 32,000 litres. Recent data suggests that there is now only a single licensed raw milk producer servicing the South Australian market. Small volumes of raw goat milk are also sold in Queensland and Western Australia. There are currently two accredited raw goat milk dairies operating in Queensland and an estimated three in Western Australia supplying to the public.

The majority of raw goat milk sold in Australia is distributed through health food shops or via the farm gate.

Raw cow milk, currently not permitted in Australia, is purportedly available through health food shops and farmers markets labelled as either pet milk or for cosmetic purposes. Anecdotal information suggests that this product is being purchased by some people for human consumption.

3.2 Imports of raw milk cheeses

A number of raw milk cheeses are currently permitted to be imported into Australia, including:

- the extra hard grating cheeses Parmigiano Reggiano, Grana Padano, Pecorino Romano, Asiago and Montasio;
- the Swiss cheeses Emmentaler, Gruyere and Sbrinz; and
- Roquefort cheese.

It is estimated that approximately 118 tonnes of Roquefort cheese, 90 tonnes of the Swiss cheeses and 400 tonnes of the extra hard cheeses are imported annually[7].

4. Hazards associated with raw milk products

4.1 Microbiological hazards

A broad range of microbiological hazards may be introduced into raw milk products during primary production and processing[8].

[7] These figures are conservative estimates only obtained from speaking to Food and Beverage Importers Association and AQIS.

Milking animals can carry a wide range of microorganisms, some of which are human pathogens and therefore raw milk may have a mixed microflora which is derived from several sources including the interior of the udder, exterior surfaces of the animals, the environment, milk-handling equipment, and personnel. The organisms generally regarded as the most significant to public health and safety for the dairy industry due to their association with reported incidents of foodborne illness include *Listeria monocytogenes*, Salmonella *spp*, *Staphylococcus aureus*, pathogenic *E.coli*, *Yersinia enterocolitica* and Campylobacter *spp*.

4.2 Chemical hazards

Hazards of a chemical nature associated with dairy products may be endogenous to the product (milk-based allergens), a result of further processing (e.g. biogenic amines) or introduced throughout the primary production and processing chain (e.g. chemical contaminants, agricultural and veterinary chemicals and chemicals used in food processing).

These hazards were assessed for Proposal 296 (Primary Production & Processing Standard for Dairy) and it is unlikely that additional chemical hazards would be associated with raw milk products. Chemical hazards will not, therefore, be specifically assessed for this Proposal.

4.3 Physical hazards

The physical hazards associated with dairy products are mostly extrinsic (e.g. metal inclusions, plastic, glass and other material that is foreign to the nature of the food).

Extrinsic physical hazards are potentially introduced at all stages along the dairy processing chain. Sources for such contaminants include facilities and equipment, improper production procedures, packaging materials and poor employee practices. Physical hazards will not be specifically assessed for this Proposal.

5. Public health risks

In countries where raw milk products are routinely available, they have frequently been implicated in foodborne illness. Internationally over the last 30 years, raw cow and goat milk has been associated with over 50 outbreaks of food borne illness involving 1051 cases and 38 deaths. Over the same time period, raw milk cheeses produced from either cow, goat or sheep milk, were implicated in a similar number of outbreaks (n = 56), although were more serious in their impact. More than double the number of people (n = 2691) were affected than in raw milk outbreaks, with 56 deaths reported.

Despite limited permissions and availability of raw milk products in Australia there have been a number of reported cases of foodborne illness attributed to their consumption.

[8] Information on microbiological hazards associated with dairy products is contained in the Risk Profile of Dairy Products in Australia (FSANZ, 2006)

In 1990, there were nine cases of Salmonellosis attributed to the consumption of raw goat milk, whilst two cases of raw goat milk mediated illness were attributed to *Cryptosporidium parvum* in 1984

Between 1995 and 2004[9], consumption of raw cow milk on farm visits and during school camps was responsible for 101 cases of foodborne illness with Campylobacter, Salmonella and Cryptosporidium as the aetiological agents.

Historically in Australia, the drinking of raw milk and consumption of raw milk products such as raw milk cheese has been considered by governments to present an unacceptable level of health risk to the general population. As outlined in Section 4.2, pasteurisation has been mandated as an important public health measure to destroy microbiological hazards that may be present in milk. While the presence of Mycobacterium bovis and Coxiella burnetii in milk is now largely controlled by improvements in animal health and farm sanitation, pasteurisation destroys other potential milk-borne pathogens such as those listed above in Section 4.5.1.

Where permissions to produce and sell raw milk products have been given, they have been subject to stringent controls. The assessments of raw milk Swiss cheeses and very hard grating cheeses by FSANZ were based on an assessment of the production process achieving an 'equivalent' level of safety as pasteurised product. At that time this was taken as a 5 log reduction of specified pathogens. The permission for raw milk Roquefort cheese was based on an assessment which showed Roquefort poses a low risk to public health and safety. Permissions for these cheeses required no specific education10 or information strategies on the nature of the product to the general population. Labelling provisions require such products to be labelled with an advisory statement to the effect that the product has not been pasteurised

State regulations relating to the sale of raw goat milk in Australia manage this food as presenting a high risk to public health. In addition to the on farm controls and pathogen testing required, jurisdictions also require or advise that consumers are informed of this risk (in addition to the requirements in Standard 1.2.3) through labelling such as 'Caution – this milk is an unpasteurised product and may contain organisms that could be injurious to health', as required under the Queensland *Food Production (Safety) Regulations 2002*. These labelling messages required, however, vary between jurisdictions.

In general, the risk posed by a particular food depends on the hazards that might be present (severity and likelihood), and the population group that may consume the food (e.g. general population, children, the elderly). Depending on the level of risk posed, risk management strategies are developed with, in general, the greatest level of intervention/control required for higher risk foods. Communicating public health risks to the community may be an important aspect of this Proposal. Consumer research is being undertaken to help inform risk management options and communication strategies.

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9 Domestic and international epidemiological data on raw milk products is contained in Risk Profile of Dairy Products in Australia (FSANZ, 2006)

10 FSANZ advice to people at risk for listeriosis recommends that unpasteurised dairy products and soft and semi soft cheeses are not consumed.

Attachment 2: Australian State and International Requirements

1. Australian State requirements

Four States currently permit the production for sale of raw goat milk. The requirements for production are specified in each States' legislation as shown below.

State/Responsible Authority	Legislation / Associated Requirements
Queensland (Safe Food Queensland)	*Food Production (Safety) Regulations 2002* Part 3 Goat milk
New South Wales (NSW Food Authority)	*Food Production (Dairy Food Safety Scheme) Regulation, 1999* Code of Practice for Dairy Buildings (Goat/Sheep farms) Code of Practice for the Goat Milk Industry Goat dairy farm HACCP Manual NSW dairy Manual – Unpasteurised Goat Milk Producer
South Australia (Dairy Authority of South Australia)	*Primary Produce (Food Safety Schemes)(Dairy Industry) Regulations 2005* Code of Practice for Dairy Food Safety Guidelines for Raw or Unpasteurised Goat Milk
Western Australia	*Health (Food Hygiene) Regulations, 1993* Code of Practice for the Goat Dairy Industry

In general terms, Authorities in Queensland, NSW and South Australia require producers of raw goat milk to have a HACCP based food safety program or scheme and apply a pathogen testing program.

In addition, the Queensland *Food Production (Safety) Regulations 2002* specifies labelling requirements for raw goat milk such that the label must include the statement 'Caution – This milk is an unpasteurised product and may contain organisms that could be injurious to health'.

The South Australian Guidelines for Raw or Unpasteurised Goat Milk recommends that the label on raw goat milk includes the words 'Boil Before Consumption'.

New South Wales requires raw goat milk producers to provide a warning on the label with a statement to the effect that the product is unpasteurised.

2. International requirements

2.1 The Codex Code of Hygienic Practice for Milk and Milk Products

The Codex Alimentarius Commission (Codex) was created in 1963 by the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) to develop food standards, guidelines and related texts under the Joint FAO/WHO Food Standards Programme. It is the international food standards setting body recognised by the World Trade Agreements on Sanitary and Phytosanitary and Technical Barriers to Trade. Codex's main aims are to protect the health of consumers, ensure fair trade practices and promote coordination of all food standards work undertaken by international organisations

The Codex Code of Hygienic Practice for Milk and Milk Products (Codex Code) provides control measures relating to the areas and premises for milk production, animal health, general hygienic practice on farm and hygienic milking. The Codex Code applies to all products derived from milk including raw milk products but does not extend to the production of raw drinking milk.

The Codex requirements in relation to raw milk products are considered when proposing any changes to the Code as the promotion of consistency between domestic and international food standards is important in terms of international trade.

Codex provides a number of overarching principles that should apply to the production, processing and handling of all milk and milk products as follows:

- From raw material production to the point of consumption, dairy products should be subject to a combination of control measures, and these control measures should be shown to achieve the appropriate level of public health protection.

- Good hygienic practices should be applied throughout the food chain so that milk and milk products are safe and suitable for their intended use.

- Wherever appropriate, hygienic practices for milk and milk products should be implemented within the context of HACCP as described in the Annex to the Recommended International Code of Practice – General Principles of Food Hygiene. (Codex notes that there are limitations to the full application of HACCP principles at the primary production level.)

- Control measures should be validated as effective.

The Codex Code provides additional provisions for the production of milk used for raw milk products (Annex 1):

- Only potable water to be used in milking areas, product storage areas and in contact with milking equipment and other milk contact surfaces.

- Milk shall originate from individual animals:

    - that are identifiable such that the health status of each animal can be followed (registered herds)
    - that do not show visible impairment of the general state of health
    - that do not show any evidence of infectious diseases caused by human pathogens that are transferable to humans through milk
    - that come from herds that are free of tuberculosis and brucellosis.

- When using fermented feed, particular attention should be given to compliance with good practices concerning:
    - the design of silos
    - good production practices of silage
    - regular check of the quality of the fermented feed (e.g. pH).

- For milk not collected or used within 2 hours after milking, it should be cooled:
  - to 6 °C or below when collected on a daily basis; or
  - to 4 °C or below when not collected every day.

- Milk to be used for the manufacture of raw milk products should be collected separately (no mixing or cross-contamination with other milk).

- Unless the milk has been collected within 2 hours after milking, the temperature of the milk during transport should not exceed 8 °C.

With respect to control measures during processing of raw milk products (Annex 2), the Codex Code notes that specific microbiological criteria regarding pathogens may need to be established, depending on the hazard analysis performed by the manufacturer and the combination of microbiological control measures applied during and after processing of milk products. Dairy farms supplying milk for the manufacturing of raw milk products should be able to demonstrate their compliance with the provisions of the Codex Code and their ability to provide milk of an appropriate standard for the processing of raw milk products.

2.2 European Union

The European Union (EU) permits the sale of raw milk products subject to the following EU 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 (relates to the organisation of official controls on products of animal origin intended for human consumption).

This legislation, which took effect in member countries on 1 January 2006, introduces a 'farm to fork' approach to food safety, by including primary production in food hygiene legislation. Since publication of the consolidated EU Food Hygiene Regulations in 2004, a number of implementing regulations and transitional measures that support the application of the EU regulations have also been published, including:

- Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Under the EU requirements, there are specific provisions for raw milk production in relation to:

- Animal health requirements
- Hygiene of milking, storing and collection operations
- Health and hygiene of personnel
- Labelling
- Manufacturing
- Microbiological criteria

2.3 United States of America

United States regulations11 require cheese to be pasteurised or, as an alternative treatment, cheeses made from unpasteurised milk require a minimum 60 day aging period. This 60 day aging requirement permits the import of raw milk cheeses. However, the interstate trade of raw milk products within the United States is prohibited.

There are provisions within US State regulations to permit the production and sale of raw milk products. The sale of raw drinking milk, for example, is legal in 26 of the 50 states of the US. The raw milk regulations vary between states but may include:

- requirements for warning labels;
- requirements for licensing;
- requirements for a five day maximum period of the sale of raw milk commencing from the time the farmer fills the container;
- requirements that restrict sales from the farm gate only; and
- requirements that sales are restricted to individuals who have a signed prescription from a physician.

2.4 Canada

The sale of raw drinking milk has been strictly prohibited under the Canadian Food and Drug Regulations since 1991. However the sale of raw milk cheeses is permitted subject to storage conditions. Current Canadian regulations require that raw milk cheese be stored at a temperature of 2˚C or above for a period of at least 60 days prior to sale.

Canada has, more recently, attempted tighter regulatory control with respect to soft and semi soft cheeses. Health Canada, in collaboration with the Canadian Food Inspection Agency (CFIA) and the Quebec Provincial Government, has been developing a Code of Hygienic Practices for raw milk soft and semi soft cheeses. This Code of Practice has recently been distributed for comment among provincial and territorial governments.

In addition, there is currently an agreement between the CFIA and the authorities in France which allows for the importation of raw milk soft and semi-soft cheeses without having to meet the 60 days storage requirement.

[11] US FDA Code of Federal Regulations 21CFR133

Canada has undertaken to develop and evaluate education campaigns aimed at industry and consumers to enhance the awareness of the potential hazards associated with raw milk soft and semi soft cheeses.

2.5 New Zealand

In New Zealand, all dairy products are either sold domestically or exported and most 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 criteria which can be used by producers or processors to develop an FSP or RMP.

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 they pose to consumers.

Under the Trans Tasman Mutual Recognition Agreement, New Zealand and Australia are bound by the requirements of the Code. The Code covers the content and labelling of food sold in New Zealand. Australia's processing requirements are contained in the Code but in New Zealand, processing requirements for milk and milk products are regulated under the *Animal Products Act 1999* (APA) and the *Food Act 1981.*

Attachment 3: Microbiological Risk Assessment

1. Approach

FSANZ has commenced evaluating the microbiological risks to public health and safety from raw milk products along the dairy product supply chain. The approach utilises available information including current microbiological surveillance data, epidemiological data, consumption data and existing published and unpublished risk assessments from a variety of sources.

The microbiological risk assessment is assessing the public health and safety risks posed by the consumption of raw milk products in Australia to address the following overarching questions:

- What are the risks to public health and safety posed by the consumption, in Australia, of raw milk products?

- What are the factors that would have the greatest impact on public health and safety along the production chain for raw milk products?

The microbiological hazards being considered in each risk assessment may differ depending on the extent to which each hazard has been associated with the product and/or the significance of its association with foodborne illness.

A number of tools can be used to assess risks to public health and safety, including risk profiling, quantitative and qualitative risk assessments and scientific evaluations. The application of these tools to the assessment of the risk to public health and safety is dependent on the purpose of the assessment and on the availability, quality, and quantity of relevant data.

The process of undertaking a risk assessment12 has been established internationally by the Codex Alimentarius Commission, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The risk assessment process used by FSANZ is consistent with international protocols.

The assessments will draw upon the findings of the Risk Profile of Dairy Products in Australia (FSANZ, 2006) conducted previously as part of Proposal P296 Primary Production and Processing Standard for Dairy. The Risk Profile was undertaken within the framework of existing management and regulations in Australia. It identified and examined hazards along the entire dairy supply chain from milk production through to consumption of dairy products and considered relevant inputs e.g. feed, water, etc. along the dairy primary production and processing chain.

[12] Risk assessment is a scientific process undertaken to characterise the risk to public health and safety posed by foodborne hazards associated with a food commodity.

2. Raw milk products and foodborne disease in Australia

In Australia, the Australian Government Department of Health and Ageing established OzFoodNet in 2000 as a collaborative project between the Commonwealth and States and Territories to enhance the surveillance of foodborne diseases and to provide a means for facilitating the national investigation of and determine the causes of foodborne illness. Where there is an absence of Australian data, overseas data may be considered taking into account the similarities differences in farming practices, production methods, etc.

Specific pathogens and the food vehicles for illness are rarely identified. Nationally and internationally, only a small proportion of cases that occur in the community are notified to health departments. Therefore the exact cause of illness is usually only determined when specific epidemiological studies are conducted or when an outbreak has occurred13. Due to the retrospective nature of outbreak investigations, limitations exist in the ability to positively identify the cause; investigators may identify the specific food that people had eaten before becoming ill, but often cannot identify the aetiological agent, the original source of product contamination, such as infected humans, animals or errors in food handling procedures.

3. Consumption data

In addition to data on food borne illness associated with raw milk products, the risk assessment will gather food consumption data to assist in determining exposure to a particular hazard. Two types of data sources are typically employed: food production statistics and food consumption surveys. Food production statistics provide an estimate of the amount of food commodities available to the total population. Consumption surveys (such as national nutrition surveys) provide detailed information regarding the types and amounts of foods consumed by individuals or households and sometimes the frequency with which the foods are consumed.

4. Exclusions from the microbiological risk assessment

Animal health issues other than those that specifically impact upon human health via foodborne transmission are not part of FSANZ's responsibility and will not be considered in this assessment. For imported raw milk products, the Australian Quarantine and Inspection Service (AQIS) and Biosecurity Australia maintain import requirements that are concerned with animal health and biosecurity issues. A quarantine permit must be obtained in order to import dairy products into Australia. These requirements must be met prior to compliance with the Code.

5. Scientific Advisory Panel

FSANZ has established a Dairy Scientific Advisory Panel14 to provide technical assistance and advice to FSANZ during the preparation of the scientific assessment. The Panel consists of a number of scientific experts from industry and government and its terms of reference are to:

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13 Hall, G.V., D'Souza, R.M., Kirk, M.D. (2002). Food-borne disease in the new millennium: Out of the frying pan and into the fire? *Med J Aust* **177**;614–618.

14 Membership of the Scientific Advisory Panel is provided on page 37.

- provide comment and advice on the scientific assessment undertaken by FSANZ as part of the dairy standard development process

- provide guidance in identifying additional sources of data

- assist in addressing uncertainty or variability in the information underpinning the scientific assessments - which may impact on the final output.

The Panel will meet periodically during the drafting and finalisation of the risk assessment reports. A list of panel members is provided below:

Nominee	Jurisdiction	Employer/Affiliation	Experience
Mr Steve Rice	South Australia	Dairy Authority of South Australia	Chief Executive Officer, Dairy Authority of South Australia
Mr Doug Eddy	Victoria	Dairy Food Safety Victoria	On-farm dairy industry knowledge
Dr Roger MacBean	Australia	Parmalat Australia – Consultant	Dairy processing industry knowledge and data management
Mr Martyn Kirk	Australia	DoHA/OzFoodNet	Public health epidemiological expertise
Dr Patricia Desmarchelier	Australia	Food Science Australia	Risk assessment and microbiological expertise
Dr Rod Dyson	Australia	Veterinarian/Dairy farmer	Animal health, on-farm knowledge and practices
Mr Neil Willman	Australia	Consultant	Cheese making
Dr Jenny Robertson	Australia	National Foods	Dairy processing industry expertise and knowledge
Mr John O'Regan	Australia	Murray Goulburn	Dairy processing industry expertise and knowledge
Dr Robin Condron	Australia	Dairy Australia	Veterinary microbiology and research management
Mr Les Hammond	Australia	Consultant	Cheese making
Dr Lisa Oakley	New Zealand	NZFSA	Risk assessment

Attachment 4: Standard Development Committee Membership

Nominee	Jurisdiction	Employer/Affiliation
Ms Slava Zeman	Australian Government	Australian Quarantine and Inspection Service - Canberra
Ms Vikki Fischer Ms Joanna Burley	Australian Government	Dept. of Agriculture Fisheries and Forestry-Canberra
Ms Jane Raupach	Australian Government	Dept. of Health and Ageing and South Australia OzFoodNet- (Dept of Human Services SA)
Dr Scott Crerar	New Zealand	New Zealand Food Safety Authority
Mr Peter Sutherland	New South Wales	New South Wales Food Authority
Mr Phil Pond	Queensland	Safe Food Production Qld
Mr Bill Calder	Western Australia	WA Health
Mr Steve Rice	South Australia	Dairy Authority of South Australia
Dr Anne Astin	Victoria	Dairy Food Safety, Victoria
Mr Doug Eddy	Victoria	Dairy Food Safety, Victoria
Mr Neil Willman	Australia	Cheese Expertise (Private company)
Dr Jenny Robertson	Victoria	Jenny Robertson Consulting Services
Dr Steven Roberts	Australia	Australian Quarantine and Inspection Service - Canberra
Mr John O'Regan	Australia	Murray Goulburn Co-op Ltd
Mr Wes Judd	Queensland	Queensland Dairy Farmers
Mr Ross Greenaway	Australia	Murray Goulburn Co-op Ltd
Ms Carol Bate	Australia	Fonterra Co-op Group Ltd
Dr Roger MacBean	Australia	Parmalat Australia Limited
Ms Karen Armitage	Australia	Dairy Australia, Victoria
Ms Helen Dornom	Australia	Dairy Australia, Victoria
Mrs Denise Riches	Australia	Goat Industry Council of Australia
Mr Tony Beaver	Australia	Food and Beverage Importers Association
Mrs Lesley Young	Australia	Country Women's Association of Australia (CWAA)