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

19 August 2011
[15-11]

PROPOSAL P1007
PRIMARY PRODUCTION & PROCESSING REQUIREMENTS FOR RAW MILK PRODUCTS
2nd ASSESSMENT REPORT

Executive Summary

Purpose

FSANZ has prepared this 2nd Assessment Report for public consultation on Proposal P1007 which is assessing the current restrictions on the production and processing of raw milk products for sale in Australia. It has been prepared in accordance with the principles of best practice regulation recommended by the Council of Australian Governments: identifying the problem that has prompted government action; the objectives of such action; and possible options for achieving the objectives.

A draft variation to the Australia only Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products has been prepared, reflecting this approach.

This Proposal is being assessed under the Major Procedure.

The Problem

The problem being addressed is whether the processing requirements currently mandated for milk and dairy products in the *Australia New Zealand Food Standards Code* (the Code) are appropriate. That is, can an acceptable level of public health and safety be achieved through alternative processing and/or production measures to those currently specified.

Objectives

The primary objective of Proposal P1007 is to enable a greater range of dairy products to be produced in, or imported into Australia while maintaining an acceptable level of public health and safety for the Australian population.

Assessment Framework

Based on risk assessment work undertaken for this proposal, three categories of product have been defined in terms of the effect processing factors and product properties of the final product have on pathogen survival and growth:

Category 1 products are defined as those products for which the properties and/or processing factors *eliminate* pathogens that may have been present in the raw milk.

Category 2 products are defined as those products for which the properties and/or processing factors *may allow the survival* of pathogens that may have been present in the raw milk but *do not support the growth* of these pathogens.

Category 3 products are defined as those products for which the intrinsic characteristics and/or processing factors *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.

Risk Management Options

At 1st Assessment, based on the assessment framework, four options were provided for consultation:

- **Option 1** – Maintain the status quo
- **Option 2** – Amend the Code to allow for category 1 products only
- **Option 3** – Amend the Code to allow for category 1 & 2 products
- **Option 4** – Amend the Code to allow for category 1, 2 & 3 products.

Option 3 was the preferred approach at 1st Assessment.

Impact Analysis

Outcomes of the technical assessment found:

- For category 1 and 2 products, combinations of specific production and processing controls have been identified that will provide a product with an acceptable level of public health risk.
- For category 3 products, the level of risk cannot be reduced sufficiently and such products present a high level of public health and safety risk. No control measures for these products, therefore, have been elaborated.

At 1st Assessment, some submitters supported the preferred option on the basis that FSANZ provide greater detail about how category 2 products will be defined and specify the complete set of control measures for ensuring their safety in the 2nd Assessment Report. This information is still being determined at this stage. Concerns were also raised over the lack of existing validation and verification guidelines and procedures for ensuring the safety of category 2 products. FSANZ acknowledges that such guidance would need to be developed to support permissions for category 2 products and that this will take some time to finalise.

At this stage, therefore, category 1 products are assessed as best meeting the primary objective (option 2).

Category 3 products present too high a risk to public health and safety to be permitted. The current exemption that allows raw goat milk will be reviewed separately.

Preferred Approach

To prepare draft variations to the current dairy processing requirements in Standard 4.2.4 to allow for the production and import of raw milk products that meet the definition of category 1 in Australia.

Reasons for preferred approach

At 2nd Assessment, FSANZ considers that the processing requirements for dairy products in Standard 4.2.4 should be amended because:

- Category 1 products provide for elimination of pathogens, and by definition, the risk presented by such products is very low

- Option 2 will allow some alternative processing measures (while maintaining the current level of public health and safety

- the measures are consistent with principles of minimum effective regulation.

A process for permitting category 2 products (Option 3), including the development of technical materials to support implementation will be progressed thorough a separate new Proposal. This new Proposal will be prepared at the end of 2011 and will include the timeframe for completion. The assessment work for category 2 products already undertaken will be incorporated into the new Proposal.

Option 4 is ruled out completely on the basis that category 3 products present too high a risk to public health and safety. The current exemption that allows raw goat milk will be reviewed separately.

The proposed new Proposal for category 2 products will determine the boundary between category 2 and category 3 products (i.e. what will be permitted) and will consider the current exemption for raw goat milk.

Conclusion

FSANZ, in consultation with the SDC, has limited the scope of the current Proposal to category 1 products only (option 2) and will develop a separate new Proposal to progress the technical work to provide the regulatory framework for category 2 products. Regulatory changes to permit category 2 products are more involved and will need to be supported with additional technical work to develop implementation materials.

This approach means that the further technical work needing to be progressed on the product and performance criteria for category 2 products (and supporting guidance) will not slow down permissions for category 1 products.

Invitation for Submissions

FSANZ invites public comment on this Report based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. 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) 14 October 2011

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:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
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SUPPORTING DOCUMENTS

The following material used in the preparation of this Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1007primary3953.cfm

SD1: Requirements in the Code relating to milk and dairy products
SD2: Membership of the Raw Milk Products SDC
Attachment 1 to the 1st Assessment Report

Introduction

1. Background to Proposal P1007

Standard 4.2.4 – Primary Production and Processing Standard[1] for Dairy Products came into effect on 5 October 2008. It 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 development of Standard 4.2.4, consideration was given to undertaking an assessment of raw milk products. This work was deferred until completion of Standard 4.2.4. FSANZ then commenced work on raw milk products through Proposal P1007, including addressing public health and safety issues, existing applications to amend the *Australia New Zealand Food Standards Code* (the Code) and regulatory inconsistencies.

A Standard Development Committee (SDC), consisting of representatives from the industry, government regulators and consumers, has been established by FSANZ to assist and advise on this standard development Proposal.

There have been two rounds of public consultation already undertaken during the assessment of this Proposal[2]: A discussion paper was released for public comment in 2008 and the 1st Assessment Report was released for comment in December 2009. This 2nd Assessment Report provides a third opportunity for stakeholders to provide comment on the assessment process and proposed amendments to the Code.

FSANZ, in consultation with the SDC, has decided to limit the scope of the current Proposal to category 1 products only (option 2) and will develop a separate new Proposal to progress the technical work to provide the regulatory framework for category 2 products. Following the two rounds of public comment, no further work will be undertaken on category 3 products, with the exception of raw goat milk which will be addressed under the proposed new Proposal for category 2 products.

2. Scope of this Proposal

2.1 Raw Milk Products

Raw milk products are not defined in the Code but have been defined for the purpose of this Proposal as those products which have not undergone pasteurisation or an equivalent pathogen reduction process[3]. These products may be derived from a number of milking animals including cow, goat, sheep, buffalo and camel.

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[1] A primary production & processing standard is a set of obligations on primary producers and processors of food commodities. These standards are incorporated into Chapter 4 of the Code and apply in Australia only. Along with other standards in the Code they provide an approach to managing food safety and suitability in Australia that extends from production on the farm through to sale to the consumer.

[2] The Discussion Paper and 1st Assessment Report are available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/primaryproductionprocessingstandardsaustraliaonly/dairyrawmilkproducts/

[3] 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'.

The assessment framework developed for this proposal, described under Section 3, categorises raw milk products into one of three categories depending on processing and product characteristics.

The 1st Assessment Report identified options for permitting category 1, 2 and 3 products and identified the preferred option was permission for category 1 and 2 products (option 3). Technical issues relating to the requirements for category 2 products have impacted on progressing Proposal P1007. Following consultation with the SDC, FSANZ has limited the scope of the current Proposal P1007 to category 1 products only and will develop a new Proposal to progress the technical work to provide the regulatory framework for category 2 products. The rationale for this approach is outlined in this report.

The Problem

The problem is whether the processing requirements currently mandated for milk and dairy products in the Code are appropriate. That is, can an acceptable level of public health and safety be achieved through alternative processing and/or production measures to those currently specified. The Code currently contains a number of requirements for milk and dairy products (Attachment 4).

There are a number of drivers for reviewing the current processing requirements including:

- ensuring an efficient and competitive food industry
- consumer demand for raw milk products
- national consistency in legislative requirements.

Objectives

2. Objectives of the Proposal

The objective of Proposal P1007 is to enable a greater range of dairy products to be produced in, or imported into, Australia while maintaining an acceptable level of public health and safety for the Australian population.

As a matter of good regulatory practice, this Proposal also aims to address the current inconsistencies in the regulation of raw milk products in Australia. This includes:

- providing nationally applicable requirements rather than differing State-based provisions for raw milk products, and

- providing consistent permissions for the sale of imported and domestically produced raw milk products which enables domestic producers to compete fairly with international producers.

2.1 Statutory considerations

2.1.1 FSANZ Act

Where regulatory interventions are required (e.g. by developing or varying a food standard), FSANZ is required by its legislation to meet 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 developing and varying food regulatory measures, 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, and
- any written policy guidelines formulated by the Ministerial Council.

5.2.2 Policy guidelines

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) developed an *Overarching Policy Guideline on Primary Production and Processing Standards*. This policy guideline specifies a number of high order principles for primary production and processing standards outlining that they will:

- be outcomes-based
- have a consistent regulatory approach across the Standards
- be consistent with the approach outlined in Chapter 3 of the Code
- be consistent with Codex standards
- address food safety across the entire food chain where appropriate
- facilitate trade and comply with Australia's obligations under WTO[4] agreements
- promote consumer confidence
- ensure the cost of the overall system is commensurate with the assessed level of risk
- provide a regulatory framework that only applies to the extent justified by market failure

Any regulatory measures developed should be commensurate with risk and not impose any unnecessary additional economic burden on the dairy industry.

[4] WTO refers to the World Trade Organization.

3. Assessment Framework

FSANZ has undertaken three risk assessments to generate information on the public health risks which may be associated with raw milk products[5].
The *Microbiological Risk Assessment of Raw Milk Cheese* has been used to help identify the factors that have the greatest contribution to pathogen control during cheese manufacture and the key parameters for determining pathogen reduction, and conditions for growth and no growth. Risk assessments have also been undertaken for raw goat milk and raw cow milk that highlight the milk production factors that impact on the prevalence of pathogens in raw milk as well as the risks associated with the consumption of raw drinking milk. The outputs of these assessments have been used to assess the level of risk that raw milk product categories pose under certain production and processing controls.

This information is summarised in the Technical Assessment (SD1).

Based on risk assessment work, three categories have been defined in terms of the effect processing factors and product properties of the final product have on pathogen survival and growth:

Category 1 products are defined as those products for which the:

- properties or
- processing factors

eliminate pathogens that may have been present in the raw milk (e.g. non-pasteurised hard to very hard cheeses; Gruyère, Sbrinz or Emmental cheese).

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Category 2 products are defined as those products for which the:

- properties or
- processing factors

may allow the survival of pathogens that may have been present in the raw milk but do not support the growth of these pathogens (e.g. raw milk semi-hard cheeses; cheddar, blue cheese).

Category 3 products are defined as those products for which the:

- intrinsic characteristics or
- processing factors

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 (e.g. raw drinking milk).

Given the increased potential for pathogens to be present, the food safety risk associated with each category increases from Category 1 to Category 3. In effect, the category approach provides for the assessment of combinations of microbiocidal and microbiostatic control measures ("hurdles") on pathogen growth or survival as well as through chain factors that impact on pathogen presence.

[5] The three microbiological risk assessments (raw cow milk, raw goat milk and raw milk cheese) can be found on the FSANZ website
http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp1007primary3953.cfm

4. Risk Management Options

FSANZ must consider various risk management options in order to decide the most effective and efficient approach to address the problem and achieve the objectives of the Proposal.

At 1st Assessment, and based on the outcomes of the Technical Assessment, four options were provided for consultation:

- **Option 1** – Maintain the status quo
- **Option 2** – Amend the Code to allow for Category 1 products only
- **Option 3** – Amend the Code to allow for Category 1 & 2 products
- **Option 4** – Amend the Code to allow for Category 1, 2 & 3 products.

4.1 Option 1 – *Status Quo*

Under Option 1, Proposal P1007 would be abandoned and the Code would not be amended. Consequently, no additional products would be permitted to those already allowed by the processing requirements in Standard 4.2.4 or by Standard 4.2.4A.

Further permissions for raw milk products would require a case-by-case assessment through an application process to FSANZ.

4.2 Option 2 – Amend the Code to allow for Category 1 products only

Option 2 would require the preparation of amendments to the current processing requirements in Standard 4.2.4 to allow for products that meet the definition of Category 1.

In addition to pasteurisation and thermisation, Option 2 would allow for dairy products to be produced or imported that met the appropriate process, product and performance criteria for category 1 products (such as curd cooking at >48°C, extended ripening (≥120 days) at ≥10°C and a moisture content ≤39%).

Existing permissions for specified Swiss and Roquefort cheeses would remain.

4.3 Option 3 – Amend the Code to allow for Category 1 & 2 products

Option 3 would require the preparation of amendments to the current processing requirements in Standard 4.2.4 to allow for products that meet the definition of Category 1 and 2.

In addition to pasteurisation and thermisation, Option 3 would allow for dairy products to be produced or imported that met appropriate process, product and performance criteria for category 1 and 2 products. As discussed in the Technical Assessment, additional control measures for raw milk production, transport and processing would need to be included in the Code to permit the safe production of Category 2 products. .

4.4 Option 4 – Amend the Code to allow for Category 1, 2 & 3 products

Option 4 means the preparation of amendments to Standard 4.2.4 to allow for the production and sale of all raw milk products, including raw drinking milk, provided they met production and processing requirements that could manage the safety of the product.

At 1st Assessment, however, it was concluded that adequate control measures could not be elaborated for Category 3 products to ensure they could present a low level of risk. As such, Option 4 is not considered a viable option.

Impact Analysis

The preferred risk management option is based on an analysis that considers:

- scientific evaluation of the risks
- efficacy and practicality of risk mitigation measures (control measures) identified
- who is affected by the problem and the proposed solution, and
- costs and benefits to affected parties of the interventions associated with each option.

5. Evaluation of the risks

In regard to the scientific evaluation of the risks, the Technical Assessment identified:

- the milk production factors that affect the prevalence of pathogens in raw milk
- the factors that have the greatest contribution to pathogen control during cheese manufacture (the primary raw milk product)
- the key parameters for determining pathogen reduction, and conditions for growth and no growth
- the level of risk associated with each category
- the control measures required to support production.

The key findings were:

- For Category 1 and 2 products, combinations of specific production and processing controls have been identified that will provide a product with an acceptable level of public health risk.

- For Category 3 products, the level of risk cannot be reduced sufficiently and such products present a high level of public health and safety risk. No control measures for these products, therefore, have been elaborated.

5.1 Category 1

As Category 1 products provide for elimination of pathogens, by definition, the risk presented by such products is very low. A qualitative risk assessment undertaken for raw milk extra hard cheeses and cooked curd Swiss cheeses within the *Microbiological Assessment of Raw Milk Cheese* supports a **very low** risk for both the general and susceptible population groups where production includes:

- curd cooking at high temperatures (>48°C); and
- ripening (in combination with a low moisture environment).

5.2 Category 2

The *Microbiological Risk Assessment of Raw Milk Cheese* qualitatively determined the level of risk for a number of selected cheese styles (cheddar, blue, feta, camembert) based on probabilistic modelling. The risk levels determined were very conservative due to the data gaps and assumptions made and cannot be directly ascribed to a product category.

What the modelling indicated, however, is the importance of certain parameters that determine whether pathogens survive or grow (e.g. pH and salt-in-moisture) and, therefore, the level of risk presented.

Where such controls can be met the risk to public health is **low,** (as determined in the assessment for Roquefort cheese) for both general and susceptible population groups.

5.3 Category 3

Category 3 products have been defined as those products likely to allow for the survival of pathogens that may have been present in the raw milk and may support the growth of these pathogens. For cheeses, this would include softer mould ripened varieties and fresh cheeses, which have a higher moisture and pH profile and can support the growth of pathogens. Raw drinking milk falls into Category 3.

Outcomes from the Risk Assessment reports have determined that Category 3 products present a **medium to high** level of risk (depending on the pathogen) to both general and susceptible population groups because there are no measures to ensure pathogens are not present in bulk milk nor can subsequent handling and processing prevent survival and growth. The severity of illness that results from enterohaemorrhagic *E. coli* infection is a significant contributor to the level of risk for Category 3 products. Additionally, *L. monocytogenes* presents a high risk in these products for vulnerable groups.

6. Control measures

6.1 Category 1

For category 1 products, the safety of the product is provided through establishing process and product criteria that give a net 5 log reduction of pathogens. In addition to pasteurisation, the assessment has identified two examples of processing factors and intrinsic characteristics for cheese that would meet category 1 requirements:

1. Thermisation of milk at 64.5˚C for 16 seconds in combination with a storage period of at least 90 days at no less than 7°C[6].

2. Curd cooking at elevated temperatures (>48°C) in combination with a storage period of at least 120 days at no less than 10°C. The final product moisture content must be less than 39%.

These products can be permitted through amending parameters in the existing processing provisions of clause 16 of Standard 4.2.4. The change in temperature from 62°C to 64.5°C for thermisation of milk is to provide greater assurance that the required log reduction would be met and to align with New Zealand requirements. The relaxation of moisture content from 36% to 39% is based on risk assessment work which showed that pathogens were eliminated at this moisture range for the maturation period specified.

No additional on-farm requirements for raw milk for processing category 1 products are recommended (i.e. beyond those already required by Standard 4.2.4).

[6] As described in section 2.1 of the Technical Assessment (Attachment 1), FSANZ is proposing to amend the current Thermisation parameters in the Code to align with New Zealand.

6.2 Category 2

So far, FSANZ has identified the likely combination of processing factors and intrinsic characteristics that would need to be controlled in the production of raw milk cheeses in order to meet category 2 requirements. The factors are:

- the use of an active starter culture to achieve rapid acid production and pH drop
- a pH/salt-in-moisture profile that will not support the growth of pathogens
- a minimum ripening period and temperature.

These parameters, and others, are still being investigated at this stage to inform the boundary between category 2 and 3 products.

6.3 Category 3

By definition, there are no or limited processing factors to prevent survival of pathogens in category 3 dairy products and their intrinsic characteristics may support pathogen growth. Therefore, achieving 'pathogen free' raw milk, through the management of risk factors on farm, is a critical control.

Implementing practices to reduce the pathogen load in the farm and dairy environment and improving hygienic control over milk harvest may reduce the level and frequency of milk contamination but are not elimination measures. The *Microbiological Risk Assessment of Raw Cow Milk* indicates that even when there is very low contamination of the bulk milk (below the level of detection) some pathogens will grow and cases of illness from *Campylobacter* spp., EHEC, *Salmonella* spp. and *L. monocytogenes* can be expected. No measures have been identified that would ensure pathogens would not be present in the raw milk.

7. Affected Parties

Parties that have been identified as being affected by the Proposal include:

- **industry**, including current dairy producers and processors, businesses looking to enter a raw milk products industry, importers and retailers

- **consumers**, including those demanding raw milk products and those against raw milk products

- **governments**, including State and Territory enforcement agencies, Commonwealth government and member nations of the World Trade Organization (WTO).

7.1 Consultation

Consultation with affected parties has included the FSANZ statutory consultation processes, (with the release of a Discussion Paper and 1st Assessment Report) as well as engagement through the Raw Milk Products Standard Development Committee (SDC). Targeted consultations have also been undertaken with raw goat milk producers and specialty cheese manufacturers, who have expressed an interest in manufacturing raw milk cheeses, in order to identify drivers for stakeholder positions and attitudes.

The SDC for P1007 evolved from the Dairy SDC for Proposal P296. In May 2007, the FSANZ Board appointed members of the Dairy SDC to continue the work on raw milk products under Proposal P1007, as well as increasing membership by adding additional expertise in raw milk issues. SDC2 lists current SDC members.

Additionally, two technical workshops were held in June and July 2010 to further develop and refine additional control measures that would be needed to support any production of raw milk products. These workshops involved a small group of scientific and dairy industry experts with expertise in a range of areas (veterinary/animal husbandry, cheese and dairy processing, microbiology, audit). Discussion at the workshops helped elaborate the control measures that would be required from an Australian industry perspective and highlighted the guidance and other supporting material that would need to be developed (for industry and government) to support implementation and compliance.

7.1.1 Public submissions

A summary of the submissions received and issues raised in response to the Discussion Paper for P1007 was provided in the 1 st Assessment Report. Similar issues were also raised in response to the 1st Assessment Report which was opened for an 11-week consultation period from 16 December 2009. A total of 228 submissions were received, 198 of these from individual consumers writing in support of access to raw milk products such as cheeses and a greater level of consumer choice (including 29 submissions specifically supporting access to raw drinking milk). An overview of the submissions received and main issues identified is provided at Attachment 3. In summary:

- The majority of submissions were from consumers wanting access to raw milk products. In particular, many raised that Australian consumers would benefit from increased permissions for domestic and imported raw milk cheeses (including category 3 cheeses). Submissions in support of raw drinking milk were primarily driven by health reasons, stating that raw milk is more nutritious and provides other additional health benefits. Reasons for supporting access to raw drinking milk also included taste, quality and the freedom or right to choose this product. FSANZ has taken these comments into account in reviewing the Technical Assessment and re-affirms its view that category 3 products present too high a risk to public health to be permitted.

- Technical comments were provided for consideration relating to the category framework, risk assessment work and hazard control measures, particularly concerning category 2 products

- Most government and industry submissions supported the preferred option proposed in the 1st Assessment Report, that is, to amend the Code to allow for 'category 1' and 'category 2' raw milk products to be produced in and imported into Australia. However, many of these submitters supported this option on the basis that FSANZ provide greater detail about how category 2 products will be defined and specify the complete set of control measures for ensuring their safety in the 2nd Assessment Report. This information is still being determined at this stage.

- A number of issues were raised in regard to implementation of a standard that permitted category 2 products. Concerns related to requiring more certainty in the criteria to distinguish between category 1 and category 2 products, and the lack of existing validation and verification guidelines and procedures for ensuring the safety of category 2 products. FSANZ acknowledges that such guidance would need to be developed to support permissions for category 2 products and that this will take some time to finalise.

- There are still technical issues related to the boundary between category 2 and category 3 products.

7.1.2 World Trade Organization notification

As members of the 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.

There are relevant international standards and amending the Code to allow some raw milk products is likely to have an effect on international trade due to the greater potential for imports and exports of raw milk products.

FSANZ will recommend notification to the agency responsible in accordance with Australia's obligations under the WTO Sanitary and Phytosanitary Measures (SPS) Agreement. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact upon them.

8. Risk Management Decision

Table 1 provides a qualitative assessment of the impacts on affected parties posed by each option.

At this stage and based on this assessment of the options, Option 2 (permitting category 1 products) is assessed as best meeting the primary objective of this Proposal.

Option 3 (permitting category 1 and category 2 products) was the preferred approach at 1st Assessment. However, the additional control measures and systems required to implement the safe production of category 2 products still need to be developed as part of any regulatory requirements. In regard to microbiological limits, further technical work to support permissions for category 2 products will help determine appropriate food categories description and the safety limits required. FSANZ will be examining the current microbiological limits in the Code under a separate review of Standard 1.6.1.

To enable the process and time to undertake this work, it is now proposed that a staged approach is taken such that:

- the current Proposal (P1007) permits category 1 products only (option2)
- a new Proposal is prepared to progress the work required to support the production and sale of category 2 products (option 3).

The assessment work for category 2 products already undertaken will be incorporated into the proposed new proposal. The issues related to category 2 products raised in submissions to the 1st Assessment Report will also be considered in this new proposal. This has been acknowledged in the summary of submissions (Attachment 3).

At this stage, category 3 products (except the current exemption that allow raw goat milk) present too high a risk to consider any permissions. In regard to the current clause 15 in Standard 4.2.4 that allows the production of raw goat milk for sale for human consumption (as is the situation in four States), FSANZ will address this issue under the proposed new proposal.

In conclusion, this proposed approach will allow some alternative processing measures (following amendments to the parameters in the existing processing provisions of Standard 4.2.4) while maintaining the current level of public health and safety.

Table 1: Qualitative overview of the impacts on affected parties posed by each option

Primary objective: to enable a greater range of dairy products to be produced in or imported into Australia while maintaining an acceptable level of public health and safety for the Australian population.

Option	Impact on affected party			Overall Assessment
	Consumers	**Industry**	**Government**	
Option 1 Status quo	Does not provide a greater range of products. No change to risk to public health and safety	Restricts opportunity for producers, retailers and importers to access new product or markets. High level of consumer confidence in dairy sector maintained.	Current and potential future applications resource intensive. No change to existing implementation or enforcement costs.	Does not enable a greater range of dairy products to be sold in Australia. + Maintains an acceptable level of public health and safety. **Primary objective not met.**
Option 2 Category 1 products only	Some increase in range of product (imported and domestically produced) available (limited to category 1 products) Risks to public health and safety very low.	Opportunity for production and sale of increased range of products (limited to category 1) Minimal compliance costs. Market and consumer confidence in sector can be maintained.	Minimal changes required for implementation and enforcement.	Enables an increased range of dairy products to be sold in Australia. + An acceptable level of public health and safety can be maintained through specified process and product criteria. **Meets primary objective.**

Option	Impact on affected party			Overall Assessment
	Consumers	**Industry**	**Government**	
Option 3 Category 1 and 2 products	Increased range of products (imported and domestically produced) available. Risks to public health and safety low.	Opportunity for production and sale of a much greater range of products (category 1 and 2). Given the additional control measures required to support the safe production of category 2 products, there will be increased compliance costs.	Increased implementation and enforcement costs associated with the additional control measures required to support safe production. Evaluation of compliance and enforcement costs would be dependent on the further elaboration of control measures (systems required in practice).	Enables a greater range of dairy products to be sold in Australia. + An acceptable level of safety can be maintained with appropriate controls during raw milk production and processing. - Validation and Verification guidelines and other supporting materials are essential to ensure safe production of these products. Further technical work needs to be progressed before these can be developed. **At this stage the primary objective is not met. Further work on the product and performance criteria for category 2 products needs to be completed and supporting guidance would need to be developed.**
Option 4 Category 1, 2 and 3 products	Greatest range of raw milk products available but a medium to high level of risk is posed to public health and safety. Individual costs associated with foodborne illness (which can include serious illness and death).	Opportunity for production and sale of greatest range of products (category 1, 2 and 3). Potential safety risks may impact on market and consumer confidence in sector.	Implementation and enforcement of systems to address the potential increase in risk to public health and safety. Community costs associated with cases or outbreaks of foodborne illness (which can include serious illness and death).	Enables the greatest range of dairy products to be available. + Does not maintain an acceptable level of public health and safety for the Australian population. **Primary objective not met.**

9. Amendments to the Code to Permit Category 1 Products

The attached draft variation (Attachment 1) sets out changes to the processing requirements in Standard 4.2.4 to provide increased flexibility in the measures a dairy processing business must take to reduce to safe levels any pathogens that may be present in the food. In particular, a broader range of production parameters will be specified for cheese and cheese products e.g. minimum moisture content, minimum storage time. Variations to the processing requirements in Standard 4.2.4 results in a consequential amendment to Standard 4.2.4A i.e. specific cheeses in Standard 4.2.4A to be deleted (e.g. Swiss cheeses). These cheeses will be now be covered by the processing provisions of subclause 16(3) of Standard 4.2.4.

9.1 Clause 16 of Standard 4.2.4

Clause 16 has been expanded into three subclauses (1), (2) and (3) to:

- provide clarification as to the time temperature processing parameters required for milk used to make cheese or cheese products as opposed to other dairy products (e.g. cream) that are used to make cheese or cheese products;

- to distinguish between processing requirements on milk and dairy products used to make cheese from cheese processing and product parameters.

Subclause 16(1) specifies processing requirements for milk used to make cheese or cheese products.

Subclause 16(2) specifies processing requirements for dairy products used to make cheese or cheese products, noting that the combination of time and temperature required may differ for other products to achieve the same lethal effect on pathogenic microorganisms in milk. This reflects the approach in Clause 15 for the processing of milk and dairy products.

Subclause 16(3) permits cheese to be made using processing and product controls other than those specified in subclauses 16(1) and 16(2). These include a combination of curd cooking, minimum moisture content and storage time or in accordance with clause 1 of Standard 4.2.4A.

Existing subclause 16(b) is amended to vary the existing parameters specified such that the time / temperature limits are increased to 64.5 °C for 16 seconds and the temperature of storage is increased to 7°C. These parameters are now specified in paragraph 16(1)(b).

Existing subclause 16(c) is amended to vary the existing parameters specified such that the moisture content is increased 39% and the storage period decreased to 120 days from the date of processing. These parameters are now specified in paragraph16(3)(a).

The processing parameters and product characteristics specified in Clause 16 have been assessed as achieving, at a minimum, a net 5 log reduction of pathogens.

9.2 Table to Clause 1

The table to clause 1 is amended to delete the cheese and cheese products entry “Gruyere, Sbrinz or Emmental cheese” and the legislation or documentation “The *Ordinance on Quality Assurance in the Dairy Industry* of the Swiss Federal Council of 18 October 1995”.

10. Cost Benefit Analysis (RIS ID: 12495)

The recent approval of a "non-pasteurised" cheese in Tasmania (made in accordance with the existing Clause 16(c) of Standard 4.2.4) provides an implementation framework for extension to additional category 1 products. These products can be permitted through amending parameters in the existing processing provisions of Standard 4.2.4.

Following consultation with the Office of Best Practice Regulation (OBPR), the proposed changes to Standard 4.2.4 to permit category 1 products only at this stage are considered to have a minor impact on businesses and individuals. Consequently, the OBPR has advised that a Regulation Impact Statement is not required.

A Regulation Impact Statement will be developed during the development of the proposed new Proposal that considers category 2 products.

11. Communication Strategy

This 2nd Assessment Report contains a draft variation to the processing requirements in the existing Standard 4.2.4 to provide permissions only for category 1 products. At 1st Assessment, the preferred approach was to permit category 1 and category 2 products. As further work on the product and performance criteria for category 2 products needs to be completed and supporting guidance needs to be developed, FSANZ has progressed category 1 products ahead of category 2 products. .

The key messages are:

- The 2nd Assessment Report will be limited to permission for category 1 products (e.g. non-pasteurised hard to very hard cooked curd cheeses). This can be done by minor changes to the storage time and moisture content requirements in the existing Dairy Standard (Standard 4.2.4).

- Category 2 products will be progressed under a proposed new proposal to allow further work on the product and performance criteria for category 2 products, and supporting guidance to be developed.

- The assessment work for category 2 products already undertaken will be incorporated into the proposed new Proposal. The issues related to category 2 products raised in submissions to the 1st Assessment Report will also be considered in the proposed new proposal.

- Raw drinking milk is a category 3 product. At this stage, category 3 products present too high a risk to consider any permissions. The current exemption that allows raw goat milk will be reviewed separately in the proposed new Proposal.

- The proposed new Proposal for category 2 products will determine the boundary between category 2 and category 3 products (i.e. what will be permitted) and will consider the current exemption for raw goat milk.

In consultation with the SDC Communication Sub-Committee, FSANZ will develop communication messages around the key issues such as the risk posed by raw drinking milk.

This 2nd Assessment Report is a significant document with a number of attachments and FSANZ will develop a short communication document reflecting the key aspects and impacts of this work to assist in the next phase of public consultation.

Organisations or individuals with an interest in this Proposal can seek to have their names listed as an interested party (to receive direct notifications about this Proposal) by emailing the Standards Management Officer at standards.management@foodstandards.gov.au with their full contact details.

Conclusion

12. Conclusion and preferred option

Technical issues around category 2 products have affected the progress of the current Proposal P1007. Following consultation with the SDC, FSANZ has decided to limit the scope of the current Proposal to category 1 products only (option 2) and will develop a new proposal to progress the technical work to provide the regulatory framework for category 2 products. Regulatory changes to permit category 2 products (option 3) are more involved and will need to be supported with additional technical work to develop implementation materials such as:

- guidelines (including validation guidelines)
- monitoring/verification criteria
- competencies for additional skills and knowledge requirements.

Option 4 (regulatory changes to permit category 3 products) is being ruled out altogether. Raw goat milk will be addressed under the proposed new Proposal.

This approach means that the further technical work needing to be progressed on the product and performance criteria for category 2 products (and supporting guidance) will not slow down permissions for category 1 products which can be permitted through straightforward amendments to existing processing parameters in Standard 4.2.4.

Preferred Approach

To prepare draft variations to the current dairy processing requirements in Standard 4.2.4 to allow for the production and import of raw milk products that meet the definition of category 1 in Australia.

12.1 Reasons for preferred approach

At 2nd Assessment, FSANZ considers that the processing requirements for dairy products in Standard 4.2.4 of the Code should be amended because:

- Category 1 products provide for elimination of pathogens, and by definition, the risk presented by such products is very low

- Option 2 will allow some alternative processing measures (while maintaining the current level of public health and safety

- The measures are consistent with principles of minimum effective regulation.

A process for permitting category 2 products (Option 3), including the development of technical materials to support implementation will be progressed thorough a separate new Proposal that will be prepared by FSANZ at the end of 2011 and will include the timeframe for completion.

Option 4 is ruled out completely on the basis that category 3 products present too high a risk to public health and safety. The current exemption that allows raw goat milk will be reviewed separately in the proposed new Proposal.

The proposed new Proposal for category 2 products will determine the boundary between category 2 and category 3 products (i.e. what will be permitted) and will consider the current exemption for raw goat milk.

13. Implementation and Review

It is suggested at this stage that the draft variation comes into effect from the date of gazettal.

Implementation of the Code is the responsibility of the State and Territory Governments. The Implementation Sub-Committee[7] (ISC) facilitates the consistent national implementation of the Code and is responsible for developing nationally consistent implementation approaches.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Draft Explanatory Memorandum
3. Summary of issues raised in public submissions on the 1st Assessment Report

[7] The Implementation Sub-Committee (ISC) is a sub-committee of the Food Regulation Standing Committee. Its role is to develop and oversee a consistent approach across jurisdictions to implementation and enforcement of food regulations and standards, regardless of whether food is sourced from domestic producers, export-registered establishments or from imports.

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Food Standards (Proposal P1007 – Primary Production & Processing Requirements for Raw Milk Products) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated

[DRAFT – NOT FOR SIGNATURE]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal P1007 – Primary Production & Processing Requirements for Raw Milk Products) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

These variations commence **on the date of gazettal.**

SCHEDULE

[1] ***Standard 4.2.4*** *is varied by omitting clause 16, substituting –*

16 Processing of dairy products to make cheese and cheese products

(1) Milk used to make cheese or cheese products must be processed –

(a) in accordance with subclause 15(1); or
(b) by being held at a temperature of no less than 64.5°C for a period of no less than 16 seconds, and the cheese or cheese product stored at a temperature of no less than 7°C for a period of 90 days from the date of processing.

(2) Dairy products used to make cheese or cheese products must be processed –

(a) in accordance with subclause 15(3); or
(b) using a heat treatment that uses a combination of time and temperature of equal or greater lethal effect on any pathogenic micro-organisms in the dairy product achieved by paragraph 16(1)(b).

(3) However, milk or dairy products used to make cheese or cheese products do not need to be processed in accordance with subclauses 16(1) and 16(2) if the cheese or cheese product is processed –

(a) such that –

(i) the curd is heated to a temperature of no less than 48°C; and
(ii) the cheese or cheese product has a moisture content of less than 39%, after being stored at a temperature of no less than 10°C for a period of no less than 120 days from the date of processing; or

(b) in accordance with clause 1 of Standard 4.2.4A.

[2] ***Standard 4.2.4A*** *is varied by –*

[2.1] *omitting from the* Table to clause 1 –

Gruyere, Sbrinz or Emmental cheese	The *Ordinance on Quality Assurance in the Dairy Industry* of the Swiss Federal Council of 18 October 1995	

[2.2] *omitting the* Editorial note *following clause 1, substituting –*

Editorial note:

Clause 4 of Standard 1.2.4 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 cow's milk, should also include the common name of the species from which the milk is sourced.

Attachment 2

Explanatory Statement

***Food Standards (Proposal P1007 – Primary Production & Processing Requirements for Raw Milk Products) Variation*.**

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a Proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1007 to develop food regulatory measures for some raw milk products (category 1 products). The Authority considered Proposal P1007 in accordance with Division 2 of Part 3 and has prepared a draft variation to a Standard (Standard 4.2.4).

Following consideration by Ministerial Council, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting.

2. Purpose and Operation

The Authority has prepared variations to the processing requirements in Standard 4.2.4 to provide increased flexibility in the measures a dairy processing business must take to reduce to safe levels any pathogens that may be present in cheeses and cheese products. In particular, a broader range of production parameters will be specified for cheese and cheese products e.g. minimum moisture content, minimum storage time. Variations to the processing requirements in Standard 4.2.4 allows for specific cheeses in Standard 4.2.4A to be deleted (e.g. Swiss cheeses). These cheeses will be now be covered by the processing provisions of subclause 16(3) of Standard 4.2.4.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1007 has included one round of public consultation, at 1st Assessment, as well as public consultation on a Discussion Paper. A Discussion Paper was released for consultation on 6 August 2008 for a six-week consultation period. The 1st Assessment Report for P1007 was released for public comment on 16 December 2009 for a consultation period of 11 weeks.

A Standards Development Committee (SDC) was established with representatives from the industry sector, the relevant State and Territory government agencies and consumer organisations to provide ongoing advice to the Authority throughout the standard development process. The SDC contributed a broad spectrum of knowledge and expertise covering industry, government, research and consumers

A Regulation Impact Statement (RIS) is not required because the proposed variations to Standard 4.2.4 are likely to have a minor impact on business and individuals.

5. Contents of the Variations

5.1 Clause 16 of Standard 4.2.4

Clause 16 has been expanded into three subclauses (1), (2) and (3) to:

- provide clarification as to the time temperature processing parameters required for milk used to make cheese or cheese products as opposed to other dairy products (e.g. cream) that are used to make cheese or cheese products;

- to distinguish between processing requirements on milk and dairy products used to make cheese from cheese processing and product parameters.

Subclause 16(1) specifies processing requirements for milk used to make cheese or cheese products.

Subclause 16(2) specifies processing requirements for dairy products used to make cheese or cheese products, noting that the combination of time and temperature required may differ for other products to achieve the same lethal effect on pathogenic microorganisms in milk. This reflects the approach in clause 15 for the processing of milk and dairy products.

Subclause 16(3) permits cheese to be made using processing and product controls other than those specified in subclauses 16(1) and 16(2). These include a combination of curd cooking, minimum moisture content and storage time or in accordance with clause 1 of Standard 4.2.4A.

Existing subclause 16(b) is amended to vary the existing parameters specified such that the time temperature limits are increased to 64.5°C for no less than 16 seconds and the temperature of storage is increased to no less than 7°C. These parameters are now specified in paragraph 16(1)(b).

Existing subclause 16(c) is amended to vary the existing parameters specified such that the maximum permitted moisture content is increased to less than 39% and the storage period decreased to 120 days from the date of processing. These parameters are now specified in paragraph16(3)(a).

The processing parameters and product characteristics specified in clause 16 have been assessed as achieving, at a minimum, a net 5 log reduction of pathogens.

5.2 Table to Clause 1 of Standard 4.2.4A

The table to clause 1of Standard 4.2.4A is amended to delete the cheese and cheese products entry “Gruyere, Sbrinz or Emmental cheese” and the legislation or documentation “The *Ordinance on Quality Assurance in the Dairy Industry* of the Swiss Federal Council of 18 October 1995”. Conditions for the manufacture of these cheeses are now covered by the requirements of Standard 4.2.4 and processing provisions of paragraph 16(3)(a).

The Editorial note has been reduced to remove material that reflects an historical approach to permitting individual cheeses prior to the development of primary production and processing requirements in Standard 4.2.4 and the assessment process developed through Proposal P1007.

Attachment 3

Summary of Submissions

Introduction

FSANZ released the 1st Assessment Report for P1007 in December 2009 to seek public feedback on the the progress of the Proposal at that time, including the outcomes of the technical assessment, preliminary impact analysis and the proposed preferred option.

The 1st Assessment Report was open for public consultation for eleven weeks, including a one-week extension. A total of 228 submissions were received. Submitters were grouped into either 'government', 'industry' or 'consumers'. 198 of the submissions were from individual consumers writing in support of access to raw drinking milk, raw milk products such as cheeses and a greater level of consumer choice. 29 of these consumer submissions wrote in support of raw drinking milk specifically. 11 submissions were received from government agencies and 19 from industry.

Issues Raised

Support for the proposed preferred option

Most government and industry submissions supported the preferred option proposed in the 1st Assessment Report, that is, to amend the Code to allow for 'category 1' and 'category 2' raw milk products to be produced in and imported into Australia. However, many of these submitters supported this option with the caveat that FSANZ provide greater detail about how such products will be defined and the control measures that will be specified for ensuring their safety. They expressed reservations about the additional resources that will be needed to implement any changes. They are also cautious that any changes need to be well managed to prevent any negative impact to consumer confidence in the safety of all dairy foods, particularly if there are outbreaks associated with raw milk products.

A small number of government and industry submitters supported the option to allow 'category 1' products only, while very few supported maintaining the status quo. There was unanimous support from consumer submissions for permitting a greater range of raw milk products.

FSANZ response: FSANZ will be progressing additional work to provide greater detail about category 2 products and the control measures to be specified to ensure their safety in a proposed separate new proposal. Permissions for category 1 products will be progressed through the existing Proposal P1007.

FSANZ Category Framework and Technical Assessment

A range of comments were provided on the category framework and the technical assessment. These were mostly provided by government and industry submitters and included:

- Comments about different control measures that can be applied during raw milk production and subsequent processing of raw milk products. This includes comments on the efficacy of control measures and clarifying current industry practices.

- Statements to the effect that further research is required on certain aspects of the technical assessment - some of the suggested areas included the effectiveness of on-farm control measures, risks associated with consuming raw goat's milk, expanding the scope of the consumer research and undertaking microbiological risk assessments on milk from other species (sheep, camel and buffalo).

- Objections to raw milk cheeses being included in 'category 3' with raw drinking milk (which these submitters consider to be higher risk).

- Comments on the effect of competitive microflora on inhibiting or eliminating pathogens during cheesemaking.

- Disagreement with the finding that raw milk presents a high risk to public health and safety and suggestions that its safety can be sufficiently ensured by the use of through-chain control measures to prevent contamination of the milk.

FSANZ response: these comments will be taken into account when progressing further work for category 2 products through the proposed separate new Proposal.

Ensuring the safety of raw milk products

Submitters provided information about potential safety hazards in the production and processing of raw milk products, and how these can be managed.

Hazard control measures

The importance of on-farm control measures to ensure the safety of the raw milk was acknowledged. Some of the hazards and control measures discussed included subclinical infection of milking animals, the role of veterinary inspections and microbiological testing of the raw milk. There was also the suggestion that a commercial system be introduced where processors pay more for raw milk shown to be high quality or pathogen free.

Submitters discussed the use of through-chain approaches to assess hazards and apply appropriate control measures, particularly using HACCP Plans or Food Safety Programs. Some submissions stated it is important that FSANZ align the control measures with those specified in the new Specifications for raw milk products in New Zealand[8]. Others highlighted the need to remain consistent with requirements in the Codex Code of Hygienic Practice for Milk and Milk Products or that recommended the through-chain control measures used in the European Union be applied in Australia.

Some comments were provided on whether small businesses or large scale processors would face greater potential safety problems.

Some advocates for raw drinking milk described qualities that render it inherently safe. Several submitters acknowledged that consumers are accessing raw drinking milk. However, these submitters considered that, as there is no evidence that these consumers are getting ill from the milk, it suggests that raw drinking milk is not a high risk product.

Many submitters who support increased permissions for raw milk cheese stated that the control of pathogens relies on the effect of pH, salt concentration, maturation time and competitive microflora.

Microbiological criteria

There was general support for FSANZ to review the current microbiological limits specified in the Code for raw milk products.

[8] www.nzfsa.govt.nz/dairy/publications/specifications/final-raw-milk-spec.pdf

There were different views on whether microbiological criteria should be specified throughout cheese production as control measures and means of enforcement, or whether they be used as a tool for the business to validate the effectiveness of their food safety program and through-chain control measures.

There was concern that the limitations of detection in microbiological testing means that safety cannot be adequately assured for vulnerable persons. It was suggested that the acceptable threshold for microbiological criteria should be based on the infective dose required to cause illness in vulnerable persons.

FSANZ response: these comments will be taken into account when progressing further work for category 2 products through the proposed separate new Proposal.

Implementation practicalities

Many industry and government submissions requested details of how the Standard will be implemented and enforced. There was desire for more information about how different raw milk products will be categorised and who would be responsible for making this assessment. Some submitters want highly prescriptive requirements that specify the products in each category. Others suggested that the Standard should be broad enough to ensure that products with a variety of characteristics are not excluded unintentionally.

Government and industry submitters expressed concern over how the import of raw milk products will be managed. There were suggestions that AQIS will not be able to enforce through-chain control measures and will rely on microbiological criteria alone to ensure the safety of imported products. There was concern that imported cheeses will be less safe as a result, and that this will confer a commercial advantage on imported cheese as they will have to meet fewer regulatory requirements. The traceability of imported cheese was raised as an issue to be addressed.

FSANZ response: FSANZ has noted the additional work required to support implementation of raw milk (category 2) products and will be progressing this through the proposed separate new Proposal.

Costs associated with changing permissions for raw milk products

Costs to governments

It was suggested that state enforcement agencies would incur greater costs of implementing and enforcing new permissions for raw milk products. One agency expects businesses that make raw milk cheeses will experience more food safety incidents which will, in turn, increase the burden on the regulator. It was also suggested that additional training requirements for government staff and auditors will add to this cost.

Several government agencies stated that the administration and enforcement of their food regulations is fully funded by industry. Some stated that they want to ensure that additional regulatory costs are placed on the producers of raw milk products only, and not spread over the whole dairy industry.

Costs to industry

Comments were made that it will be mainly small producers that will want to make raw milk products. A potential producer of raw milk products expressed concern that high compliance costs may prevent small businesses from entering the market. Submitters requested FSANZ estimate the compliance costs to businesses.

Some submitters expressed concern that permitting raw milk products may lead to more frequent outbreaks of foodborne illness and therefore, will damage the reputation of the whole Australian dairy industry and affect the sales of Australian dairy products nationally and internationally.

There were also comments on the potential biosecurity risks from imported products and the damage that an exotic disease could cause to Australia and the domestic dairy industry. Comments were made that testing the imported products may not be sufficient and that there will be additional costs to AQIS for hosting and performing international audits for the purpose of biosecurity or trade facilitation.

Competition from imported products was also highlighted as a potential cost to the Australian industry.

Costs to consumers

Of the consumers that commented on the price they would be willing to pay for raw milk products, the majority indicated they would be willing to pay a premium for good quality raw milk cheeses should costs of ensuring safety of these products be passed on to the consumer. However, some were also wary of unreasonably onerous and costly regulatory requirements.

The majority of consumer respondents indicated they would pay more for raw milk cheeses than they currently pay for pasteurised milk cheeses. The majority also stated they would choose to buy Australian raw milk cheeses over imported products, others would only do so if the Australian product was of greater or equivalent quality.

FSANZ response: changes to the Food Standard Code required to permit category 1 products are minimal and have not required a cost benefit analysis. The proposed separate new Proposal to assess category 2 products will include detailed costings for affected parties and these comments will be take into account in that process.

Skills and knowledge requirements

There were comments made about the likely lack of producer skill level and experience in making raw milk products in Australia, particularly in regard to controlling food safety hazards.

There were some submissions that suggested industry training in safe production of raw milk and raw milk cheeses should be facilitated and that competency requirements be included as part of producer/processor accreditations. It was also suggested that on-going support and guidance from government agencies would be required. It was noted in one submission that international training would be required.

FSANZ response: Additional skills and knowledge requirements for raw milk production and processing will be required. These will be considered further in the proposed separate new Proposal for assessment of category 2 products.

Black market sales of raw drinking milk

Many submitters acknowledged that there is a growing public interest in accessing and consuming raw drinking milk. Some individuals indicated that they were accessing illegal or ‘black-market’ raw cows’ milk for drinking. Others stated they were buying ‘cosmetic’ or ‘pet food’ raw milk that is labelled as ‘not for human consumption’ because it was not possible to obtain supplies legally.

Some government and industry submissions expressed concern that if raw goat milk is banned in those four States that currently permit it, it will lead to increased black market sales.

A concern was also expressed that any increase in permissions for raw milk cheeses could lead to black market sales of the raw milk intended for cheese production.

FSANZ response: There is no evidence to suggest that regulating a raw milk supply for processing will result in increased black market sales. The drinking of raw milk is inherently risky, particularly for vulnerable groups such as young children and pregnant women and FSANZ will continue to communicate this risk.

Labelling and consumer education

Government, industry and consumers presented mixed views on whether raw milk products need to be labelled and what labels should say.

Many submitters made claims that if raw milk products are labelled and consumers are educated about the risks, then the products pose less of a food safety risk. As such, if raw milk products are to be allowed it was suggested there must be an accompanying consumer education campaign.

Labelling was also raised by many as a necessary control measure to protect vulnerable persons. Conversely, one submission presented the argument that labelling has not been shown to be an effective risk management tool and suggested that if it is to be used as such, efficacy data should be provided in the 2nd Assessment Report.

There were statements made that specialist cheese retailers provide more consumer education than supermarkets and, therefore, sales from these outlets pose a lower safety risk.

FSANZ response: the use of labelling as a risk management measure will be assessed further in the proposed separate new Proposal for raw milk (category 2) products. These comments will be taken into account in that process.

Consumer support for access to raw milk products

The majority of submissions were from consumers who want access to raw milk products, particularly raw milk cheeses. Most of these submissions used a form letter which stated that the safety risk of raw milk cheeses was exaggerated by FSANZ in the 1st Assessment Report. These submitters also provided their individual views about the superior organoleptic qualities of raw milk cheeses compared with their pasteurised equivalents. There was consensus amongst these submitters that Australian consumers would benefit from increased permission for locally produced and imported raw milk cheeses. Many also highlighted that there is a growing consumer interest in these cheeses and that the Australian dairy industry would benefit from being able to access this market.

Submissions in support of raw drinking milk were primarily driven by health reasons, stating that raw milk is more nutritious and provides other additional health benefits. Reasons for supporting access to raw drinking milk also included taste, quality and the freedom or right to choose this product.

Individuals supporting increased permission for raw drinking milk noted there is a growing consumer demand for the product. Ten individuals indicated that they currently consume raw drinking milk, including one which specified that they buy raw goats' milk.

FSANZ response: The drinking of raw milk is inherently risky, particularly for vulnerable groups such as young children and pregnant women and FSANZ will continue to communicate this risk. Current permissions that allow for raw goat milk to be produced and sold in four jurisdictions will be assessed further in the proposed separate new Proposal for raw milk (category 2) products.

References and data provided in submissions

Many submissions provided data and/or suggested references to support some of their comments.

FSANZ response: much of the additional data or references provided related to category 2 and 3 raw milk products. This will be taken into account when FSANZ progresses the proposed separate new proposal for raw milk (category 2) products.