

## 8 November 2013 [21-13]

## **Call for submissions – Proposal P1022**

## Primary Production & Processing Requirements for Raw Milk Products

FSANZ has assessed a Proposal to consider permissions for the production and sale of raw milk products. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the Proposal.

For information about making a submission, visit the FSANZ website at information for submitters

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at <u>information for submitters</u>.

Submissions should be made in writing; be marked clearly 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 via the link on <u>documents for public comment</u>. You can also email your submission directly to <u>submissions@foodstandards.gov.au</u>.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

## DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 January 2014

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

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 +61 2 6271 2222 Food Standards Australia New Zealand PO Box 10559 The Terrace WELLINGTON 6143 NEW ZEALAND Tel +64 4 978 5630

## Table of Contents

EXECUTIVE SUMMARY					
1	INTF	RODUCTION			
	1.1 1.2 1.3 1.4	THE PROPOSAL	1 1		
2	SUM	IMARY OF THE ASSESSMENT	;		
	2.1 2.2 2.3	SUMMARY OF ISSUES RAISED IN SUBMISSIONS FOR P1007	5		
	2.3.1	1 Risk management options	7		
	2.3.2 2.4 2.4.1 2.4.2 2.5 2.5.1 2.5.2	RISK COMMUNICATION 10   1 Previous consultation 10   2 World Trade Organization (WTO) 10   2 FSANZ ACT ASSESSMENT REQUIREMENTS 10   1 Section 59 10   2 Subsection 18(1) 12	) ) ) ) 2		
3.	2.5.3 DEE	3 Subsection 18(2) considerations			
J.					

#### Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at <a href="http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1022primary5627.aspx">http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1022primary5627.aspx</a>

- SD1 Guide to the requirements for raw milk products in Standard 4.2.4 Primary Production and Processing Standard for Dairy Products.
- SD2 Guide to the Validation of Raw Milk Products
- SD3 Scientific information for the assessment of raw milk products Cheeses

## **Executive summary**

Proposal P1022 has been prepared to assess additional requirements for the safe production of raw milk products where it can be demonstrated:

- that the intrinsic physico-chemical characteristics of the raw milk product do not support the growth of pathogens, and
- there is no net increase in pathogen levels during processing.

This Proposal follows on from Proposal P1007 (Primary Production and Processing Requirements for Raw Milk Products), which established a risk-based category approach to assess permissions for raw milk products.

P1007 concluded that raw milk products could be processed with an acceptable level of public health risk where there are combinations of specific production and processing controls in place. P1007 also identified additional through-chain control requirements for raw milk products.

The current requirements prescribed for dairy businesses in Standard 4.2.4 provide a baseline set of regulatory measures upon which the additional requirements for raw milk products can be built. This includes:

- the requirement for a documented food safety program for primary production, transport and processing businesses;
- specific control measures that must be included in the food safety program; and
- specified processing measures (e.g. pasteurisation or equivalent processes).

Two options are being considered under Proposal P1022:

- Option 1 prepare a draft variation to Standard 4.2.4 to permit raw milk products where the abovementioned safety outcomes can be demonstrated.
- Option 2 Status quo. This means the proposal would be abandoned and no amendments made to Standard 4.2.4 through this process.

Under option 1, the additional requirements would be included in the *Australia New Zealand Food Standards Code* (the Code). and supported by guidance materials, including validation guidance.

During the assessment of P1007, it had also been identified that there was a need for guidance materials to assist industry and enforcement agencies implement additional requirements for raw milk products. FSANZ has therefore prepared two draft guidance documents:

- Guide to the requirements for raw milk products in Standard 4.2.4 Primary Production and Processing Standard for Dairy Products (SD1)
- Validation of Raw Milk Products (SD2)

FSANZ has also prepared SD3 (Scientific information for the assessment of raw milk products – Cheeses) to assist industry and enforcement agencies in relation to the data requirements for validating the outcomes required for raw milk products. FSANZ welcomes comment on these draft documents as part of this first round of public consultation on P1022.

# 1 Introduction

## 1.1 The Proposal

Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products was developed through assessment of Proposal P296 and took effect on 5 October 2008. This Standard provides the through-chain framework to consider permissions for raw milk products<sup>1</sup>.

Standard 4.2.4 was amended in June 2012 to permit raw milk products for which the properties and/or processing factors eliminate pathogens that may have been present in the raw milk. These amendments were the result of Proposal P1007 - Primary Production & Processing Requirements for Raw Milk Products.

FSANZ established a risk-based category approach to assess permissions for raw milk products under P1007. That proposal and approach identified three categories for assessment and defined them in terms of the effect processing factors and product properties of the final product have on pathogen survival and growth:

- Category 1 products are 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 those products for which the properties and/or processing factors may allow 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 those products for which the intrinsic properties 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.

Proposal P1007 concluded that, for category 1 and 2 products, there are combinations of specific production and processing controls that can 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.

The scope of Proposal P1007 was limited to category 1 products only during its assessment. This was to allow for a separate process to assess category 2 products and to provide further time to develop guidance materials to support the additional control measures that would be required.

Category 3 products, in particular raw drinking milk, have previously been assessed as presenting too high a risk to be permitted through amendments to the *Australia New Zealand Food Standards Code* (the Code). The Approval Report for P1007 did state that the exemption in Standard 4.2.4 that allows for State or Territory laws to provide otherwise in relation to pasteurised milk would be further considered. FSANZ has given this matter further consideration and concluded that the exemption will not be assessed by FSANZ at this stage. State and Territory laws will continue to provide for the sale of unpasteurised milk.

Proposal P1022 has been prepared to assess raw milk products that meet the additional requirements for previously defined category 2 products.

<sup>&</sup>lt;sup>1</sup> Raw milk products are dairy products that have not been processed in accordance with clauses 15 and 16 of Standard 4.2.4.

## 1.2 The current Standard

Standard 4.2.4 sets out food safety requirements for the primary production, collection, transportation and processing of dairy products. Processing requirements currently require pasteurisation (or an equivalent process) of milk and dairy products under clause 15. Alternative processing requirements to pasteurisation are permitted for cheeses under clause 16, including curd cooking in combination with ripening and minimum moisture content (minimum heating temperature of 48°C; minimum storage time of 120 days; minimum moisture content of 39%). Standard 4.2.4A permits the sale of raw milk Roquefort cheese produced in accordance with French Ministerial Orders.

An amendment to Standard 4.2.4 would be required to prescribe additional requirements for raw milk production, collection, transport and processing for raw milk product manufacture for products not processed in accordance with clauses 15 and 16. Documented food safety programs of dairy primary production businesses that produce milk for raw milk products; dairy transport businesses that collect and transport milk for raw milk products; and dairy processing businesses that process milk for raw milk products, would need to include control measures ensuring all additional requirements are met.

## **1.3** Reasons for preparing the Proposal

The processing requirements currently mandated for milk and dairy products in Standard 4.2.4 prescribe processing and/or production measures that must be used for milk and dairy processing which restrict the use of raw milk. Permissions for specific raw milk cheeses, such as Roquefort, have been included in Standard 4.2.4A as a result of an application process.

The development of through-chain requirements in Standard 4.2.4 and the risk management approach for raw milk products that was established under P1007 provide a framework in which general permissions for raw milk products can be assessed. This approach:

- eliminates the need for a product-by-product assessment by FSANZ
- recognises consumer demand for raw milk products
- supports an efficient and competitive food industry.

P1022 has been prepared to assess additional requirements for the safe production of raw milk products and the amendments to the Code needed to support this.

## **1.4 Procedure for assessment**

The Proposal is being assessed under the Major Procedure set out in Division 2 of Part 3 of the FSANZ Act.

The FSANZ Act requires FSANZ to assess Proposal P1022 in accordance with section 59 of that Act, after which it must seek public submissions before making a decision on whether to abandon the Proposal or to prepare a draft variation to the Code to implement it. A further round of consultation will occur in the event that a draft variation is prepared.

This assessment summary presents the first opportunity for interested parties to provide comment and additional information.

## 2 Summary of the assessment

## 2.1 Summary of issues raised in submissions for P1007

Submissions received in response to the 1<sup>st</sup> Assessment report for P1007 identified issues relating to category 2 products. The 2<sup>nd</sup> Assessment Report for P1007 stated that these would be considered in a new proposal (now P1022). A broad summary of these issues is provided in Table 1.

## 2.2 Risk assessment

In assessing P1007, FSANZ prepared three risk assessments to generate information on the public health risks which may be associated with raw milk products:

- The <u>Microbiological Risk Assessment of Raw Milk Cheese</u> (FSANZ 2009a) was 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.
- The <u>Microbiological Risk Assessment of Raw Goat Milk</u> (FSANZ 2009b) and <u>Microbiological Risk Assessment of Raw Cow Milk</u> (FSANZ 2009c) highlighted the milk production factors that affect the prevalence of pathogens in raw milk as well as the risks associated with consumption of raw drinking milk.

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). The quantitative modelling in the exposure assessment component indicated the importance of pH and salt in moisture parameters in determining whether pathogens survive or grow and, therefore, the level of risk presented. The potential control measures for raw milk cheese identified in the risk assessment included:

- rapid acidification of raw milk by lactic acid producing starter cultures, and
- the combination of pH and salt-in-moisture phase of cheeses during maturation/ripening to prevent the growth of pathogenic microorganisms.

The probabilistic modelling undertaken for the *Microbiological Risk Assessment of Raw Cow Milk* indicated that even when there is low pathogen prevalence in the dairy herd and a low level of bulk milk contamination (below the level of detection), cases of illness from *Campylobacter* spp., enterohaemorrhagic *E. coli* (EHEC), *Salmonella* spp. and *L. monocytogenes* can be expected. The severity of illness that results from EHEC infection is a significant contributor to the high level of risk associated with category 3 products, in particular raw drinking milk.

## Table 1: Summary of issues

Issue	Comments	FSANZ Response
Sale of raw goat milk	Many submissions provided during the assessment of P1007 were from consumers in support of access to raw drinking milk. In the approval report for P1007 FSANZ stated that it would further assess the current exemption in subclause 15(1) allowing the laws of States and Territories to provide otherwise in relation to pasteurised milk.	FSANZ will not be considering the exemption allowing the laws of States and Territories to provide otherwise in relation to pasteurised milk under P1022. This remains a State and Territory issue.
Additional detail on the measures to be specified for raw milk products	Submissions from enforcement agencies, in particular, raised the need for additional information around the proposed control measures for raw milk products so that it could be clearly understood what outcomes were required and how these could be monitored and verified. This would assist implementation.	FSANZ has developed and is seeking comment on a draft guidance document on the measures proposed for raw milk products.
Microbiological criteria	Submissions from government agencies, industry and consumers raised the need to amend the microbiological standards in Standard 1.6.1 to reflect the approach that has been taken. The current <i>E. coli</i> limit in cheese was highlighted as too onerous and inconsistent with international standards.	Amendments to Standard 1.6.1 to set appropriate limits for raw milk products will be progressed through P1022.
	In addition to limits in Standard 1.6.1, submissions from government and industry recommended that microbiological criteria for testing raw milk (at primary production) and finished product is needed.	FSANZ has developed and is seeking comment on a draft guidance document that includes criteria for monitoring and verification purposes.
Imported products	The need for clearly defined and verifiable processes to manage the risks from imported raw milk products was raised.	FSANZ will work closely with the Department of Agriculture to inform the risk management approach to be applied to imported products. This approach will be outlined in the 2 <sup>nd</sup> call for submissions report.

## 2.3 Risk management

#### 2.3.1 Risk management options

Two options are being considered under Proposal P1022:

- Option 1 prepare a draft variation to Standard 4.2.4 to permit raw milk products where it can be demonstrated:
  - that the intrinsic physico-chemical characteristics of the raw milk product do not support the growth of pathogens, and
  - there is no net increase in pathogen levels during processing;
- Option 2 status quo. This means the proposal would be abandoned and no amendments made to Standard 4.2.4 through this process. FSANZ would then need to individually assess applications currently on the FSANZ Work Plan relating to raw milk cheeses (Applications A5302 and A5313).

### 2.3.2 Risk management approach under option 1

The current requirements prescribed for dairy businesses in Standard 4.2.4 provide a baseline set of regulatory measures upon which additional requirements for raw milk products can be built. This includes:

- the requirement for a documented food safety program for primary production, transport and processing businesses
- specific control measures that must be included in the food safety program
- specified processing measures (e.g. pasteurisation or equivalent processes).

The current requirements are implemented and enforced through state and territory laws, including Food Acts and regulations.

Additional through-chain control measures for raw milk products were identified through the assessment of P1007. These measures are highlighted in the SD1. Under option 1, the additional measures for raw milk products would be included in Standard 4.2.4 and supported by guidance materials, including validation guidance. A schematic representation of this approach is provided in Figure 1.

<sup>&</sup>lt;sup>2</sup> Application A530 seeks an amendment to the Code to permit the sale of the raw milk cheeses KEENS FARM CHEDDAR and MONTGOMERY CHEDDAR (products of Britain)

<sup>&</sup>lt;sup>3</sup> Application A531 – Use of Raw Milk in Cheese Production – 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.

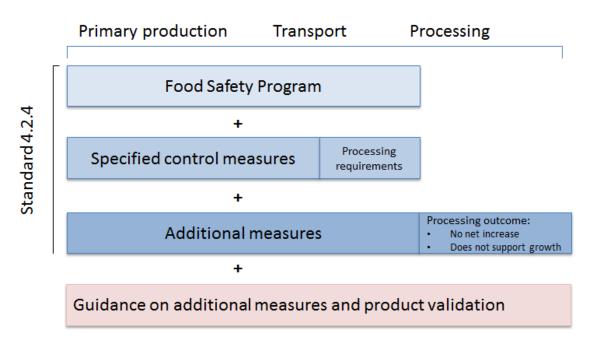


Figure 1: Schematic representation of the risk management approach for raw milk products

It should also be noted that a proposal assessing limits for *Listeria monocytogenes* in ready-to-eat foods, P1017, proposes to establish criteria based on whether the ready-to-eat food can support the growth of *L. monocytogenes* or not.

### 2.3.2.1 Standard 4.2.4

The approach proposed under option 1 could be delivered through the following amendments to Standard 4.2.4:

- Clarify that existing measures under Divisions 2, 3 and 4 of Standard 4.2.4 apply and provide the basis for additional requirements for raw milk products.
- Include a new division to the Standard that would set out additional requirements for primary production, transport and processing for raw milk products. These requirements would reflect the additional measures that have been identified for the safe production of raw milk products.
- Prescribe the processing outcome to be met for raw milk products (i.e. no net increase of pathogens during processing and no growth in the final product). Under food safety program obligations, businesses would need to be able to validate and verify that the process used and final product meets the outcome required.

## 2.3.2.2 Labelling

Generic labelling provisions are provided in the Code to protect the health and safety of consumers and to provide adequate information to enable consumers to make informed choices. Existing generic labelling requirements in Part 1.2 of the Code will apply to raw milk products, including:

- name of the food (Standard 1.2.2), sufficient to indicate the true nature of the food
- mandatory warning and advisory statements (Standard 1.2.3)
- labelling of ingredients (Standard 1.2.4), using either the common name, or a name that describes the true nature of the ingredient, or a generic name (where applicable)

- date marking (Standard 1.2.5)
- directions for use and storage (Standard 1.2.6).

There are some exemptions to these generic labelling requirements, as set out in Standard 1.2.1. For example, raw milk products that are packaged in the presence of the purchaser, or packaged and displayed in an assisted service display cabinet, are not required to bear a label setting out all the information prescribed in the Code. In these instances, certain information, such as the name of the food and allergen declarations, is required to be declared on or in connection with the food, or provided to the purchaser upon request.

As the outcome of P1007 was that raw milk products meeting category 2 requirements pose a low risk, FSANZ considers the existing generic labelling requirements in Part 1.2 of the Code are appropriate for raw milk products, as for example, is currently in place for raw milk Roquefort cheese. Manufacturers will not, however, be precluded from providing further voluntary information on raw milk products, should they choose to do so.

#### 2.3.2.3 Standard 1.6.1

Existing ad hoc limits for unpasteurised/raw milk products (e.g. butter and raw milk cheese varieties) in Standard 1.6.1 can be replaced with a single set of limits for 'raw milk products'. It is proposed that sampling plans are established for:

- Salmonella
- Staphylococcal enterotoxin.

Limits for *Listeria monocytogenes* would also apply as an outcome of P1017 – Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods<sup>4</sup>. P1022 will also assess the current limit for *Escherichia coli* in cheese. This will be in line with a wider review of the microbiological limits in Standard 1.6.1, particularly the role of indicator and index (or model) microorganisms.

Additional microbiological criteria for monitoring and verification purposes for raw milk products are being developed and are incorporated in SD1.

### 2.3.2.4 Supporting guidance and information

During the assessment of P1007, it was identified that there was a need for guidance to be developed to assist implementation of additional requirements for raw milk products. To accompany P1022, FSANZ has developed a guidance document, Guide to the requirements for raw milk products in Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products (SD1). FSANZ welcomes comment on this draft document as part of this first round of public consultation on P1022.

In addition, a validation guide has been developed to assist processors and enforcement agencies with information requirements for the validation of raw milk products. The Guide to the Validation of Raw Milk Products is provided as SD2.

To help inform data requirements for validating the outcomes required for raw milk products, FSANZ has also prepared a report, Scientific information for the assessment of raw milk products – Cheeses (SD3). The scientific assessment includes consideration of:

- physico-chemical characteristics of retail cheeses
- the utility of predictive equations to determine the likelihood of pathogen growth

<sup>&</sup>lt;sup>4</sup> <u>http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1017criteri5439.aspx</u>

- milk and cheese challenge studies to determine the behaviour of pathogens during production and maturation
- information required to demonstrate no net increase in pathogen levels.

## 2.4 Risk communication

All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are notified about the availability of reports for public comment.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation to the Code. FSANZ places all related Proposal documents and submissions on the FSANZ website. All public comments received are reviewed and considered before approval of a variation to the Code by the FSANZ Board.

### 2.4.1 Previous consultation

Targeted consultations were also 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.

A Standard Development Committee (SDC), consisting of industry representatives, government regulators and consumers, is assisting and advising on the standard development process for raw milk products. Additionally, a Technical Working Group is providing advice on the guideline documents.

### 2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged 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 at the next stage of the assessment and, if necessary, notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on any proposed amendments.

## 2.5 FSANZ Act assessment requirements

### 2.5.1 Section 59

When assessing P1022 and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act.

### 2.5.1.1 Cost benefit analysis

In assessing Proposals such as P1022, FSANZ is required to have regard to whether the costs that would arise from a proposed measure outweigh the direct or indirect benefits of the proposed measure.

The Office of Best Practice Regulation (OBPR) has advised FSANZ that, at this stage, a detailed analysis of non-regulatory and regulatory options is not required for P1022.

However, a basic cost benefit analysis has been undertaken (see below). This is not intended to be an exhaustive, quantitative dollar analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value.

The points below list the effect that a draft variation required for option 1 would be expected to have on various sectors.

- *Consumers:* Increased choice and a broader availability of food products, including imported products from overseas. Labelling of products in accordance with the Code would allow consumers wishing to avoid raw milk products to do so.
- *Government:* Option 1 is deregulatory in that it would remove the need for industry to lodge applications to amend the Code to permit the sale of certain raw milk products.

A variation would result in additional monitoring and compliance costs to Government. However, OBPR advice is that, based on New Zealand experience, the raw milk products permitted by such a variation would be a niche component of the market and few businesses would be likely to produce them.

*Industry:* Current dairy producers and processors, businesses looking to enter a raw milk products industry, importers and retailers would benefit from a greater range of safe raw milk products compliant with the Code, allowing broader market access.

The above suggests that the potential benefits of approving a variation outweigh the potential costs. The above also suggests that the potential costs of option 2 (abandoning the proposal) outweigh the potential benefits.

#### 2.5.1.2 Other measures

At this stage, FSANZ considers that there are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

Standard 4.2.4 prescribes milk production, transport and processing measures that must be used for milk and dairy processing which restrict the use of raw milk. An amendment to the Standard is needed to change current requirements. The proposed approach is consistent with regulatory requirements in other countries where raw milk products are permitted.

#### 2.5.1.3 Any relevant New Zealand standards

Standard 4.2.4 is an Australia-only standard.

New Zealand has its own food safety legislation for food businesses and primary producers which is developed by the Ministry for Primary Industries (MPI). New Zealand introduced new regulations that allow for production and importation of raw milk products in 2009.

FSANZ has consulted with New Zealand on the approach taken by each country and the category approach developed under P1007 is consistent with New Zealand.

## 2.5.1.4 Any other relevant matters

Draft guidance materials have been prepared with a view to assisting industry and enforcement agencies. These are provided for comment and to support the assessment of this Proposal.

## 2.5.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

## 2.5.2.1 Protection of public health and safety

The assessment framework developed under P1007 defined three categories of products based on the effect processing factors and product properties of the final product have on pathogen survival and growth. In arriving at its risk management decision in P1007, FSANZ considered the level of risk associated with each category and whether the control measures required for the safe production could be implemented and verified. Category 1 products presented a negligible to low risk and were permitted through amendments to Standard 4.2.4 under P1007. Category 2 products present a low risk when additional through-chain controls and food safety outcomes are met (see option 1 above). Category 3 products present too high a risk to be permitted through changes to the Code.

The additional control measures and systems required to implement the safe production of category 2 raw milk products are being progressed through P1022. See in this regard, option 1 as described above and the draft guidance materials.

# 2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

FSANZ considers that the existing generic labelling requirements in Part 1.2 of the Code provide adequate information about raw milk products to enable consumers to make informed choices. Manufacturers will also not be precluded from providing further voluntary information on raw milk products.

### 2.5.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

### 2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

# • the need for standards to be based on risk analysis using the best available scientific evidence

FSANZ prepared three risk assessments which informed the risk management framework for assessment (category approach) and determined the level of risk that different categories of raw milk products pose under certain production and processing controls. These were developed using the best scientific evidence available.

# • the promotion of consistency between domestic and international food standards

In assessing P1022, and in developing the two options described above, FSANZ has had regard to the Codex *Code of Hygienic Practice for Milk and Milk Products* CAC/RCP 57-2004 and requirements of the European Commission (EC) sanitary and food hygiene regulations which underpin existing permissions in the Code for French Roquefort. FSANZ has also collaborated with New Zealand to provide a consistent regulatory approach to raw milk products sold in Australia and New Zealand.

## • the desirability of an efficient and internationally competitive food industry

Several imported raw milk cheeses had previously been assessed by FSANZ and permitted in the Code. This raised the issue of an unlevel playing field as domestic production of such cheeses was not permitted. An outcome from P1007 was amendments to the processing requirements in Standard 4.2.4 (for raw milk hard cooked curd cheeses) that apply equally to domestically produced and imported products. P1022 will assess further the through-chain requirements required for additional raw milk products.

### • the promotion of fair trading in food

Consideration of notification to the WTO will be made in accordance with the WTO TBT or SPS Agreements at the next stage of assessment.

## • any written policy guidelines formulated by the Ministerial Council<sup>5</sup>.

The Australia and New Zealand Food Regulation Ministerial Council developed an *Overarching Policy Guideline on Primary Production and Processing Standards*<sup>6</sup>. FSANZ has had regard to the policy guidance and higher order principles in these guidelines.

## 3. References

FSANZ (2009a). *Microbiological Risk Assessment of Raw Milk Cheeses*. <u>http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1007primary3953.aspx</u>

FSANZ. (2009b). *Microbiological Risk Assessment of Raw Goat Milk*. <u>http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1007primary3953.aspx</u>

FSANZ. (2009c). Micorbiological Risk Assessment of Raw Cow Milk. http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1007primary3953.aspx

<sup>&</sup>lt;sup>5</sup> Now known as the COAG Legislative and Governance Forum on Food Regulation

<sup>&</sup>lt;sup>6</sup> The Policy Guideline is available at

http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policy-guidelines#11