

**10 July 2014**  
**[13–14]**

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

### **Primary Production & Processing Requirements for Raw Milk Products**

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Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist FSANZ's consideration of the draft food regulatory measure it has prepared arising from a proposal to consider permissions for the production and sale of raw milk products

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 [information for submitters](#).

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 [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

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) 21 August 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](mailto:standards.management@foodstandards.gov.au).

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## Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at

<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1022primary5627.aspx>

- 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 milk production, transport and processing 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.

Raw milk products are dairy products made with raw milk, but do not include milk. Consideration of the production and sale of raw drinking milk is not within the scope of this proposal.

FSANZ is consulting on draft variations to standards 4.2.4 – Primary Production and Processing Standard for Dairy Products, 4.2.4A – Primary Production and Processing Standard for Specific Cheeses and 1.6.1 – Microbiological Limits). Standards 4.2.4 and 4.2.4A do not apply in New Zealand.

This assessment has had regard to submissions received on the 1<sup>st</sup> Call for Submissions and the scientific assessment undertaken for raw milk products.

The current measures specified in standard 4.2.4 for dairy primary production, transport and processing provide the baseline set of requirements (food safety program, specified processing measures/outcomes at manufacture). Additional requirements for primary production, transport and processing of milk for raw milk products are included in a new division of Standard 4.2.4. These measures are specified under subdivisions for each stage of production.

FSANZ is proposing to repeal Standard 4.2.4A as the requirements for Roquefort cheese are now subsumed by the draft variations to Standard 4.2.4.

The draft variation to Standard 1.6.1 will replace existing limits for “butter made from unpasteurised milk”, “all raw milk cheese” and “raw milk unripened cheese” with limits for the single food category “raw milk products”. Microbiological limits for raw milk products include *Salmonella* and Staphylococcal enterotoxin.

Limits for *Listeria monocytogenes* will also apply to raw milk products (as a ready-to-eat food) following gazettal of amendments to Standard 1.6.1 arising from Proposal P1017.

FSANZ has prepared two draft guidance documents to support the draft variations:

- 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 also prepared SD3 (Scientific information for the assessment of raw milk products – Cheeses) to assist industry and enforcement agencies in relation to the scientific information for validating the outcomes required for raw milk products. FSANZ is seeking comment in relation to the value in development of a predictive or other tool(s) and potential process and resources available.

# 1 Introduction

## 1.1 The Proposal

FSANZ established a risk-based category approach to assess permissions for raw milk products<sup>1</sup> under Proposal P1007 – Primary Production & Processing Requirements for Raw Milk Products. That Proposal 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.

P1007 concluded that, for category 1 and 2 products, there are combinations of specific production and processing controls that can achieve a product with an acceptable level of public health risk. However, FSANZ identified that additional guidance materials would need to be developed to support the permissions for category 2 products and therefore limited the scope of P1007 to assessment of category 1 products only.

Proposal P1022 has been prepared to assess additional requirements for milk production, transport and processing 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.

Category 3 products, in particular raw drinking milk, were assessed as presenting too high a risk to be permitted through amendments to the *Australia New Zealand Food Standards Code* (the Code). The Code requires that milk is pasteurised or equivalently processed to eliminate pathogenic bacteria that may be present. There is an exemption to this processing requirement that allows for state and territory legislation to regulate and permit the sale of raw drinking milk. No states currently have legislated to allow for raw cow milk to be sold, however raw goat milk is permitted for sale in four states: Queensland, New South Wales, South Australia and Western Australia. States and territories will continue to have scope to allow for the sale of unpasteurised milk.

A Standard Development Committee (SDC) was established in the early stages of work considering raw milk products (commencing with P1007) and has continued to provide advice to FSANZ on P1022.

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<sup>1</sup> Raw milk products are those manufactured without pasteurisation or an equivalent treatment

## **1.2 The current Standards**

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. Under clause 16, alternatives to pasteurisation are permitted for:

- cheeses 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%); and
- raw milk Roquefort cheese manufactured in accordance with French Ministerial Orders.

Standards 4.2.4 and 4.2.4A do not apply in New Zealand.

Microbiological limits for some unpasteurised dairy products are currently specified in Standard 1.6.1.

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

The risk management approach for raw milk products that was developed under P1007 established a framework in which generic permissions for raw milk products could be included in Standard 4.2.4 that would eliminate the need for a product-by-product assessment by FSANZ.

P1022 has been prepared to assess additional requirements for the safe production of raw milk products and the amendments to the relevant standards in the Code needed to support this. The standards are the Australia only Standards 4.2.4 and 4.2.4A and Standard 1.6.1 which applies in Australia and New Zealand.

## **1.4 Procedure for assessment**

The Proposal is being assessed under the Major Procedure.

# **2 Summary of the assessment**

## **2.1 Summary of issues raised in submissions**

Two options were posed for consultation in the 1<sup>st</sup> call for submissions:

- 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 would have meant the proposal would be abandoned and no amendments made to Standard 4.2.4. FSANZ would need to assess applications currently on the FSANZ Work Plan relating to raw milk cheeses (Applications A530 and A531).

The 1<sup>st</sup> call for submissions was released for public comment from 8 November 2013 to 10 January 2014. A total of 34 submissions was received with 21 of these relevant to the scope of the Proposal. The majority of these submissions (16) supported option 1 i.e. prepare a draft variation to Standard 4.2.4 to permit raw milk products where specific safety outcomes can be demonstrated.

An additional 13 submissions were from consumers seeking access to raw drinking milk and from primary producers wanting the ability for the farmer to be able to sell raw drinking milk direct to the consumer, with appropriate regulations in place. Consideration of the production and sale of raw drinking milk is not within the scope of this Proposal.

Submissions focussed on two main issues:

- the need for guidance material for enforcement agencies and industry, particularly in relation to validation
- the importance of managing imported products

### **2.1.1 Guidance material**

In regard to guidance material and resources, submitters raised the following concerns:

- Small-scale artisan producers are more likely to want to make raw milk cheeses compared to industrial producers in Australia and access to the necessary scientific and technical resources to meet validation requirements is critical.
- There is a need for national training for regulators to ensure monitoring of businesses is undertaken in a consistent manner.

FSANZ prepared two draft guidance documents to support the assessment of P1022:

- 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).

To highlight the scientific information which may be used 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
- 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.

Submitters stated that the additional guidance provided was appropriate and useful and provided technical comments to inform further changes and inclusions needed in these guidance documents. It was queried whether further work may be required to enable this information to be implemented. The SDC discussed how it would be useful to collaborate on the development of a predictive tool to screen cheeses for their ability to support growth of *L. monocytogenes* based on product pH and water activity to identify whether and what further validation may be required.

In a submission from the Centre National Interprofessionnel de l'économie laitière (Cniel), two main toolkits available to the French dairy sector were described. These include a statistical toolkit using analytical test results and a set of stochastic Quantitative Microbiological Risk Assessment models. The development of the software Sym'previus provides a web-based interface to test predictive microbiological models:

[http://www.symprevius.net/index.php?vrs=sym\\_previus\\_predictive\\_microbiology](http://www.symprevius.net/index.php?vrs=sym_previus_predictive_microbiology).

Noting that as there may already be resources available, FSANZ is seeking comment in relation to the value in development of a predictive or other tool(s) and potential process and resources available.

### **2.1.2 Management of imports**

Submitters raised the need for a high level of assurance that imported product has been manufactured under production and processing controls that ensure public health and safety.

There are two aspects to managing raw milk products at the border:

- the rate of referral for inspection, and
- the means of demonstrating assurance that product has been produced under conditions at least equivalent to domestic requirements.

FSANZ will provide assessment advice to the Department of Agriculture on whether imported raw milk products present a medium or high risk to public health.

The Department of Agriculture will use this assessment to inform their risk management approach under the Imported Food Inspection Scheme. It should be noted that border actions may not be finalised for implementation at the time of gazettal of the amended Standard, if approved.

Where relevant, the submissions and responses have been discussed in the body of this report and a summary of all of the submissions and the responses is provided in Table 1.

**Table 1: Summary of issues**

Issue	Raised by	FSANZ response
<b>Application to imported products</b>	Many submissions raised the importance of ensuring imported products are compliant	FSANZ will provide the Department of Agriculture with detailed advice in relation to imported raw milk products. This information will be documented as a Risk Statement, including identifying the pathogens of concern and the level of public health risk.
<b>Guidance and resources</b>	Submissions highlighted the need for guidance material for both enforcement agencies and industry, particularly in relation to validation.	As discussed above under Section 2.1, FSANZ will investigate the feasibility of, and process for, developing a predictive tool.
<b>Scope</b>	A submission queried whether raw milk products other than raw milk cheese will be permitted under P1022 (e.g. butter)	The proposed definition of “raw milk product” limits the scope of products to cheese or a cultured or fermented dairy product which has been made using raw milk.
<b>Microbiological limits</b>	<p>A submission raised the potential inconsistency between limits for Lm in ready-to-eat foods (Proposal P1017) and proposed guidance for raw milk products specifying absence of Lm in raw milk products.</p> <p>Additionally it has been raised whether criteria for monitoring and verification purposes (contained in the guidance document) should be included in Standard 4.2.4.</p> <p>It was noted that the <i>E. coli</i> limit in cheese, while it should be assessed, is broader than just raw milk products and is included in a joint Australia New Zealand standard. As such, it should not be within the scope of this proposal.</p>	<p>A separate limit for <i>L. monocytogenes</i> in raw milk products will not be set in standard 1.6.1 – these products will be covered by the limits included for RTE foods under proposal P1017. In relation to specifying the “absence” of <i>L. monocytogenes</i>, such a criterion would be appropriate to apply during production (process hygiene criteria) as part of verification.</p> <p>Food safety criteria (applicable to product for sale) will be included in Standard 1.6.1. These limits are consistent with the food safety criteria established in the New Zealand <i>Animal Products (Raw Milk Products s Specifications) Notice 2009</i>. The guidance document includes additional criteria for monitoring and verification purposes (both for raw milk production and for processing) which should be considered within a businesses’ food safety program as appropriate/applicable.</p> <p>It is intended that the existing <i>E. coli</i> limit for “all cheese” will now be addressed through a separate proposal to be raised in the latter half of 2014.</p>

Issue	Raised by	FSANZ response
<b>Cost-benefit analysis</b>	Some government submissions raised that costs to small business associated with validation and costs to government of monitoring and verification activities should be considered. A jurisdiction suggested a regulation impact analysis could be useful.	<p>This issue was explored further with government agencies noting the different levels of concern regarding potential costs ranged from minimal impost (as there is already a structure in place for dairy products currently permitted to be produced) to significant concerns over the cost impost to the regulator resulting from the potential demand from individual small businesses for on-going advisory services to assist them in establishing the required robust systems. FSANZ developed the guidance material as part of P1022 to reduce potential resource implications for government agencies and also notes government's ability to cost recover some or all of these costs from industry to ensure the costs are appropriately borne by those who hope to benefit financially from making these products.</p> <p>The Office of Best Practice Regulation (OBPR) has previously advised FSANZ that a regulation impact statement is not required because:</p> <ul style="list-style-type: none"> <li>• the exemptions on raw goat milk products will not be altered;</li> <li>• based on FSANZ's review of alternative regulatory arrangements for raw milk products, it is not viable to adopt a less restrictive approach to risk mitigation ;</li> <li>• given the New Zealand experience, and the characteristics of the Australian market for milk products, few, if any, suppliers are likely to produce products under the standards; and</li> <li>• any increased imports of raw milk products as a result of the standard are very likely to remain a niche component of the Australian market.</li> </ul> <p>The OBPR recognised that the measures to be specified in Standard 4.2.4 to allow for raw milk product manufacture are consistent with requirements imposed internationally where raw milk products are permitted and are required to support safe production. The uptake by business would be part of a voluntary business decision to produce these products.</p> <p>FSANZ is, however, required to have regard to whether the costs that would arise from a proposed measure outweigh the direct or indirect</p>

Issue	Raised by	FSANZ response
		<p>benefits of the proposed measure. These qualitative costs are outlined in section 2.5.1 of this report.</p> <p>FSANZ has reaffirmed previous advice with the OBPR i.e. no further analysis (in the form of a Regulation Impact Statement) is required (see section 2.5.1).</p>
<b>Stringency of requirements</b>	<p>Submissions stated that due to the nature of these products control measures should be detailed in the standard similar to the approach for the production of uncooked comminuted fermented meats in Standard 4.2.3.</p>	<p>The draft variation to Standard 4.2.4 captures all of the additional control measures for raw milk products that were identified and agreed during the assessment of P1007 (assessed as category 2 products under that process). Specific parameters for cheese production (starter culture activity/pH reduction, salt concentration, storage time and temperature) are specified in the draft amendment.</p>
<b>Labelling</b>	<p>Only one submission raised that reliance on generic labelling provisions may not be adequate to inform consumers that the food is a raw milk product. It was also raised that the current editorial note for specific cheeses in Standard 4.2.4A should be retained in the Code and that it should provide further guidance on the naming of the food, or alternatively be provided as specific labelling provisions in the Code. Also, the provision of guidance for consumers on handling and storage of products could be considered.</p>	<p>Raw milk products meeting the additional requirements to be specified in Standard 4.2.4 present a low risk. Based on this level of 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. These include:</p> <ul style="list-style-type: none"> <li>• name of the food (<i>Standard 1.2.1</i>), sufficient to indicate the true nature of the food</li> <li>• labelling of ingredients (<i>Standard 1.2.4</i>), using either the common name, or a name that describes the true nature of the ingredient, or a generic name (where applicable)</li> <li>• directions for use and storage (<i>Standard 1.2.6</i>), if required for health and safety reasons.</li> </ul> <p>Standard 4.2.4A will be repealed along with the current editorial note in that Standard. An editorial note on the application of generic labelling provisions specifically for raw milk products is considered unnecessary and is not provided for any other food product in the Code. Editorial notes are not legally binding and should not contain substantive provisions.</p>

Issue	Raised by	FSANZ response
<p><b>Comments on guidance documents</b></p>	<p>Submitters provided a number of specific comments on the supporting documents based on the French/European experience. These were in relation to:</p> <ul style="list-style-type: none"> <li>• General animal health and carrier status (including herd monitoring of EHEC/STEC and monitoring criteria)</li> <li>• Milk cooling</li> <li>• Process hygiene criteria for <i>E. coli</i> and <i>staphylococci</i></li> <li>• Validation</li> <li>• Use of databases in which microbiological analyses and technological parameters are combined</li> </ul> <p>The Australian Specialty Cheesemakers' Association also provided several pages of technical comment, particularly in relation to SD1 and SD2.</p>	<p>The 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) and "Validation of Raw Milk Products" (SD2) have been revised since the 1<sup>st</sup> Call for Submissions to incorporate the draft variation to Standard 4.2.4 and technical comment received as appropriate. The "Scientific Information for the Assessment of Raw Milk Products – Cheeses" (SD3) has also been revised following consideration of comments.</p>

## 2.2 FSANZ Act assessment requirements

FSANZ has assessed the options and decided to prepare draft variations to standards 4.2.4, 4.2.4A and 1.6.1 (i.e. option 1) because this:

- is considered warranted after having regard to relevant statutory objectives and criteria (see below)
- is supported by the scientific assessment
- is supported by submitters
- eliminates the need for a product-by-product assessment by FSANZ (assessment of applications)
- recognises consumer demand for additional raw milk products
- supports an efficient and competitive food industry by addressing the disparity between the approach to imports and requirements applied to the domestic dairy industry.

The current measures specified in standard 4.2.4 for dairy primary production, transport and processing provide the baseline set of requirements upon which additional provisions for raw milk products will be included in the standard. The baseline measures include:

- the requirement for a food safety program
- specific control measures for primary production, transport and processing businesses that must be included in the food safety program
- specified processing measures/outcomes at manufacture.

The additional through chain measures to support the safe production of raw milk products, along with microbiological limits, were identified and agreed through the assessment of P1007. Noting the request from a number of submitters for requirements for raw milk products to be detailed and clearly distinguished from existing requirements in Standard 4.2.4, these additional requirements are grouped together in a separate division of Standard 4.2.4. The package of regulatory requirements that will apply to raw milk products are outlined in Figure 1.

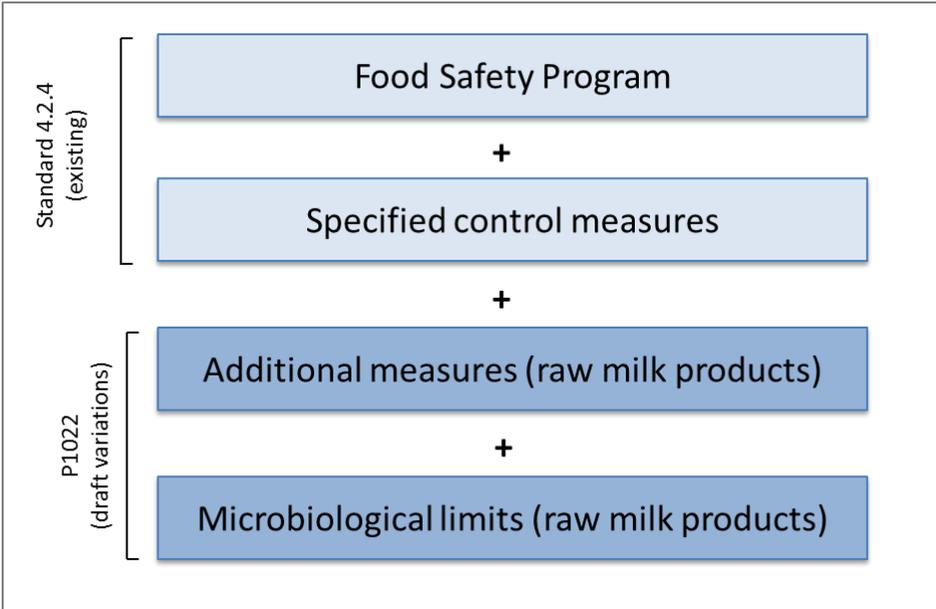


Figure 1. Package of regulatory requirements to be applied to raw milk products in the Code

The measures specified in the draft variation to Standard 4.2.4 include:

- a new division for raw milk products (Division 5) that sets out additional requirements for primary production, transport and processing of milk for raw milk products. These measures are specified under subdivisions for each stage of production.
- clarity that the existing measures under Divisions 2, 3 and 4 of Standard 4.2.4 apply and provide the basis for the additional requirements under Division 5.
- additional requirements for:
  - Animal health
  - Animal identification
  - Use of fermented feeds and potable water
  - Health and hygiene requirements for milking activities
  - Teat cleaning prior to milking
  - Milk cooling and storage (at milking and during storage, transport and receipt)
  - Maintaining a system (at primary production, transport and processing) to ensure the integrity of the milk supply for raw milk products
  - The time from milking to processing of raw milk products must not exceed 48 hours
  - Microbiological monitoring of the milk to be used for raw milk product processing
  - Processing measures to specify that there must be no net increase of pathogens during processing and the final product must not support growth of pathogenic microorganisms.
  - For raw milk cheese, factors that must be addressed are listed (starter culture activity, pH reduction, salt and moisture concentration, storage time and temperature).
- definitions for “diseased animal”, “raw milk herd”, “raw milk product” and “milk for raw milk products”.

Standard 4.2.4A is proposed to be repealed as the requirements for Roquefort cheese are now subsumed by the draft variations to Standard 4.2.4

The draft variation to Standard 1.6.1:

- replaces existing limits for “butter made from unpasteurised milk”, “all raw milk cheese” and “raw milk unripened cheese” with limits for the single food category “raw milk products”.
- includes microbiological limits for raw milk products include *Salmonella* and staphylococcal enterotoxin.

The amendments proposed to Standard 1.6.1 take into account developments since the previous review of microbiological limits in the Code, including international approaches, but primarily are a result of the risk assessment work undertaken for P1007 and the resultant risk management approach. These limits are consistent with the food safety criteria for raw milk products specified in the New Zealand *Animal Products (Raw Milk Products Specifications) Notice 2009*.

It should be noted that limits for *L. monocytogenes* will also apply to raw milk products (as a ready-to-eat food) following gazettal of amendments to Standard 1.6.1 arising from Proposal P1017 Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods.

## 2.2.1 Section 59

When assessing P1022 and developing the draft amendments to Standards 4.2.4, 4.2.4A and 1.6.1, FSANZ has had regard to the following matters listed in section 59 of the FSANZ Act.

### 2.2.1.1 Cost benefit analysis

The Office of Best Practice Regulation (OBPR) has advised (advice received on 06/02/2013 and confirmed on 18/06/14; OBPR reference ID 7876) that P1022 is of a 'minor nature' because the exemptions on raw goat milk products will not be altered; the New Zealand experience indicates that only a few suppliers are likely to produce products under the standards; and any increased imports are very likely to remain a niche component of the Australian market

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. A basic cost benefit analysis has been undertaken. This is not intended to be an exhaustive, quantitative analysis of the options.

The issue of implementation costs was raised by submitters, particularly the costs to government of monitoring and verification activities. This issue was explored further with government agencies. In discussion with most jurisdictions it is recognised that small-scale applicants will place a demand for advice and resources to assist them in establishing the required robust systems, however these additional imposts were considered a cost that these agencies bare in accordance with their regulatory remit. Government also has the ability to recover some or all of these costs from industry to ensure costs are appropriately borne by those who hope to benefit financially from making these products

#### *Consumers:*

Benefits	Increased choice and a broader availability of food products, including imported products from overseas.
Costs	-

#### *Government:*

Benefits	The draft variations establish certainty within the regulatory framework on the status of these products. A state enforcement agency identified a major benefit from the draft variations being the ability to capture businesses into an established compliance system where they can be monitored through a controlled system rather enforcement through costly prosecutions.
Costs	All dairy businesses operate under a compliance regime, including licensing and audit arrangements and associated fees and charges. The following information provided by state regulatory authorities identify additional potential costs and impacts associated with this new area of regulation.

*Example 1: Resource allocation*

Tasmania advised that small-scale applicants place a demand on government for advice to assist them in establishing the required robust systems. Although FSANZ and state regulatory authorities have developed guidance material, as part of P1022 and broader food safety requirements, there are resource implications in meeting this demand. The Tasmanian Dairy Industry Authority (TIDA) exists to protect public health and safety by administering and enforcing dairy food safety legislation. TIDA understand and accept that they must invest a disproportionately large amount of resources in assisting and advising new applicants; this can be time consuming and require additional expense, through phone calls, emails, posting advice and printed material, as well as preliminary meetings and site visits. This process is repeated following licence issue, particularly with small operators whom they expect will be applicants for raw milk product processing, who turn to TIDA for ongoing support. TIDA accept this usually drawn out and lengthy process, as a normal part of business as a regulator.

TIDA will explain, in general terms, the cost to aspiring businesses of implementing a food safety management system, and with raw milk products applicants, the need for additional validation and verification controls and costs based on risk assessment and hazard management and control. These additional imposts on TIDA's resources are simply a cost born in accordance with their regulatory remit. Anyone intending to produce raw milk products under P1022 should be aware of any additional control measures and subsequent costs and make a commercial, decision whether to proceed or not. The TDIA explains the economics and business risk, as well as food safety risk early on in the process of engagement with new applicants.

TIDA expects that they might receive 2 or 3 enquiries a year for raw milk product processing.

The Dairy Authority of South Australia (DASA) is of the view that if the raw milk product operators have sound knowledge of their operation and past experience then costs will be easily managed by enforcement agency.

However, costs of dealing with new operators that have not previously been licensed are likely to be much higher. For example, the costs of handling enquiries about setting up a new raw milk product operator is not cost recoverable since there is no mechanism to charge an unlicensed business (the \$110 application fee is charged once an application is made). The extra time commitment to DASA is estimated as follows (it is assumed that the applicant is currently accredited rather than them being a new to the dairy manufacturing industry):

- Assessment of food safety plans 1-2 days/application
- Inspection and initial accreditation 1-2 days/application.
- Through the year assessment of test results and advice on corrective action 2-3 days/ applicant on average

DASA would therefore estimate that the extra work for managing raw milk cheese producers, if everything is working well and the knowledge base of the processors is adequate to be 4 to 7 days per year /processor. The issue of processor knowledge is crucial to this assessment. If DASA finds itself in a position of being de facto advisers because no alternative competency can be found, then several weeks of time may be needed. The resource requirements and costs cannot be quantitated or quantified at this time.

A significant failure leading to recall and further corrective action could lead to a very significant expansion of these timelines. One counteracting factor is that the likely participants are small and therefore the quantity of product which may be involved is also likely to be low and the delivery arrangements to and from the processor more flexible.

In these circumstances the necessary corrective action can be much swifter and less costly than might be the case with a larger processor.

*Example 2: Monitoring and compliance costs*

Safe Food Production Queensland (SFPQ) advised that the cost of compliance monitoring based on high risk (2 per annum) would be in the order of approximately \$540 (\$255.65 excluding GST per hour). The length of the audit would be dependent upon their ability to provide the necessary information and would be expected to be a maximum of 2 hours. These costs are fully cost recovered and each applicant would also be subject to an accreditation fee as a 'processor' as they are making cheese. SFPQ has one standard fee for anyone operating as a processor of approximately \$1360 along with a one off application fee in the order of \$140.

*Industry:*

**Benefits** 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 draft variations are deregulatory in nature as they removes the need for industry to lodge applications to amend the Code to permit the sale of certain raw milk products. Where an application is likely to result in an amendment to the Code that provides exclusive benefits to the applicant, the application is considered to confer an 'exclusive capturable commercial benefit' (ECCB) and the applicant is required to pay the full cost of processing their application. The associated cost could be greater than \$100,000 which is likely to be prohibitive for small businesses.

**Costs** The measures to be specified in Standard 4.2.4 to allow for raw milk product manufacture are consistent with requirements imposed internationally where raw milk products are permitted and are required to support safe production. The uptake by business would be part of a voluntary business decision to produce these products if they saw the benefits as likely to exceed the costs.

This analysis indicates that the potential costs that would arise from the draft amendments to Standards 4.2.4, 4.2.4A and 1.6.1 do not outweigh the benefits.

**2.2.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure varied as a result of the Proposal.

Standard 4.2.4 currently 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 additional through chain measures required to support the safe production of raw milk products are consistent with regulatory requirements in other countries where raw milk products are permitted.

### **2.2.1.3 Any relevant New Zealand standards**

Standards 4.2.4 and 4.2.4A are Australia only standards.

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: *Animal Products (Raw Milk Products Specifications) Notice 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.

### **2.2.1.4 Any other relevant matters**

There are no other relevant matters.

## **2.2.2. Subsection 18(1)**

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

### **2.2.2.1 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. 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.

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 3 products present too high a risk to be permitted through changes to the Code.
- 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 and are the raw milk products within the scope of P1022.

The draft amendments reflect the necessary measures to protect public health and safety.

### **2.2.2.2 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.

### **2.2.2.3 The prevention of misleading or deceptive conduct**

No issues were identified.

### **2.2.3 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**

In assessing P1007, FSANZ prepared three risk assessments to generate information on the public health risks which may be associated with raw milk products. These assessments were used to inform the risk management for P1022:

The [Microbiological Risk Assessment of Raw Milk Cheese](#) (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 [Microbiological Risk Assessment of Raw Goat Milk](#) (FSANZ 2009b) and [Microbiological Risk Assessment of Raw Cow Milk](#) (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 access details for these documents are listed in section 4.

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.

Microbiological limits for *Salmonella* and Staphylococcal enterotoxin for raw milk products result from the risk assessment work undertaken for P1007.

- **the promotion of consistency between domestic and international food standards**

The additional measures identified to support the safe production of raw milk products are consistent with the principles underpinning the Codex *Code of Hygienic Practice for Milk and Milk Products* CAC/RCP 57-2004.

- **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 has raised the issue of an unlevel playing field as domestic production of such cheeses was not permitted. A draft variation to Standard 4.2.4 and supporting guidelines provides the framework for the safe production of some raw milk cheeses domestically.

- **the promotion of fair trading in food**

A notification to the WTO in accordance with the SPS Agreement has been made (see section 2.3.2).

- **any written policy guidelines formulated by the Ministerial Council<sup>2</sup>.**

Australia and New Zealand Food Regulation Ministerial Council developed an *Overarching Policy Guideline on Primary Production and Processing Standards*<sup>3</sup>. FSANZ has had regard to the policy guidance and higher order principles in these guidelines.

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of FSANZ's standards development process.

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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. 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.

FSANZ also acknowledges the expertise of members of the Standards Development Committee.

### **2.3.2 World Trade Organization (WTO)**

The draft variations to Standards 4.2.4, 4.2.4A and 1.6.1 are consistent with the principles underpinning the Codex *Code of Hygienic Practice for Milk and Milk Products* CAC/RCP 57-2004 and will potentially be a trade facilitating measure. Notification under the WTO Sanitary and Phytosanitary Measures Agreement has been made to enable other WTO member countries to comment on the draft variations.

## **3 Draft variations**

The draft variations to Standards 4.2.4, 4.2.4A and 1.6.1 are at Attachment A. The draft variations are intended to take effect on gazettal.

The draft variation also reflects the amendments to be made to the Schedule of Standard 1.6.1 by P1017. These amendments are expected to take effect during consultation on P1022.

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<sup>2</sup> Now known as the Legislative and Governance Forum on Food Regulation

<sup>3</sup> The Policy Guideline is available at

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

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

### 3.1.1 Transitional arrangements for Code Revision

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – details of which are on the FSANZ website.<sup>4</sup> FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions has been released.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the draft variations at Attachment A.

### 3.1.2 Implementation and review

Food standards are enforced in the Australian dairy industry predominately by State Dairy Food Authorities (SDFAs) in conjunction with State Health Departments and local government. From farm to product storage, all dairy businesses must be licensed. Individual food safety programs for farms and factories are validated by SDFAs before licences are granted and compliance is monitored through regular audits.<sup>5</sup>

Implementation for imported product is discussed in section 2.1.2.

## 4 References

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

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

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

## Attachments

- A. Draft variations to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

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<sup>4</sup> <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

<sup>5</sup> <http://www.dairyaustralia.com.au/Industry-information/Food-safety-and-regulation/Regulatory-Framework/Regulatory-overview.aspx>

## Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



### Food Standards (Proposal P1022 – Primary Production & Processing Requirements for Raw Milk Products) Variation

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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 [To be completed by Standards Management Officer]

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

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Proposal P1022 – Primary Production and Processing Requirements for Raw Milk Products) Variation*.

## 2 Repeal and variation of Standards in the *Australia New Zealand Food Standards Code*

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

## 3 Commencement

This instrument commences on the date of gazettal.

### SCHEDULE

[1] **Standard 4.2.4** is varied by

[1.1] inserting in subclause 1(2), in alphabetical order

“**diseased animal** means an animal that has signs of an infection.”

“**documented alternative** means a method that –

- (a) minimises the growth of pathogenic microorganisms in the milk to the same or greater extent as that the method prescribed by this Standard; and
- (b) does not adversely affect the microbiological safety of any raw milk product produced from that milk; and
- (c) is documented in a food safety program required by this Standard; and
- (d) the business has demonstrated will result in the outcomes required by paragraphs (a) and (b) of this definition.”

“**infection** means the entry, development or multiplication of a pathological microorganism that is capable of being transferred to humans through raw milk.”

“**milk for raw milk products** means raw milk that is used or is to be used to make a raw milk product.”

“**raw milk** means milk that has not been processed in accordance with clause 15 or clause 16 of this Standard.”

“**raw milk herd** means any group of animals from which milk for raw milk products is or will be sourced.”

“**raw milk product** means a dairy product made with raw milk, but does not include milk.”

[1.2] omitting the heading “Division 2 – Dairy primary production requirements” and substituting “Division 2 – General dairy primary production requirements”

[1.3] omitting the heading “Division 3 – Dairy collection and transportation” and substituting “Division 3 – General dairy collection and transportation”

[1.4] omitting the heading “Division 4 – Dairy processing” and substituting “Division 4 – General dairy processing”

[1.5] omitting from clause 12

“To avoid doubt, Standards 3.2.2 and 3.2.3 apply to the processing of dairy products.”

and substituting

- “(1) To avoid doubt, Standards 3.2.2 and 3.2.3 apply to the processing of dairy products.
- (2) Clauses 15 and 16 of this Standard do not apply to milk for raw milk products.”
- [1.6] omitting from subparagraph 16(3)(a)(ii) “; or” and substituting “.”
- [1.7] omitting paragraph 16(3)(b)
- [1.8] inserting after clause 16

## **“Division 5 – Additional requirements for raw milk products**

### **Subdivision 1 – General**

#### **17 Application of Divisions 1 to 4**

To avoid doubt, unless the contrary intention appears, the requirements imposed by Divisions 1 to 4 of this Standard apply to the production, transport and processing of milk for raw milk products and to raw milk products.

### **Subdivision 2 – Primary production of milk for raw milk products**

#### **18 Application**

A dairy primary production business that produces milk for raw milk products must ensure that each requirement of this subdivision is met.

#### **19 Requirement for additional and specific control measures**

The documented food safety program required by clause 3 must include control measures that ensure that the requirements of this subdivision are met.

#### **20 Animal health requirements**

- (1) Milk for raw milk products must not be obtained from a diseased animal.
- (2) A diseased animal must not be introduced into a raw milk herd.
- (3) A diseased animal in a raw milk herd must be –
  - (a) separated immediately from the herd; and
  - (b) kept separate from any other animal that will be milked for milk for raw milk products.

#### **21 Requirements for animal identification and tracing**

Each animal that will be or has been milked for milk for raw milk products must be subject to a stock identification system that ensures that the animal is uniquely identifiable and traceable.

#### **22 Requirement to control specific inputs**

- (1) Fermented feeds must not be fed to animals milked for raw milk.
- (2) Subclause (1) does not apply if the dairy primary production business uses a documented alternative to feed animals milked for raw milk.
- (3) Only potable water must be used –
  - (a) on equipment used to milk animals;

- (b) to clean the teats of animals; and
- (c) for washing by persons milking animals.

## **23 Health and hygiene requirements**

The production of milk for raw milk products must comply with the requirements of Division 4 of Standard 3.2.2.

## **24 Requirement for milking practices**

The teats of an animal milked for milk for raw milk products must be clean and dry before the animal is milked.

## **25 Requirements relating to the cooling and storage of milk for raw milk products**

- (1) Milk for raw milk products must be cooled to a maximum temperature of 6°C within two hours of milking.
- (2) Milk for raw milk products that is stored must be kept at a temperature not exceeding 5°C while in storage.
- (3) Subclause (1) does not apply if the dairy primary production business uses a documented alternative to the method prescribed by that subclause.
- (4) Subclauses (1) and (2) do not apply to milk that is processed within two hours of it being milked.
- (5) Milk for raw milk products must be kept separate from milk used or intended to be used for dairy products that are not raw milk products.

## **26 Requirements relating to non-conforming milk for raw milk products**

Milk must not be supplied for raw milk products if the milk was produced other than in accordance with this Division or is otherwise unacceptable.

# **Subdivision 3 – Transport of milk for raw milk products**

## **27 Application**

A dairy transport business that collects and transports milk for raw milk products must ensure that each requirement of this subdivision is met.

## **28 Requirement for additional and specific control measures**

The documented food safety program required by clause 7 must include control measures that ensure the requirements of this subdivision are met.

## **29 Requirements for temperature control**

- (1) The temperature of milk for raw milk products must not exceed 8°C at any point between the collection of that raw milk from the dairy primary production business that produced it and the delivery of that raw milk to a dairy processing business for processing.
- (2) Subclause (1) does not apply if –
  - (a) the milk is collected from the dairy primary production business within 2 hours of it being milked; or
  - (b) the dairy transport business uses a documented alternative to the method prescribed by subclause (1).

### **30 Raw milk handling requirements**

Milk for raw milk products must be kept separate from milk used or intended to be used for dairy products that are not raw milk products.

## **Subdivision 4 – Processing of milk for raw milk products**

### **31 Application**

A dairy processing business that processes milk for raw milk products must ensure that each requirement of this subdivision is met.

### **32 Requirement for additional and specific control measures**

The documented food safety program required by clause 13 must include control measures that –

- (a) ensure that the requirements of this subdivision are met; and
- (b) for a dairy processing business that make cheese using raw milk, address each of the following in relation to that processing –
  - (i) starter culture activity,
  - (ii) pH reduction,
  - (iii) salt concentration and moisture content,
  - (iv) storage time; and
  - (v) storage temperature.

### **33 Requirements relating to milk receipt and storage**

- (1) The temperature of milk for raw milk products must not exceed 8°C at any point between its collection by a dairy processing business and the commencement of processing of that milk.
- (2) Subclause (1) does not apply if –
  - (a) the processing of the milk commences within two hours of it being milked; or
  - (b) the dairy processing business uses a documented alternative to the method prescribed by subclause (1).
- (3) Raw milk products must not be made from milk that was milked more than 24 hours before processing of that milk commenced.
- (4) Subclause (3) does not apply if the dairy processing business uses a documented alternative to the method prescribed by that subclause.
- (5) Milk for raw milk products must be kept separate from milk used or intended to be used for dairy products that are not raw milk products.

### **34 Requirements to control specific food safety hazards**

- (1) Prior to the commencement of its processing, milk for raw milk products must be monitored to ensure its suitability.
- (2) The monitoring required by subclause (1) must involve appropriate microbiological testing.
- (3) The level of pathogenic microorganisms in a raw milk product must not exceed the level of pathogenic microorganisms in the milk from which the product was made as at the commencement of the processing of that milk.
- (4) A raw milk product must not support the growth of pathogenic microorganisms.

### 35 Requirements relating to non-conforming milk

A dairy processing business must only use milk for raw milk products that has been produced and transported in accordance with this Division to make raw milk products.

[2] **Standard 4.2.4A** is repealed.

[3] **Standard 1.6.1** is varied by

[3.1] omitting from the Schedule

“

Butter made from unpasteurised milk and/or unpasteurised milk products	<i>Campylobacter</i>	5	0	not detected in 25 g	10 <sup>2</sup> /g
	Coagulase-positive staphylococci	5	1	10 /g	
	Coliforms	5	1	10 /g	
	<i>Escherichia coli</i>	5	1	3 /g	
	<i>Salmonella</i>	5	0	not detected in 25 g	
	SPC	5	0	5x10 <sup>5</sup> /g	

[3.2] omitting from the Schedule

“

All raw milk cheese (cheese made from milk not pasteurised or thermised)	<i>Salmonella</i>	5	0	not detected in 25 g	
Raw milk unripened cheeses (moisture content > 50% with pH > 5.0)	<i>Campylobacter</i>	5	0	not detected in 25 g	

and substituting

“

Raw milk products	<i>Salmonella</i>	5	0	not detected in 25 g	
	Staphylococcal enterotoxins	5	0	not detected in 25 g	

## **Attachment B – Draft Explanatory Statement**

### **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 P1022 to amend the Code to include the additional requirements for the safe production of raw milk products. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation.

### **2. Purpose**

The Authority has prepared draft amendments to Standards 4.2.4 and 1.6.1 to include requirements in the Code for raw milk products. Amendments to Standard 4.2.4 specify additional through-chain measures to support the safe production of raw milk products where processing ensures no net increase of pathogen levels and the intrinsic physico-chemical characteristics of the raw milk product will not support pathogen growth.

Standard 4.2.4A is proposed to be repealed as the requirements for Roquefort cheese are now subsumed by the draft variations to Standard 4.2.4 and imports referred to the Department of Agriculture.

Standard 1.6.1 is amended to replace existing limits for “butter made from unpasteurised milk”, “all raw milk cheese” and “raw milk unripened cheese” with limits for the single food category “raw milk products”.

### **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 P1022 will include two rounds of public consultation following an assessment and the preparation of a draft Standard and associated reports.

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 was not required because the proposed variations to Standard 4.2.4 are likely to have a minor impact on business and individuals.

## 5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

## 6. Variation

### 6.1 *Item [1]*

Item 1 amends Standard 4.2.4.

Item 1.1 includes definitions in subclause 1(2) for “diseased animal”, “documented alternative”, “infection”, “milk for raw milk products”, “raw milk”, “raw milk herd” and “raw milk product”.

Item 1.2 omits the heading “Division 2 – Dairy primary production requirements” and substitutes “Division 2 – General dairy primary production requirements”.

Item 1.3 omits the heading “Division 3 – Dairy collection and transportation” and substitutes “Division 3 – General dairy collection and transportation”.

Item 1.4 omits the heading “Division 4 – Dairy processing” and substitutes “Division 4 – General dairy processing”.

Item 1.5 includes an additional subclause under clause 12 to state that clauses 15 and 16 of the Standard do not apply to milk for raw milk products.

Item 1.6 omits from subparagraph 16(3)(a)(ii) the wording “or” as no additional alternatives will be included under subclause 16(3).

Item 1.7 omits paragraph 16(3)(b) as Standard 4.2.4A is repealed under item [2].

Item 1.8 inserts an additional division in the Standard, Division 5, for raw milk products.

Division 5 – Additional requirements for raw milk products includes four subdivisions:

- Subdivision 1 – General
- Subdivision 2 – Primary production of milk for raw milk products
- Subdivision 3 – Transport of milk for raw milk products
- Subdivision 4 – Processing of milk for raw milk products

Subdivision 1 comprises clause 17. Clause 17 applies the requirements of Divisions 1 to 4 to the production, transport and processing of raw milk products.

Subdivision 2 comprises clauses 18 to 26.

- Clause 18 specifies the businesses that must comply with the requirements of Subdivision 2.
- Clause 19 requires that the documented food safety program required by clause 3 of the Standard must include control measures that ensure each requirement imposed by Subdivision 2 is met.
- Clause 20 provides additional requirements relating to diseased animals.
- Clause 21 provides an additional requirement for a stock identification system that ensures animals are identifiable and traceable.

- Clause 22 provides an additional requirement in relation to feed and water use
- Clause 23 requires the primary production of milk for raw milk products to comply with the requirements of Division 4 of Standard 3.2.2
- Clause 24 provides a teat washing and drying requirement
- Clause 25 provides cooling, storage temperature and time requirements for milk for raw milk products.
- Clause 26 provides a requirement that only milk produced in accordance with Division 5 can be supplied for processing of raw milk products.

Subdivision 3 comprises clauses 27 to 30.

- Clause 27 specifies the businesses that must comply with the requirements of Subdivision 3.
- Clause 28 requires that the documented food safety program required by clause 7 of the Standard must include control measures that ensure each requirement imposed by Subdivision 3 is met.
- Clause 29 provides additional temperature and time requirements for the transport of milk for raw milk products.
- Clause 30 requires that milk for raw milk products must be kept separate from other milk.

Subdivision 4 comprises clauses 31 to 35.

- Clause 31 specifies the businesses that must comply with the requirements of Subdivision 4.
- Clause 32 requires that the documented food safety program required by clause 13 of the Standard must include control measures that ensure each requirement imposed by Subdivision 4 is met requirement. Clause 32 also provides that the documented food safety program for a dairy processing business that makes cheese using raw milk address the matters specified in paragraph 32(b).
- Clause 33 provides additional requirements in relation to the temperature and time limits for processing of milk for raw milk products.
- Clause 34 provides additional requirements in relation to microbiological monitoring and processing outcomes.
- Clause 35 requires that only milk produced in accordance with Division 5 can be used for processing of raw milk products.

## 6.2 *Item [2]*

Item 2 repeals Standard 4.2.4A

## 6.3 *Item [3]*

Item 3 omits existing limits for “butter made from unpasteurised milk and/or unpasteurised dairy products”, “all raw milk cheese (cheese made from milk not pasteurised or thermised)” and “raw milk unripened cheeses (moisture content >50% with pH > 5.0)”. The Item also inserts limits for Salmonella and Staphylococcal enterotoxins for “raw milk products”.