

16 December 2014
[26–14]

Approval Report – Proposal P1022

Primary Production & Processing Requirements for Raw Milk Products

Food Standards Australia New Zealand (FSANZ) has assessed a proposal for additional requirements for milk production, transport and processing for the safe production of raw milk cheese.

On 10 July 2014, FSANZ sought submissions on draft variations and published an associated report. FSANZ received sixteen submissions.

FSANZ approved the draft variation on 4 December 2014. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 15 December 2014.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

Table of Contents

| | |
|---|-----------|
| EXECUTIVE SUMMARY | 3 |
| 1 INTRODUCTION | 4 |
| 1.1 THE PROPOSAL | 4 |
| 1.2 THE CURRENT STANDARDS | 5 |
| 1.3 REASONS FOR PREPARING PROPOSAL | 5 |
| 1.4 PROCEDURE FOR ASSESSMENT | 5 |
| 1.5 DECISION | 5 |
| 2 SUMMARY OF THE FINDINGS | 6 |
| 2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS | 6 |
| 2.1.1 <i>Scope of the proposal and definition of raw milk products</i> | 6 |
| 2.1.2 <i>Application of microbiological testing and appropriate criteria</i> | 6 |
| 2.2 CHANGES TO THE DRAFT VARIATIONS FOLLOWING CONSULTATION | 8 |
| 2.3 FSANZ ACT ASSESSMENT REQUIREMENTS | 12 |
| 2.3.1 <i>Section 59</i> | 12 |
| 2.3.2 <i>Subsection 18(1)</i> | 16 |
| 2.4 RISK COMMUNICATION..... | 18 |
| 2.4.1 <i>Consultation</i> | 18 |
| 2.4.2 <i>World Trade Organization (WTO)</i> | 19 |
| 3 TRANSITIONAL ARRANGEMENTS | 19 |
| 3.1 <i>Transitional arrangements for Code Revision</i> | 19 |
| 4 IMPLEMENTATION AND REVIEW | 19 |
| 5 REFERENCES | 20 |
| ATTACHMENT A – APPROVED DRAFT VARIATION/S TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE..... | 21 |
| ATTACHMENT B – EXPLANATORY STATEMENT | 27 |
| ATTACHMENT C – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (CALL FOR SUBMISSIONS) | 31 |
| ATTACHMENT D – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE IN 2015 FOLLOWING P1025 | 37 |

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 cheese in Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products (at Approval)
- SD2 Guide to the Validation of Raw Milk Cheese (at Approval)
- SD3 Scientific information for the assessment of raw milk products – Cheeses (at Approval)

Executive summary

Under Proposal P1022, Food Standards Australia New Zealand (FSANZ) has assessed additional requirements for milk production, transport and processing for the safe production of raw milk cheese where it can be demonstrated:

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

FSANZ consulted on draft variations to three Standards from 10 July 2014 to 21 August 2014. These were 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.

Sixteen submissions were received. Stakeholders generally supported the draft variations.

Following this second round of consultation, FSANZ decided to limit the amendments to Standard 4.2.4 to raw milk cheese, rather than the more general category of raw milk products. Raw milk cheese is cheese that has not been processed using a heat treatment prescribed under clause 16 of Standard 4.2.4. Consideration of the production and sale of raw drinking milk was not in the scope of this proposal.

FSANZ has approved draft variations to Standards 4.2.4, 4.2.4A and 1.6.1 to:

- clarify that current measures in Standard 4.2.4 for dairy primary production, transport and processing also provide a baseline set of requirements for raw milk cheese
- include additional requirements for primary production, transport and processing of milk for raw milk cheese in a new division of Standard 4.2.4
- repeal Standard 4.2.4A, as the legislation and conditions specified for Roquefort cheese in Table 1 of that Standard are now subsumed by the approved draft variations to Standard 4.2.4
- delete existing limits for “butter made from unpasteurised milk”, “all raw milk cheese” and “raw milk unripened cheese” and including limits specifically for “raw milk cheese”. Microbiological limits for raw milk cheese include *Salmonella* and Staphylococcal enterotoxin.

The limits for *Listeria monocytogenes* also apply to raw milk cheese (as a ready-to-eat food) following gazettal of amendments to Standard 1.6.1 in July 2014.

FSANZ prepared and also consulted on a *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)* and *Scientific information for the assessment of raw milk products – Cheeses (SD3)*. These guidance documents will support the implementation of the approved draft variations.

1 Introduction

1.1 The Proposal

In 2009, FSANZ established a risk-based category approach to assess permissions for raw milk products² 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.

For P1007, FSANZ 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.

Under P1022, FSANZ has assessed additional requirements for milk production, transport and processing for the safe production of raw milk products where it can be demonstrated:

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

For P1007, FSANZ concluded that for category 3 products, in particular raw drinking milk, the level of risk cannot be sufficiently controlled and such products present a high level of public health and safety risk. The *Australia New Zealand Food Standards 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 or Territories 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 continued to provide advice to FSANZ on P1022.

² Raw milk products are those manufactured without pasteurisation or an equivalent treatment

1.2 The current Standards

Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products 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 as specified under Standard 4.2.4A – Primary Production and Processing Standard for Specific Cheeses.

Standards 4.2.4 and 4.2.4A do not apply in New Zealand. The New Zealand Ministry for Primary Industries has its own food safety legislation for food businesses and primary producers, including requirements for raw milk products.

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

1.3 Reasons for preparing 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 was 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 was assessed under the Major Procedure.

1.5 Decision

The draft variations, as proposed following assessment, were approved with amendments. The variations take effect on the date of gazettal.

The approved draft variations, as varied after consideration of submissions, are at Attachment A. The 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.

The draft variations on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

The 2nd Call for Submissions occurred from 10 July 2014 to 21 August 2014. Sixteen submissions were received. Stakeholders generally supported the draft variations to the relevant standards in the Code. Specific issues raised in relation to the proposed draft variations included:

- the scope of the Proposal and corresponding definition of raw milk products
- the application of microbiological testing and appropriate criteria
- various implementation issues
- suggested improvements to the guidance documents (SD1 and SD2) and scientific basis (SD3)
- recognition of the costs for regulators implementing the draft variations.

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.

2.1.1 Scope of the proposal and definition of raw milk products

A number of comments were received seeking clarification on:

- whether butter, yoghurt, crème fraiche and kefir were included in the definition of raw milk products and, if so, whether separate guidance will be provided or whether the validation requirements apply to all of these products
- whether liquid dairy products such as cream are included in the definition and products other than cheese if a validated process is provided.

There were submissions that also supported limiting the scope of the amendments to cheese made from raw milk only as control measures for dairy products other than cheese have not been scientifically assessed.

While the risk management framework and through-chain control measures developed are applicable for all raw milk products (defined as category 2 products under P1007), a decision has been made to limit the amendments to Standard 4.2.4 at Approval to cheese only. This is based on cheese being the primary product of concern and that, apart from drinking milk initially; no particular case has been made for other products through submissions. As a result, changes to the draft variations have been made so that the requirements for raw milk products and associated definitions now apply to raw milk cheese only, including limits in Standard 1.6.1.

2.1.2 Application of microbiological testing and appropriate criteria

A number of comments were received in relation to the microbiological limits either included or not included in Standard 1.6.1 for raw milk products, as well as limits proposed in SD1. In general, there seemed to be a lack of clarity as to how limits specified in Standard 1.6.1 are intended to apply, particularly alongside other criteria proposed in SD1.

2.1.2.1 *The role of microbiological testing in food safety management*

Microbiological testing should be carried out to make a decision about a food or process. Decision-making using microbiological data may be required to:

- determine the acceptance or rejection of a specific lot of food (intended purpose of Standard 1.6.1)
- verify the performance of a food safety control system or its elements along the food chain
- monitor/verify that selected control measures are working as intended.

The reason for carrying out microbiological testing should be established before use as it will determine:

- the type of test used (e.g. for a pathogen or an indicator organism)
- the sample taken (e.g. end product or in-line sample)
- the interpretation of the result and action taken (e.g. rejection of a lot or readjustment of process).

The International Commission on Microbiological Specifications for Foods (ICMSF) provides detailed information in its publications on developing and applying microbiological criteria (ICMSF, 2002; ICMSF, 2011).

2.1.2.2 Microbiological limits and criteria established through P1022

The microbiological tests and limits proposed in SD1 and Standard 1.6.1 need to be considered and applied for different purposes throughout the production and processing chain. As outlined below in Figure 1, this includes:

- to establish that good hygienic practices have been correctly implemented and are being followed
- to monitor/verify that the control measures validated to achieve product safety are working as intended
- to assess the acceptability of a lot intended for direct consumption.

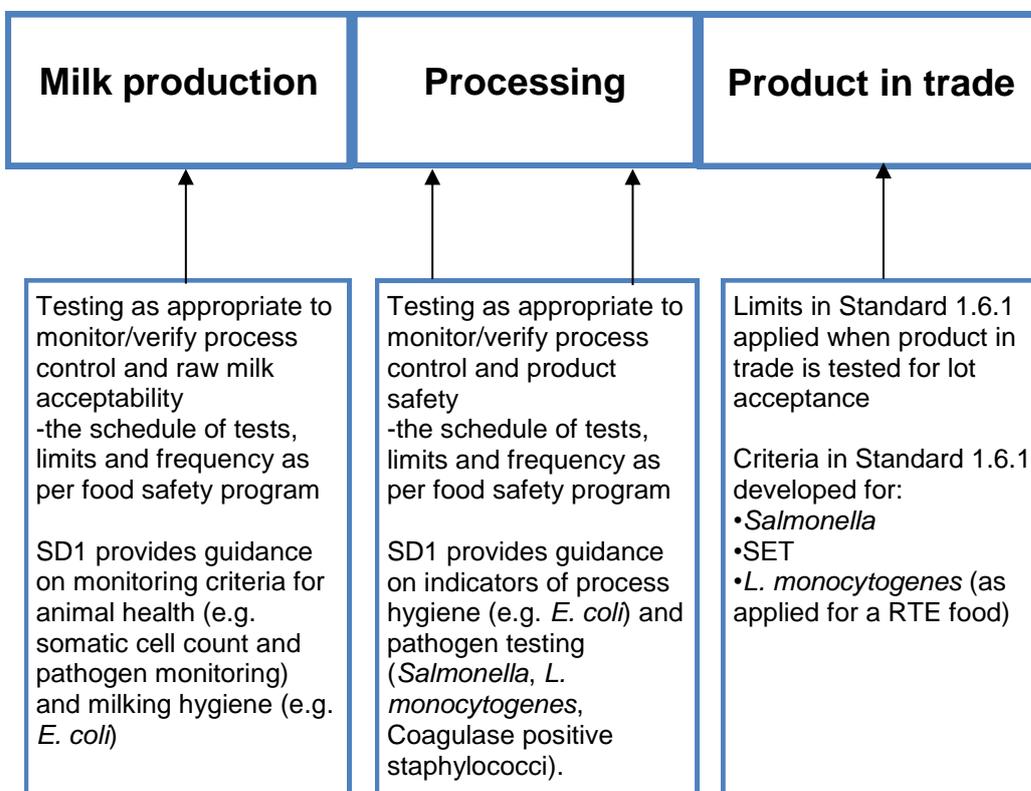


Figure 1. The application of microbiological testing through-chain

The criteria included in Standard 1.6.1 for raw milk cheese are for *Salmonella* and staphylococcal enterotoxin (SET). It was raised in submissions that a limit for coagulase-positive staphylococci should be set rather than for SET. However, a decision to set criteria for SET has been made based on the toxin in the final product being the hazard of concern. The potential for coagulase-positive staphylococci to be present in the milk and grow to high levels during production should be managed and monitored in accordance with a business's food safety program. There are recommended microbiological monitoring criteria in SD1 in relation to coagulase-positive staphylococci:

| Test | Limit |
|---|--|
| Coagulase positive staphylococci | 1000 cfu/g Testing should be undertaken at the time during processing when it would be expected that the number of staphylococci are highest. |
| Staphylococcal enterotoxins (if coagulase positive staphylococci exceed 1000 cfu/g) | Not detected (5 x 25g sample) |

A limit for coagulase positive staphylococci is of limited value in the final product as, by the time the product has reached the marketplace, numbers of coagulase positive staphylococci would have reduced and may not be detected (<100 cfu/g) even though SET may be present if a problem has occurred and staphylococci grew to a high number.

The microbiological criteria for raw milk cheese to be included in Standard 1.6.1 are consistent with the food safety criteria established by New Zealand for raw milk products in their *Animal Products (Raw Milk Products Specifications) Notice 2009*.

2.1.2.3 Microbiological testing for *E. coli*

A number of queries were raised in submissions as to the appropriateness of the *E. coli* limits proposed in SD1, their purpose and relationship to safety of the final product.

The *E. coli* limits proposed for monitoring/verification purposes in SD1 are for generic *E. coli* and should be applied as a measure of hygienic practice. It is important that the limits applied aren't unnecessarily stringent but that they provide a reasonable benchmark against which a decision can be made as to whether the process is in control or improvements in hygiene or other corrective actions are needed. It is important that any testing undertaken against *E. coli* limits should be related to hygiene control and should not be related to pathogenic *E. coli*. Pathogenic *E. coli* should be managed through animal health controls, hygienic milking and processing controls during cheesemaking, not through microbiological testing.

The limits proposed in SD1 at the second call for submissions were based on expert elicitation³ and were considered achievable under best practice. Given concerns raised, changes to limits have been made and clarified in SD1 at Approval.

2.2 Changes to the draft variations following consultation

The approved draft variations, as amended following consideration of submissions, is at Attachment A. In summary, the changes relate to:

- **Scope**

As discussed in section 2.1.1, the approved draft variations have been limited to raw milk cheese rather than raw milk products.

³ A Technical Working Group of government dairy authorities and dairy industry experts provided advice

- **Documented alternative**

The draft variations provide an exemption for certain requirements if a documented alternative method is followed. The definition for documented alternative has been amended in the approved draft variations to clarify that the alternative method has to have been recognised or approved by the relevant authority.

- **Control of specific inputs**

The reference to fermented feed has been replaced by the term 'silage' which is a more specific description.

The approved draft variations also clarify that only potable water should be used in contact with equipment/surfaces that will contact the milk.

- **Exemptions relating to “2 hours of milk being milked”**

The draft variations, as originally drafted, provided exemptions from certain requirements if the milk is processed within 2 hours of milking or if milk is collected within 2 hours of it being milked. See subclauses 25(4), 29(2)(a) and 33(2)(a) of the original draft variation.

Submitters argued that these exemptions were unnecessary and confusing as they were already covered by clauses by allowing for a “documented alternative”. As such, situations applying within the 2 hours from milking timeframe can already be accommodated (and covered in the guidance document).

FSANZ agreed and the exemptions and related subclauses were deleted from the approved draft variations.

- **Clause 34 monitoring requirements**

The draft variations, as originally drafted, required that monitoring activities (as prescribed under subclause 34(1)) include microbiological testing. See subclause 34(2). Submitters pointed out that this is an implementation matter. FSANZ agreed and the requirement was deleted from the approved draft variation and is now covered in guidance documents.

Table 1: Summary of issues

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|--|---|--|
| Scope | Submitters queried whether products other than raw milk cheeses were included in the definition and, if so, whether separate validation guidance would be provided. | Following the 2 nd Call for Submissions, a decision was made to limit the amendments to Standard 4.2.4 to raw milk cheese only. The resulting changes to the draft variations are discussed in section 2.1.1. |
| Microbiological limits | Submitters requested additional information for the proposed changes to Standard 1.6.1 and issues around limits for specific pathogens | Addressed under Section 2.1.2. Limits for butter made from unpasteurised milk and raw milk unripened cheese will be deleted from Standard 1.6.1 as they are products that are now not in scope. The scientific assessment work showed that <i>Campylobacter</i> is not a concern in raw milk cheese and testing for this in the final product is unnecessary. |
| Assistance to industry particularly technical support to meet validation requirements | Submitters raised concerns over the specialty cheese industry's access to scientific and technical resources for challenge studies and proposed dairy authorities and industry develop a national code of practice. | State and territory regulators, along with the Dairy Authorities Technical Advisory Committee, will be considering relevant implementation materials. FSANZ offered support and assistance with guidance material such as the <i>Guide to the requirements for raw milk cheese in Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products and Validation of Raw Milk Cheese</i> as part of the implementation framework. |
| Implementation | A submission raised concern over the potential for inconsistent implementation of the standard. | Addressed in above response. |
| Labelling | Generally submitters supported the use of existing labelling requirements. However, one submitter suggested a note be provided in Standard 1.2.2 – Food Identification Requirements or 1.2.4 – Labelling of Ingredients and another suggested more explicit labelling requirements be prescribed. | <p>Raw milk cheese meeting the additional requirements specified in Standard 4.2.4 present a low risk. Based on this assessment, FSANZ considers that the existing generic labelling requirements in the Code are appropriate. All food producers must meet the generic labelling requirements, including those in Standards 1.2.2 and 1.2.4 where these requirements apply. The provision of additional labelling requirements specifically for raw milk cheese would be incommensurate with the level of risk posed. However, industry may provide additional voluntary information about their raw milk cheese (e.g. for marketing purposes) providing such information is not false, misleading or deceptive.</p> <p>Guidance on meeting the generic labelling requirements for raw milk cheese could be prepared by industry itself, or developed as part of the implementation materials that will be considered by the state and territory regulators as discussed above.</p> |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|--|---|
| Cost-benefit analysis | A submitter provided information and costs associated with establishing the regulatory framework for inclusion in the Approval report | This information is included in section 3.1.1. |
| Supporting documents | Submitters provided specific comments and corrections to the three supporting documents. | <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) were amended since the 2nd Call for Submissions to incorporate the changes to 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) was amended following consideration of comments and was externally peer-reviewed.</p> <p>The supporting documents can be used by dairy authorities and industry to inform implementation.</p> |
| Imported products | Submitters stressed the importance of implementation activities and timing. | FSANZ will provide draft assessment advice to the Department of Agriculture by December 2014 on whether imported raw milk cheeses 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. |
| Amendments to the draft variations | <p>A number of submissions provided suggested changes to particular clauses in Standard 4.2.4</p> <p>In relation to the skills and knowledge requirement, it was raised that there may be a need to specify competencies in the draft variation to Standard 4.2.4.</p> | <p>The consequential changes to the draft variations are discussed in section 2.2</p> <p>There are no existing nationally agreed competencies that can be specified in the standard. A generic requirement to ensure people have ‘skills, knowledge and competencies’ in relation to raw milk production and processing is considered too vague and subjective and does not really add to the existing skills and knowledge provisions. As such, specific competencies will be an implementation issue.</p> |

2.3 FSANZ Act assessment requirements

2.3.1 Section 59

2.3.1.1 Cost benefit analysis

The Office of Best Practice Regulation (OBPR) advised (advice received on 06/02/2013 and confirmed on 18/06/14; OBPR reference ID 7876) that P1022 is of a 'minor nature' as the exemptions for raw goat milk products will not be altered.

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 was undertaken.

The issue of implementation costs was raised by submitters, particularly the costs to government of monitoring and verification activities. Additional information related to the steps needed to establish the regulatory framework, based on guidance documentation and expected industry and regulator capabilities, was provided by Victoria during the 2nd Call for Submissions (elaborated in example 4 below). In aggregate, Victoria provided expected costs of:

- establishment costs (regulatory system design and documentation, IT changes, staff training) – \$74,000
- application assessment and approval:
 - per manufacturer applicant – \$9,000
 - per farmer applicant – \$2,875
- enquiry service per year – \$64,000 (anticipated for two years after which the demand would be expected to decrease).

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 (TDIA) exists to protect public health and safety by administering and enforcing dairy food safety legislation. TDIA understands and accepts 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 TDIA for ongoing support. TDIA accept this usually drawn out and lengthy process, as a normal part of business as a regulator.

TDIA will explain, in general terms, the cost to aspiring businesses of implementing a food safety management system, and with raw milk cheese applicants, the need for additional validation and verification controls and costs based on risk assessment and hazard management and control. These additional imposts on TDIA's resources are simply a cost borne in accordance with their regulatory remit. Anyone intending to produce raw milk cheese 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.

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

Example 2: Resource allocation

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 being 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/average applicant |

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 3: 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.

Example 4: A State-based regulatory framework

Dairy Food Safety Victoria (DFSV) documented the steps that it will need to take to establish the regulatory framework, assess individual applications and deal with the businesses that start the process, but do not reach the application step. The following information provides a detailed description of the steps that will be needed to establish the regulatory framework and assess applications. This has been based on the guidance documentation and expected industry and regulator capabilities.

System Establishment (one off costs)

In preparation for the regulation of the production of raw milk products, DFSV will need to develop, document and implement systems that are able to deliver:

1. Accreditation, Monitoring, and Risk Management systems for:

Farms

- Herd health monitoring and management
 - Milk sampling and testing
 - Milking practice and cooling verification
 - Preventative and corrective action monitoring
 - Monitoring frequency and system proportionate to new risk classification (hazards introduced at this stage will not be controlled by a CCP further down the chain)
- 6 monthly audits (as opposed to 24 monthly), more frequent monitoring of performance data (requires DFSV resource)

Carriers

- Temperature control
- Cooling controls
- Contamination prevention
- Monitoring frequency and system proportionate to new risk classification (hazards introduced at this stage will not be controlled by a CCP further down the chain)
- 6 monthly audits (as opposed to none), more frequent monitoring of performance data (requires DFSV resource).

Manufacturers

- Validation system

The development of a system through which to validate that a product qualifies against the criteria and can be produced to consistently qualify will be of critical importance. It is here that the heaviest regulatory risk resides. Regulators will be called upon to provide approval of the food safety system as it relates to production of raw milk products on the basis of this validation. The criteria that SRAs use to construct an appropriate validation program may become a significant barrier to entry to the market. National consistency may be an issue here and implementation should be considered by the SRAs in a suitable forum.

- Communication program
- Sampling system (risk management, in-process samples, finished product)
- Production/GMP
- Product controls

2. Food Safety Manager and in-house Technical Services Provider training

3. Licencing processes: the additional criteria and standards that farms, carriers and manufacturers must meet will require specific approval from the licencing regulator which may take the form of a new licence category or an endorsement on an existing licence. The regulator will need to examine and endorse the validation of production processes and products and the necessary controls and provide specific approval that would preclude existing licensees incorporating raw milk products under an existing licence. Dairy farms and carriers that seek to participate in the raw milk product chain will potentially increase in their risk classification and therefore level of compliance monitoring again necessitating new licence categories.

4. IT support changes (Licence Manager – to facilitate licence endorsement fields, additional checklists etc)

Costs

36 people days – \$24,000)
IT development costs – \$50,000
TOTAL \$74,000

System implementation (ongoing)

1. Pre-validation processes at a manufacturer level (per business): (5 days Technical Services, 10 days Compliance Staff)
 - Technical advice on validation plans and expectations (including critical limits) (2d Technical Services)

- Pre-screening of product phys/chem parameters to qualify for validation (1d Technical Services)
 - Review and approve validation plan (incl critical limits) (2d Technical Services)
 - Site Inspection/Approval (Compliance Staff 2 Days)
 - Compliance advice (Food Safety Program, Product testing, raw milk receival etc)
 - Farm/Carrier accreditation (Compliance Staff 4)
 - Monitoring of validation phase (sale/no-sale of product?) 12 months (Compliance Staff 4 days)
2. Accreditation at farmer (5 FTE days \$2876)
- Review individualised FSP (iterative process that can take large amounts of time) not cost-recovered
 - Inspect dairy
 - Approve system/licence endorsement
3. Enquiry handling
- Technical Services 0.5 FTE for first two years (NZ experience = 1 FTE x 2 years)
4. DFSV participation in SRA proposed “expert assessment committee” (Executive)

In discussion with most jurisdictions, it was 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 would 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 than by enforcement through costly prosecutions. |
| Costs | All dairy businesses operate under a compliance regime, including licensing and audit arrangements and associated fees and charges. The information provided by state regulatory authorities identify additional potential costs and impacts associated with this new area of regulation. |

Industry:

| | |
|----------|---|
| Benefits | Current dairy producers and processors, businesses looking to enter the raw milk cheese industry, importers and retailers would benefit from a greater range of safe raw milk cheese compliant with the Code, allowing broader market access and profit opportunities. The draft variations are deregulatory in nature allowing a wider range of products. The draft variations are also deregulatory in nature in that they remove the need for industry to lodge individual applications to amend the Code to permit the sale of specific types of raw milk cheese. |
|----------|---|

Such applications, if approved, may confer an exclusive benefit to the applicant and, if so, the applicant would be 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. These sorts of costs are now avoidable for a range of cheeses.

Costs The measures to be specified in Standard 4.2.4 to allow for raw milk cheese manufacture are consistent with requirements imposed internationally where raw milk cheeses 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 indicated 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.

2.3.1.2 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. These restrict the use of raw milk. An amendment to the Standard is needed to change current requirements. The draft variations are consistent with regulatory requirements in other countries where raw milk cheese are permitted.

2.3.1.3 Any relevant New Zealand standards

Standards 4.2.4 and 4.2.4A are Australia-only standards. Standard 1.6.1 applies in Australia and New Zealand. The New Zealand legislation for dairy products is summarised at <http://www.foodsafety.govt.nz/industry/sectors/dairy/documents/legislation.htm>.

2.3.1.4 Any other relevant matters

Other relevant matters are considered below.

2.3.2. Subsection 18(1)

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

2.3.2.1 Protection of public health and safety

FSANZ is satisfied that the approved draft variations are consistent with the statutory objective of 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. Category 3 products present a medium to high level of risk (depending on the pathogen) to both general and susceptible population groups because there are no measures to ensure pathogens are not present in bulk milk nor can subsequently prevent survival and growth through further handling and processing steps.

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 for the raw milk products within the scope of P1022.

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

FSANZ considered that the existing generic labelling requirements in Part 1.2 of the Code provide adequate information about raw milk cheese to enable consumers to make informed choices. Manufacturers may provide further voluntary information on raw milk cheese, providing such information is not false, misleading or deceptive.

2.3.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

2.3.3 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 is satisfied that the risk analysis on which the approved draft variations are based uses 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 *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
- 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 cheese result from the risk assessment work undertaken for P1007.

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

The draft variations reflect 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 Agreement on the Application of Sanitary and Phytosanitary Measures was made (see section 2.4.2).

- **any written policy guidelines formulated by the Ministerial Council⁴**

The Australia and New Zealand Food Regulation Ministerial Council developed an *Overarching Policy Guideline on Primary Production and Processing Standards⁵*. FSANZ has had regard to the policy guidance and higher order principles in these guidelines.

2.4 Risk communication

2.4.1 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.

⁴ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

⁵ The Policy Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

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 SDC.

When the FSANZ Board approves a draft variation to the Code, that decision is notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review, stakeholders are notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.4.2 World Trade Organization (WTO)

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

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. FSANZ made a notification to the WTO for this Proposal in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. No WTO member nation provided comment on this Proposal.

3 Transitional arrangements

3.1 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 website⁶. 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 was released in July 2014.

The FSANZ Board approved the proposed changes to the Code in December 2014. The new Code will commence in March 2016 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 variations at Attachment A if not rejected by the Forum. The new Code will then need to be amended to incorporate any outstanding changes made to Chapters 1 and 2 of the current Code, including the variations to Standard 1.6.1 at Attachment A. Chapters 3 and 4 will be automatically incorporated into the new Code.

The amendment to Chapter 1 of the new Code resulting from this Proposal is provided at Attachment D.

4 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.

⁶ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

Individual food safety programs for farms and factories are validated by SDFAs before licences are granted and compliance is monitored through regular audits.⁷

Implementation for imported product is discussed in section 2.2.

5 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. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)

⁷ <http://www.dairyaustralia.com.au/Industry-information/Food-safety-and-regulation/Regulatory-Framework/Regulatory-overview.aspx>

Attachment A – Approved draft variation/s to the *Australia New Zealand Food Standards Code*



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

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

Dated [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 Cheese) 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 the method prescribed by this Standard; and
- (b) does not adversely affect the microbiological safety of any raw milk cheese produced from that milk; and
- (c) is documented in a food safety program required by this Standard; and
- (d) has been recognised or approved by the relevant authority.”

“**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 cheese** means raw milk that is used or is to be used to make a raw milk cheese.”

“**raw milk** means milk that has not been processed in accordance with subclause 16(1), subclause 16(2) or paragraph 16(3)(a) of this Standard.”

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

“**raw milk cheese** means a cheese or cheese product made with raw 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 cheese.”

[1.6] omitting from subparagraph 16(3)(b) “clause 1 of Standard 4.2.4A” and substituting “Division 5 if used to make raw milk cheese”

[1.7] inserting after clause 16

“Division 5 – Additional requirements for raw milk cheese 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 cheese and to raw milk cheese.

Subdivision 2 – Primary production of milk for raw milk cheese

18 Application

A dairy primary production business that produces milk for raw milk cheese 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 cheese 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 cheese.

21 Requirements for animal identification and tracing

Each animal that will be or has been milked for milk for raw milk cheese 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) Silage must not be fed to animals milked for milk for raw milk cheese.
- (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 that comes into contact with milk for raw milk cheese;
 - (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 cheese 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 cheese must be clean and dry before the animal is milked.

25 Requirements for cooling and storage

(1) Milk for raw milk cheese must be cooled to a maximum temperature of 6°C within two hours of milking.

(2) Subclause (1) does not apply if the dairy primary production business uses a documented alternative to the method prescribed by that subclause.

(3) Milk for raw milk cheese that is stored must be kept at a temperature not exceeding 5°C while in storage.

(4) Milk for raw milk cheese must be kept separate from milk used or intended to be used for dairy products that are not a raw milk cheese.

26 Requirements relating to non-conforming milk

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

Subdivision 3 – Transport of milk for raw milk cheese

27 Application

A dairy transport business that collects and transports milk for raw milk cheese 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 cheese 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 the dairy transport business uses a documented alternative to the method prescribed by that subclause.

30 Handling requirements

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

Subdivision 4 – Processing of milk for raw milk cheese

31 Application

A dairy processing business that processes milk for raw milk cheese 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) address each of the following in relation to 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 cheese 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 the dairy processing business uses a documented alternative to the method prescribed by that subclause.
- (3) Raw milk cheese 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 cheese must be kept separate from milk used or intended to be used for dairy products that are not a raw milk cheese.

34 Requirements to control specific food safety hazards

- (1) Prior to the commencement of its processing, milk for raw milk cheese must be monitored to ensure its suitability.
- (2) The level of pathogenic microorganisms in a raw milk cheese 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.
- (3) A raw milk cheese 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 cheese that has been produced and transported in accordance with this Division to make a raw milk cheese.”

[1.8] Updating the Table of Provisions to reflect these variations.

[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 ² /g 10 ² /g 9/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 ⁵ /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 cheese | <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
| | Staphylococcal enterotoxins | 5 | 0 | not detected in 25 g | |

”

Attachment B – 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.

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

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation⁸, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

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

Standard 4.2.4A is proposed to be repealed as requirements for raw milk cheese are now covered by the draft variations to Standard 4.2.4 and assessment advice for imports referred to the Department of Agriculture.

Standard 1.6.1 is amended to replace existing limits for “all raw milk cheese” and “raw milk unripened cheese” with limits for *Salmonella* and *Staphylococcal* enterotoxin in “raw milk cheese”. Limits for “butter made from unpasteurised milk” are deleted as this food is not intended to be covered by the amendments to Standard 4.2.4 to apply to raw milk cheese. Limits for “raw milk unripened cheeses” are also deleted as this food would not meet the requirements for a raw milk cheese under Standard 4.2.4.

3. Documents incorporated by reference

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

⁸ convening as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1022 included two rounds of public comment following an assessment and the preparation of a draft Standard and associated reports. The 1st Call for Submissions report was released for public comment from 8 November 2013 to 10 January 2014. Submissions on the draft amendments to Standards 4.2.4 and 1.6.1 were called for on 10 July 2014 for a six-week consultation period.

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 only 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 cheese", "raw milk", "raw milk herd" and "raw milk cheese". These definitions are required to apply the additional requirements under Division 5.

Item 1.2 changes the heading of Division 2 to "Division 2 – General dairy primary production requirements".

Item 1.3 changes the heading of Division 3 to "Division 3 – General dairy collection and transportation".

Item 1.4 changes the heading of Division 4 to "Division 4 – General dairy processing". The addition to the heading of the word "general" under items 1.2, 1.3 and 1.4 is to distinguish between primary production, transport and processing requirements raw milk cheese under Division 5 from those for pasteurised or otherwise heat treated cheese.

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 cheese. This reflects that that milk must comply with the requirements of Division 5.

Item 1.6 replaces the reference in subparagraph 16(3)(b) to Standard 4.2.4A with a reference to Division 5. This reflects the repeal of Standard 4.2.4A under item [2].

Item 1.7 inserts an additional division in the Standard, Division 5, for raw milk cheese.

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

Subdivision 1 – General

Subdivision 2 – Primary production of milk for raw milk cheese

Subdivision 3 – Transport of milk for raw milk cheese

Subdivision 4 – Processing of milk for raw milk cheese

Subdivision 1 comprises clause 17. Clause 17 applies the requirements of Divisions 1 to 4 to the production, transport and processing of raw milk cheese. This provides the baseline set of requirements to which the measures under Division 5 are additional.

Subdivision 2 comprises clauses 18 to 26.

Clause 18 specifies that a dairy primary production business that produces milk for raw milk cheese that must comply with each requirement 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. Subclause 20(1) requires that milk for raw milk cheese not be sourced from a diseased animal. Subclauses 20(2) and 20(3) require that diseased animals be immediately removed and kept separated from other animals from which milk for raw milk cheese is sourced.

Clause 21 requires that animals from which milk for raw milk cheese is sourced be subject to an identification system that ensures individual animals are uniquely identifiable and traceable.

Clause 22 provides additional requirements in relation to feed and water use.

Clause 23 requires the primary production of milk for raw milk cheese to comply with the requirements of Division 4 of Standard 3.2.2 in relation to health and hygiene requirements.

Clause 24 provides a teat washing and drying requirement in relation to animals to be milked.

Clause 25 provides prescriptive cooling and storage requirements for milk for raw milk cheese. Subclause 25(1) provides a requirement to cool milk to a prescribed temperature within a prescribed timeframe. Subclause 25(2) provides that this requirement does not apply if a documented alternative is used. Subclause 25(3) provides a temperature requirement for milk storage. Subclause 25(4) provides a requirement to ensure raw milk cheese is kept separate from milk for other dairy products.

Clause 26 provides a requirement that only milk produced in accordance with Division 5 can be supplied for processing of raw milk cheese.

Subdivision 3 comprises clauses 27 to 30.

Clause 27 specifies that dairy transport businesses that transport milk for raw milk cheese 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 control requirements for the transport of milk for raw milk cheese. Subclause 29(1) specifies temperature time requirements. Subclause 29(2) provides that this requirement does not apply if a documented alternative is used.

Clause 30 requires that milk for raw milk cheese must be kept separate from other milk during transport.

Subdivision 4 comprises clauses 31 to 35.

Clause 31 specifies that dairy processing businesses that process milk for raw milk cheese 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. Clause 32 also requires that the documented food safety program address each of the processing factors 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 cheese. Subclause 33(1) requires that milk for raw milk cheese be kept below a prescribed maximum temperature from its collection by the processor and the commencement of its processing. Subclause 33(2) provides that this requirement does not apply if a documented alternative is used. Subclause 33(3) requires that the processing of milk for raw milk cheese commence within 24 hours of that milk being milked. Subclause 33(4) provides that this requirement does not apply if a documented alternative is used. Subclause 33(5) requires that milk for raw milk cheese be kept separate from milk for other dairy products.

Clause 34 provides additional requirements in relation to microbiological monitoring and processing outcomes. Subclause 34(1) requires the dairy processing business to monitor the suitability of milk for raw milk cheese prior to the commencement of its processing. Subclauses 34(2) and 34(3) requires that the raw milk cheese produced meet prescribed outcomes in relation to pathogenic microorganisms.

Clause 35 requires that only milk produced in accordance with Division 5 can be used for processing of raw milk cheese.

Item 1.8 updates the table of provisions.

6.2 Item [2]

Item 2 repeals Standard 4.2.4A.

6.3 Item [3]

Items 3.1 and 3.2 omit 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)”.

Item 3.3 inserts limits for Salmonella and Staphylococcal enterotoxins for “raw milk cheese”.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



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

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

Dated [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 ² /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 ⁵ /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 D – Draft variation to the Australia New Zealand Food Standards Code in 2015 following P1025

Background

FSANZ is reviewing the Australian New Zealand Food Standards Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025. FSANZ released a draft revision of the Code for public comment in 2014.

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 Chapters 1 and 2 of the current Code, such as the variations to Standard 1.6.1 proposed by P1022. This is the rationale for the draft variation below.

This draft variation is provided for background only. Its content and structure may change as P1025 progresses.

Draft instrument

Food Standards Code—Variation

Made under the *Food Standards Australia New Zealand Act 1991*

1 Name of instrument

This instrument is the *Food Standards Australia New Zealand Code — Revocation and Transitional Variation 2015 (No. 1)*.

2 Commencement

This instrument commences on the day after it is registered.

3 Variation of Schedule 27

Schedule 1 varies the Australia New Zealand Food Standards Code — Schedule 27 — *Microbiological limits for foods*.

Schedule 1 Variation of Schedule 27

(section 3)

Butter made from unpasteurised milk and/or unpasteurised milk products

| | | | | |
|-------------------------------------|---|---|-------------------------|--------------------|
| <i>Campylobacter</i> | 5 | 0 | not detected in 25 g | |
| Coagulase-positive staphylococci | 5 | 1 | 10 /g | 10 ² /g |
| Coliforms | 5 | 1 | 10 /g | 10 ² /g |

| | | | | |
|-------------------------|---|---|-------------------------|------|
| <i>Escherichia coli</i> | 5 | 1 | 3 /g | 9 /g |
| <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
| SPC | 5 | 0 | 5x10 ⁵ /g | |

[2] Omit from the table to section S27—3

All raw milk cheese (cheese made from milk not pasteurised or thermised)

| | | | | |
|-------------------|---|---|-------------------------|--|
| <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
|-------------------|---|---|-------------------------|--|

[3] Omit from the table to section S27—3

Raw milk unripened cheeses (moisture content > 50% with pH > 5.0)

| | | | | |
|----------------------|---|---|-------------------------|--|
| <i>Campylobacter</i> | 5 | 0 | not detected in 25 g | |
|----------------------|---|---|-------------------------|--|

[4] Insert into the table to section S27—3, after the entry for *All cheese*

Raw milk cheese

| | | | | |
|------------------------------------|---|---|-------------------------|--|
| <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
| <i>Staphylococcal enterotoxins</i> | 5 | 0 | not detected in 25 g | |