

**2 May 2012**  
**[9-12]**

## **Approval Report – Proposal P1007**

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

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Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to examine whether the processing requirements currently mandated for milk and milk products in the *Australia New Zealand Food Standards Code* (the Code) were appropriate. That is, could an acceptable level of public health and safety be achieved through alternative processing and/or production measures to those currently specified.

On 19 August 2011, FSANZ sought submissions on a draft variation to Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products and published an associated report. FSANZ received 73 submissions.

FSANZ approved the draft variations to Standard 4.2.4 and 4.2.4A on 18 April 2012. The COAG Legislative and Governance Forum on Food Regulation<sup>1</sup> (FOFR) was notified of FSANZ's decision on 30 April 2012.

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

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<sup>1</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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### Supporting documents

The following material used in the preparation of this Report, is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1007primary3953.cfm>

- SD1 Technical Assessment (Approval)
- SD2 Membership of the Raw Milk Products SDC

# 1. Executive summary

FSANZ prepared Proposal P1007 to assess whether the processing requirements currently mandated for milk and dairy products in the *Australia New Zealand Food Standards Code* (the Code) were appropriate. Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products specifies processing provisions for milk and dairy products that essentially require pasteurisation (or an equivalent process). Alternative processing requirements for cheese and permissions for specific raw milk cheeses (Swiss Emmental, Gruyère, Sbrinz and Roquefort) have previously been included in the Code following a case-by-case assessment process.

Based on the risk assessment work undertaken, three categories of raw milk products were defined in terms of the effect processing factors and product properties of the final product have on pathogen survival and growth.

- **Category 1** products are 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.

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

The technical assessment found:

- 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.

Following three rounds of public consultation, FSANZ has decided to amend the Code to permit category 1 products. A new proposal will be prepared to consider permissions for category 2 products, including the development of technical materials that would be required to implement their safe production. The current exemption that allows raw goat milk will also be reviewed under this new proposal.

## **2. Introduction**

### **2.1 The Proposal**

During development of Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products<sup>2</sup>, consideration was given to undertaking an assessment of raw milk products. This work was deferred until completion of Standard 4.2.4. FSANZ then began work on raw milk products through Proposal P1007, including addressing public health and safety issues, existing applications to amend the Code and regulatory inconsistencies.

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

### **2.2 The current Standard**

Standard 4.2.4 specifies processing requirements for milk and dairy products that dairy processing businesses must comply with. Clause 15 of Standard 4.2.4 requires milk that is to be sold as liquid milk or used in the manufacture of dairy products (excluding cheese) to be pasteurised (or equivalently processed).

Alternative processing requirements to pasteurisation are permitted for cheese production under clause 16, including thermisation (in combination with ripening) and curd cooking<sup>3</sup> in combination with ripening and minimum moisture content.

Standard 4.2.4A – Primary Production and Processing Standard for Specific Cheeses permits the sale of four raw milk cheeses produced in accordance with French (Roquefort cheese) or Swiss regulations (Swiss Gruyère, Sbrinz, Emmental). These permissions were provided following assessment of applications made to FSANZ.

In addition to the processing provisions, Standard 4.2.4 specifies through chain food safety requirements which require dairy primary production businesses, dairy transport businesses and dairy processing business to control food safety hazards by implementing a documented food safety program.

### **2.3 Reasons for preparing the Proposal**

There were a number of drivers for reviewing the current processing requirements in Standard 4.2.4 including:

- ensuring an efficient and competitive food industry
- consumer demand for raw milk products (noting applications on the FSANZ Work Plan requesting permissions for raw drinking milk and raw milk cheeses)
- national consistency in legislative requirements.

The Proposal was prepared to assess whether the processing requirements currently mandated for milk and dairy products in the Code are appropriate. That is, can an acceptable level of public health and safety be achieved through alternative processing and/or production measures to those currently specified.

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<sup>2</sup> Standard 4.2.4 is an Australia only standard came into effect on 5 October 2008. It contains measures to address food safety for the dairy industry from production of milk through to processing, including manufacture of specified dairy products.

<sup>3</sup> Curd cooking is the application of heat to cheese for technical purposes such as expelling moisture.

## 2.4 Procedure for assessment

The Proposal was assessed under the Major Procedure.

## 2.5 Decision

The draft variations to Standards 4.2.4 and 4.2.4A as proposed following assessment were approved without change. The approved variations are at Attachment A.

# 3. Summary of the findings

## 3.1 Risk assessment

FSANZ prepared three risk assessments to generate information on the public health risks which may be associated with raw milk products<sup>4</sup>. The *Microbiological Risk Assessment of Raw Milk Cheese* 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. Risk assessments were also undertaken for raw goat milk and raw cow milk and these 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 outputs of these assessments were used to assess the level of risk that raw milk product categories pose under certain production and processing controls.

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

- **Category 1** products are 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.

The category approach provided for the assessment of combinations of microbiocidal and microbiostatic control measures (“hurdles”) on pathogen growth or survival as well as through chain factors that impact on pathogen presence.

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

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

- the milk production factors that affect the prevalence of pathogens in raw milk

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<sup>4</sup> The three microbiological risk assessments (raw cow milk, raw goat milk and raw milk cheese) can be found on the FSANZ website <http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp1007primary3953.cfm>

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

The key findings were:

- For category 1 and 2 products, 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.

### **3.2 Risk management**

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

Following consultation, FSANZ adjusted the scope of the Proposal to category 1 products only. This decision was based on an analysis that considered:

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

The decision to permit category 1 products was based on the scientific assessment work and a qualitative cost benefit analysis and supported by submissions. The draft amendment specifies a broader range of production parameters for cheese and cheese products (e.g. minimum moisture content, minimum storage time) to provide increased flexibility in the measures a dairy processing business can take to reduce to safe levels any pathogens that may be present in the food. Variation to the processing requirements in Standard 4.2.4 has also resulted in a consequential amendment to Standard 4.2.4A with the deletion of Swiss Emmental Gruyère and Sbrinz cheeses from the Table. These cheeses will now be captured by the amended processing parameters specified in subclause 16(3) of Standard 4.2.4.

FSANZ has decided to prepare a new proposal to assess requirements for category 2 products. This will enable development of additional materials to support the control measures and systems required to implement the safe production of category 2 products.

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

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

### **3.2.1 Summary of submissions**

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal.

Every submission on an application or proposal is reviewed by FSANZ staff who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

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

The 2<sup>nd</sup> Assessment Report for P1007 was released for public comment from 19 August to 14 October 2011 and sought comment on draft amendments to Standards 4.2.4 and 4.2.4A. Seventy-three submissions were received, the majority (56) from consumers wanting greater access to raw milk products, in particular, raw drinking milk. In general, those submissions wanting greater access to raw milk products supported the draft variation to the Code to permit category 1 products. However, many wanted further changes to permit category 2 and 3 products. Submissions received during assessment are available on the FSANZ website.

A summary of the main issues or matters raised in submissions and FSANZ responses is provided below in Table 1.

**Table 1: Summary of issues raised in submissions**

Issue	Raised by	FSANZ Response
<b>Sale of raw goat milk</b>	More than half the submissions from consumers were in support of access to raw goat milk, in particular the continued supply of legal raw goat milk in Queensland.	The risk assessment undertaken for this project concluded that raw drinking milk presents a high risk to consumers. The exemption for states and territories from the processing requirement under Clause 15 will be considered in the new proposal.
<b>Change of scope</b>	A number of submitters were disappointed with the change of scope with the current proposal, only permitting category 1 products. This was evident in submissions from the EU Commission and in several industry and consumer responses that argued that artisanal cheesemakers should not be restricted to category 1 products.	FSANZ intends to consider permissions for category 2 products through a new proposal. The time taken for this work may be frustrating for stakeholders, but reflects the importance of establishing appropriate safety controls and verification measures to minimise risk to consumers and to support the industry and enforcement agencies given that these products have no history of manufacture in this country.
<b>Microbiological limits</b>	Several submissions raised the need to amend the microbiological standards in Standard 1.6.1 to reflect the approach that has been taken. These included submissions from government agencies (WA Health, NZ MAF and EU commission) and industry and consumer submissions that included proforma wording stating that the current <i>E. coli</i> limit is too onerous and inconsistent with international standards.	<p>A review of Standard 1.6.1 commenced in 2012. Rather than progressing this work as a single complex proposal, a number of pieces of work are proposed. One of the first areas that will be looked at is limits for <i>Listeria monocytogenes</i> in ready to eat foods (which in its scope would include all RTE dairy products). It is proposed that microbiological criteria needed to support the production of category 2 products, which will result in amendments to current limits, is progressed under the new proposal for raw milk products. This would include:</p> <ul style="list-style-type: none"> <li>• aligning food descriptions/terminology with the category approach</li> <li>• removing unnecessary limits (e.g. products that are not permitted)</li> <li>• reviewing limits for indicator organisms.</li> </ul>

Issue	Raised by	FSANZ Response
<b>Consistency with New Zealand</b>	Several submissions raised that Australia should be consistent with the approach taken by New Zealand in permitting raw milk products.	The category approach undertaken by FSANZ has been consistent with New Zealand. The new proposal will consider permissions for category 2 products. It is anticipated that any permissions resulting from that should be consistent with New Zealand. Microbiological limits in Standard 1.6.1 and generic labelling standards are already joint Australia New Zealand standards.
<b>Labelling</b>	Some submissions raised the issue that labelling/provision of information to consumers is required to enable consumers to make an informed choice about any risks associated with raw milk products.	Existing generic labelling requirements in the Code will apply to category 1 products (e.g. name of the food, ingredient labelling and date marking). Generic labelling provisions are provided in the Code to protect the health and safety of consumers and to provide adequate information to enable consumers to make informed choices. As the risk presented by category 1 products is very low, no additional labelling requirements were prescribed. Labelling requirements for category 2 products and other consumer information needs will be considered in the new proposal.
<b>Inconsistent implementation</b>	One submission from a specialty cheese retailer raised that there is a need to address inconsistencies in state-based approaches to cheese permissions.	Consistent implementation is addressed through the Implementation Sub-Committee <sup>5</sup> of FRSC. Members have been asked to agree to the formation of an Implementation Working Group for the regulation and enforcement of category 1 raw milk products under Standard 4.2.4.

<sup>5</sup> The Implementation Sub-Committee is a sub-committee of the Food Regulation Standing Committee. Its role is to develop and oversee a consistent approach across jurisdictions to implementation and enforcement of food regulations and standards, regardless of whether food is sourced from domestic producers, export-registered establishments or from imports.

### 3.3 Risk Communication

FSANZ publishes a Notification Circular and media releases announcing all calls for submissions and also uses social media and publications such as *Food Standards News* to promote these releases.

Further website material in the form of a question and answer fact sheet was developed to help explain the progress of the Proposal and FSANZ's ongoing work in this area.

Three rounds of public consultation were undertaken during the assessment of this Proposal<sup>6</sup>: A discussion paper was released for public comment in 2008, the 1<sup>st</sup> Assessment Report was released for comment in December 2009 and the 2<sup>nd</sup> Assessment Report which included a draft variation to the Code, published for comment in August 2011.

Targeted consultations were also undertaken with raw goat milk producers and specialty cheese manufacturers, who have expressed an interest in manufacturing raw milk cheeses, in order to identify drivers for stakeholder positions and attitudes.

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

#### 3.3.1 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.

FSANZ made a notification to the WTO for this Proposal in accordance with the WTO Sanitary and Phytosanitary Measures (SPS) Agreement. Comments were received from the EU SPS Notification Authority and these are addressed under section 3.2.1.

## 4. Reasons for decision

FSANZ considered that the processing requirements for dairy products in Standard 4.2.4 of the Code should be amended because:

- category 1 products provide for elimination of pathogens, and by definition, the risk presented by such products is very low
- option 2 will allow some alternative processing measures while maintaining the current level of public health and safety
- the measures are consistent with principles of minimum effective regulation.

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<sup>6</sup> The Discussion Paper, 1<sup>st</sup> Assessment Report and 2<sup>nd</sup> Assessment Report are available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/primaryproductionprocessingstandardsaustraliaonly/dairyrawmilkproducts/>

A process for considering permissions for category 2 products, including the development of technical materials to support implementation, can be progressed through a new Proposal.

## 4.1 Section 59

FSANZ had regard to the following matters under section 59 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Proposal outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

The parties identified as being affected by Proposal P1007 included:

- **industry**, including current dairy producers and processors, businesses looking to enter a raw milk products industry, importers and retailers
- **consumers**, including those demanding raw milk products and those against raw milk products
- **governments**, including State and Territory enforcement agencies, Commonwealth government and member nations of the World Trade Organization (WTO).

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

- there were no other measures that would be more cost-effective than a variation to Standard that could achieve the same end

No other measures were considered as processing requirements for dairy products are prescribed in the Code. Any changes to these requirements require a variation to Standard 4.2.4.

- any relevant New Zealand standards

New Zealand has its own food safety legislation for food businesses and primary producers which is developed by the Ministry of Agriculture and Forestry (MAF). Standard 4.2.4 is an Australia-only standard.

New Zealand introduced new regulations that allow for production and importation of raw milk products in 2009. FSANZ has consulted with New Zealand on the approach taken by each country and the category approach developed under P1007 has been consistent with New Zealand.

- any other relevant matters.

The need for implementation materials to assist industry and enforcement agencies, such as technical guidelines, was a consideration in the assessment of this proposal. The assessment concluded that further technical work and supporting materials would be required for category 2 products and that this be developed under a new proposal.

## **4.2 Addressing FSANZ’s objectives for standards-setting**

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Proposal as follows.

### **4.2.1 Protection of public health and safety**

The assessment framework developed for this Proposal defined three categories of products based on the effect processing factors and product properties of the final product have on pathogen survival and growth. The risk management decision considered the level of risk associated with each category and whether the control measures required to support safe production could be implemented and verified.

The decision to permit category 1 products varies Standard 4.2.4 to allow some alternative processing measures while maintaining the current level of public health and safety.

The additional control measures and systems required to implement the safe production of category 2 products still need to be developed and will be progressed through a new proposal.

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

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

FSANZ has determined that the existing generic labelling requirements in the Code provide adequate information about category 1 products to enable consumers to make informed choices. No additional labelling provisions or information requirements have been prescribed. Manufacturers will also not be precluded from providing further voluntary information on category 1 products.

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

The prevention of misleading or deceptive conduct was not relevant to the assessment of P1007.

### **4.2.4 Subsection 18(2) considerations**

FSANZ has also had regard to the objectives set out in subsection 18(2):

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

FSANZ prepared three risk assessments which generated information to inform the risk management framework for assessment (category approach) and determined the level of risk that different categories of raw milk products pose under certain production and processing controls.

- the promotion of consistency between domestic and international food standards

In assessing P1007, FSANZ has had regard to the Codex *Code of Hygienic Practice for Milk and Milk Products* CAC/RCP 57-2004 and requirements of the European Commission (EC) sanitary and food hygiene regulations which underpin existing permissions in the Code

for Swiss Gruyère, Sbrinz and emmental cheese and French Roquefort. FSANZ has also collaborated with New Zealand to provide a consistent regulatory approach to raw milk products sold in Australia and New Zealand.

- the desirability of an efficient and internationally competitive food industry

Several imported raw milk cheeses had previously been assessed by FSANZ and permitted in the Code. This raised the issue of an unlevel playing field as domestic production of such cheeses was not permitted. An outcome from P1007 is amendments to the processing requirements in Standard 4.2.4 that apply equally to domestically produced and imported product.

- the promotion of fair trading in food

Notification was made to the WTO in accordance with the WTO Sanitary and Phytosanitary Measures (SPS) Agreement.

- any written policy guidelines formulated by the Ministerial Council.

The Australia and New Zealand Food Regulation Ministerial Council (now known as the Legislative and Governance Forum on Food Regulation) developed an [Overarching Policy Guideline on Primary Production and Processing Standards](#). FSANZ has had regard to the policy guidance and higher order principles in these guidelines.

## 4.4 Implementation

The draft variation comes into effect from the date of gazettal.

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

## Attachments

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

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



### **Food Standards (Proposal P1007 – 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

*[DRAFT – NOT FOR SIGNATURE]*

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

**1 Name**

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

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

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

**3 Commencement**

This variation commences **on the date of gazettal**.

**SCHEDULE**

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

**16 Processing of dairy products to make cheese and cheese products**

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

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

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

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

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

- (a) such that –
  - (i) the curd is heated to a temperature of no less than 48°C; and
  - (ii) the cheese or cheese product has a moisture content of less than 39%, after being stored at a temperature of no less than 10°C for a period of no less than 120 days from the date of processing; or
- (b) in accordance with clause 1 of Standard 4.2.4A.

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

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

Gruyere, Sbrinz or Emmental cheese	The <i>Ordinance on Quality Assurance in the Dairy Industry</i> of the Swiss Federal Council of 18 October 1995	
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[2.2] *omitting the Editorial note following clause 1, substituting –*

**Editorial note:**

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

## **Attachment 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.

FSANZ prepared Proposal P1007 to examine whether the processing requirements currently mandated for milk and milk products in the Code were appropriate. That is, could an acceptable level of public health and safety be achieved through alternative processing and/or production measures to those currently required. The Authority considered Proposal P1007 in accordance with Division 2 of Part 3 of the FSANZ Act and has prepared draft variations to Standards 4.2.4 and 4.2.4A.

Following consideration by the Legislative and Governance Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft standard or draft variation of a standard.

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

### **2. Purpose and Operation**

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

### **3. Documents incorporated by reference**

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

### **4. Consultation**

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1007 has included two rounds of public consultation, at 1<sup>st</sup> Assessment and 2<sup>nd</sup> Assessment, as well as public consultation on a Discussion Paper. The Discussion Paper was released for consultation on 6 August 2008 for a six-week consultation period. The 1<sup>st</sup> Assessment Report for P1007 was released for public comment on 16 December 2009 for a consultation period of 11 weeks. The 2<sup>nd</sup> Assessment Report was released for public comment from 19 August to 14 October 2011.

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

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

## **5. 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. Contents of the Variations**

### **6.1 Clause 16 of Standard 4.2.4**

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

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

Subclause 16(2) specifies processing requirements for dairy products used to make cheese or cheese products. The combination of time and temperature required for dairy products differs from the combination required for milk because of the variation in fat or solids content of dairy products. This reflects the approach in clause 15 for the processing of milk and dairy products.

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

The requirement contained previously in paragraph 16(b) has been replaced with paragraph 16(1)(b). The parameters have been amended to increase the required processing temperature to no less than 64.5°C, the required time period to no less than 16 seconds, and the required storage temperature to no less than 7°C.

The requirement previously contained in paragraph 16(c) has been replaced with paragraph 16(3)(a). The parameters have been amended such that the moisture content must be less than 39% (replacing 36%) and the storage period must be no less than 120 days from the date of processing (reduced from 6 months).

The amended processing parameters and product characteristics in clause 16 have been assessed as achieving an acceptable level of safety.

### **6.2 Table to Clause 1 of Standard 4.2.4A**

The table to clause 1 of Standard 4.2.4A is amended to delete the entry for “Gruyere, Sbrinz or Emmental cheese”. Conditions for the manufacture of these cheeses are now covered by the Standard 4.2.4 requirements.

### **6.3 Editorial note following clause 1 of Standard 4.2.4A**

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