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

**2-04**
**17 March 2004**

# INITIAL ASSESSMENT REPORT

# APPLICATION A499

# TO PERMIT THE SALE OF ROQUEFORT CHEESE

**DEADLINE FOR PUBLIC SUBMISSIONS** to FSANZ in relation to this matter:
**28 April 2004**
*(See 'Invitation for Public Submissions' for details)*

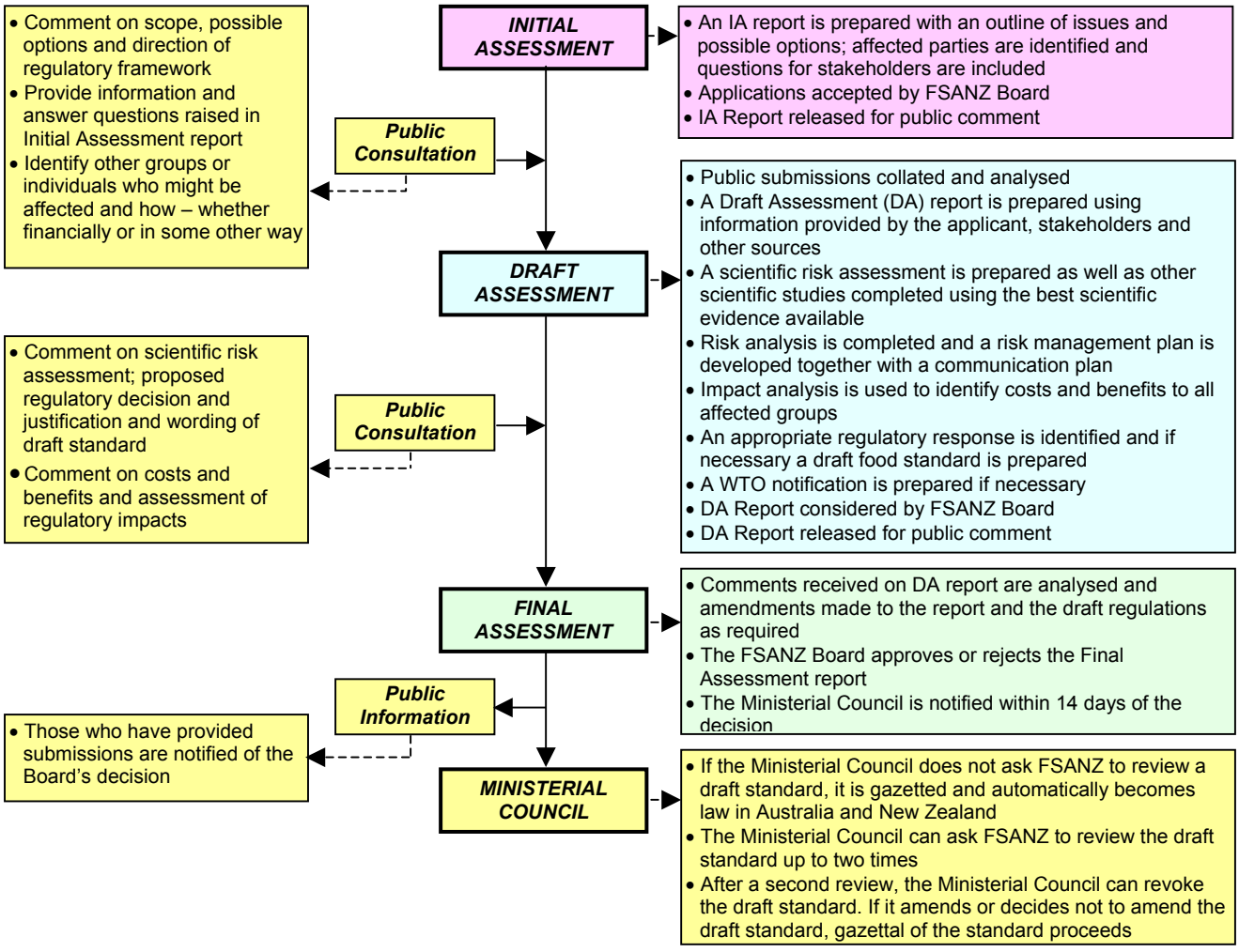
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



## INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A499, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand**
**PO Box 7186**
**Canberra BC ACT 2610**
**AUSTRALIA**
**Tel (02) 6271 2222**
**www.foodstandards.gov.au**

**Food Standards Australia New Zealand**
**PO Box 10559**
**The Terrace WELLINGTON 6036**
**NEW ZEALAND**
**Tel (04) 473 9942**
**www.foodstandards.govt.nz**

Submissions should be received by FSANZ **by 28 April 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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## Executive Summary

An Application has been received from the French Government (Ministry of Agriculture and Fisheries) to amend Standard 2.5.4 in the *Australia New Zealand Food Standards Code* (the Code) to permit the sale of Roquefort cheese made from raw sheep's milk.

Roquefort cheese is a traditional French blue-veined cheese made from raw sheep's milk and ripened with the mould *Penicillium roqueforti* and subjected to a maturation period of at least 90 days in caves. This cheese has AOC status (Appellation-controlled origin, or protected designation of origin), which means that the cheese can only be produced in the region surrounding the town of Roquefort-sur-Soulzon. This Application therefore seeks specific permission for Roquefort cheese, rather than a general permission for all raw milk blue cheeses.

Currently the Code allows the importation of raw milk cheeses that have been assessed to have an equivalent level of safety as cheeses made from heat-treated milk. Three raw milk cheeses are permitted to be imported from Switzerland through specific permission under conditions as specified in Standard 2.5.4. In addition, the manufacture of raw milk very hard cheeses is specifically permitted through an exemption to the heat treatment requirements in Standard 1.6.2. This exemption is based on the assessment that these cheeses are safe due to their low moisture content and long maturation time which control the level of pathogens in this product.

There is currently no approval for the sale of Roquefort cheese in Australia or New Zealand. This Application will be assessed to determine if a variation to Table to clause 3 of Standard 2.5.4. is warranted that would permit the sale of Roquefort cheese.

This Initial Assessment Report considers whether the Application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). This Application has been assessed against the requirements for Initial Assessment of section 13 of the FSANZ Act, and is accepted and will be progressed to Draft Assessment for the following reasons.

- The Application seeks to amend the Code to permit the sale of Roquefort cheese.
- Current permitted raw milk cheeses in the Code are listed in the Table to clause 3 of Standard 2.5.4. There is currently no permission for Roquefort cheese.
- Therefore, if further assessment of Roquefort cheese derived from raw sheep's milk shows it to have an equivalent level of safety as cheese made from heat-treated milk, this Application relates to a matter that warrants a variation to Standard 2.5.4.
- The Application is not so similar to any previous application that it ought not be accepted.
- At this stage of the assessment, there is no reason to believe that costs arising from such a variation to permit the sale of Roquefort cheese would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.

- There are no available measures other than a variation to the Code to permit the sale of Roquefort cheese.

The purpose of this Initial Assessment Report is to provide relevant information to assist in identifying the affected parties and to outline the relevant issues necessary for FSANZ to complete assessment of the Application. The information needed to complete the assessment will include information received from public submissions. Comments are therefore sought from all interested parties in all matters relevant to consideration of this Application. In considering the matter further, FSANZ will assess the public health and safety issues. It is also necessary for FSANZ to understand the potential impacts and implications of any amendment to this particular standard in the fashion sought by this Application.

Public submissions are now invited on this Initial Assessment Report. Comments are specifically requested on the scientific aspects of this Application, in particular, information relevant to assessing the safety of Roquefort cheese, as well as on impacts on the industry and consumers.

# 1. Introduction

An Application (Application A499) has been received from the French Government (Ministry of Agriculture), on behalf of French manufacturers and exporters of AOC (Appellation d'origine contrôlée) Roquefort cheese made from raw sheep's milk, to amend Standard 2.5.4 in the Code to permit its sale. The processing requirements for cheese and cheese products as specified in the Code do not apply in New Zealand under the New Zealand (*Australia New Zealand Food Standards Code*) Food Standards 2002.

Instead, processing requirements for cheese and cheese products are specified in New Zealand (Milk and Milk Products Processing) Food Standards 2002 (Attachment 3). A variation to the Code permitting the importation of Roquefort will automatically apply in Australia. However, the importation of Roquefort into New Zealand will only be permitted if the New Zealand (Milk and Milk Products Processing) Food Standards 2002 are amended, which is a matter for the New Zealand Government to determine.

Roquefort cheese is a traditional French blue-veined cheese made from raw sheep's milk and ripened with the mould *Penicillium roqueforti* and subjected to a maturation period of at least 90 days in caves. This cheese has AOC status (Appellation-controlled origin, or protected designation of origin), which means that the cheese can only be produced in the region surrounding the town of Roquefort-sur-Soulzon. This Application therefore seeks specific permission for Roquefort cheese, rather than a general permission for all raw milk blue cheeses.

Roquefort cheese is manufactured according to relevant European and French legislation and regulations (Attachment 1). A description of the manufacturing process is provided in Attachment 2.

All cheese sold in Australia, including imported products, must comply with Standard 1.6.2 of the Code, which requires pasteurisation of milk and milk products used for the manufacture of cheese. Alternatively, thermisation may be used if combined with a storage period of the subsequent cheese.

The heat treatment requirements, under Standard 1.6.2 – Processing Requirements of the Code, prohibit the use of raw milk to manufacture cheeses except where these are:

- expressly permitted within the Table to clause 3 to Standard 2.5.4 (Gruyere, Sbrinz and Emmental manufactured in accordance with specified Swiss regulations): or,

- exempted from the milk heat treatment requirement (extra hard grating cheeses only).

In addition, all cheese sold in Australia must comply with Standard 1.6.1 - Microbiological Limits for Food.

# 2. Regulatory Problem

There is currently no approval for the sale of Roquefort cheese in Australia or New Zealand. However, the Code allows the importation of raw milk cheeses that have been assessed to have an equivalent level of safety as cheeses made from heat-treated milk.

Three raw milk cheeses are permitted to be imported from Switzerland through specific permission under conditions as specified in Standard 2.5.4. In addition, the manufacture of raw milk very hard cheeses is specifically permitted through an exemption to the heat treatment requirements in Standard 1.6.2. Therefore in order for Roquefort to be sold in Australia, specific permission in the Code is required.

## 2.1 Current Standard

*2.1.1 Extract from Standard 1.6.2 - Processing Requirements (Australia Only)*

**2 Processing of cheese and cheese products**

(1) Cheese and cheese products must be manufactured -

(a) from milk and milk products that have been heat treated -

(i) by being held at a temperature of no less than 72°C for a period of no less than 15 seconds, or by using a time and temperature combination providing an equivalent level of bacteria reduction; or

(ii) by being held at a temperature of no less than 62°C for a period of no less than 15 seconds, and the cheese or cheese product stored at a temperature of no less than 2°C for a period of 90 days from the date of manufacture; or

(b) 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 36%, after being stored at a temperature of no less than 10°C for a period of no less than 6 months from the date of manufacture; or

(c) in accordance with clause 3 of Standard 2.5.4.

*2.1.2 Extract from Standard 2.5.4 – Cheese*

**3 Processing of milk and milk products used to produce Gruyere, Sbrinz or Emmental cheese**

Milk and milk products used to manufacture cheese or cheese products specified in Column 1 of the Table to this clause must be produced and processed using a method that –

(a) ensures that the cheese produced achieves an equivalent level of safety protection as cheese prepared from milk or milk products that have been heat treated in accordance with paragraph (2)(a) in Standard 1.6.2; and

(b) is set out in the legislation or documentation listed in Column 2 of the Table to this paragraph.

**Table to clause 3**

| Column 1 | Column 2 documentation |
|---|---|
| **Milk and milk products** | **Legislation or** |
| Milk and milk products used to produce Gruyere, Sbrinz or Emmental cheese only | The Ordinance on Quality Assurance in the Dairy Industry of the Swiss Federal Council of 18 October 1995 |

*2.1.3 New Zealand*

The processing requirements for cheese and cheese products specified in Standard 1.6.2 of the Code do not apply to New Zealand. For New Zealand purposes, processing requirements are specified in New Zealand (Milk and Milk Products Processing) Food Standards 2002 (Attachment 3).

*2.1.4 Standard 1.6.1 – Microbiological Limits for Food*

Standard 1.6.1 – Microbiological Limits for Food includes several microbiological standards for cheese. Of relevance to this Application is the limit for *Escherichia coli* for all cheeses and the standards for *Listeria monocytogenes* and *Salmonella* in all raw milk cheese. The sampling plans specified in Standard 1.6.1 are provided below.

| **Food** | **Microorganism** | **n** | **c** | **m** | **M** |
|---|---|---|---|---|---|
| ALL CHEESE | *Escherichia coli* | 5 | 1 | 10 | $10^2$ |
| All raw milk cheese (cheese made from milk not pasteurised or thermised) | *Listeria monocytogenes*/25g | 5 | 0 | 0 | |
| | *Salmonella*/25g | 5 | 0 | 0 | |

Where:
n = the minimum number of sample units which must be examined from a lot of food

c = the maximum allowable number of defective sample units (the number of samples that may exceed 'm')

m = the acceptable microbiological level in a sample unit.

M = the level which, when exceeded in one or more samples, would cause the lot to be rejected.

These microbiological limits mean that Roquefort cheese must have no detectable levels of *Listeria monocytogenes* and *Salmonella*. Additionally, the level of *E. coli* should not exceed 10 per gram, though a maximum level of 100 per gram may be allowed for 1 in 5 samples.

## 2.2 International regulations

There are no Codex Alimentarius Commission (Codex) requirements for the heat treatment of milk for cheese making. However, the Codex Committee for Food Hygiene (CCFH) at the end of January 2003 recommended to move to Step 5 the "proposed Draft Code of Hygienic Practice for Milk and Milk Products". This includes requirements relating to the areas and premises for milk production, animal health, general hygienic practice on farm and hygienic milking. It is foreseen that this Code will apply to all products derived from milk including raw milk cheeses.

Canada permits the sale of raw milk cheese, provided the cheese has been stored at a temperature of 2°C or more for a period of 60 days or more.[1] In addition cheese made from an unpasteurised source must not contain more than 500 *E. coli* or 1,000 *S. aureus* per gram.[2]

US regulations[3] require cheese to be pasteurised or, as an alternative treatment, cheeses made from unpasteurised milk require a minimum 60 day aging period. However, the interstate trade of raw milk products within the United States is prohibited. The US permits the import of Roquefort cheese. The US is currently reviewing the 60 day aging requirement.

### *2.2.1 Relevant European and French legislation or regulation*

French legislation and regulation of Roquefort cheese is listed in Attachment 1.

The European Union permits the manufacture of raw milk cheeses, subject to EU sanitary and food hygiene regulations listed in Attachment 1, along with the following microbiological criteria requirement of Directive 92/46EEC:

> In compliance with the requirements of directive 92/46/EEC, blue-veined cheese made using raw milk or thermized milk must, on leaving the establishment, meet the following criteria:
>
> | | | | |
> |---|---|---|---|
> | *Listeria monocytogenes* (1): | Absence in 25 g. | n=5, | c=0 |
> | *Salmonella* spp (1): | Absence in 25 g. | n=5, | c=0 |
> | *Staphylococcus aureus* (2), (3): | m=1000, M=10 000, | n=5, | c=2 |
> | *Escherichia coli* (2), (3): | m=10 000, M=100 000, | n=5, | c=2 |
>
> (1) Parameters 'n' and 'c' are defined as follows:
>
> n = number of sample units comprising the sample.
> c = maximum number of sample units (comprising n units) in which bacteria may be detected but nevertheless allow the outcome "batch or product considered satisfactory" or "batch acceptable".
>
> (2) Parameters 'M', 'm' and 'c' are defined as follows:
>
> m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed 'm'.
> M = maximum value for the number of bacteria. The outcome is considered unsatisfactory if the number of bacteria in one or more sample units is 'M' or more.

[1] Food and Drug Regulations B.08.044
[2] Food and Drug Regulations B.08.048, and as determined by official method MFO-14, Microbiological Examination of Cheese, November 30, 1983.
[3] US FDA Code of Federal Regulations 21CFR133

c = number of sample units where the bacteria count may be between 'm' and 'M', the sample being considered acceptable if the bacteria count of the other sample units is 'm' or less.

(3) The levels specified by standards are expressed per gram (g).

# 3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

In considering this Application, the key objective is to protect public health and safety while minimising the barriers/restrictions on the trade of Roquefort cheese.

# 4. Background

## 4.1 Historical Background

The Code specifies that milk and milk products for cheese production must be heat-treated. Such heat treatment includes pasteurisation (e.g. holding at a temperature of at least 72$^{o}$C for no less than 15 seconds) and thermisation (e.g. holding at a temperature of at least 62$^{o}$C for no less than 15 seconds, providing the final product is stored for 90 days at a temperature not below 2$^{o}$C). The Code does allow, however, for an alternative process to be used (e.g. the use of raw milk under Standard 2.5.4 or different heat treatments of milk under Standard 1.6.2) where it can be demonstrated that this process will achieve an equivalent level of safety as cheese prepared from milk that has been heat-treated.

In April 1997, the then Australia New Zealand Food Authority (ANZFA) rejected an Application (A270) to amend the former Australian *Food Standards Code* to permit cheese to be made from unpasteurised milk on the grounds that consumption of cheese made from unpasteurised milk would pose a significant risk to public health and safety.

ANZFA also considered a previous Application (A348) to allow the sale of Roquefort cheese in Australia from the French Federation of Roquefort Cheese Manufacturers (Société des Caves) in August 1997. At this time, there was insufficient information provided to allow a comprehensive scientific assessment of the Roquefort cheese manufacturing process, and the Application was eventually withdrawn at Full Assessment (as Draft Assessment was formerly known).

In 1998, ANZFA received an Application from the Swiss Federal Veterinary Office (A357) in order to allow the sale of Emmental, Gruyere, Sbrinz, Appenzellar, Tilsiter, Vacherin Fribourgeois and Tête de Moine cheese made from raw milk. The risk assessment process concluded that the hard cheeses Emmental, Gruyere and Sbrinz could meet an appropriate level of safety, and therefore, the Code was amended to specifically permit these cheeses. Appenzellar, Tilsiter and Vacherin were produced using thermised milk, and so already complied with Australia's food regulation. The cheese Tête de Moine was not permitted because the microbiological safety assessment concluded that the process of manufacture could not ensure an equivalent level of safety to cheese made in accordance with Australian regulations. The Application from the Swiss Federal Veterinary Office included a HACCP plan conforming to the Codex standard, and a number of Ordinances (regulations) that Swiss cheese manufacturers must comply with. The Application also demonstrated verification, audit and approval processes by Swiss regulatory authorities such as the Swiss Veterinary Office, Swiss Federal Office for Agriculture and the Swiss Federal Office of Public Health.

In 2002, FSANZ undertook a scientific evaluation of raw milk extra hard grating cheeses, which resulted in the exemption of this category of cheeses from the milk heat treatment requirement on the basis that these cheeses achieve an equivalent level of safety as cheeses using heat treated milk and do not pose any significant public health and safety risk.

# 5. Relevant Issues

## 5.1 Equivalence Determination

### *5.1.1 General principles*

The principle of equivalence in food safety is based on the recognition that the same level of food safety can be achieved by applying alternative hazard control measures. The objective is to determine if these alternative measures, when applied to a food, achieve the same level of food safety as that achieved by applying other specified measures.

Equivalence of food safety measures is recognised in the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures[4] (SPS Agreement) and the WTO Agreement on Technical Barriers to Trade[5] (TBT Agreement). These agreements require member countries to ensure their measures are objective, science-based and consistent.

[4] http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

[2] http://www.wto.org/english/tratop_e/tbt_e/tbtagr_e.htm#Agreement

They should also conform with international standards, where they exist, unless they are considered to be an ineffective or inappropriate means for the fulfilment of a country's legitimate policy objectives (TBT) or insufficient to achieve what the country determines to be an appropriate level of sanitary or phytosanitary protection (SPS). Because measures can take many forms, member countries are encouraged to accept as equivalent, measures and regulations of other members, provided they are satisfied these alternative measures and regulations meet their appropriate level of protection.

In October 2001, the SPS committee published a decision (G/SPS/19)[6] outlining principles to facilitate the application of equivalence provisions of the SPS Agreement for all WTO members.

Codex is aiming to better articulate the concept of equivalence and its application to food safety. In particular, the Codex Committee for Food Inspection and Certification Systems (CCFICS) has developed guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems[7]. In relation to TBT measures, CCFICS has also initiated the development of a discussion paper on the judgement of equivalence of technical regulations associated with food inspection and certification systems.

### *5.1.2 FSANZ's general approach to determining equivalence*

The purpose of equivalence determination is to ensure that alternative food safety measure(s) achieve at least the same level of consumer health and safety as that achieved by applying the standard/traditional measures. FSANZ has developed Guidelines for Determining the Equivalence of Food Safety Measures[8] and include the following general principles:

- Scientific basis and objectivity;
- Harmonisation with international approach to equivalence determination;
- Consistency of safety requirements in food produced in Australia and, where relevant, New Zealand with food imported from other countries;
- Transparency of process; and
- Expert and community consultation.

These principles are consistent with Australia's and New Zealand's international obligations and with domestic policies and legislation.

### *5.1.3 Equivalence determination for Roquefort cheese*

The equivalence determination sought for the safety of Roquefort cheese will consider:

[6] http://www.wto.org/english/tratop_e/sps_e/equivalence2001_e.htm

[4] Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (Adopted at CAC at its meeting 30 June – 7 July 2003)

[8] http://www.foodstandards.gov.au/_srcfiles/Equivalence_Determination_Guidelines_pdf.pdf

- Infrastructure including legislation (e.g. food law and enforcement law) and administration (e.g. organisation of national and regional authorities and enforcement systems).

- Program design, implementation and monitoring (including documentation, laboratory capability, decision criteria and audit).

- Specific requirements including premises and equipment requirements, process-related requirements (e.g. HACCP plans) and product-related requirements (e.g. microbiological limits).

## 5.2 Trade Implications

Pasteurisation of milk for cheese making was historically introduced as a public health measure for the control of tuberculosis and brucellosis. While these diseases are no longer common in the Australian dairy herd, the reliance on pasteurisation of milk to control non-specific bacterial contamination of cheese has continued. In contrast, in Europe there is a greater emphasis placed on herd management and a hygienic system of control of the cheese making process to prevent contamination of cheese, rather than relying on pasteurisation.

Under the conditions of the World Trade Organization Agreement on Sanitary and Phytosanitary measures (SPS), Australia is obliged to ensure that its public health and safety measures are consistent, focus on outcomes, rather than processes and recognise the equivalence of overseas measures to ensure safe food where the level of public health protection is the same.

## 5.3 Appellation status of Roquefort cheese

Roquefort is recognised throughout Europe with AOC status. This means that the cheese can only be produced in the region surrounding the town of Roquefort-sur-Soulzon. Therefore this Application seeks specific permission for Roquefort cheese only, and will not consider general permission for all raw milk blue cheeses.

## 5.5 Heat treatment of milk

### *5.5.1 Pasteurisation*

Pasteurisation is a heat treatment process applied to a food which is, primarily, designed to destroy pathogens. Spoilage organisms may also be eliminated during the process, increasing the stability and shelf life of the food. Vegetative bacteria subjected to heat are killed at a rate that is proportional to the number of organisms present (the greater the number of bacteria present, the greater the rate of destruction required). This rate of destruction is dependent both on the temperature and time of exposure and the heat resistance of the organism itself. The pasteurisation parameters of time and temperature are generally determined by the most heat resistant vegetative microorganism likely to be present in the food.

The pasteurisation of milk is historically based on the destruction of *Mycobacterium bovis*, the causative agent of bovine tuberculosis which, in the past, was also responsible for causing tuberculosis infections in humans.

The temperature used for milk pasteurisation was then increased to ensure the destruction of *Coxiella burnetii*, the causative agent of Q fever in humans and the most heat resistant vegetative pathogen found in milk. High temperature short time pasteurisation (HTST) of milk at 72 ºC for 15 seconds has been shown to be effective in eliminating this organism and is accepted internationally as the standard process for milk pasteurisation. Additionally, batch pasteurisation using the lower temperature of 63ºC for 30 minutes will give an equivalent measure of bacterial destruction. Other time and temperature conditions of equivalent effect can be calculated graphically by using a log time versus temperature graph. This is obtained by passing a line through the points 72º/15 seconds and 63 ºC/ 30 minutes. Equivalent time temperature conditions should not include temperatures below 63 ºC[9].

While the presence of *Mycobacterium bovis* and *Coxiella burnetii* in milk is now largely controlled by improvements in animal health and farm sanitation, pasteurisation destroys other potential milk-borne pathogens such as *Salmonella spp*, *Staphylococcus aureus*, pathogenic *Escherichia coli*, *Listeria monocytogenes* and *Campylobacter spp*. The temperature-time parameters specified for pasteurisation are generally accepted as being able to achieve at least a 5 log reduction of these pathogens.

### *5.5.2 Thermisation*

The Code permits a time-temperature process of milk for cheese production that is less rigorous than pasteurisation (62ºC for 15 seconds), providing that the cheese is stored for at least 90 days at no less than 2ºC from the date of manufacture. This heat treatment is generally referred to as thermisation. The purpose of thermisation is to kill spoilage microorganisms (such as *Pseudomonas* and other psychrotrophs) in the milk which may cause flavour and textural defects in the cheese.[10] Thermisation results in less inactivation of enzymes and non-starter lactic acid bacteria which may be important during ripening for the development of cheese flavour.

While thermisation kills psychrotrophs (microorganisms active at lower temperatures), it may not destroy all pathogenic microorganisms that may be present. A further safeguard is therefore required and the cheese produced must be stored for at least 90 days at a temperature greater than 2 ºC. During this time, depending on the physical and chemical characteristic of the cheese such as pH, water activity and salt content, any pathogenic bacteria present are reduced to a level that protects public health and safety.

## 5.6 Raw milk microbiological quality

The microbiological quality of raw milk for cheese manufacture is an essential component in producing good quality raw milk cheese which is microbiologically safe. Raw milk should have total bacterial counts below 20 000 cfu/ml and somatic cell counts below 400 000/ml[11]. Hygienic milk production systems should be in place, preferably as part of an overall HACCP (Hazard Analysis Critical Control Points) program.

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[9] Codex draft Code of Hygienic Practice for Milk and Milk Products, 1998.

[10] Fox P.E., Guinee T. P., Cogan T. M., McSweeney P. L. H. *Fundamentals of Cheese Science*. Aspen Publishers Inc. 2000.

[11] Fox et al, 2000. *Fundamental of Cheese Science*. Aspen Publishers, Maryland.

In recent years, Codex has initiated work on a *Draft Code of Hygienic Practice for Milk and Milk Products* (at step 5) which includes the hygienic production of milk as an essential element. The Codex draft Code of Practice sets hygienic practices to ensure good microbiological quality.

Within the European Community, Council Directive 92/46/EEC lays down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products. It sets out requirements for the hygienic production of milk and provides microbiological criteria for raw milk for direct consumption and for use in the manufacture of products not involving any heat treatments. Under Council Directive 92/46/EEC raw goat or sheep milk intended for the manufacture of products "made with raw milk" must meet the following standards:

| | |
|---|---|
| Total plate count (at 30 ºC) | must not exceed 500 000/ml |
| *Staphylococcus aureus* (per ml) | n=5, c=2, m=500, M=2 000 |

### 5.7 Pathogens in milk and cheese

Raw milk can be contaminated with a variety of pathogens originating from the animal, equipment, handlers and the environment. Zoonoses (organisms that can cause disease in animals and humans) such as *Mycobacterium bovis* and *Brucella* spp. are controlled primarily through good animal health practices and jurisdictional requirements that milk be collected from healthy animals only. Other pathogens associated with raw milk and which have been implicated in food-borne illness due to the consumption of contaminated cheeses include *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus* and pathogenic *E. coli*. *Campylobacter jejuni/coli* has also been frequently associated with human infections due to the consumption of raw milk.

When we next report on this work (with a Draft Assessment Report), a microbiological risk evaluation of Roquefort cheese will be presented.

### 5.8 Proposed scientific safety evaluation

FSANZ will undertake a scientific safety evaluation on Roquefort cheese. As part of this evaluation it is proposed that an assessment of the documentation provided by the French Government to establish the safety, and in particular assess the adequacy of the HACCP plan, for Roquefort cheese produced from raw sheep milk will also be undertaken.

The assessment will involve the following:

(a) determine if sufficient information has been provided by the applicant to conduct a thorough evaluation (as described under B and C) and identify any information or data gaps therein;

(b) determine if the process used to manufacture Roquefort cheese can achieve a safe product as demonstrated by:

- the absence of pathogens *Campylobacter jejuni/coli, Listeria monocytogenes*, pathogenic *Escherichia coli*, and *Salmonella* and others such as *Brucella melitensis* and *Coxiella burnetii* in the final product;

- presence of *Staphylococcus aureus* at levels that do not constitute a potential health hazard as defined in the FSANZ 'Guidelines for the microbiological examination of ready-to- eat foods' [12] (Attachment 1) and
- whether the microbiological requirement in Std 1.6.1 for *E. coli* (n=5, c=1, m=10, M=100) can be met;

(c) evaluate the potential of the HACCP plan (and associated material) to control the manufacturing process of Roquefort cheese to achieve a safe product as defined under (B). Including:

- Does the HACCP plan identify all hazards associated with the manufacture of Roquefort cheese?
- Have all critical control points been identified?
- Is the monitoring (both parameter and frequency) of critical control points appropriate for achieving in-process control of hazards?
- Do the documented corrective actions effectively address variances from critical limits?
- Do the corrective actions fully consider the implications of a situation where monitoring indicates loss of control at a critical control point?
- Is the HACCP plan effectively supported by pre-requisite programs (e.g. cleaning and sanitation, pest control, personal hygiene)?

(d) Does the information provided by the applicant demonstrate:

- the requirement for industry to implement a HACCP plan and comply with associated French and EC regulations; and
- actual compliance with the HACCP plan and associated French and EC regulations;

For the purposes of the evaluation, the following definitions and criteria apply:

1. Raw milk is milk that has not been treated by pasteurisation or thermisation

2. The pathogens of concern are: *Campylobacter jejuni/coli*, *Staphylococcus aureus*, *Listeria monocytogenes*, pathogenic *Escherichia coli*, *Salmonella*, *Brucella melitensis* and *Coxiella burnetii*.

3. FSANZ 'Microbiological Guidelines for Ready-to-eat (RTE) Foods' consider S. aureus levels of <102 cfu/g in RTE Foods to be satisfactory, and S. aureus levels of ≥ 104 cfu/g in RTE foods as potentially hazardous.

4. Roquefort cheese is made from unpasteurised and curdled ewe's milk with spores of *Penicillium roqueforti*.

[12]Guidelines for the microbiological examination of ready-to- eat foods
http://www.foodstandards.gov.au/mediareleasespublications/publications/guidelinesformicrobi1306.cfm

### 5.9 Labelling requirements

Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations of the Code, states under subclause 2(1), unpasteurised milk and liquid milk products must be labelled with an advisory statement to the effect that the product has not been pasteurised. However, there are no specific requirements for unpasteurised cheese.

### 5.10 Quarantine requirements

The Australian Quarantine and Inspection Service (AQIS) / Biosecurity Australia maintain import requirements for dairy products into Australia. A quarantine permit must be obtained in order to import cheeses into Australia. The conditions for import depend on whether the country exporting is free from Foot and Mouth Disease. Import from these countries must be accompanied by an import permit for each consignment and each consignment must be accompanied by a specific sanitary certificate signed by an Official Government Veterinarian of the exporting country.

While these requirements are mainly concerned with the transfer of Foot and Mouth Disease, they effectively require that dairy products are sourced from healthy animals and that there are appropriate controls in place within the country of origin to ensure this. The import requirements are provided in Attachment 4.

When considering the approval of countries to export dairy products into Australia, AQIS takes into account the following criteria:

- the animal health status of the country;
- the effectiveness of veterinary services and other relevant certifying authorities;
- legislative controls over animal health, including quarantine policies and practices;
- the standard of reporting to the Office International des Epizooties (OIE) of major contagious disease outbreaks;
- effectiveness of veterinary laboratory services, including compliance with relevant international standards; and
- effectiveness of systems for control over certification/documentation of products intended for export to Australia.

In effect, the AQIS import requirements for dairy products provide an additional control over the source and microbiological quality of raw milk used in the manufacture of dairy products imported into Australia. Similar quarantine measures are applied in New Zealand.

## 6. Regulatory Options

In developing a standard, FSANZ must identify two or more regulatory options and consider the pros and cons (including impacts and implications) of each option. For this Application two options are considered appropriate, to either amend the Code to permit the sale of imported Roquefort cheese or to reject the Application.

- **Option 1 – reject the Application**

Maintain the status quo by not amending the code to permit the sale of imported Roquefort cheese.

- **Option 2 – permit the sale of imported Roquefort cheese**

Amend the Code to permit the sale of imported Roquefort cheese.

# 7. Impact Analysis

## 7.1 Affected Parties

- Consumers, particularly those who consume speciality cheeses;
- Food importers of Roquefort cheese;
- Industry; and
- Government.

## 7.2 Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

FSANZ seeks input from all affected and interested parties to enable it to undertake this analysis.

The regulatory impact of the Application will be assessed at Draft Assessment.

# 8. Consultation

The Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the Application.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FSANZ will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this Application. Comments that would be useful could cover:

- scientific aspects of this Application, in particular, information relevant to the safety of Roquefort cheese;

- parties that might be affected by having this Application approved or rejected;

- arguments in support or opposition to permitting the sale of imported Roquefort cheese; and

- potential costs and benefits to consumers, industry and government.

### 8.1 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. There are relevant international standards and amending the Code to allow the sale of Roquefort cheese is likely to have a significant effect on international trade as Roquefort cheese is traded internationally.

This issue will be fully considered at Draft Assessment and notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

## 10. Conclusion

This Initial Assessment Report is based on information provided by the Applicant and discusses relevant issues in relation to permitting the sale of Roquefort cheese. After having regard to the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has accepted the Application. Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.

## ATTACHMENTS

1. Relevant European Union and French regulation and legislation
2. Manufacturing process for Roquefort cheese
3. New Zealand (Milk and Milk Products Processing) Food Standards 2002
4. Quarantine import requirements for dairy products into Australia

## ATTACHMENT 1

# RELEVANT EUROPEAN UNION AND FRENCH REGULATION AND LEGISLATION

### 1. EU legislation on dairy products

- Commission Directive 89/362/EEC of 26 May 1989 on general conditions of hygiene in milk production holdings,

- Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products.

- Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs.

- Regulation (EC) N° 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Safety Authority and laying down procedures in matters of food safety.

### 2. French legislation on dairy products

- This comprises the 3 principal Ministerial "arrêtés" or orders detailed below, which constitute the embodiment in French regulations of both Commission Directive 89/362/EEC and Council Directive 92/46/EEC :

- The Ministerial order of 30 December 1993 (Journal Officiel of the French Republic = JORF dated 11/01/93) regarding the installation, equipment and operating conditions of milk collection or standardization centres and of treatment and processing establishments for milk and milk-based products ;

- The Ministerial order of 18 March 1994 (JORF dated 19/04/94) relating to hygiene in milk production and collection ;

- The Ministerial order of 30 March 1994 (JORF dated 21/04/94) regarding the microbiological criteria that drinking milk and milk-based products must satisfy prior to their placing on the market.

In addition, also included are the two Ministerial orders below:

- The Ministerial amended order of 28 June 1994 relating to the identification and sanitary accreditation of establishments that place animal foodstuffs and animal-derived foodstuffs onto the market, and to sanitary quality marking (JORF dated 31/07/94) .

- The Ministerial order of 2 March 1995 (JORF dated 06/04/95) relating to the licensing of milk collection or standardization centres and of treatment, and processing establishments for milk and milk-based products.

## 3. French regulations specifically applicable to Roquefort

- Decree of 22 January 2001 (JORF dated 25/01/01) laying down the conditions to be met for the award of Roquefort's AOC ("Appellation d'origine contrôlée") = protected designation of origin "Roquefort".

**ATTACHMENT 2**

## Cheese making process for Roquefort cheese

Roquefort is made only from unpasteurised sheep's milk and are ripened in caves in a defined area of south-eastern France. Raw milk is heated to 28 – 34$^{o}$C for a few minutes. Rennet is added and during curding the pH drops from 6.5 to 4.8. The curds are not cooked but are mixed with spores of *P. roqueforti* and placed in perforated metal moulds for whey drainage. The whey is allowed to drain for 4-5 days, during which the cheeses are inverted periodically and acidity develops. The cheeses are then removed from the moulds and dry-salted over a period of 5 days, after which they are placed in limestone caves that have the correct temperature and relative humidity to encourage mould growth. The cheeses are matured for 3 months, during which their surface is cleared to remove adventitious moulds or smear-forming bacteria.

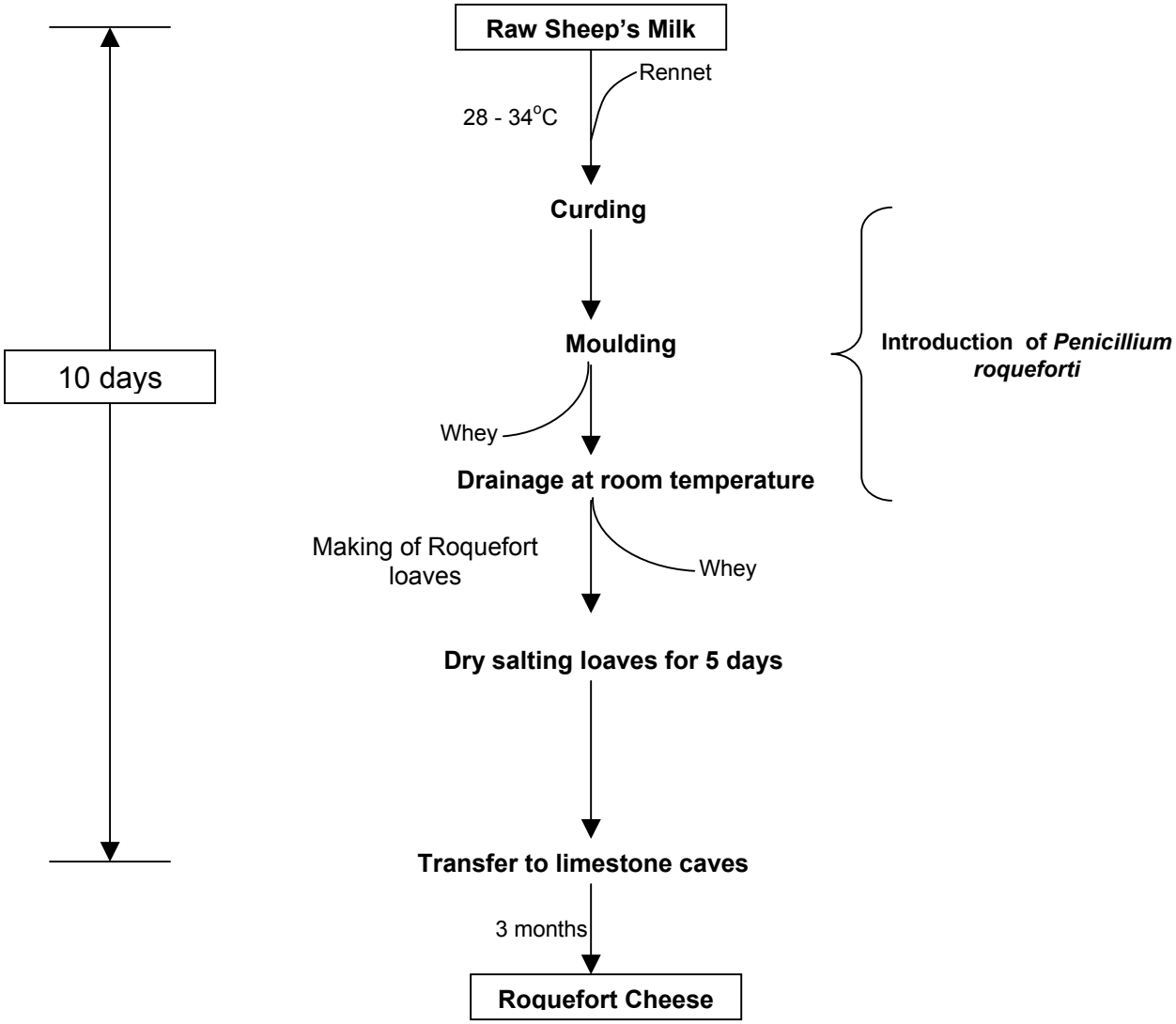


**Figure 1: Manufacturing stages of Roquefort cheese**

**ATTACHMENT 3**

# New Zealand (Milk and Milk Products Processing) Food Standards 2002

The Minister for Food Safety, under section 11C of the Food Act 1981, issues the following food standards:

**1. Title**
These standards are the New Zealand (Milk and Milk Products Processing) Food Standards 2002.

**2. Commencement**
These standards come into force on 20 December 2002.

**3. Interpretation**
In these standards, unless the context otherwise requires;

(a) The term "ice cream treatment" means heat treatment of an ice cream mix to be used in ice cream by retaining the ice cream mix-

(i) At a temperature of not less than 69°C for not less than 20 minutes; or
(ii) At a temperature of not less than 74°C for not less than 10 minutes; or
(iii) At a temperature of not less than 79.5°C for not less than 15 seconds; or
(iv) At a temperature of not less than 85.5°C for not less than 10 seconds; or
(v) At another temperature for a time which achieves an equivalent result to the treatments in paragraphs (i) to (iv) above;
and then freezing the ice cream mix.

(c) The term "pasteurisation" for milk or a milk product means treatment according to one of the following methods-

(i) The holding method, by which the milk or milk product is rapidly heated to a temperature of not less than 63°C and not more than 66°C, retained at that temperature for not less than 30 minutes, and then—

(A) Immediately and rapidly reduced to 5°C or less in the case of milk or milk products other than cream, or to 7°C or less in the case of cream; and
(B) Maintained at or below that temperature until the milk or milk product is removed from the premises for delivery;

(ii) The high-temperature short-time method, by which the milk or milk product is rapidly heated to a temperature of not less than 72°C, retained at that temperature for not less than 15 seconds, and then treated in accordance with subparagraphs (A) and (B) of the method in paragraph (i);
(iii) Any other heat treatment method that is as effective in terms of bacterial reduction as methods (i) and (ii).

(d) The term "cheese treatment" means-

(i) The rapid heating of milk or a milk product to be used in the manufacture of cheese to a temperature of not less than 64.5°C, retaining it at that temperature for not less than 16 seconds; and

(ii) Storing the cheese prior to sale at a temperature of not less than 7°C for not less than 90 days from the date of commencement of manufacture.

(b) The term "Food Standards Code" has the same meaning as in the New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002.

**4. Alternative standards for processing of milk or milk products**

(1) Subject to section 11A of the Food Act 1981 (which relates to the sale of small quantities of raw milk at farm premises), all milk and milk products manufactured for sale, used as ingredients in the manufacture of any food for sale, or sold by retail must-

(a) Be processed in accordance with clause 5 and clause 6 of these standards, or

(b) Be processed in accordance with a product safety programme approved under the Dairy Industry Regulations 1990; or

(c) Be processed on premises in respect of which an exemption from the Food Hygiene Regulations 1974 has been granted by the Director-General under section 8F of the Food Act 1981, and be processed in accordance with the terms of that exemption.

(2) Clause 4(1) does not apply to raw milk which is sold only by wholesale and which will be processed to the requirements of clause 4(1) before being sold for retail or used as an ingredient in products which are sold for retail.

**5. Methods of processing milk or milk products**

(1) A dairy product listed in the left hand column of the Table complies with clause 4(1)(a) of these standards if the milk or milk products from which it is made are processed according to a treatment listed for that dairy product in the adjoining column of the Table and the product complies with clause 6 in respect of any added substance.

(2) Under section 11F of the Food Act 1981, these standards incorporate the method set out in the *Ordinance on Quality Assurance in the Dairy Industry* of the Swiss Federal Council of 18 October 1995 as a method for Emmental, Gruyere or Sbrinz Cheese.

**TABLE**

| **Dairy product** | **Permitted methods of processing** |
|---|---|
| Milk (of any type) | Pasteurisation |
| Cream (of any type) | Pasteurisation |
| Fermented milk products, including yoghurt | Pasteurisation |
| Cheese | Pasteurisation |
| Cheese with a moisture content < 39% moisture and a pH level < 5.6 | Pasteurisation<br>Cheese treatment |

| | |
|---|---|
| Emmental, Gruyere or Sbrinz Cheese | Pasteurisation<br>Cheese treatment<br>The method set out in the *Ordinance on Quality Assurance in the Dairy Industry* of the Swiss Federal Council of 18 October 1995 |
| Butter | Pasteurisation |
| Ice cream | Ice cream treatment |
| Dried, evaporated and condensed milk | Pasteurisation |

**6. Further provisions in relation to milk and milk products**

After any milk or milk product has been processed according to the treatment described in the Table to clause 5, any substance added must meet appropriate food safety standards in order to maintain the overall safety of the milk or milk product.

**7. Relationship between this food standard and the Food Standards Code**

Where a manufacturer or retailer of a dairy product complies with clauses 4(1)(a) or 4(1)(b) of these standards when manufacturing or selling that product, such compliance is sufficient to meet, as appropriate for that product, the following requirements of the Food Standards Code:

(a) clause 4(3) of Standard 2.5.1;
(b) clause 3 of Standard 2.5.2;
(c) clause 3 of Standard 2.5.3;
(d) clause 4 of Standard 2.5.4;
(e) clause 3 of Standard 2.5.5;
(f) clause 3 of Standard 2.5.6; and
(g) clause 4 of Standard 2.5.7.

Issued at Wellington this 18th day of November 2002
Signed
Hon Annette King
**Minister for Food Safety**

***Explanatory Note***

*This note is not part of the standards and has been included to explain their general effect.* The New Zealand (Milk and Milk Products Processing) Food Standards 2002 were notified in the New Zealand *Gazette* on 21st November 2002 and come into effect on 20 December 2002. Milk and milk products are subject to the standards in the Australia New Zealand Food Standards Code ("the Food Standards Code"). For New Zealand purposes, under the Food Standards Code, the processing requirements for milk and milk products are provided in these standards. They replace those in the Food Regulations 1984, which are revoked on 20 December 2002 when the Food Standards Code comes fully into effect.

**Food standards subject to Regulations (Disallowance) Act 1989**

Food standards, including these standards, are subject to the Regulations (Disallowance) Act 1989. Any person has the right to make a complaint about a food standard to the Regulations Review Committee.

## ATTACHMENT 4

## Quarantine import requirements for dairy products in Australia[13]:

1 The milk or the milk from which the cheese is made must originate from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

2 The country of origin must have controls in place to ensure only healthy animals are used for milk production.

3 The products must be processed in a foot and mouth disease-free country/zone.

4 EITHER:

(a) The milk or the milk from which the cheese or butter was made must be subjected to one of the following heat treatments:

pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of phosphatase destruction or

a UHT treatment of 135°C for a minimum of 1 second.

OR

(b) The milk from which the cheese was made was not heat treated as above and the milk or the milk from which the cheese or butter was made must originate from a country/zone which meets the OIE requirements for freedom from rinderpest in accordance with Code Article 2.1.4.2.

5 The packaging or immediate container must be stamped with the date of manufacture of the products.

6 Cheese or butter not heat treated in accordance with requirement 4.4(a) will not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture*.

*[Note: For cheese the date of manufacture is the date the curd was set.]

Conditions for the importation of cheese from countries not free from foot and mouth disease include additional requirements:

1 The milk or the milk from which the cheese is made must originate from a country/zone approved by AQIS for the export of dairy products to Australia.

2 The country of origin must have controls in place to ensure only healthy animals are used for milk production.

3 EITHER

(a) the milk from which the cheese was made was pasteurised at a minimum of 72°C for 15 seconds or equivalent treatment, in terms of phosphatase destruction and the cheese has attained a pH of less than 6 and the cheese has aged for 30 days or more.

[13] AQIS quarantine requirements for the importation of dairy products from approved countries as at 27 September 2000.

OR

(b) the cheese has attained a pH of less than 6 and has aged for 120 days or more at a temperature not less than 2°C.

4 The packaging or immediate container must be stamped with the date of manufacture of the products.

5 Cheese made according to requirement 5.3(a) above will not be released from quarantine until a minimum of 30 days after the date of manufacture. Sampling of cheeses prior to release from quarantine to ensure the pH is not above 6 may be required by the Director of Quarantine.

6 Cheese made according to requirement 2.5.3(b) above shall not be released from quarantine until a minimum period of 120 days storage at a temperature not less than 2°C after the date of manufacture. Sampling of cheeses prior to release from quarantine to ensure the pH is not above 6 may be required by the Director of Quarantine.

*[Note: For cheese the date of manufacture is the date the curd was set.]