# EXPLANATORY STATEMENT

# APPLICATION A499

# TO PERMIT THE SALE OF ROQUEFORT CHEESE

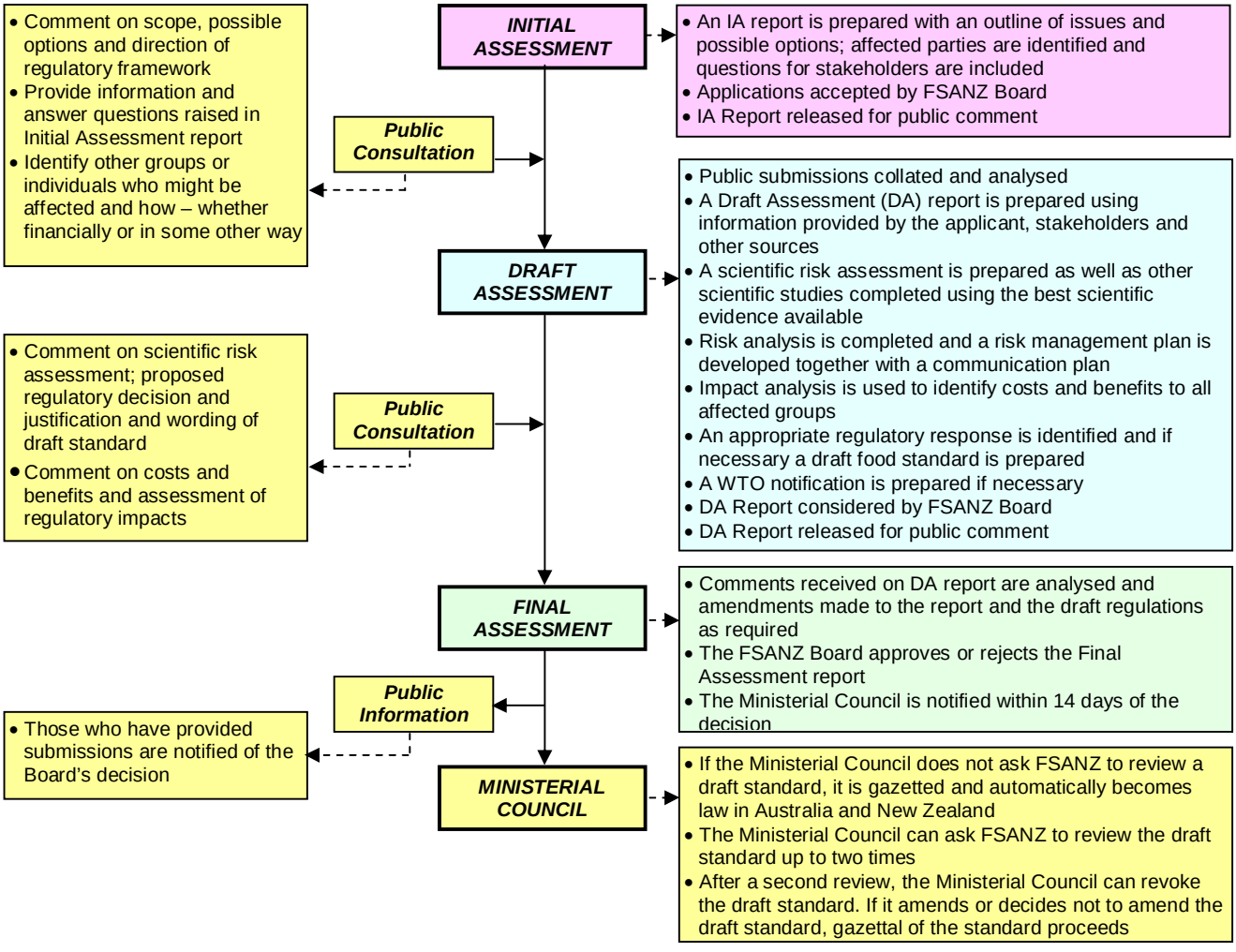
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Australian Government; 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 Australian Government, 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 Australian Government, 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.



**Final Assessment Stage**

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

**Further Information**

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at 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**


Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general inquiries and requests for information.

# CONTENTS

## Executive Summary and Statement of Reasons

An Application (Application A499) has been received from the French Government (Ministry of Agriculture, Food, Fisheries and Rural Affairs) to amend the *Australian New Zealand Food Standards Code* (the Code) to permit the sale of Roquefort cheese in Australia only. This Application was made on behalf of French manufacturers and exporters of Roquefort cheese.

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. This Application seeks a specific permission for Roquefort cheese, rather than a general permission for all raw milk blue cheeses.

### Regulatory Problem

The Code requires that milk and milk products for cheese production are heat-treated in order to manage potential microbiological hazards. However, the Code does allow the sale of raw milk cheeses where they have been assessed to have an equivalent level of safety as cheeses made from heat-treated milk. Three raw milk Swiss cheeses are currently allowed with a specific permission for these cheeses in Standard 2.5.4. In addition, the sale of raw milk very hard cheeses is specifically permitted through an exemption to the heat treatment requirements in Standard 1.6.2. In order to permit the sale of Roquefort cheese, a safety assessment is required that can determine that Roquefort cheese can be produced to an equivalent level of safety as cheese made from heat-treated milk.

### Initial Assessment

FSANZ made an Initial Assessment of Application A499 on 4 March 2004. The Initial Assessment Report was released for public comment on 17 March 2004, inviting submissions on the application and on particular issues identified at that time:

- equivalence of food safety outcomes;
- scientific evaluation;
- trade implications; and
- labelling requirements.

### Draft Assessment

FSANZ made a Draft Assessment of Application A499 on 8 March 2005. The Draft Assessment Report was released for public comment on 23 March 2005, inviting submissions on the application and on particular issues identified at that time. The Draft Assessment addressed:

- the scientific evaluation of the safety of the cheese;
- the review of the regulatory environment and safety control measures under which sheep milk is produced and Roquefort cheese manufactured; and
- the proposed risk management options.

**Safety Assessment**

The assessment of the safety of Roquefort cheese has involved a three-stage process:

1. A scientific evaluation of the safety of the cheese to examine the effect of the cheese manufacturing processes on selected microbial pathogens.

2. A review of the regulatory environment and safety control measures under which sheep milk is produced and Roquefort cheese manufactured.

3. Verification of the implementation of these control measures.

The first two stages of this process were finalised at Draft Assessment and determined the following conclusions:

- The Scientific Evaluation of the safety of Roquefort cheese concluded that if Roquefort cheese is manufactured according to the submitted regulatory and industry processes, its consumption poses a low risk to public health and safety.

- All hazards considered potentially significant in Roquefort cheese are subject to management through on-farm systems and the application of HACCP-based control during processing. These procedures operate in combination with the application of standard operating procedures (SOPs) and good manufacturing practice (GMP) as determined and controlled by the Confederation of Roquefort Producers.

- The French system of regulating the safety of raw milk and subsequent manufacture of Roquefort cheese is considered comprehensive and adequate. Sanctions against producers and manufacturers that fail to meet the requirements of the Ministerial Orders and the requirements of the Confederation of Roquefort Producers are severe.

- The regulatory system is consistent with the Codex Code of Hygienic Practice for Milk and Milk Products.

Subsequent to Draft Assessment, an on-site audit has taken place and verified that the French Government adequately enforces the control measures implemented by the Confederation of Roquefort Producers.

**Regulatory options**

Two regulatory options were identified:

- Option 1 – to reject the Application and not permit the sale of Roquefort cheese; or

- Option 2 – to amend the Code and permit the sale of Roquefort cheese.

The regulatory impact analysis indicated little difference in the cost/benefit impact of each of these options on stakeholders. Overall, Option 2 is the preferred option as it provides greater benefit and is supported by the scientific evaluation.

## Consultation

*Consultation at Draft Assessment*

A total of seventeen submissions were received in response to the Initial Assessment Report from consumers, industry, importers and Government regulators. These submissions and face-to-face consultations with stakeholders identified the following concerns, which were addressed in the Draft Assessment Report:

- the safety of Roquefort cheese and verification of control measures;
- the impact on the Australian dairy industry of permitting Roquefort cheese;
- implications for Australia's approach to geographical indications;
- the transparency of the FSANZ process;
- labelling;
- implementation and ongoing safety assurances, and
- WTO obligations

*Consultation at Final Assessment*

Fifteen submissions were received in response to the Draft Assessment Report from consumers, industry and Government regulators. These submissions and further face-to-face consultations with stakeholders identified the following issues:

- implications for the development of a Dairy Primary Production and Processing Standard;
- transparency of the FSANZ process;
- robustness of the challenge studies;
- clarification of technical issues relating to pH, *Salmonella*, *Mycobacterium* spp, storage temperature;
- impact on the Australian dairy industry;
- clarification of the Imported Food Program risk categorisation; and
- outcomes of the audit process.

## Decision

The assessment of the safety of Roquefort cheese concluded that the sale of this cheese would pose a low risk to the public health and safety of Australian consumers. This conclusion is supported by an examination of the regulatory and industry management framework for the safe production of Roquefort cheese and verified through an on-site audit in France. The decision at Final Assessment is, therefore, to amend the Code to permit the sale of Roquefort cheese in Australia. This decision is supported by the following risk management measures:

- hygiene controls on-farm, including a microbiological standard for *Listeria monocytogenes* in raw milk;

- hygiene controls within milk production and cheese processing and maturation facilities;

- identification of key processing steps to be controlled, including acidification, moisture and salt content, and storage time; and

- end product microbiological standards for *Escherichia coli*, *Salmonella* and *Listeria monocytogenes.*

**Statement of Reasons**

At Final Assessment, FSANZ considers that the Code should be amended to permit the sale of Roquefort cheese in Australia for the following reasons:

- The scientific evaluation of the safety of Roquefort cheese concluded that the sale of Roquefort cheese poses a low risk to public health and safety.

- All hazards considered to potentially pose a significant risk in Roquefort cheese are subject to management through on-farm systems and the application of HACCP-based control during processing. This is in combination with the application of SOPs and GMP as determined and controlled by the Confederation of Roquefort Producers.

- The regulatory system is consistent with the Codex Code of Hygienic Practice for Milk and Milk Products.

- The system of regulating the safety of raw milk and subsequently Roquefort cheese manufacture is considered comprehensive and adequate.

- FSANZ is satisfied that ewe's milk producers and cheese manufacturers comply with the French Regulatory system and that the French Government adequately enforces these control measures.

- Appropriate risk management measures have been proposed to address any public health and safety risks.

- The proposed amendments to the Code are consistent with the section 10 objectives of the FSANZ Act.

- The proposed amendments support Australia's WTO obligations.

- The Impact Analysis supports the proposed amendment to the Code.

# 1. Introduction

## 1.1 Nature of Application

Application A499 was received from the French government (Ministry of Agriculture, Food, Fisheries and Rural Affairs) to amend the Code to permit the sale of Roquefort cheese in Australia only. This Application was made on behalf of French manufacturers and exporters of Roquefort cheese.

Roquefort cheese is a traditional French blue-veined cheese made from raw ewe's milk[1] and subjected to a maturation period of at least 90 days. All cheese sold in Australia, including imported products, must comply with Standard 1.6.2 - Processing Requirements, of the Code. Standard 1.6.2 requires milk or milk products used for the manufacture of this type of cheese to be pasteurised or thermised (a lesser heat treatment) in combination with a minimum storage period. Exceptions to this requirement do exist for other raw milk cheeses where these are:

- expressly permitted within the Table to clause 3 in 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).

FSANZ made an Initial Assessment of Application A499 in March 2004. The Initial Assessment Report was released for public comment on the 17 March 2004, inviting submissions on the Application and particularly on several key issues identified at that time:

- equivalence of food safety outcomes;
- scientific evaluation;
- trade implications, and
- labelling requirements.

FSANZ made a Draft Assessment of Application A499 in March 2005. The Draft Assessment Report was released for public comment on the 23 March 2005, inviting submissions on the risk management measures proposed.

# 2. Regulatory Problem

The Code requires the heat treatment of milk and milk products for cheese production. This processing measure has been in place historically as an important public health measure to manage microbiological hazards that may be present in raw milk cheeses. However, the Code does allow the sale of raw milk cheeses in Australia where an assessment process has shown that they can be produced to an equivalent level of safety as cheeses made from heat-treated milk.

Three raw milk cheeses (Swiss Gruyere, Sbrinz and Emmental cheeses) have been permitted in the Code through a specific permission in Standard 2.5.4 – Cheese. In addition, the sale of raw milk very hard cheeses (specified as having a moisture content of less than 36% and stored for a minimum of 6 months) has been permitted through an exemption to the heat treatment requirements in Standard 1.6.2 - Processing Requirements.

---

[1] Raw milk is milk which has not been heat treated (pasteurised or thermised) in accordance with Standard 1.6.2 – *Processing Requirements* of the Food Standards Code.

There is currently no approval for the sale of Roquefort cheese in Australia. To allow the sale of this raw milk cheese, a specific permission for Roquefort in the Code would be required. This permission would reflect the capacity of the French regulatory system and processing conditions to consistently produce Roquefort cheese to an equivalent level of safety as those made from pasteurised or thermised milk.

# 3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives that 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 objectives are to protect public health and safety and to achieve consistency between domestic and international food standards that apply to Roquefort cheese.

# 4. Background

## 4.1 Previous assessment of raw milk cheeses

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 72ºC for no less than 15 seconds) and thermisation (e.g. holding at a temperature of at least 62ºC for no less than 15 seconds) combined with a minimum storage period of 90 days. 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) from the Australian Specialist Cheesemakers' Association to amend the former Australian *Food Standards Code* to permit a range of cheese types (soft, semi-soft and hard) made from raw milk. This Application was rejected on the grounds that consumption of cheese made from raw milk, particularly softer varieties, would pose a significant risk to public health and safety. At that time, there was no evidence that an industry Code of Practice or HACCP-based food safety management system had been developed to support such an application.

In August 1997, ANZFA considered an Application (A348) to allow the sale of Roquefort cheese in Australia from the French Federation of Roquefort Cheese Manufacturers (Société des Caves). At that time, there was insufficient information provided to allow a comprehensive scientific assessment of the Roquefort cheese manufacturing process. Requests for further information were made, but the Application was eventually withdrawn by the Applicant before Draft Assessment (known as Full Assessment in 1997).

In 1998, ANZFA received an Application from the Swiss Federal Veterinary Office (A357) to allow the sale of Emmental, Gruyere, Sbrinz, Appenzellar, Tilsiter, Vacherin Fribourgeois and Tête de Moine cheese made from raw milk. The risk assessment 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 regulations. The cheese Tête de Moine was not permitted because the microbiological safety assessment could not confirm the manufacturing process would provide an equivalent level of safety to cheese made in accordance with Australian regulations in force at that time.

The Application from the Swiss Federal Veterinary Office was supported by documentation that demonstrated that manufacturers of the raw milk Swiss cheeses must comply with a number of Swiss Ordinances (regulations) relating to milk and cheese production, including the requirement for HACCP plans based on Codex principles. 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 prepared a proposal (P263) to assess the safety of extra hard grating cheeses made from raw milk. A scientific evaluation of the manufacture of extra hard grating cheeses supported the exemption of this category of cheese from the milk heat treatment requirements of Standard 1.6.2 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. Standard 1.6.2 was amended to permit the manufacture of very hard grating cheeses using milk that has not been heat treated, under specified conditions i.e. the final cheese contained <36% moisture, had been stored for >6 months, and was prepared using a curd cooking temperature of at least 48ºC.

### 4.2 Existing Regulatory Requirements within the Food Standards Code

Application A499 specifically relates to three Standards within the Code. The heat treatment requirements for the manufacture of cheese and cheese products sold in Australia are specified within Standard 1.6.2 – Processing Requirements. A part of these requirements, relating to certain Swiss cheeses made from raw milk, is contained within Standard 2.5.4 - Cheese. In addition, all cheese sold in Australia and New Zealand must comply with Standard 1.6.1 – Microbiological Limits for Food.

The processing requirements for cheese and cheese products specified in Standard 1.6.2 of the Code do not apply to New Zealand. New Zealand processing requirements are specified in the *New Zealand (Milk and Milk Products Processing) Food Standards 2002* (Attachment 6).

### *4.2.1 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.

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

### *4.2.3 Standard 1.6.1 – Microbiological Limits for Food*

Standard 1.6.1 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 | |

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 they 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 *L. 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.

### 4.3 Development of a Primary Production and Processing Standard for Dairy

FSANZ has commenced development of a Primary Production and Processing (PPP) Standard for Dairy (Proposal P296), to apply in Australia only. A Standard Development Committee (SDC) has been established to advise and assist FSANZ throughout this process and comprises representatives of the dairy industry, State and Territory Governments, Australian Government agencies, New Zealand and consumers.

The standard development process will require an assessment of public health and safety risks associated with the consumption of dairy products, the current food safety management controls and also an understanding of the practical issues associated with the production and processing of dairy products.

The Initial Assessment Report (IAR) for P296 was released for public comment on the 15 December 2004[2]. The Report discussed issues and raised questions in relation to:

- the current operation of the dairy industry;
- hazards potentially present in dairy products that could result in food-borne illness and how these are controlled;
- evaluating the risk to public health from dairy products;
- existing regulatory requirements; and
- potential scope of the new national Dairy PPP Standard.

The issue of raw milk dairy products is raised within the IAR. It notes that many countries allow the production and import of raw milk products, though in Australia this is currently limited to specific imported raw milk cheese varieties, and the production of unpasteurised goat milk in some Australian States.

As part of the development of the PPP Standard for Dairy, FSANZ will consider the safety of raw milk products from cows, goats and sheep and whether these may be produced with appropriate management techniques (by use of, for example, extended ripening or alternative technologies) to ensure an equivalent level of safety as products produced from pasteurised or thermised milk. This safety determination will be based on a careful consideration of the food safety risks and what, if any, process or end point controls would be effective and necessary to ensure these products are safe for human consumption.

The assessment of raw milk dairy products for the PPP Standard for Dairy may elaborate a framework to assess the safety of these products, in the future, through a more general approach rather than a product-by-product basis that has been applied with the Swiss cheese and Roquefort applications.

---

[2] The Initial Assessment Report for P296 – Primary Production and Processing Standard for Dairy can be accessed on the FSANZ website: http://www.foodstandards.gov.au/_srcfiles/P296%20Dairy%20PPPS%20IAR%20FINAL.pdf

## 4.4 International regulations

### *4.4.1 Codex*

There are no Codex Alimentarius Commission (Codex) requirements for the heat treatment of milk for cheese making. However, there is a Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57, 2004). This Code of Practice contains requirements relating to the areas and premises for milk production, animal health, general hygienic practice on farm and hygienic milking. The Code applies to all products derived from milk including raw milk cheeses.

### *4.4.2 European Union legislation on dairy products*

The European Union (EU) permits the sale of raw milk cheeses, subject to the following EU sanitary and food hygiene regulations:

- 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.

Directive 92/46EEC specifies the following microbiological criteria for blue-veined cheese made from raw or thermised milk:

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 25g | | n=5 | c=0 |
| *Salmonella* spp (1): | Absence in 25g | | 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.
- 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).

In France, the Commission Directive 89/362/EEC and Council Directive 92/46/EEC are embodied in Ministerial Orders (‘arrêtés’).

### *4.4.3 Other Countries*

Canada permits the sale of raw milk cheese, provided the cheese has been stored at a temperature of 2ºC or more for a period of 60 days or more[3]. In addition cheese made from an unpasteurised source must not contain more than 500 *E. coli* or 1,000 *S. aureus* per gram[4].

United States regulations require cheese to be pasteurised or, as an alternative treatment, cheeses made from unpasteurised milk require a minimum 60-day aging period[5]. This 60 day aging requirement, which is currently being reviewed by the US, permits the import of raw milk cheeses including Roquefort. However interstate trade of raw milk products within the US is prohibited.

## 4.5 Quarantine Requirements

The Australian Quarantine and Inspection Service (AQIS) and Biosecurity Australia maintain import requirements for dairy products entering 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. All consignments must be accompanied by an import permit and 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 for countries recognised as free of foot and mouth disease[6] are as follows:

| | |
|---|---|
| 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:<br>(a) The milk or the milk from which the cheese or butter was made must be subjected to one of the following heat treatments:<br>pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of phosphatase destruction or<br>a UHT treatment of 135°C for a minimum of 1 second.<br>OR<br>(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*. |

[3] Food and Drug Regulations B.08.044

[4] Food and Drug Regulations B.08.048, and as determined by official method MFO-14, Microbiological Examination of Cheese, November 30, 1983.

[5] US FDA Code of Federal Regulations 21CFR133

[6] The Office International des Epizooties (OIE) lists France as free of foot and mouth disease.

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

(AQIS quarantine requirements for the importation of dairy products from approved countries as at 27 September 2000)

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.

# 5. Relevant Issues

## 5.1 Determining equivalent food safety outcomes

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.

### *5.1.1 General principles*

Equivalence of food safety measures is recognised in the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures[7] (SPS Agreement) and the WTO Agreement on Technical Barriers to Trade[8] (TBT Agreement). These agreements require member countries to ensure their measures are objective, science-based and consistent.

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)[9] outlining principles to facilitate application of equivalence provisions of the SPS Agreement for all WTO members.

[7] http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm
[8] http://www.wto.org/english/tratop_e/tbt_e/tbtagr_e.htm#Agreement
[9] http://www.wto.org/english/tratop_e/sps_e/equivalence2001_e.htm

### *5.1.2 FSANZ's approach to assessing equivalence of food safety outcomes*

FSANZ has developed Guidelines for Determining the Equivalence of Food Safety Measures[10] which include the general principles:

- scientific basis and objectivity;
- harmonisation with international approaches 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 international obligations and with domestic policies and legislation.

### *5.1.3 Assessment for Roquefort cheese*

The assessment of Roquefort cheese involved a three-stage process:

1. A scientific evaluation of the safety of the cheese to examine the effect of the cheese manufacturing processes on selected microbial pathogens (Attachment 2).
2. A review of the regulatory environment and safety control measures under which sheep milk is produced and Roquefort cheese manufactured (Attachment 3), and
3. Verification of the implementation of these control measures (accomplished by performing an on-site verification audit, reported in Attachment 4).

This process is represented below in Figure 1.

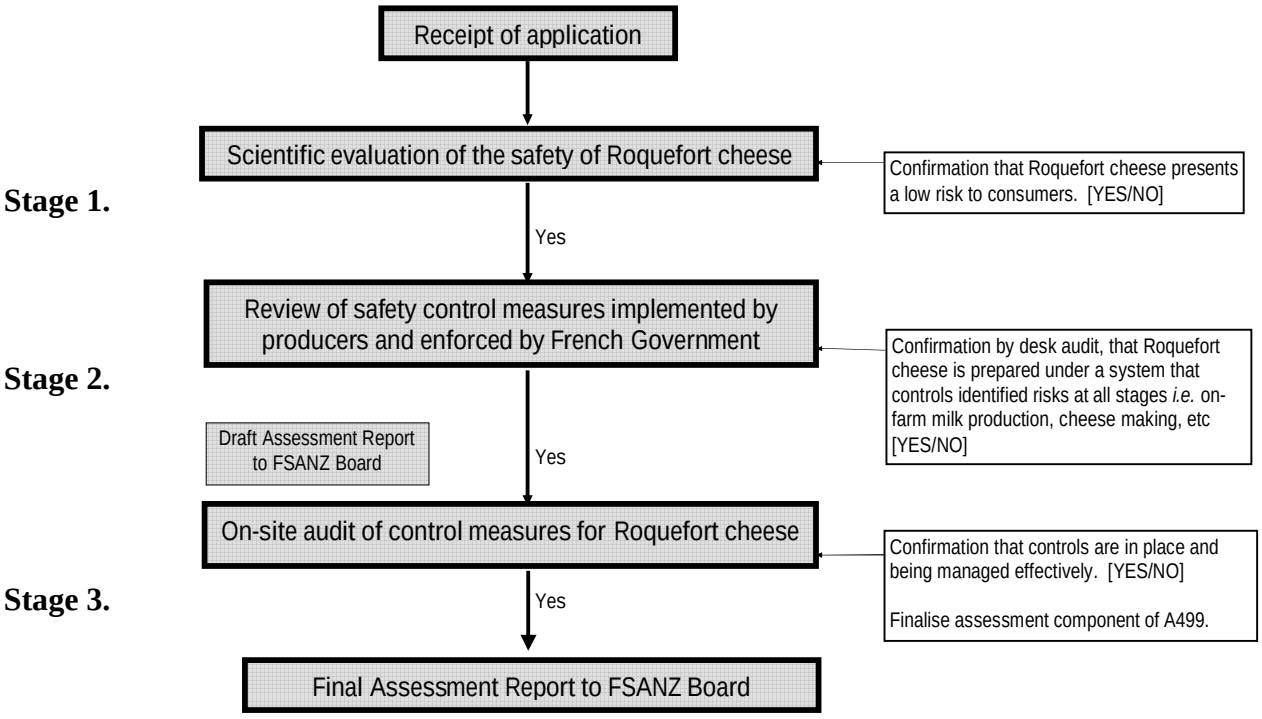



**Figure 1: Stages of the assessment of Roquefort cheese**

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

## 5.2 Scientific Evaluation of the Safety of Roquefort cheese

The report of the scientific evaluation of Roquefort cheese is provided at Attachment 2. This evaluation examined surveillance data on food-borne illness, described the manufacturing process for Roquefort cheese, identified potential pathogens that may arise, and determined their fate during processing and maturation. In addition a qualitative risk assessment undertaken by Food Science Australia, categorised the risk of each potential pathogen considered in this evaluation.

### *5.2.1 Public Health Status of Raw Milk Cheese*

Outbreaks attributed to raw milk cheeses are typically associated with soft or fresh cheeses where the physio-chemical properties of the cheese (i.e. moderate pH, low salt content, high water activity) permit the growth and/or survival of pathogenic microorganisms. Roquefort cheese has not been implicated in reported outbreaks of food-borne illness.

### *5.2.2 Impact of Roquefort manufacturing on key hazards*

The scientific evaluation considered microbiological hazards typically associated with raw milk and focused on hazards that have been implicated in food-borne illness from raw milk cheeses (*Campylobacter, E. coli, Salmonella, S. aureus; L. monocytogenes*; and *Brucella melitensis*) (ICMSF, 1998). In addition *Coxiella burnetii* was also included as it is the most heat-resistant non-sporulating pathogen likely to be present in raw milk.

Several factors are involved in the controlling the growth of bacteria in cheese including pH, temperature, salt, and water activity of the cheese. While each has an impact, it is their combined effect, which influences the growth and survival of pathogens in cheese. Roquefort cheese has an average water activity of 0.92, contains 3% salt, and after prolonged ageing ($90^{+}$ days) a final pH in the range 6.0-6.5.

The process of manufacturing Roquefort cheese makes it unlikely pathogens will survive or proliferate. Challenge studies undertaken by the Institut Pasteur de Lille and the Ecole National Veterinaire Toulouse support this conclusion.

### *5.2.3 Qualitative risk assessment*

A qualitative risk assessment was undertaken by Food Science Australia to categorise the risk from each potential pathogen in Roquefort cheese. The findings from the two qualitative risk assessment models used (Risk Ranger and qualitative framework model) found that consumption of this cheese represents a low to negligible public health and safety risk to consumers in the general population. A comparison of both models is summarised in Table 1.

**Table 1: Comparison of qualitative risk assessment models** (Food Science Australia, 2004)

| Hazard | Risk Ranger | Risk Characterisation Framework |
|---|---|---|
| *Campylobacter jejuni* | Negligible | Negligible |
| *S. aureus* (enterotoxin) | Low | Low |
| *Listeria monocytogenes* | Very Low | Negligible |
| *Escherichia coli* (EHEC) | Very Low | Very Low |
| *Salmonella* | Low | Very Low |
| *Brucella melitensis* | Negligible | Negligible |
| *Coxiella burnetii* | Negligible | Low |

### *5.2.4 Conclusions of scientific evaluation*

It was concluded that during manufacture of Roquefort cheese, pathogens, if present, would be unlikely to survive or proliferate. Therefore, consumption of Roquefort cheese poses a low risk to public health and safety. This conclusion is supported by the finding there have been no reported outbreaks of food-borne illness due to consumption of Roquefort cheese.

Table 2 summarises the effect of Roquefort cheese production on pathogens.

**Table 2: Effect of cheese manufacture on selected pathogens**

| Pathogen | Risk associated with Roquefort Cheese |
|---|---|
| *Campylobacter* | *Campylobacter* is unlikely to survive processing and maturation, hence is not considered to be a problem in raw milk cheeses and is a negligible risk. |
| Pathogenic *E. coli* | Very low risk if the level of raw milk contamination with *E. coli* is low. Challenge study demonstrates organism numbers initially increase, but the organism doesn't survive cheese maturation. |
| *Salmonella* | *Salmonella* contamination of raw milk is likely to be very low/low. Challenge study shows inactivation during cheese making and maturation. |
| *Staphylococcus aureus* | Risk from staphylococcal enterotoxin is considered low. Conditional on good control over cheese making, specifically acidification of the curd. Challenge study shows the organism fails to produce enterotoxin in Roquefort cheese. |
| *Listeria monocytogenes* | Very low/negligible risk if the organism is not present in raw milk and there is effective control over cheese making and ripening operations. |
| *Coxiella burnetii* | Risk is low/negligible, although no real control measures for raw milk. Organism unable to survive processing. |
| *Brucella melitensis* | Risk is negligible. Milk is only collected from Brucellosis free herds. Organism doesn't survive the cheese making process. |

The hazards identified as of most concern in Roquefort cheese are, in order of importance, *S. aureus* enterotoxin, *Salmonella*, EHEC and *L. monocytogenes*, but the risk to the general population is considered to be low. For at-risk consumers EHEC is the hazard posing the greatest risk (low). *Listeria* poses the same risk to at-risk consumers as other soft cheeses made from pasteurised milk, based on the assumptions made in this assessment[11].

[11] Note that in existing FSANZ listeria risk management material (the pamphlet ***Listeria and food – advice for people at risk***) at-risk populations are advised to avoid raw milk products and blue cheese.

Vital for the control of all hazards is the use of raw milk of good microbiological criteria; the application of standard operating procedures (SOPs) and good manufacturing practices (GMPs) during ewe's milk collection and processing; effective implementation of hazard analysis and critical control point (HACCP) plans during cheese manufacture and ripening; and microbiological monitoring of the final product.

Critical stages or steps during manufacture which control pathogens are summarised as follows:

- the microbiological status of the incoming raw milk;
- the rapid acidification of the milk during the initial phase of cheese manufacture (i.e. drop in pH from 6.5 to <5.0 within 6 to 8 hours and then to pH 4.8 within 24 hours);
- desiccation of the curd during subsequent processing stages (i.e. a final water activity of approximately 0.92) ; and
- prolonged ripening (i.e. >90 days).

The conclusions in this evaluation are based on information supplied by the Applicant, including the challenge studies; the review by Food Science Australia; and scientific literature and they confirm:

- Roquefort cheese is an unfavourable medium for the elaboration of *S. aureus* enterotoxin;
- the cheese making process and subsequent maturation achieves a significant reduction in *Salmonella*, EHEC, *L. monocytogenes* and *S. aureus*; and
- the milk used in cheese production is derived from sheep flocks which are free from *B. melitensis.*

In addition the evaluation determined that:

- *B. melitensis, C. burnetii* and *C. jejuni* are eliminated during cheese making and maturation;
- if low levels of *Salmonella*, EHEC, *Listeria* and *S. aureus* were present in raw milk, conditions during cheese making and maturation make it unlikely they would survive or proliferate; and
- *L. monocytogenes* is unlikely to grow in Roquefort cheese during maturation and subsequent storage.

The uncertainties in this evaluation are largely related to data on the management of the cheese making process (rate of acid production, final pH, and water activity) and the extent to which incoming milk may contain pathogenic bacteria. These matters were scrutinized during the on-site verification audit and are discussed in Section 5.4.

### 5.3 Review of safety control measures implemented by the Confederation of Roquefort Producers and enforced by the French Government

The microbiological safety of Roquefort cheese is managed by control and/or regulatory oversight of processes at various stages during milk production, storage and transport and cheese processing and maturation.

The report of the review of control measures implemented by the Confederation of Roquefort Producers and enforced by the French Government is provided at Attachment 3. This review was undertaken to examine the framework in place in France to support the safe production of Roquefort cheese. The examination considered:

- Infrastructure including legislation (e.g. food law and enforcement) and administration (e.g. organisation of national/regional authorities, enforcement systems);
- Program design, implementation and monitoring (including documentation, decision criteria and audit); and
- Specific process-related requirements (e.g. HACCP plans) and product-related requirements (e.g. microbiological limits).

### *5.3.1 Legislation*

The hygiene controls imposed in France on sheep milk production and processing of Roquefort cheese are legislated in France through several key regulations listed in Table 3.

**Table 3: Selected regulations covering milk and milk products**

| French Government | Overview of Content |
|---|---|
| Ministerial Order of 30 December 1993 (J.O. No. 8 of 11 January 1994) | ▪ Requirements relating to premises, equipment and operation of milk collection or standardization centres and of establishments involved in treatment or processing of milk or milk-based products.<br>▪ Critical control points are identified and monitored. |
| Ministerial Order of 18 March 1994 (J.O. No. 91 of 19 April 1994) | ▪ Hygiene of milk production and collection. |
| Ministerial Order of 30 March 1994 (J.O. No. 93 of 21 April 1994) | ▪ Microbiological criteria that drinking milk and milk-based products must satisfy in order to be placed on the market |
| Ministerial Order of 28 June 1994 (J.O. No. 176 of 31 July 1994) | ▪ Identification and sanitary approval of establishments placing on the market animal foodstuffs or foodstuffs of animal origin and on health marking. |
| Ministerial Order of 2 March 1995 (J.O. No. 82 of 6 April 1995) | ▪ Approval of milk collection, standardization or treatment centres and of establishments involved in the processing of milk or milk-based products |
| Decree of 22 January 2001 (J.O. No. 21 of 25 January 2001) | ▪ Relating to the protected designation of origin of Roquefort cheese |
| Regulation (14 May 2001) | ▪ Regarding the Decree for the Protected designation of origin of Roquefort cheese |

A summary of the requirements of the Ministerial Orders is provided at Attachment 5.

### *5.3.2 Desk audit of control infrastructure*

The Review of safety control measures implemented by the Confederation of Roquefort Producers and enforced by the French Government was undertaken as a desk audit of the documentation provided by the Applicant (Attachment 3). This information included:

- European Council and Commission Directives;
- French regulations and Ministerial orders;
- Guide of Good Manufacturing Practices (Confederation of Ewe Milk producers and Roquefort Producers);

- selected data on inspections and audits:
- generic HACCP Plans: raw milk production and cheese manufacture, ripening and packaging; and
- general internal inspection plan implemented throughout the chain from ewe livestock farms up to the final marketing of Roquefort.

### *5.3.3 Control over raw milk*

Raw milk in France is controlled by Ministerial Orders. These orders identify on-farm activities that must be managed and are consistent with the Codex Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57, 2004). The Codex Code applies to all products derived from milk including raw milk cheeses.

The **Codex Code of Hygienic Practice for Milk and Milk Products** states that *it does not mandate or specify the use of any one set of controls to be used, but leaves it up to those responsible for assuring the safety of the finished product to choose the most appropriate set of control measures for the particular situation. There are a wide variety of raw milk products, most of which are cultured products such as cheeses. The range of moisture content, pH and salt content (among other parameters) in these products will have varying degrees of impact on any potential microbiological hazards that may be present in the milk used for their manufacture. The degree to which inherent characteristics of the product (or process used to manufacture the product) will control the hazard should guide the extent to which these potential hazards need to be prevented or controlled during primary production.*

In addition, to assist producers and manufacturers, French Ministerial Orders have been translated into a **Guide of Good Manufacturing Practices for the Production of Ewe's milk in the manufacture of Roquefort.** (Confédération Générale des Producteurs de lait de Brebis et des Industriels du Roquefort). The Confederation Guide summarises the current on-farm regulations and sets out the hygienic practices required for production of quality milk.

Compliance with French Regulations and Confederation Guidelines is monitored by French Government Officials, the Confederation and cheese producers themselves. In addition, there are incentives and sanctions for producers to ensure compliance with Regulations and Guidelines.

Inspectors from the Departmental Veterinary Services Directorates (DDSV) and the Departmental Competition, Consumerism and Fraud Investigation Directorates (DDCCRF) monitor and verify the safety of foodstuffs in the market place. Inspections focus on relevance and proper implementation of procedures for the control of critical points identified throughout the manufacturing process. As part of their work they routinely inspect manufacturers of Roquefort cheese.

### *5.3.4 HACCP*

A HACCP plan was submitted for the manufacture of Roquefort cheese. The HACCP plan is general in nature and relies heavily on microbiological testing to ensure the safety of the final product. A full analysis of the HACCP plan as submitted by the applicant was conducted by Food Science Australia and is summarised in Table 4. The audit team also reviewed the HACCP plans of Roquefort manufacturers during their on-site visits.

**Table 4: Analysis of the Roquefort HACCP program** (Food Science Australia, 2004)

| Question | Observations |
|---|---|
| Does the HACCP plan identify all hazards associated with the manufacture of Roquefort cheese? | HACCP Plan was only provided and therefore it is not clear if hazards not mentioned were considered.<br>*C. burnetii* was not considered. |
| Are all critical control points identified | Yes - for the hazards specified |
| Is monitoring (both parameter and frequency) of critical control points appropriate for the control of the hazards | No real record of the frequency of monitoring for parameters such as pH and temperature. |
| Do the documented corrective actions effectively address variances from the critical limits | No - corrective actions are not quantitative or decisive in nature (they are presented in the form of corrective measures).<br>Corrective measures usually take the form of increased surveillance, *i.e.* no corrective action given for non-compliance with required milk temperature.<br>The ***more-intensive surveillance plan*** for slow fermenting batches in not clearly specified and appears to be the same as routine surveillance. |
| Do the corrective actions fully consider the implications of a situation where monitoring indicates loss of control at a critical control point | This is critical for pH during fermentation.<br>Corrective measures do not included identification of the source of the fermentation failure. |
| Is the HACCP plan effectively supported by pre-requisite programs (e.g. cleaning and sanitation, pest control, personal hygiene) | It would appear so, although little information is supplied on pre-requisite programs. More information is required on programs in place on-farm. |
| Is there a requirement for industry to implement a HACCP plan and comply with associated French and EC regulations | Yes - HACCP in mandated and inspections are undertaken.<br>The frequency on internal inspections is provided.<br>External audits are undertaken at least once a year, more frequently if problems occur. |
| Actual compliance with the HACCP plan and associated French and EEC regulations | No evidence of actual compliance with HACCP requirements is given.<br>Certification is removed if the processor is non-compliant, but no data is provided. |

All hazards considered potentially significant in Roquefort cheese are subject to management through on-farm systems and the application of HACCP-based control during processing. This is in combination with the application of standard operating procedures (SOPs) and good manufacturing practice (GMP) as determined and controlled by the Confederation of Roquefort Producers.

### *5.3.5 Conclusions of the review of safety control measures implemented by the Confederation of Roquefort Producers and enforced by the French Government*

The system of regulating the safety of raw milk and subsequently Roquefort cheese manufacture is considered comprehensive and adequate. Sanctions against producers and manufacturers that fail to meet the requirements of the Ministerial Orders and the requirements of the Confederation of Roquefort Producers are severe. In addition, the DDSV has a key role in enforcement of Ministerial Orders controlling milk safety.

The regulatory system is consistent with the Codex Code of Hygienic Practice for Milk and Milk Products.

## 5.4 Verification of control measures

An onsite verification audit was undertaken to finalise the evaluation of the safety of Roquefort cheese. The components of the audit included verification of the integrity and regulatory control implemented by the Confederation of Roquefort Producers and enforced by the French Government; inspection of facilities (along the entire supply chain), and examination of the results of routine monitoring and testing.

The Terms of Reference for the on-site verification audit were to:

- verify that milk production and cheese manufacturing requirements described by relevant French legislation are in place and followed, and
- verify that the official inspection and certification systems are robust and can deliver safe product to Australia.

The audit team undertook site visits, reviewed documentation and data, and audited the extent to which production and cheese-making facilities met regulatory requirements and/or their documented food safety (HACCP) plans. This included:

- visits to farms (*élevage*s), cheese making plants (*laiterie*), the caves (*affinage*) at Roquefort sur Soulzon, and maturation (*conditionement*) and packaging facilities;
- general inspection of milk production and processing facilities;
- examination of HACCP Plans;
- audits of HACCP system documentation; and
- reviewing data and monitoring results.

A report prepared by the audit team (provided at Attachment 5) describes the execution and findings of the verification audit (Part 2). The specific findings that impact on the assessment of this application are summarised below.

### *5.4.1 Animal Health*

The on-site audit confirmed that all farms supplying milk for Roquefort cheese production are under the supervision of the Departmental Veterinary Services Directorates (DDSV) in Aveyron. Each farm must be registered with DDSV and subjected to a minimum number of veterinary checks for animal health purposes. Aveyron Department and surrounding departments from which milk for Roquefort cheese are drawn are officially brucellosis free. Typically 50 animals from each farm are tested annually.

Sheep dairy farms are also under constant supervision by the Confederation, and farmers must keep records on animal health including veterinary treatments, breeding activity, transport to and from the farm, and animal treatments. The Confederation provides monthly veterinary support (or more frequently), with advice on prophylaxis and prevention of animal health issues including diarrhoeic diseases, worm control, and vaccinations. All veterinarians must be approved by the DDSV.

Farms have adopted detailed recording systems to ensure compliance to the Roquefort Decree (Decree of 22 January 2001, J.O. No. 21 of 25 January 2001) as well as for monitoring animal health and this provides good traceability from final product back to raw milk supply.

### *5.4.2 Control of raw milk*

The audit team visited several sheep dairies representative of those that supply milk for Roquefort cheese production, and determined that farm practices and official control measures are adequate to ensure milk production is achieved with minimum contamination or opportunity for outgrowth of pathogenic bacteria. Importantly, there is a clear, physical separation of milking area from milk storage room. Hence ingress of dust and aerosols is minimised. In all facilities observed, raw milk was rapidly chilled to temperatures of 8°C or less. Milk temperatures were not recorded on farm, but the tanker driver confirms that temperatures are 8°C or less at the time of pick up, otherwise the milk is not collected.

Cleaning and sanitation was undertaken using automated cleaning-in-place (CIP) systems.

Currently there is no requirement for on-farm HACCP programs. A new set of EU Regulations[12] promoting the use of good hygienic practices on farm will be introduced in 2006. Regulation (EC) No 852/2004 states that the application of HACCP principles to primary production is not yet generally feasible, but endorses the use of specific hygiene rules and guidelines. The production and on-farm implementation of the **Guide of Good Manufacturing Practices for the Production of Ewe's milk in the manufacture of Roquefort.** (Confédération Générale des Producteurs de lait de Brebis et des Industriels du Roquefort) is consistent with this approach. The audit confirmed that milk suppliers closely follow the practices outlined in the Guide.

As described in the documentation provided by the Applicant, milk producers are heavily penalised when their raw milk falls outside criteria i.e. somatic cell count, total count, coliform count, pathogens, etc. The on-site verification audit confirmed the veracity of these requirements and the strong financial incentives for suppliers to manage milk production and achieve appropriate hygiene levels.

### *5.4.3 Cheese-making*

The audit team found that the systems in place for the production of Roquefort Cheese from raw ewe's milk are sophisticated and competently implemented. All manufacturing premises were clean, tidy, maintained in good condition and many were using state-of-the-art processing equipment including robotics for materials handling. All staff and visitors were required to meet stringent dress codes.

Processing stages, including cheese making, maturation and packaging had well documented systems to comply with agreements with the DDSV. HACCP plans were sighted and were comprehensive in their design and coverage of steps along the Roquefort cheese processing chain. Records of monitoring were audited at selected sites, and in all situations conformance with documented requirements was confirmed.

---

[12] **Regulation (EC) No 852/2004** of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
**Regulation (EC) No 853/2004** of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
**Regulation (EC) No 854/2004** of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Most facilities also had HACCP documentation to meet the requirements of specific customers e.g. supermarket chains in the United Kingdom such as Marks and Spencer, Tesco's, etc.

Cheese manufacturers were also certified to other standards such as the International Standards Organization (ISO) quality management standard ISO 9001; the requirements of the Global Standard (British Retail Consortium) which requires adoption and implementation of HACCP; EFSIS which is a leading global food chain inspection and certification agency handling supply chain assurance; the International Food Standard (IFS) developed in Germany for food companies seeking distribution to German food retailers.

All tanker loads of incoming raw milk are screened for *Listeria*, and where possible *Listeria* positive milk is segregated and pasteurised for feta cheese production. In situations where the results are not available before cheese making has commenced, *Listeria*-positive batches are clearly marked and segregated. These cheeses are then subjected to further testing and segregated during the entire cheese making process. All cheeses are branded and traceability was observed to be effective and in place during the audit. Some facilities use transponders to track each trolley of cheese, and will not dispatch cheese until it has been cleared.

In Section 5.3.4, specific issues were raised with respect to the generic HACCP plan provided by the applicant. The audit team confirmed the following:

**Table 5: Updated analysis of the Roquefort HACCP program**

| Question | Observations |
|---|---|
| Do company HACCP plans identify all hazards associated with the manufacture of Roquefort cheese? | All hazards identified |
| Is monitoring (both parameter and frequency) of critical control points appropriate for the control of the hazards | Individual company HACCP plans list the parameter to be monitored, the frequency of monitoring and the critical limits. The auditors were satisfied with the monitoring plans. |
| Do the documented corrective actions effectively address variances from the critical limits | Auditors found that most corrective actions were decisive in nature. However in some circumstances corrective action takes the form of increased surveillance *i.e*. where *Listeria* positive milk has been turned into curd. In this situation, corrective action also includes intensive follow-up with milk suppliers.<br>The ***more-intensive surveillance plan*** for slow fermenting batches includes testing the cheese for *S. aureus*. Note, slow fermentation was not observed during audits of documentation and was reported as a rare event. |
| Do the corrective actions fully consider the implications of a situation where monitoring indicates loss of control at a critical control point | Yes |
| Is the HACCP plan effectively supported by pre-requisite programs (e.g. cleaning and sanitation, pest control, personal hygiene) | Comprehensive pre-requisite programs in place during cheese making i.e. cleaning and sanitation, pest control, staff training, etc.<br>HACCP plans not required on-farm, but cleaning and sanitation and pest control programs in place. |
| Actual compliance with the HACCP plan and associated French and EEC regulations | Cheese manufacturers must comply with HACCP requirements as described in French Ministerial orders.<br>Manufacturers are unable to supply major markets if they fail to meet their requirements e.g. certification to ISO 9001, BRC, etc. |

Storage of the cheese in the caves of Roquefort Sur Soulzon for 14 - 25 days forms an essential part of the process for making Roquefort cheese. Processors are unable to exercise control over the cave environment, aside from screening cave adits and implementing pest control programs. The cave temperature is consistently around 6-7°C in winter and 12-13°C in summer. Monitoring the cave environment (e.g. environmental swabs for *Listeria* spp.) and testing the product subsequent to cave storage ensures there is minimal risk of contaminated product entering the food supply chain.

The cheese continues to be monitored during maturation which is often well beyond 90 days. The audit team observed batches of cheese matured for periods up to 9 months. The temperature of the maturation facilities is not standardised and may range from -5°C to 6°C. Such variations do not adversely impact on the public health and safety of cheese and represent a means by which manufacturers can manipulate the rate and extent of Roquefort cheese maturation. Metabolic activity within the cheese mass will result in temperatures above the ambient temperature of the maturation facility.

Once matured, the cheese is tested and decisions about its eventual market are made at this time. Where specific and stringent market requirements are in place, only cheese batches meeting those requirements are selected and packaged. Traceability is essential at this stage. Importantly, the final cheese is not routinely tested for its water activity. Cheese is tested for water content and salt concentration and these parameters represent suitable surrogates for water activity measurement.

### *5.4.4 Conclusions of the on-site verification audit*

The on-site verification audit team concluded that the combination of controls over milk production and cheese manufacture and the existence of the system of regulation results in Roquefort cheese that can reliably meet the requirements stipulated in the proposed draft Standard.

The audit report lists some areas of concern that were reported to the French Authorities during the exit meeting. These included observations of a technical nature and comments on the management of the regulatory system.

A hygiene package to be introduced on 1 January 2006 will address some of the on-farm concerns, in accordance with three EU regulations - Regulations (EC) No 852/2004, No 853/2004, and No 854/2004 of the European Parliament and of the Council. This is a consequence of the Food Law 2002[13] that requires application of a full chain approach, from farm-to-fork including implementation of on-farm HACCP (where feasible) and the development of guidelines for hygienic practice.

Improvements in consistency in the audit process between Departements and staff will result when DGAL introduces its internal audit system, in accordance with the EU regulations.

[13] REGULATION (EC) No 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 Food Safety Authority and laying down procedures in matters of food safety

Concerns that non-accredited laboratories are conducting critical raw material and product monitoring will be addressed when DGAL introduces a Decree requiring the notification of laboratories involved in food testing and the compulsory accreditation of these laboratories by the French Committee for Accreditation (Comité Français d'Accreditation – COFRAC) in late 2005. While laboratories are not required to be accredited at present, they use standard methods developed and validated by AFNOR (Association Française de Normalisation) and are involved in inter-laboratory comparative analyses.

## 5.5 Critical steps identified in the scientific evaluation that impact on safety and their current regulatory control

The scientific evaluation determined that the safety of Roquefort cheese is influenced by a combination of factors, including on-farm control of animal health; on-farm production hygiene; the microbiological status of the incoming raw milk; the rapid acidification of the milk during the initial phase of cheese manufacture; desiccation of the curd during subsequent stages; prolonged ripening; and microbiological testing of the final product before release to the market. The review of safety control measures examined the control and/or regulatory oversight of these conditions and factors at various stages during milk production, storage and transport, and cheese processing and maturation.

### *5.5.1 Animal health and on-farm and production hygiene*

French legislation (Ministerial Orders) imposes hygiene controls both on farm and within production and processing establishments. A summary of these measures against the microbiological hazards identified to be of most concern in the production of Roquefort cheese (*S. aureus* enterotoxin, *Salmonella*, EHEC and *L. monocytogenes*) is provided below.

**Table 6: Analysis of the pathogen control**

| Hazard | Control measures |
|---|---|
| *S. aureus* enterotoxin | **On farm:**<br>• Ministerial Order of 18 March 1994 on the Hygiene of milk Production and Collection<br>- milk derived from healthy animals<br>- criteria for Plate Count at 30 °C<br>- temperature/time requirements for milk storage (≤8°C) and transport (≤10°C)<br>**Processing and production:**<br>• Ministerial Order of 30 December 1993<br>- requirement for hazard analysis/identification of critical control points and ongoing monitoring and checking (*e.g.* HACCP plan) |
| *Salmonella* | **On farm:**<br>• Ministerial Order of 18 March 1994<br>- hygiene requirements for production, holding, milking, storage and collection operations<br>- temperature/time requirements for milk storage (≤8°C) and transport (≤10°C)<br>**Production and Processing:**<br>• Ministerial Order of 30 December 1993<br>- requirement for hazard analysis/identification of critical control points and ongoing monitoring and checking (*e.g.* HACCP plan) |

| Hazard | Control measures |
|---|---|
| Pathogenic *E. coli* | **On farm:**<br>• Ministerial Order of 18 March 1994<br>- hygiene requirements for production, holding, milking, storage and collection operations<br>**Processing and production**<br>• Ministerial Order of 30 December 1993<br>- general hygiene requirements |
| *Listeria monocytogenes* | **On farm:**<br>• Ministerial Order of 18 March 1994<br>- hygiene requirements for production, holding, milking, storage and collection operations<br>**Processing and Production:**<br>• Ministerial Order of 30 December 1993<br>- general hygiene requirements<br>- requirements for hazard analysis/identification of critical control points and ongoing monitoring and checking (e.g. HACCP plan) |

### *5.3.2 Microbiological status of the incoming raw milk*

The French Ministerial Orders of 18 March 1994 and 2 March 1995 specify that raw ewe's milk intended for the manufacture of raw milk products must have a standard plate count (at 30°C) that is <1,000, 000. No other microbiological criteria are provided.

The scientific evaluation recommends that specifying the absence of *L. monocytogenes* in the raw sheep milk is an important measure in controlling/eliminating this hazard throughout the production of Roquefort.

### *5.3.3 Acidification*

Progressive acidification during cheese making was identified as an important control for ensuring the safety of Roquefort cheese. The pH should fall rapidly within the first 6 to 8 hours to below pH 5.0, reaching 4.8 within 24 hours.

### *5.3.4 Water activity*

The scientific evaluation highlighted that a final water activity ($a_w$) less than 0.92 resulting from desiccation of the curd and the salting process, was another critical processing parameter for ensuring the safety of Roquefort. Confirmation that the final product achieves a moisture content of 43-45% (often reported as 55-57% dry matter) and a salt concentration of 3.6-4.3% provides similar assurance regarding availability of moisture in the final product.

### *5.3.5 Ripening*

An extended ripening/maturation period for Roquefort cheese was identified as an important processing measure contributing to the safety of this product. A minimum storage time of 90 days has been recommended.

*5.3.6 Microbiological testing of end product*

The European Union has microbiological limits for *Salmonella, L. monocytogenes, S. aureus* and *E. coli* in raw milk cheeses (presented in Section 4.4.2). Standard 1.6.1 – Microbiological Limits for Food, contains a number of microbiological criteria that apply to cheese produced from both heat-treated and raw milk (Section 4.2.3). The limit in the Food Standards Code for *E. coli* is significantly different to that in the European Union. Roquefort cheese must meet the limits specified in the Code.

*5.3.7 Summary of measures*

In summary, the hygiene measures identified as critical in ensuring the safety of Roquefort cheese are largely implemented through the French Ministerial Orders (as outlined above). However, there are several critical parameters which have been identified as important in ensuring the safety of Roquefort cheese that are not explicitly covered by existing legislative requirements. These include:

- the absence of *L. monocytogenes* in raw milk;
- the acidification process;
- water activity (achieved through desiccation and the salting process), and
- a minimum ripening time (no less than 90 days).

In addition to the existing legislative framework for the production of Roquefort cheese, a mandatory requirement for Roquefort cheese to comply with the conditions of these critical parameters would ensure an equivalent food safety outcome to cheeses made from heat-treated milk.

# 6. Regulatory Options

Two regulatory options were posed for this Application - to either amend the Code to permit the sale of imported Roquefort cheese or to reject the Application.

## 6.1 Option 1 – reject the Application

A rejection of this application would mean that the Code would not be amended to permit the sale of Roquefort cheese produced from raw milk (the status quo).

## 6.2 Option 2 – permit the sale of Roquefort cheese

The conclusion from the scientific evaluation of the safety of Roquefort cheese is that the sale of this cheese would pose a low risk to the public health and safety of Australian consumers. This conclusion is supported by an examination of the regulatory and industry management framework for the safe production of Roquefort cheese and verified through an on-site audit in France. Option 2, therefore, is the preferred option.

The proposed amendment to the Code to permit the sale of Roquefort cheese produced from raw milk requires that Roquefort is produced in compliance with the current regulatory framework (e.g. French Ministerial Orders).

In addition, this amendment mandates the specific conditions identified as important in ensuring the safety of Roquefort cheese that are not explicitly covered by existing regulatory requirements. These conditions are:

- the use of raw milk which is tested for the presence of *L. monocytogenes*;
- the monitoring and recording of pH during the acidification process;
- the monitoring and recording of moisture and salt content during cheese production; and
- a minimum storage time of Roquefort of 90 days at an appropriate temperature.

The draft variation to the Code is at Attachment 1.

*6.2.1 Location of the amendment*

The location of an amendment within the Code is essentially a structural issue and does not change the effect of the amendment itself. Whether an amendment should apply to both New Zealand and Australia or Australia only is, however, a consideration.

Application A499 seeks an amendment to the Code to permit the sale of Roquefort cheese in Australia (not Australia and New Zealand). It would therefore be consistent with the Application for an Australia only standard to apply. Further, the New Zealand Food Safety Authority has expressed the view that the permissions for Emmental, Gruyere and Sbrinz cheeses currently in Standard 2.5.4 – Cheese, should be placed within Standard 1.6.2 – Processing Requirements, applying to Australia only. An amendment to this Standard to permit the sale of Roquefort would then automatically apply in Australia, but not to New Zealand. The importation of Roquefort into New Zealand would only be permitted if the New Zealand (Milk and Milk Products Processing) Food Standards 2002 is amended, which is a matter for the New Zealand Government to determine.

In developing the Seafood PPP Standard and the broader Code structure for PPP Standards, it has become apparent that aspects of Chapters 1 and 2 of the Code would more appropriately be located in Chapter 4 (Primary Production Standards) of the Code (applying to Australia only). The processing requirements currently located in Standard 1.6.2 are a prime example of this. In addition, the separation of processing requirements with respect to cheese between Standards 1.6.2 and 2.5.4 does not sit logically within the structure of the Code.

FSANZ therefore intends to take the opportunity presented by this application to begin to rectify this situation by locating relevant Code requirements for cheese within Chapter 4 of the Code. This is a matter of structure, not substance. That is, changing the location of these provisions within the Code does not change the effect of the provisions. Standard 4.2.4A - Primary Production and Processing Standard for Specific Cheeses, details the requirements for certain cheese products such as Roquefort cheese. Code requirements in relation to cheese generally (including raw milk issues) can then be considered in the context of the general development of the Dairy PPP Standard (discussed in Section 4.3).

*6.2.2 Changes to the amendment following Draft Assessment*

*6.2.2.1 L. monocytogenes* standard

The sampling plan initially proposed for *L. monocytogenes* in raw milk has been amended at Final Assessment as it was considered inappropriate for the testing of bulk milk. The specification has been amended to a "not detected" limit in 25 ml per tanker of milk.

6.2.2.2 Water Activity

At Draft Assessment, water activity was included as a parameter to be monitored and recorded. During the on-site audit it was determined that moisture and salt content were measured on all batches of cheese, whereas water activity is not a practical test and is therefore not routinely measured. The draft amendment has therefore been changed at Final Assessment to include the monitoring of moisture and salt content rather than water activity.

6.2.2.3 Storage Temperature

The minimum storage temperature specified at Draft Assessment (2°C) has been deleted from the draft variation at Final Assessment.

The temperature of storage during the cheese maturation phase will not adversely impact on public health and safety. The actual temperatures controlled by Roquefort manufacturers are between -5°C and 6°C. Temperatures below 6°C will present an unfavourable environment for the growth or survival of most mesophilic pathogens. As such, maturation temperature is predominantly a variable impacting on cheese quality, influencing the rate and extent of flavour and texture development in Roquefort cheese. In addition, metabolic activity within the cheese mass will result in temperatures above the ambient temperature of the maturation facility. For this reason, specifying a temperature of maturation provides little benefit in managing the safety of Roquefort cheese therefore, the Standard requires the cheese to be stored at an appropriate temperature as deemed by Roquefort manufacturers.

6.2.2.4 Editorial notes

The revised drafting also contains editorial notes that provide additional guidance as to what the monitoring of pH should demonstrate (i.e. rapid acidification) and the labelling requirements (i.e. form of declaring ingredients).

# 7. Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia (and New Zealand where relevant), 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. As an amendment to the Code for this application would apply to Australia only, this impact analysis considers the impact of each option on Australian parties only.

The parties affected by this Application are:

- Consumers (including the hospitality industry);
- Food importers;
- Australian dairy industry (suppliers and dairy manufacturers); and
- Government (Australia).

## 7.1 Impact of Option 1

**Consumers** who have an interest in specialty cheeses would continue to be denied access to Roquefort cheese. From data prior to 1997 when Roquefort cheese was permitted for sale in Australia, imports of Roquefort cheese did not exceed 10 tonnes per annum compared with imports of all speciality cheeses of 8,000 tonnes per annum, accounting for just 0.1% of the imported speciality cheese market. While Option 1 does impose an opportunity cost on consumers, the extent of the cost is very small.

**Importers** that trade in cheese would continue to be unable to import Roquefort and establish a market for this product. Option 1 imposes an opportunity cost but, as the previous market for Roquefort was very small, the extent of the cost is commensurately small.

**The Australian dairy industry** does not produce an equivalent product to Roquefort cheese and hence the impact of Option 1 is neutral, neither a cost nor a benefit.

**Government** enforcement agencies - AQIS and food regulators of the State and Territory Governments - are unaffected by Option 1 because Roquefort cheese is not imported nor presented for sale in Australia.

## 7.2 Impact of Option 2

**Consumers** of specialty cheeses within Australia would be able to access Roquefort cheese. If the current unmet demand for Roquefort is similar to the pre-1997 levels, of 0.1% of the imported speciality cheese market, then the benefit to consumers would be very small.

**Importers** of cheese would be able to import Roquefort cheese and establish a market for this product in Australia. Option 2 therefore provides a benefit for importers. If the potential market for Roquefort is similar to pre-1997 levels, of 0.1% of the imported speciality cheese market, then the extent of the benefit would be very small.

**The Australian dairy industry** in the very short term would be unaffected by Option 2 because it does not produce an equivalent raw milk product to Roquefort cheese. In the medium to long term, Option 2 would impose an opportunity cost on industry because an approval for imported Roquefort would not permit the Australian industry to set up facilities to produce an equivalent product, and compete with imports for a share of the Roquefort market in Australia. If the potential market for Roquefort is similar to pre-1997 levels, 0.1% of the imported speciality cheese market, then the extent of the opportunity cost would be very small. It should be noted that domestic producers may make an application to FSANZ for permission to manufacture similar styles of cheese providing they have supporting information and data.

While Option 2 may be seen as providing an uneven playing field for domestic producers in the short term, this situation is currently being addressed through a process to develop a Primary Production and Processing Standard for dairy products. This process will include consideration of the domestic production of cheeses from raw milk, and include products that may be equivalent to Roquefort cheese. Furthermore, domestic manufacturers may apply to FSANZ for exemptions for similar styles of cheese, provided they supply supporting information and data.

**Government** enforcement agencies – AQIS and food regulators of the State and Territory Governments – would easily be able to enforce a food standard that allowed the import and presentation for sale in Australia of Roquefort cheese. The standard would not have any resource implications for them.

# 8. Consultation

## 8.1 Consultation at Draft Assessment

FSANZ received seventeen submissions in response to the Initial Assessment Report from consumers, industry, importers and Government regulators. In addition, a forum with stakeholders was held on 7 December 2004 to present the preliminary findings of the scientific assessment of Roquefort and to discuss the possible risk management options for this application. Attendees included representatives from the dairy industry, state dairy regulators, AQIS, and New Zealand Food Safety Authority.

Further to the stakeholder forum, the outcomes of the scientific evaluation, review of regulatory and control systems and proposed management approach were presented to state regulators and the New Zealand Food Safety Authority in a separate briefing on 10 February 2005.

The issues raised in submissions and other stakeholder consultations were addressed in the Draft Assessment Report and included:

- Safety and verification of hygiene controls;
- Impact on the Australian industry
- Geographical indications
- Transparency of the FSANZ process
- Labelling
- Primary production and processing standard for dairy
- Implementation
- WTO obligations

## 8.2 Consultation at Final Assessment

A total of 15 submissions were received in response to the Draft Assessment Report from consumers, industry and Government regulators:

- Australian Food and Grocery Council
- Australian Specialist Cheesemakers' Association
- Food Technology Association of Victoria Inc.
- Dairy Australia
- Fonterra Co-operative Ltd
- Department of Human Services Victoria
- NSW Food Authority
- Department of Human Services South Australia
- Queensland Health
- Australian Quarantine and Inspection Service
- New Zealand Food Safety Authority
- Consumers (4 submissions)

A summary of the issues raised in these submissions is provided at Attachment 6.

In addition, a stakeholder forum was held with representatives from the dairy industry, state dairy regulators, AQIS, and New Zealand Food Safety Authority on 4 May 2005 to present the findings of the on-site audit in France.

The major issues raised by stakeholders are presented and discussed below.

## 8.3 Issues raised in submissions and other stakeholder consultations

### *8.3.1 Transparency of the FSANZ process*

The process for amending the Code is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). These processes are transparent and open to public scrutiny. The application, assessment reports, submissions etc, are all placed on the public register of FSANZ and are available for inspection. The exception to this is if a request is made for commercial-in-confidence for sensitive information. 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. There was no commercial-in-confidence treatment of information relating to the Roquefort cheese Application.

Additionally, FSANZ has undertaken stakeholder consultations prior to Draft Assessment and Final Assessment to discuss with interested parties the outcomes of the scientific evaluation and audit processes. These forums have been integral to the development of the risk management options proposed.

### *8.3.2 Impact on the Australian industry of permitting Roquefort cheese*

It has been raised by stakeholders that a permission for the sale of Roquefort cheese would in effect provide an 'unlevel playing field' for domestic producers as it does not provide for the manufacture of raw milk blue cheeses domestically. The impact analysis (Section 7) discusses this issue and notes that, while permitting the sale of Roquefort may be seen as providing an unlevel playing field in the short term, in the longer term this situation would be addressed through the process of developing a primary production and processing food standard for dairy products.

### *8.3.3 Primary Production and Processing Standard for Dairy*

It has been raised that it would be preferable to consider the issue of raw milk cheeses more generally within the scope of the Primary Production and Processing (PPP) Standard for Dairy (discussed in Section 4.3) rather than deal with individual cheeses such as Roquefort. A concern raised is that the risk management options posed for Roquefort may have unintended consequences for the development of a national framework.

While the issue of raw milk products will be considered within the development of a Dairy PPP Standard, the Roquefort Application was received by FSANZ well before a proposal for the Dairy PPP Standard was raised. FSANZ must process applications according to its statutory obligations under the FSANZ Act and cannot halt or refuse to assess such applications pending the outcome of a related proposal.

Accordingly, the assessment of the Roquefort Application has progressed independently of the Dairy PPP Standard process, according to statutory timeframes.

A precedent for specifying the regulations of another country in the Code has already been established with respect to the requirements for the three Swiss cheeses. Including French Ministerial Orders as part of the amendment to the Code for Roquefort cheese is consistent with the regulatory approach taken for the existing permissions for the Swiss cheese. These existing requirements will need to be taken into account when developing a national framework for dealing with raw milk cheeses however, they will not dictate the approach to be taken.

As Discussed in section 6.2, the location of an amendment to the Code is a structural issue and has no effect on the amendment itself. Rather than continue to amend Standard 1.6.2 and 2.5.4 to permit the sale of Roquefort, FSANZ is taking this opportunity to include all the processing requirements for specific cheeses (Swiss raw milk cheeses and Roquefort cheese) in a separate standard in Chapter 4 of the Code.

*8.3.4 pH*

Rapid acidification was highlighted as one of the critical controls in ensuring the safety of Roquefort cheese. The Draft Assessment Report described the rapid acidification of the milk during the initial phase of cheese manufacture as a drop in pH from 6.5 to 4.8 within 24 hours. It has been raised, however, that a pH decrease to < pH 5.0 in 24 hours is not rapid - this decrease should occur within the first 6 to 8 hours.

During the manufacture of Roquefort cheese the pH does fall to around pH 4.8 within 24 hours. Typically, the pH decreases from 6.5 to <5.0 within 6 hours of addition of the starter culture and then to pH 4.8 within 24 hours. The acidification achieved can, therefore, be described as rapid. It is acknowledged, however, that this was not described clearly in the Draft Assessment Report. Accordingly, the Final Assessment Report and Scientific Evaluation have been amended to more accurately describe the acidification process that occurs.

*8.3.5 Management of Salmonella*

One submission raised concerns that *Salmonella* should not be detected in raw milk and a limit set. The Confederation requires that all batches of milk are tested at reception for *Salmonella*. Furthermore, tankers are tested for total coliforms and *E. coli* as indicators of faecal contamination (and hence *Salmonella* spp.), and the results observed were generally low i.e. <10-20 coliforms/ml.

In addition, the scientific evaluation determined that *Salmonella* was effectively inactivated by a combination of pH, salt, moisture conditions and storage temperature during cheese production and maturation. With routine monitoring of raw milk for *Salmonella* and *E. coli* and the inability of *Salmonella* spp to survive cheese making, specifying a requirement that raw milk should have a “not detected” level of *Salmonella* is deemed unnecessary.

### *8.3.6 Storage temperature*

The ripening temperature used in cheese production primarily impacts on the quality of the cheese[14]. Increasing the temperature, for example, accelerates the rate of ripening (increasing the biological, biochemical and chemical reactions) but may also result in the development of off-flavours. The temperature used is generally characteristic of the variety of cheese being produced and is controlled to affect the desired quality characteristics of the cheese.

Roquefort cheese is initially ripened in the caves for a period of 15 - 25 days at temperatures around 9 to 10°C. Further ripening is then carried out in controlled temperature rooms commonly at temperatures of 2 - 6°C. These rooms, however, can operate at temperatures down to -5°C. Manufacturers may use these lower temperatures (below 0°C) to control the ripening of the cheese (and resultant quality attributes) over an extended time (often greater than 120 days). The actual temperatures controlled by Roquefort manufacturers are therefore between -5°C and 6°C.

The proposed amendment at Draft Assessment included a minimum storage temperature of 2°, understood at that time to be the minimum temperature used in practice. It is now known that lower temperatures may be used (confirmed during the on-site audit) and that 2°C is therefore not an enforceable limit. The minimum temperature is not a safety issue however - the safety assessment noted that prolonged ripening (>90 days) in combination with pH, moisture content and salt is a critical step (independent of a minimum temperature). Indeed, temperatures below 6°C will present an unfavourable environment for the growth or survival of most mesophilic pathogens. The requirement for a minimum storage temperature from the draft amendment has therefore been replaced with a requirement for an appropriate temperature to be applied at storage at Final Assessment, as discussed above in Section 6.2.2.

### *8.3.7 Challenge studies*

Although no raw data was provided with the challenge studies, FSANZ was satisfied with the summary data provided in table and graph format. While the challenge studies were not peer reviewed, the Institut de Pasteur de Lille is regarded as a credible, internationally recognised and reputable institution. The data provided in the challenge studies is not dissimilar to other industry data regularly provided to FSANZ in support of other applications and proposals. Additionally, these studies were evaluated by Food Science Australia as part of their assessment work.

### *8.3.8 Mycobacterium species*

The issue of *Mycobacterium avium* subsp. *paratuberculosis* in sheep (the cause of Johne's disease in ruminants) and *Mycobacterium bovis* (the cause of tuberculosis) was raised in relation to the potential for transmission of disease to humans via cheese.

*Mycobacterium* spp were not identified as potential hazards in raw sheep milk. Other milk-borne zoonoses such as *Coxiella* and *Brucella* spp were included within the scientific evaluation for this application and considered to be of negligible risk.

[14] see Fox P. F., McSweeney P. L., Cogan T. M., and Guinee T. P. (Eds) (2004). **Cheese: Chemistry, Physics and Microbiology**. Volume 1 General Aspects. Elsevier Ltd: London.

It was noted that zoonoses are controlled primarily through good animal health practices and controlling authority requirements that milk be collected only from healthy animals. The animal health system in France for the production of milk for Roquefort cheese was subject to evaluation by the audit process. The audit team found that Government monitoring by the Departmental Directions of Veterinary Services to be well implemented in relation to animal health testing.

*8.3.9 Audit Report*

Based on the scientific evaluation and desk audit, the likely presence of pathogens was assessed as negligible to low. The uncertainty in this assessment was on the management of the cheese making process. The on-site audit has verified that the management systems in place are adequate, therefore the original assessment of risk remains the same (i.e. negligible to low).

The verification of control measures, specifically relating to animal health requirements, control of raw milk and the cheese making process, is discussed above in Section 5.4.

*8.3.10 Seasonal variation of raw milk*

Milk production for Roquefort cheese only occurs 6 months of the year. While some seasonal variation may occur, and the ratio of fat/dry matter may slightly vary, specifications for the final composition of the cheese requires a final fat content of 52 g/100 g cheese and a dry matter content of not less than 55 g/100 g cheese. In addition, the water activity of the final cheese is not solely dependent on the fat/dry matter content of the raw milk. The water activity is dependent on a number of factors such as addition of salt, pressing of the cheese and maturation (e.g. milk with a low dry matter/fat ration may require more drying out to achieve the same moisture content).

*8.3.11 IFP risk categorisation*

It was noted in submissions that, while the scientific evaluation concluded that Roquefort posed a low risk to public health and safety, this cheese would be considered high risk under the Imported Food Program.

Imported foods are normally assessed as high risk on the basis of the severity of hazards commonly associated with those foods and previous testing failures. Soft and semi-soft cheeses are generally considered to be high risk foods for the purposes of the Imported Food Program (IFP). However, the risk of these foods can be mitigated by the implementation of production systems and controls in the exporting country, and certification of these processes by the importer to Australian enforcement agencies. Roquefort cheese was evaluated in light of specific HACCP based management systems in place in France and, as a result, was determined to pose a low risk to public health and safety. While it would be considered a risk food under IFP on the basis that it is a semi-soft cheese (irrespective of whether it was made from raw or heat treated milk), it is intended that a Government to Government certification arrangement will be put in place for Roquefort, recognising the French regulatory and production systems in place which ensure its safety and having assurances that the requirements of these systems are being met. As for all foods that are imported under a certification system, inspection and testing for Roquefort will occur at a reduced audit inspection frequency (5%).

*8.3.12 Consumer information*

No specific labelling requirements are proposed for Roquefort however, in accordance with the requirements of Standard 1.2.4 - Labelling of Ingredients, ingredients must be declared for this product by their common name or a name that describes the true nature of the ingredients. As such `unpasteurised sheep (or ewe) milk' should be declared. Retail packages of Roquefort cheese, in addition to the other labelling requirements of the Code, would be expected to display such a declaration on the label. An editorial note to this effect will be included with the amendment for this application.

It was also raised that Roquefort cheese should be specifically listed as a high risk food in the FSANZ brochure *Listeria and Food: Advice for People at Risk*. This brochure currently lists soft, semi soft and surface ripened cheeses as higher risk foods giving brie, camembert, ricotta and blue cheese as examples. Roquefort cheese is clearly a blue cheese and as such is already covered by the information provided. While examples of particular categories of cheese are provided, it is not appropriate to include specific cheese names.

# 9. World Trade Organization (WTO)

## 9.1 WTO obligations

Australia is a member of the WTO and is a signatory to the SPS Agreement and the TBT Agreement. As such, the food regulatory measures applied by FSANZ must be consistent with the WTO obligations.

The WTO Agreements are predicated on a set of underlying principles that standards and other regulatory measures should be:

- based on sound scientific principles;
- developed using consistent risk assessment practices;
- transparent;
- no more trade-restrictive than necessary to achieve a legitimate objective;
- recognise the equivalency of similar measures in other countries, and
- not used as arbitrary barriers to trade.

Under the World Trade Organization Agreement on Sanitary and Phytosanitary measures (SPS), Australia is obliged to ensure that their 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.

## 9.2 WTO Notification

As a member of the WTO, Australia is 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.

With regard to this Application, FSANZ has noted relevant international standards and considers that an amendment to the Code to permit the sale of Roquefort Cheese is likely to have a significant effect on international trade as this will permit the sale of Roquefort Cheese in Australia and remove a barrier to trade which has disadvantaged another WTO member.

Notification to the WTO was therefore made in accordance with Australia's obligations under the WTO Sanitary and Phytosanitary Measure (SPS) Agreement in March 2005. The closing date for comments was the 23 May 2005, at which time no comments had been received.

## 10. Conclusions and Recommendations

At Final Assessment, FSANZ recommends that the Code be amended to permit the sale of Roquefort cheese in Australia for the following reasons:

- The scientific evaluation of the safety of Roquefort cheese concluded that the sale of Roquefort cheese poses a low risk to the public health and safety.

- All hazards considered to potentially pose a significant risk in Roquefort cheese are subject to management through on-farm systems and the application of HACCP-based control during processing. This is in combination with the application of SOPs and GMP as determined and controlled by the Confederation of Roquefort Producers.

- The regulatory system is consistent with the Codex Code of Hygienic Practice for Milk and Milk Products.

- The system of regulating the safety of raw milk and subsequently Roquefort cheese manufacture is considered comprehensive and adequate.

- FSANZ is satisfied that the producers and manufacturers comply with the French Regulatory system and that the French Government adequately enforces these control measures.

- Appropriate risk management measures have been proposed to address any public health and safety risks.

- The proposed amendments to the Code are consistent with the section 10 objectives of the FSANZ Act.

- The proposed amendments support Australia's WTO obligations.

- The Impact Analysis supports the proposed amendment to the Code.

The drafting for amendment to the Code is at Attachment 1.

## 11. Implementation and review

### 11.1 Imported Food Program

Ensuring that imported food complies with food legislation in Australia is a shared responsibility between Australian State, Territory and Local Governments. The Australian Government, through the AQIS Imported Food Program (IFP), monitors imported food at the border for compliance with the requirements of the Code.

IFP is jointly managed by FSANZ and AQIS, with FSANZ advising on food risk assessment policy for the program and AQIS having operational responsibility for inspection and sampling. AQIS implements the testing of food in accordance with the *Imported Food Control Act 1992* (the IFC Act) and its associated Regulations.

### *11.1.1 Inspection Categories for Food at the Border*

Under the IFC Act, food is placed into one of three inspection categories which determine the frequency of inspection: risk category, active surveillance category and random surveillance category. The placement of food within these categories is routinely reviewed by FSANZ.

All risk categorised foods are inspected and tested against a pre-determined list of potential hazards. All active surveillance foods referred to AQIS are inspected and tested, whereas only a proportion of random surveillance food will have tests applied.

Risk foods on initial inspection must develop a compliance history. Once this is achieved, risk foods, along with foods from the other two categories are selected for inspection on a statistically random basis. Neither AQIS nor the importer has the ability to predict which shipment or which foods will be selected for inspection.

#### 11.1.1.1 Risk category

Risk categorised food is food that has the potential to pose a high risk to public health. At the point of entry, the Australian Customs Service refers the details of 100 percent of risk categorised foods, electronically, to AQIS for inspection.

A performance-based approach applies for risk categorised foods. This means food products from overseas producers with a consistent history of compliance are selected for inspection by AQIS less frequently than products from new suppliers or those with a history of failure against Australian standards. All risk food selected for inspection and testing must be held pending the results of the analysis.

#### 11.1.1.2 Active surveillance category

Ten percent of shipments of designated active surveillance foods, from every supplying country, are referred to AQIS for inspection. Depending on the type of food and its potential hazards one or more tests may then be applied. These products are released upon sampling. The test results of active surveillance foods are periodically analysed by FSANZ to review the appropriate category classification for these foods.

#### 11.1.1.3 Random surveillance category

Five per cent of all consignments of all foods not included in the risk or active categories are referred to the Scheme for inspection. Depending on the type of food and its potential hazards one or more tests may then be applied. These products are released upon sampling.

In the event of an active or random surveillance food not complying with the standards, a holding order may be issued. A Holding Order against a foreign supplier effectively raises the inspection category of the food to ‘risk’ status.

This means that all future shipments of that food from the offending supplier are automatically detained and held until compliance with Australia's requirements is confirmed. After five clear inspections, the food reverts back to its prior category.

### *11.1.2 Testing Requirements for Cheese at the Border*

As for all imported foods referred for inspection, cheeses undergo a visual and label inspection. In addition the current testing requirements for imported cheeses at the border are:

**Random surveillance category test:**

| | | |
|---|---|---|
| All cheese and curd other than those categorised as risk | *Escherichia coli*/g | n=5, c=1, m=10, M=100 |

**Risk category tests:**

| | | |
|---|---|---|
| Cheese with moisture content >39% and pH>5 (e.g. non-fermented fresh cheeses, non-fermented curd cheeses, surface ripened cheese, soft and semi-soft cheese) | *Listeria monocytogenes/25g* | not detected |
| | *Salmonella*/25g | not detected |
| | *Escherichia coli*/g | n=5, c=1, m=10, M=100 |

n = the maximum number of sample units which must be examined from a lot of food.

c = the maximum allowable number of defective sample units i.e. that have counts between 'm' and 'M'.

m = the acceptable microbiological level in sample unit.

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

The physical parameters of cheeses in this category have been determined by FSANZ. AQIS provides guidance in respect to the types of cheeses that would typically fall within these parameters. Roquefort cheese is identified as a risk category cheese because its physical characteristics fall within the parameters specified for this category and would therefore be inspected at the highest rate.

If, however, a certification agreement is established for this product, it would be inspected at a lower rate (random surveillance rate), but against the risk category tests.

## 11.2 Certification Measures

Section 18 of the IFC Act, allows AQIS to establish Government-to-Government certification agreements for particular foods or categories of foods. Such a certificate specifies that a food of a specified kind meets applicable standards and does not pose a risk to human health.

Certification arrangements can be negotiated where an exporting country can assure AQIS that its official inspection and certification systems are at least equivalent to that in Australia. The criteria examined include:

- Legislation;
- Competent Authority;
- Assessment of control programs;
- Inspection Staff facilities and training;
- Laboratories; and

- Verification of inspection and certification systems.

Details of the criteria for assessment of foreign food inspection systems are provided within Attachment 5.

French authorities requested that AQIS enter into a certification arrangement to cover compliance of Roquefort cheese with the requirements of the Code. An audit of the French official inspection and certification system that overseas the production of Roquefort cheese was undertaken in France from March 30 to April 8 2005. As a result of that process, AQIS concluded that the French inspection and certification system can provide Australia with confidence that Roquefort cheese, certified by French authorities, will meet Australian requirements that are described in the proposed draft standard. In particular, the conclusions against the criteria examined (outlined in Part 1 of Attachment 5), are as follows:

### *11.2.1 Legislation*

The French official system has detailed legislation covering the production of Roquefort cheese. The relevant French legislation (an adoption of EU directives) forms part of the Draft standard.

### *11.2.2 Competent authority*

The role, function and funding of the French Ministry of Agriculture, Food, Fisheries and Rural Affairs and its regulatory body, Department of General Directorate for Food (DGAL), is clearly defined. Other Ministries have a role in risk management, including the Ministry of Public Health and the Ministry of Trade and Consumers. The French Agency for Food Safety is a body engaged in risk assessment functions related to food. DGAL has links with these agencies and coordinates activities accordingly.

The operational functions that DGAL administers are conducted by the departmental Directions of Veterinary Services (DDSV) which controls food hygiene services, animal health services and environment services in each of the 100 “departments” in France. The DDSV that oversees production of Roquefort cheese is the Averyon Department, based in Rodez. The role and function of the DDSV is clear and conducted according to its charter.

| |
|---|
| The French official system has competent authority with the ability to implement legislation covering the production of Roquefort cheese. |

### *11.2.3 Assessment of control programs*

AQIS examined the control programs in place for the food safety elements of Roquefort cheese. The DDSV operates programs to cover residue of agricultural and veterinary chemicals, animal health, raw milk quality, assessment of food safety programs in place within manufacturing establishments. Objective evidence was obtained to conclude that these programs are robust. The programs are linked to provide product-tracing systems that can assure certification can be made according to specific requirements - for example the requirement that cheese be made from milk that is free from *Listeria monocytogenes*.

| |
|---|
| The French official system has control programs that cover on farm through production and storage of Roquefort. |

### *11.2.4 Inspection staff: facilities and training*

Inspection staff, employed by DDSV, are trained in food science and where appropriate veterinary science. Facilities for conducting audits are record keeping for all aspects of inspection functions are very good and are being increasingly automated.

| |
|---|
| The French official system has inspection staff and facilities that provide the ability of the official system to implement legislation covering the production of Roquefort cheese. |

### *11.2.5 Laboratories*

The laboratories used are a mix of private (establishment owned), accredited Department laboratories and national public reference accredited laboratories. Rapid analyses that are needed to make decisions about (for example) the disposition of the milk are conducted in-house. Many of these laboratories are accredited to the French NATA equivalent organisation (AFNOR), and a decree to be implemented by end of 2005 will mandate accreditation.

| |
|---|
| The audit of the laboratory component of the Roquefort manufacture concluded that the laboratories used to provide objective measure of compliance with microbiological and chemical limits are satisfactory. |

### *11.2.6 Verification of inspection and certification systems*

The DDSV internal review processes are not formalised, however EU procedures include review of food safety programs that operate in France.

The ability of the French Government to certify that Roquefort cheese meets the standard as drafted depends on the system of certification. France is part of the EU and the requirement for intra-EU trade is part of a product coding system. The product coding system is sufficient to trace product back to the particular vat of milk from which it was manufactured. Where specific requirements (i.e. beyond EU requirements) are demanded, the French system can deliver attestations. The system that is in place for Roquefort cheese production is able to trace each step in the production chain from the farm forward. As each vat is checked for *Listeria monocytogenes* (Lm), it is possible to obtain only cheese made from Lm free milk. This was objectively demonstrated as some customers demand similar requirements to Australia, and the cheese that met the requirements was identifiable.

| |
|---|
| The French official system currently has informal verification applied through commercial bodies and EU oversight. |

The government-to-government certification will become the primary risk management approach for the ongoing control of the safety and compliance of Roquefort cheese. Australia will continue to verify the food safety of this product under Section 32 of the *Imported Food Control Regulations 1993*. Under Section 32 the reliability of a recognised Foreign Government Certificate or a recognised Quality Assurance Certificate may be verified by:

- drawing consignments for sampling at a rate that is not less than 5% of the total consignments certified; and

- auditing the system operated by the foreign government instrumentality or the approved overseas processing operation concerned; and
- conducting documentation checks by requiring the foreign government instrumentality concerned to verify selected certificates collected upon arrival in Australia.

**ATTACHMENTS**

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Scientific evaluation of the safety of Roquefort cheese
3. Review of Roquefort safety control measures
4. Summary of the Requirements of the French Ministerial Orders
5. AQIS Report - Assessment of official inspection and certification system (Roquefort)
6. Summary of Submissions
7. New Zealand (Milk and Milk Products Processing) Food Standards 2002

**ATTACHMENT 1**

## Draft Variations to the *Australia New Zealand Food Standards Code*

**To commence: on gazettal**

**[1]** ***Standard 2.5.4*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting the* Table of Provisions*, substituting* -

**Table of Provisions**

1 Interpretation
2 Composition of cheese
3 Deleted
4 Processing of milk and milk products in New Zealand

[1.2] *omitting clause 3 and the associated editorial note, substituting –*

**3 Deleted**

**[2]** ***Standard 1.6.2*** *of the Australia New Zealand Food Standards Code is varied by omitting paragraph 2(1)(c), substituting –*

(c) in accordance with clause 1 of Standard 4.2.4A.

**[3]** ***The Australia New Zealand Food Standards Code*** *is varied by inserting –*

### *STANDARD 4.2.4A*

### *PRIMARY PRODUCTION AND PROCESSING STANDARD FOR SPECIFIC CHEESES (AUSTRALIA ONLY)*

---

**Purpose and commentary**

This Standards sets out primary production and processing requirements for Gruyere, Sbrinz, Emmental and Roquefort cheese.

**Table of Provisions**

1 Requirements for certain cheese and cheese products

## Clauses

### 1 Requirements for certain cheese and cheese products

Cheese and cheese products specified in Column 1 of the Table to this clause may be manufactured from milk and milk products that have been 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(1)(a) of Standard 1.6.2; and

(b) is set out in the legislation or documentation listed in Column 2 of the Table to this clause; and

(c) complies with the conditions, if any, specified in Column 3 of the Table to this clause.

**Table to clause 1**

| Column 1 | Column 2 | Column 3 |
|---|---|---|
| **Cheese and cheese products** | **Legislation or documentation** | **Conditions** |
| Gruyere, Sbrinz or Emmental cheese | The *Ordinance on Quality Assurance in the Dairy Industry* of the Swiss Federal Council of 18 October 1995 | |
| Roquefort | The *Ministerial Order of 30 December 1993 on requirements relating to the premises, equipment and operation of milk collection or standardization centres and of establishments involved in the treatment or processing of milk or milk-based products*<br>The *Ministerial Order of 18 March 1994 on the hygiene of milk products and collection*<br>The *Ministerial Order of 30 March 1994 on the microbiological criteria that drinking milk and milk-based products must satisfy in order to be placed on the market*<br>The *Ministerial Order of 28 June 1994 on the identification and sanitary approval of establishments placing on the market animal foodstuffs or foodstuffs of animal origin and on health marking*<br>The *Ministerial Order of 2 March 1995 on the approval of milk collection, standardization or treatment centres and of establishments involved in the processing of milk and milk-based products* | (1) The following matters must be monitored and recorded during cheese production:<br>(a) pH during the acidification process; and<br>(b) salt concentration; and<br>(c) moisture content.<br>(2) Unpasteurised milk for cheese production must be tested and demonstrated to have no detected levels of *Listeria monocytogenes* in 25 ml of milk per tanker.<br>(3) The cheese must be stored at an appropriate temperature for a period of no less than 90 days from the date of manufacture. |

**Editorial note:**

Legislation or documentation will only be listed in the Table to clause 1 if it incorporates or provides for methods which provide a level of safety protection equivalent to that provided by a process that includes treatment of the milk or milk product in accordance with paragraph 3(2)(a) of Standard 4.2.4, and has adequate hazard identification and process controls.

AQIS quarantine requirements for the importation of dairy products from approved countries define the date of manufacture for cheese as the date the curd is set.

Cheese and cheese products must also be manufactured using measures to ensure compliance with requirements in Standard 1.6.1 – Microbiological Limits for Food, Chapter 3 - Food Safety Standards to the extent that these requirements aren't specifically covered in clause 3 of this Standard, and any applicable State and Territory requirements in relation to cheese production, including any specific requirements in relation to the safety of raw milk and raw milk cheese production.

In relation to condition (1)(a) for Roquefort, the monitoring of pH should ensure that rapid acidification occurs, that is, the pH should fall to below pH 5.0 within the first 6 to 8 hours following addition of the starter culture.

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 2**

## Scientific evaluation of the safety of Roquefort cheese

## EXECUTIVE SUMMARY

The purpose of the scientific evaluation is to inform risk managers of the public health and safety risks of Roquefort cheese. The scientific evaluation examined surveillance data on food-borne illness, described the manufacturing process for Roquefort cheese, identified potential pathogens that may arise, and determined their fate during processing and maturation. In addition a qualitative risk assessment undertaken by Food Science Australia, categorises the risk of each potential pathogen considered in this evaluation.

Roquefort cheese has not been implicated in reported outbreaks of food-borne illness. Outbreaks attributable to raw milk cheeses are typically associated with soft or fresh cheeses where the physio-chemical properties of the cheese permit the growth and/or survival of pathogenic microorganisms. These contrast with Roquefort cheese, which is a 'semi-hard' cheese and is matured for at least 90 days.

The scientific evaluation considered microbiological hazards typically associated with raw milk (ICMSF, 1998) and focused on hazards that have been implicated in food-borne illness from raw milk cheeses (*Campylobacter, E. coli, Salmonella, Staphylococcus aureus; L. monocytogenes;* and *Brucella melitensis).* In addition *Coxiella burnetii* was also included as it is the most heat-resistant non-sporulating pathogen likely to be present in raw milk.

Several factors are involved in the controlling the growth of bacteria in cheese including pH, temperature, salt, and water activity or moisture content of the cheese. While each of these has an effect, it is their combined effect, which influences the growth and survival of pathogens in cheese. The process of manufacturing Roquefort cheese makes it unlikely pathogens will survive or proliferate. Challenge studies undertaken by the Institut Pasteur de Lille and the Ecole National Veterinaire Toulouse support this conclusion.

Blue vein cheese is not a commonly consumed food in Australia. From data prior to 1997 when Roquefort cheese was permitted for sale in Australia, imports of Roquefort cheese accounted for only 0.1% of the imported speciality cheese market at this time. It is therefore considered that consumption of Roquefort cheese in Australia is likely to be extremely low.

The findings from the two qualitative risk assessment models (Risk Ranger and a qualitative framework model) found that consumption of this cheese represents a low to negligible public health and safety risk to consumers in the general population.

The scientific evaluation has concluded that pathogens, if present, would be unlikely to survive or proliferate during the manufacture of Roquefort cheese. Therefore the consumption of Roquefort cheese poses a low risk to public health and safety. This conclusion is supported by the finding that there have been no reported outbreaks of food-borne illness due to the consumption of Roquefort cheese.

The process of Roquefort cheese production outlined in the application was judged to achieve the following effects on selected pathogens:

| Pathogen | Risk associated with Roquefort Cheese |
|---|---|
| *Campylobacter* | *Campylobacter* is unlikely to survive processing and maturation, hence is not considered to be a problem in raw milk cheeses and is a negligible risk. |
| Pathogenic *E. coli* | Very low risk if the level of raw milk contamination with *E. coli* is low. Challenge study demonstrates organism numbers initially increase, but the organism doesn't survive cheese maturation. |
| *Salmonella* | *Salmonella* contamination of raw milk is likely to be very low/low. Challenge study shows inactivation during cheese making and maturation. |
| *Staphylococcus aureus* | Risk from staphylococcal enterotoxin is considered low. Conditional on good control over cheese making, specifically acidification of the curd. Challenge study shows the organism fails to produce enterotoxin in Roquefort cheese. |
| *Listeria monocytogenes* | Very low/negligible risk if the organism is not present in raw milk and there is effective control over cheese making and ripening operations. |
| *Coxiella burnetii* | Risk is low/negligible, although no real control measures for raw milk. Organism unable to survive processing. |
| *Brucella melitensis* | Risk is negligible. Milk is only collected from Brucellosis free herds. Organism doesn't survive the cheese making process. |

The hazards of most concern in Roquefort cheese are, in order of importance, *S. aureus* enterotoxin, *Salmonella*, EHEC and *L. monocytogenes*, but the risk to the general population is considered to be low. For at-risk consumers EHEC is the hazard posing the greatest risk (low). *Listeria* poses the same risk to at-risk consumers as other soft cheeses made from pasteurised milk, based on the assumptions made in this assessment.

Vital for the control of all hazards is the use of raw milk of good microbiological criteria; the application of standard operating procedures (SOPs) and good manufacturing practices (GMPs) during ewe's milk collection and processing; effective implementation of hazard analysis and critical control point (HACCP) plans during cheese manufacture and ripening; and microbiological monitoring of the final product.

Critical steps required to control the pathogens during manufacture can be summarised as follows:

- the microbiological status of the incoming raw milk;
- the rapid acidification of the milk during the initial phase of cheese manufacture (i.e. drop in pH from 6.5 to <5.0 within 6 to 8 hours and then to pH 4.8 within 24 hours);
- desiccation of the curd during subsequent processing stages (i.e. a final water activity of approximately 0.92) ; and
- prolonged ripening (i.e. 90 days).

The conclusions in this evaluation are based on information supplied by the Applicant, including the challenge studies; the review by Food Science Australia; and scientific literature and they confirm:

- Roquefort cheese is an unfavourable medium for the elaboration of *S. aureus* enterotoxin;
- the cheese making process and subsequent maturation achieves a significant reduction in *Salmonella*, EHEC, *L. monocytogenes* and *S. aureus*; and
- sheep flocks from which the milk is derived are free from *B. melitensis.*

The evaluation determined that:

- *B. melitensis, C. burnetii* and *C. jejuni* are eliminated during cheese making and maturation;
- if low levels of *Salmonella*, EHEC, *Listeria* and *S. aureus* were present in raw milk, conditions during cheese making and maturation make it unlikely they would survive or proliferate; and
- *L. monocytogenes* is unlikely to grow in Roquefort cheese during maturation and subsequent storage.

The uncertainties in this evaluation are largely related to data on the management of the cheese making process (rate of acid production, final pH, and water activity) and the extent to which incoming milk may contain pathogenic bacteria.

# 1 Introduction

An application from the French Government (Ministry of Agriculture, Food, Fisheries and Rural Affairs) seeks to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the sale of Roquefort cheese. Roquefort cheese is a semi-hard cheese manufactured from raw sheep milk.

Over the past four years, selected raw milk cheeses have been permitted into Australia, following scientific evaluations of their safety. These evaluations have been based on equivalence determinations, and have resulted in permission to import gruyere, Sbrinz, and Emmental cheeses from Switzerland and specific extra hard raw milk grating cheeses. These permissions reflect the capacity of regulatory systems and/or processing conditions to produce cheeses of equivalent food safety to those made from pasteurised or thermised milk.

# 2 Purpose

The purpose of the scientific evaluation is to inform risk managers of the public health and safety risks of Roquefort cheese manufactured under good manufacturing practice and according to French regulatory requirements.

This scientific evaluation describes the manufacturing process for Roquefort cheese, identifies potential pathogens that may arise, and determines their fate during processing and maturation.

The scientific evaluation is the first stage of a three-stage process to assess of the safety of Roquefort cheese. This three-stage process is being undertaken to determine if the manufacture of Roquefort cheese can achieve the same level of food safety as that achieved by similar blue-vein type cheeses. The three stages are:

- a scientific evaluation of the safety of the cheese to examine the effect of the cheese manufacturing processes on selected microbial pathogens.
- a review of the regulatory environment and safety control measures under which sheep milk is produced and Roquefort cheese manufactured, and
- on-site verification of the implementation of these control measures.

# 3 Scope of the Evaluation

The safety of Roquefort cheese is influenced by a combination of factors, including on-farm control of animal health; on-farm production hygiene; the microbiological status of the incoming raw milk; the rapid acidification of the milk during the initial phase of cheese manufacture; desiccation of the curd during subsequent stages; prolonged ripening; and microbiological testing of the final product before release to the market.

The scientific evaluation of the safety of Roquefort cheese focussed on consideration of surveillance data on food-borne illness attributable to raw milk cheese, and assessment of the likelihood of pathogenic organisms being present in raw sheep milk and surviving the cheese making process. The evaluation also includes a qualitative risk assessment undertaken by Food Science Australia, which categorises the risk of each potential pathogen considered in this evaluation (Appendix 2 of the report).

# 4 Roquefort Cheese

Roquefort cheese belongs to the blue or blue-veined class of cheeses, which are semi-hard cheeses characterised by the growth of *Penicillium roqueforti*, in fissures throughout the cheese. Blue cheeses tend to be strong in flavour and aroma, both of which intensify with aging.

Cheese manufacture is one of the classic examples of food preservation, with Roquefort cheese first recorded in 1070. Roquefort cheese is a variety of blue-vein cheese manufactured in the south of France from sheep milk. Roquefort cheese is made from unpasteurised and curdled ewe's milk; is cylindrical in shape and measures 18-20 cm across and from 8.5-11.5 cm high; weighs from 2.5-3 kg; is veined with spores of *P. roqueforti*; is fermented and salted with a moist crust; is ripened for at least 90 days, and contains at least 52% fat after total desiccation and at least 55% dry matter as defined by the French manufacturers of Roquefort cheese (Decree of 22 January 2001).

# 5 Scientific Evaluation of Roquefort Cheese

## 5.1 Public Health Status of Raw Milk Cheese

While cheese has been produced for centuries using raw milk, the advent of pasteurisation in the 20$^{th}$ century had an important role in enhancing the safety of many cheeses. Nevertheless, a range of safe raw milk cheeses continue to be manufactured, with hurdles such as fast and high acidification, cooking steps, low water activity and prolonged ripening providing good protection against the presence and/or proliferation of pathogenic microorganisms.

A review of outbreaks of food-borne illness arising from cheese consumption determined there were 21 confirmed outbreaks of illness in Europe from 1970-1997; seven in the United States from 1948-1997; and four in Canada from 1970-1997. Only 28 percent of these involved cheese made from raw milk (Fox *et al*., 2000), demonstrating that the majority of outbreaks were attributed to pasteurised cheese.

Pathogenic bacteria may contaminate cheese post-pasteurisation if sanitation and hygienic practices are not adequately controlled. Selected cheese made from pasteurised milk may present risk factors due to high water content, mildly acidic conditions, and multiple handling steps that provide opportunities for post-pasteurisation contamination and bacterial outgrowth. Therefore, pasteurisation is no guarantee that cheese will be safe.

Cases of food-borne illness attributed to the consumption of raw milk cheese over the past 20 years are reported overleaf (Table 1). Typically the implicated cheeses are soft, often fresh cheeses *i.e.* those produced with little or no maturation or ripening process. Although this data links raw milk cheese to documented outbreaks of food-borne illness, the epidemiological data demonstrates this occurs fairly infrequently (De Buyser *et al*., 2001). Caution should be exercised with this type of data, as epidemiological evidence alone is not sufficient to define the risk associated with consumption of raw milk cheese. Outbreaks of food-borne illness are significantly underreported, while cases of sporadic food-borne illness are rarely investigated.

A review of the role of milk and milk products in food-borne illness in selected industrialised countries (including France) demonstrated the limitations of surveillance systems and data collection, and the difficulties of estimating the contribution of these products to the burden of illness (De Buyser *et al*., 2001).

Based on the findings of this review, Roquefort cheese has not been implicated in outbreaks of food-borne illness. Outbreaks are typically associated with soft or fresh cheeses where the physio-chemical properties of the cheese permit the growth and/or survival of pathogenic microorganisms. In addition, the Applicant states that Roquefort cheese has not been involved in any case of food poisoning in the last 30 years.

Raw milk may be contaminated with a variety of pathogens originating from the milking animal, milking equipment, handlers, and the production environment. In manufacturing raw milk cheese, a key factor is the microbiological status of the raw milk. Pathogenic microorganisms introduced into raw milk may survive and even multiply during the early stages of cheese manufacture; hence measures that minimise the microbial load in raw milk are desirable.

Historically, milk-borne zoonoses such as *Mycobacterium bovis* and *Brucella* spp have been transmitted to consumers, via raw milk and raw milk products, and presented public health problems. Nowadays these zoonoses are controlled primarily through good animal health practices and controlling authority requirements that milk be collected only from healthy animals. Other pathogens associated with raw milk which have been implicated in food-borne illness due to the consumption of contaminated raw milk cheeses include *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus* and pathogenic *Escherichia coli*.

The survival and growth of pathogens in raw milk cheese is highly dependent upon the variety of cheese. Pathogens will grow more easily in cheese of high moisture content, high pH and low salt content, compared to the hostile environment of cooked, extra-hard cheese which is ripened over a prolonged period.

The European Commission has a rapid alert system for food and feed (RASFF) that was established in 1979. The rapid alert system is designed to provide European Union control authorities with information on measures taken to ensure food safety. Information is presented in two forms:

- Alert notifications that are sent when the food or feed presenting the risk is on the market and when immediate action is required. Alerts are triggered by the Member State that detects the problem and has initiated the relevant measures, such as withdrawal/recall. Consumers are reassured that products subject to alert notification have been withdrawn or are in the process of being withdrawn from the market.

- Information notifications concern a food or feed for which a risk has been identified, but for which the other members of the network do not have to take immediate action, because the product has not reached their market.

Examination of this data over a three-year period (2002-2004) revealed listings for raw milk cheeses originating from France. However, none of these listings implicated Roquefort cheese, and all demonstrate the effectiveness of control systems to identify and prevent potentially non-conforming products from reaching the marketplace.

## 5.2 Hazard Identification and Characterisation

A range of pathogenic microorganisms may be associated with dairy sheep, human handlers, milking equipment and the environment and may contaminate sheep's milk. These include milk-borne zoonotic bacteria such as *Brucella* spp. and other pathogenic bacteria implicated as causative organisms in outbreaks listed in Section 5.1 (Table 1).

Pathogens typically associated with raw milk include *Coxiella burnetii, Brucella* spp. (*B. melitensis* for goat and sheep milk), *Salmonella* spp., *Yersinia enterocolitica*, *Campylobacter jejuni, L. monocytogenes,* enterotoxigenic *S. aureus* and pathogenic *E. coli* (ICMSF, 1998).

Animals with mastitis may shed high numbers of bacteria into their milk at the time of collection. Animals that are sick may also shed organisms in their milk. Excretion of pathogens into milk is not the only source of bacterial contamination. Direct faecal contamination of the milk at the time of collection can lead to contamination by a range of organisms. Indirect contamination may also occur at low levels through poor cleaning and sanitation of milking and storage equipment and transport vessels and from poor personal hygiene of milking staff.

The scientific evaluation considered microbiological hazards typically associated with raw milk (ICMSF, 1998) and focused on hazards that have been implicated in food-borne illness from raw milk cheeses (*Campylobacter jejuni/coli, E. coli, Salmonella, Staphylococcus aureus, L. monocytogenes;* and *Brucella melitensis). C. burnetii* was also included as it is the most heat-resistant non-sporulating pathogen likely to be present in raw milk.

The list of hazards examined in this evaluation for Roquefort cheese include:

- *Campylobacter jejuni/coli*;
- *Escherichia coli* – specifically enterohaemorrhagic *E. coli* (EHEC);
- *Salmonella* spp.;
- *Enterotoxigenic Staphylococcus aureus*;
- *Listeria monocytogenes*;
- *Coxiella burnetii*; and
- *Brucella melitensis.*

A detailed characterisation of each of the seven hazards is at Appendix 1. Each hazard was described under the headings: organism, disease, infective dose, epidemiology and the effect of cheese making on each pathogen. Viruses were not considered in this assessment, as there are no viral zoonoses of concern.

## 5.3 Manufacture of Roquefort cheese

Raw milk (at a temperature of ≤10ºC) arrives at the processing facility where it is tested (both microbiologically and chemically) and stored until cheese making commences (maximum storage period of 24 hours at 3ºC). The milk is then warmed to 30ºC and *P. roqueforti* and starter culture added.

Soon after addition of the starter culture, rennet is added to form the curd (coagulated milk) and after it is cut the curd is worked over the next 3 hours (at 30ºC) to assist in whey removal. During curd formation bacteria become concentrated in the curd.

The bacteria increase the acidity of the curd, which further assists whey removal, a process termed syneresis. Through the action of the starter culture, the pH will fall, and will decrease to less than pH 5 in 6 hours.

**Table 1: Food poisoning outbreaks associated with raw milk cheese**

| Cheese | Year | No of cases (deaths) | Causative organism | Country of Origin | Reference |
|---|---|---|---|---|---|
| Cheddar | 1982 | NA | *Salmonella* muenster | Canada | D'Aoust, J. Y. et al., 1985 |
| Farm ewe cheese | 1983 | 20 | *S. aureus* (SEA & SED) | France | De Buyser, M. L. et al., 1985 |
| Vacherin Mont d'Or | 1983/ 87 | 122 (34) | *Listeria monocytogenes* | Switzerland | Bille, J., 1990 |
| Sheep milk cheese | 1984 | >13 | *Staph. aureus* | UK | Bone, F. J. et al., 1989 |
| Cheddar | 1984 | >1700 | *Salmonella Typhimurium* PT 10 | Canada | D'Aoust, J. Y. et al., 1985 |
| Vacherin Mont d'Or | 1985 | >40 | *Salmonella typhimurium* | France | Sadik, C. et al., 1986 |
| Farm cheese | 1985 | 35 | *Salmonella* | Finland | Huchot, A. et al., 1993 |
| Vacherin Mont d'Or cheese | 1985 | 215 | *Salmonella Typhimurium* | Switzerland | Anon, 1986 |
| Stilton cheese | 1988 | 155 | Unknown (*S. aureus*?) | England/Wales | Maguire, H. et al., 1991 |
| Sheep's milk cheese | 1988 | 31 | *Campylobacter* | Czechoslovakia | Kourilova and Kultan, 1990 |
| Anari goat's milk soft cheese | 1988 | sporadic case | *Listeria monocytogenes* | England | Azadian, B. S. et al., 1989 |
| Soft cheese | 1989 | 42 | *Salmonella dublin* | Ireland | Maguire, H. et al., 1992 |
| Goats milk cheese | 1990 | 277 | *Salmonella* paratyphi B | France | Grimont, P. A et al., 1991 |
| Sheep's milk cheese | 1991 | 46 | Brucellosis | Italy | Montanaro, C et al., 1989 |
| Fromage frais | 1992 | NR (1) | Veratoxic *E. coli* | France | PHLS, 1994 |
| Goat milk cheese | 1993 | 273 (1) | *Salmonella paratyphi B* | France | Desenclos, J. C. et al., 1996 |
| Raw milk cheese | 1994 | 22 | *E. coli* 0157 | Scotland | Ammon, A., 1997; Curnow, J., 1994 |
| Raw goat milk cheese | 1994 | NA | *E. coli 0103* | France | Ammon, A., 1997 |
| Farm soft cheese | 1994 | 35 | *Salmonella* berta | Canada | Ellis, A. et al., 1998 |
| Brie de Meaux | 1995 | 20 (4) | *Listeria monocytogenes* | France | Goulet, V. et al., 1995 |

| Cheese | Year | No of cases (deaths) | Causative organism | Country of Origin | Reference |
|---|---|---|---|---|---|
| Raw milk cheese | 1995 | 25 (5) | *Salmonella dublin* | France | Vaillant, V. et al., 1996 |
| Soft cheese (goats and ewe's milk) | 1995 | 135 (1) | *Brucella melitensis* | Malta | 1995 |
| Mont d'Or cheese | 1996 | 14 (1) | *Salmonella dublin* | France | Infuso, A. et al., 1997 |
| Lancashire | 1997 | 2 | *E. coli 0157* | UK | PHLS, 1997 |
| Unpasteurised Mexican-style cheese | 1997 | 31 | *Salmonella Typhimurium DT104* | US | Cody, S. H. et al., 1999 |
| Morbier cheese | 1997 | 113 | *Salmonella Typhimurium* | France | de Valk, H. et al., 2000 |
| Livarot, Pont-Lévêque cheese | 1997 | 14 | *Listeria monocytogenes* | France | Jacquet, C. et al., 1998 |
| Fresh cheese curds | 1998 | 55 | *E. coli* 0157:H7 | US | CDC, 2000 |
| Mexican style cheese | 2000 | 12 | *Listeria monocytogenes* | US | CDC, 2001 |
| Cantal cheese | 2001 | 190 | *Salmonella enteritidis* | France | Haeghebaert, S. et al., 2003 |
| Cantal cheese | 2001 | 25 | *Salmonella enteritidis* | France | Haeghebaert, S. et al., 2003 |
| Raw milk cheese | 2002 | 17 | *Listeria monocytogenes* | Canada | Health Canada, 2003 |
| Raw goat cheese | 2002 | 11 | Brucellosis | Spain | Mèndez Martinez, C. et al., 2003 |

The curd is then cut, moulded into loaves, and allowed to drain (at ~18ºC or room temperature) for a period of 48 hours. The loaves are then cooled to 12ºC before salting. Typically the cheese is salted for 4-5 days at 12ºC.

After salting the cheese is placed in caves and allowed to ripen for between 15-25 days. The temperature in the caves during the initial stages of ripening is between 9-10ºC. Further ripening is carried out in controlled temperature rooms (0-2ºC). The total processing time, from addition of rennet to final product is at least 90 days.

The major stages in the process are described diagrammatically in Figure 1.

### 5.4 Effect of processing parameters on bacterial pathogens during Roquefort cheese manufacture

Several factors are involved in the controlling the growth and survival of pathogenic bacteria in cheese including the microbiological status of incoming raw milk, pH, temperature, salt, and water activity or moisture content of the cheese.

The microbiological status of the incoming raw ewe's milk has an important influence on the safety of Roquefort cheese. Deriving milk from healthy, disease-free animals; practising good hygiene on farm; and rapid reduction in the temperature of milk immediately after the completion of milking are all critical in ensuring that pathogens do not contaminate the milk nor grow during on-farm holding and subsequent transportation and storage. Pathogens will grow in milk if the temperature of storage is above 10ºC. Raw milk used for Roquefort cheese production is kept at temperatures below 10ºC.

For example, raw milk that is not cooled rapidly or stored correctly will support the growth and possible toxin production by *S. aureus*. However at 10ºC there is a long lag time (>20h) and when growth commences it is very slow (ICMSF, 1996c). Furthermore, *S. aureus* is a poor competitor in the presence of other microorganisms, foods responsible for outbreaks are often those that have been heated to destroy microorganisms, and then contaminated. In a review of staphylococcal enterotoxins in milk products, the European Commission's Scientific Committee on Veterinary Measures relating to Public Health highlighted the validity of microbiological criteria for raw milk intended for human consumption and fresh cheese (European Commission, 2003). This reflects the concern that liquid milk is an excellent medium for the growth of *S. aureus*, hence levels at the commencement of cheese making should be as low as possible.

Once the cheese making process commences, the microbiological status of the milk and the subsequent cheese will change.

Ewe's milk is warmed to 30ºC prior to the addition of the starter culture and rennet. Any delays or reduced activity by the starter culture may provide conditions where pathogenic bacteria in the milk may multiply. Initial conditions will favour the growth of *Salmonella*, *E. coli*, *S. aureus* and *L. monocytogenes*, which may be present. Hence the rapid reduction in pH by the starter culture during the first few hours of fermentation is critical in restricting pathogen growth or toxin production by *S. aureus*.

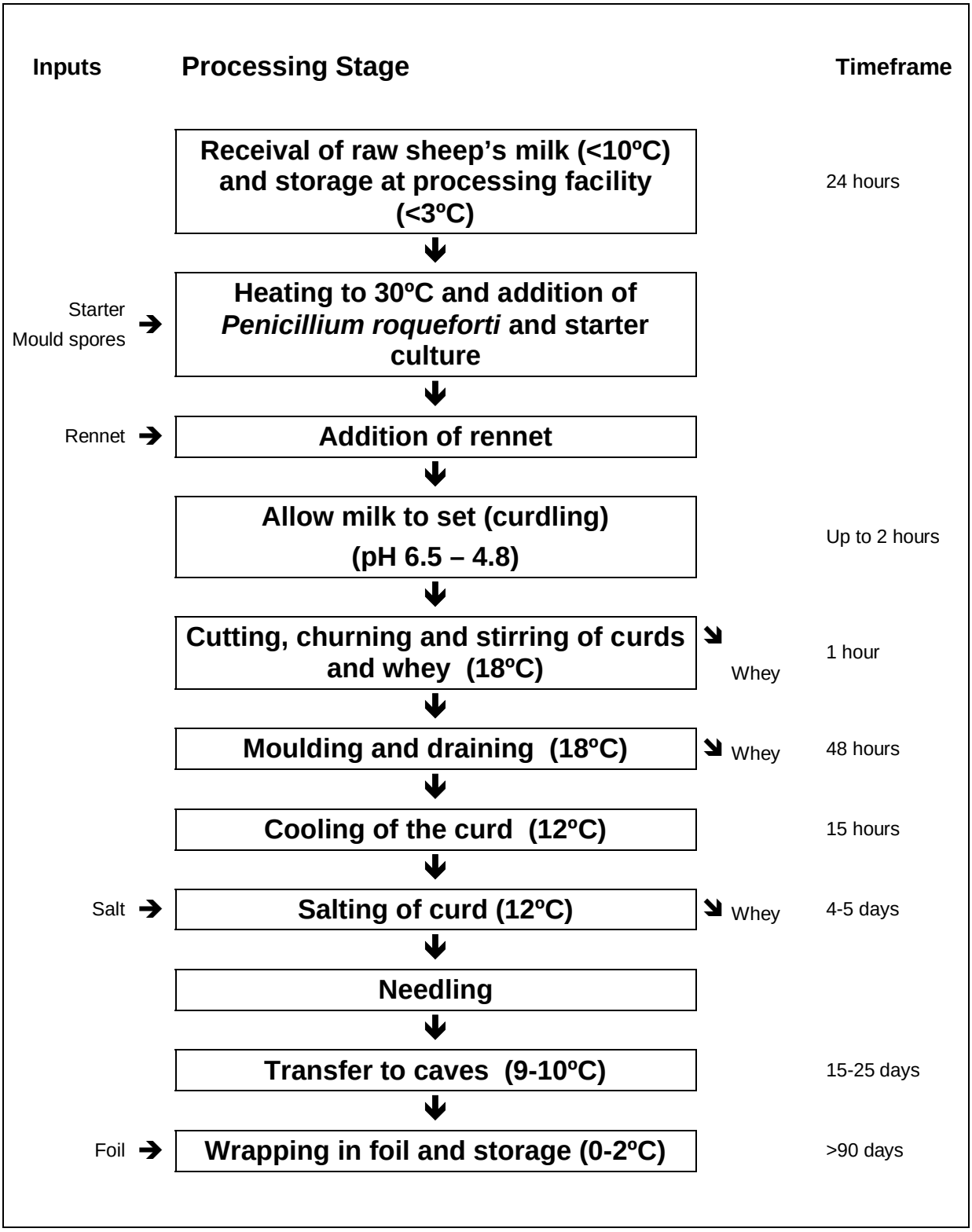



**Figure 1: Flow diagram for the manufacture of Roquefort cheese**

Progressive acidification is one of the most critical steps in Roquefort cheese making. Acid production and the resultant decrease in pH affects the growth of many non-starter bacteria, including pathogens that may be present. During the first 24 hours (including the early stages of ripening) the production of lactic acid by the starter culture is important in reducing the growth of undesirable bacteria that may produce gas and off-flavours as well as limiting the growth of pathogenic bacteria. In the production of Roquefort cheese, the initial milk pH 6.5 falls to <4.8 within 24 hours.

In properly managed cheese vats, the pH of the milk will fall rapidly within the first six hours to below pH 5.5. Papageorgiou and Marth (1989b) found the pH of blue cheese fell below pH 5 after 24 hours. Most enteric pathogens (*Salmonella* and *E. coli*) and *Listeria* will grow poorly at 5.5 and should not grow at pH values less than 5. This pH is also sufficiently low to restrict the growth of *Staphylococcus* and prevent the formation of enterotoxin.

However, even with such a rapid pH fall, some initial growth of pathogenic bacteria might be expected (Spahr and Url, 1993). *L. monocytogenes* numbers were shown to increase 100-500-fold during the initial stages of the manufacture of blue cheese (Papageorgiou and Marth (1989b). During these initial stages of cheese making it is not unusual for numbers of enteric pathogens to increase (10-100-fold), due to limited growth and the concentration of microbial cells in the cheese curd as the whey drains away (syneresis).

Salting is an important control point. Salting causes dehydration of bacterial cells and results in cell death or inhibition of growth depending on the level added and the characteristics of the particular organisms present. Salt also aids in the removal of whey from the curd, thus reducing the moisture of the cheese influences the activity of microorganisms.

Typically Roquefort cheese is salted 5 days after curd formation (Davis, 1976), although in the process described by the applicant, salting commences on day 3 and continues until day 8. Salting and the resultant drying of the curd prevent the growth of enteric pathogens and eventually leads to a decline in their numbers. The final salt content of Roquefort cheese is 3%.

After salting, pathogen growth is unlikely and numbers generally decrease, with the rate of decrease being proportional to the final pH. *Listeria* may grow if the pH rises to values near pH 6; growth is more likely to occur near or on the surface of cheese. The longer bacteria are held under conditions not supporting their growth the greater will be the reduction in their numbers. Therefore cheeses with long maturation periods are generally safer then fresh cheeses (*i.e.* those with short or no maturation period).

The combined effects of pH, salt, moisture and storage temperature come into play during ripening and promote the die off of pathogens. The decline of pathogens present during this time will be influenced by the characteristics of the cheese and the temperature of storage.

Roquefort cheese is mould ripened using *P. roqueforti* and during this phase of manufacture the pH tends to rise. Significant changes occur during ripening. Proteins, carbohydrates and fats are metabolised and liberate free amino acids and free fatty acids. While the pH becomes more benign for pathogens, there is some debate about the antimicrobial action of metabolites of *P. roqueforti*. Laporte *et al. (*1992) noted that while pH strongly contributed to bacterial destruction, *P. roqueforti* strains also had some antimicrobial action, particularly against *E. coli*.

Papageorgiou and Marth (1989b) found *L. monocytogenes* failed to grow and numbers decreased in blue cheese, and suggested the mould may produce bacteriocins against *L. monocytogenes.* This may explain some of the observed reduction in bacterial numbers reported in the literature.

Data provided by the applicant indicated that the final pH of Roquefort cheese is between 5.5-6.5. This agrees with the work of Papageorgiou and Marth (1989b), who noted the pH of blue-cheese increased to between 5.5-6.0 after 80 days of ripening. The same authors also noted that *Listeria* numbers declined during ripening, although numbers stabilised once the pH had increased beyond ~5.5.

Table 2 summarises the effect of Roquefort cheese making on the pathogens examined. The effect of cheese making on the seven hazards is discussed in greater detail at Appendix 1.

**Table 2: Summary of effects of Roquefort cheese making on pathogens**

| Pathogen | Effect of cheese making |
|---|---|
| *Campylobacter* | *Campylobacter* is unlikely to survive processing and maturation as growth requires temperatures. 32-45$^{o}$C. Campylobacter does not survive well under slightly acidic conditions or in presence of >2% salt. |
| Pathogenic *E. coli* | *E. coli* numbers initially increase, but the organisms doesn't survive cheese maturation. |
| *Salmonella* | Although there may be initial growth, inactivation occurs once pH falls to 4.8 during cheese making and maturation. |
| *Staphylococcus aureus* | *S. aureus* is a poor competitor. Rapid pH restricts pathogen growth and toxin production. |
| *Listeria monocytogenes* | Low pH and decreased water activity prevent growth of L. monocytogenes, and viable cells present decrease. |
| *Coxiella burnetii* | Organism unable to survive processing. |
| *Brucella melitensis* | Organism doesn't survive the cheese making process. |

In summary, several factors are involved in controlling the growth of bacteria in Roquefort cheese including pH, temperature, salt, and water activity or moisture content of the cheese. While each of these has an effect, it is their combined effect, which influences growth and survival of pathogens in cheese.

The process of manufacturing Roquefort cheese makes it unlikely pathogens will survive or proliferate. Challenge studies undertaken by the Institut Pasteur de Lille and the Ecole National Veterinaire Toulouse support this conclusion, and are discussed below.

### 5.5 Challenge Studies

The Confédération Générale de Roquefort initiated a series of challenge studies to examine the fate of selected pathogens during the manufacture of Roquefort cheese. The studies were undertaken by the Institut Pasteur de Lille (*L. monocytogenes, Salmonella enterica,* and *E. coli* O157,) and the Ecole National Veterinaire Toulouse (*S. aureus*), with translations of the reports provided by the Applicant.

The Institut Pasteur de Lille challenge studies involved batches of raw milk being contaminated with the test organism at two different levels, usually between 10-1,000 cfu/ml of milk (varied depending upon the test organism), which was then used to manufacture Roquefort cheese.

The results from the challenge studies indicate that these pathogens are unlikely to survive or proliferate during Roquefort cheese making.

### *5.5.1 Listeria monocytogenes and Salmonella enterica during the manufacture and storage of Roquefort cheese*

Three batches of raw milk was artificially contaminated with *L. monocytogenes* and 3 batches with *Salmonella enterica* and subsequently made into Roquefort cheese in a pilot factory. The batches compromised of a control batch (with no artificial contamination, the second batch with a level of contamination of <10 cfu/mL and the third batch with a level of contamination of <25 cfu/mL for each organism.

Eleven sampling times were defined at various points of manufacture and maturation as follows:

| **Stage** | **Description/Sampling time** |
|---|---|
| Contamination: | milk to be used in manufacture |
| Moulding: | curd, 3h after rennet addition |
| Draining: | curd, 7h30min after rennet addition |
| Draining: | 24h after rennet addition |
| Prior to salting: | 55h after rennet addition |
| End of salting: | 8 days after rennet addition |
| End of first refining: | 25 days after rennet addition |
| Storage: | at 90 days approx. |
| Storage: | at 130 days approx. |
| Storage: | at 150 days approx. |
| Storage: | at 175 days approx. |
| Storage: | pre-cut portion, 2 months in packaging |

A 10-20-fold increase in *Listeria* numbers was observed during the first 24 hours for cheese inoculated with levels of 5-30 cfu/ml, but from this point forward, *Listeria* numbers declined. Nevertheless, *Listeria* may persist in cheese although at numbers usually <1 log cfu/gram, with little if any growth. No *Listeria* was detected in packaged product after 2 months of storage. The pH in these studies was greater than 6.5 at the end of maturation, and while a cheese pH of less than 6 is required to control possible outgrowth of *Listeria*, this did not influence the numbers of *Listeria* in the final pre-cut portioned product during these challenge studies.

Despite the initial increase in numbers, *Salmonella enterica* was much less tolerant of physiochemical conditions in the cheese than *Listeria*, and was no longer culturable after the completion of the salting process, although it was detected by VIDAS[15] detection technique up until 130 days in one sample. In all cases, no *Salmonella* could be detected after 130 days.

[15] Detection technique used for *Salmonella:* VIDAS (BioMérieus) and PCR BAX™ (Qualicon)

### *5.5.2 Escherichia coli 0157 during the manufacture and storage of Roquefort cheese*

Three batches of raw milk was artificially contaminated with *E. coli 0157* and subsequently made into Roquefort cheese in a pilot factory. The batches comprised a control batch (with no artificial contamination, the second batch with a low-level of contamination ($10^1$ to $10^2$ cfu/mL) and the third batch with high-level contamination ($10^2$ to $10^3$ cfu/mL).

Eleven sampling times were defined at various points of manufacture and maturation as follows:

| **Stage** | **Description/Sampling time** |
|---|---|
| Contamination: | milk to be used in manufacture |
| Cutting: | curd 2h after rennet addition |
| Moulding: | curd, 3h after rennet addition |
| Draining: | curd, 7h30min after rennet addition |
| Draining: | 24h after rennet addition |
| Prior to salting: | 55h after rennet addition |
| End of salting: | 8 days after rennet addition |
| Mid-first refining: | 18 days after rennet addition |
| End of first refining: | 25 days after rennet addition |
| Storage: | at 90 days approx |
| Storage: | at 130 days approx |
| Storage: | at 175 days approx |

The numbers of *E. coli* increased up until the time of salting (reaching levels >3,000 cfu/g). However, following salting there was a numbers declined, and *E. coli* O157 was not detected, using enrichment techniques, at or after 90 days.

### *5.5.3 Detection and Characterisation of enterotoxinogenic staphylococci by PCR*

Studies on *S. aureus* examined 100 strains (80% of which were toxigenic) derived from ewes with mastitis, and two strains (one toxin C-producing strain and one toxin C and toxin A producing strain) were selected for challenge studies. Four milk vats of raw milk were artificially contaminated with *S. aureus* and subsequently made into Roquefort cheese in a pilot factory. Two vats were artificially contaminated with a toxin C-producing strain (representative of the majority of ovine strains) and two vats were artificially contaminated with a strain producing toxins A and C. An additional vat was used to serve as a control. For both strains, two levels of contamination were used, the first chosen to reflect average contamination ($10^3$ cfu/mL) and the second level to reflect a high contamination level ($10^5$ cfu/mL).

Ten sampling times were defined at various points of manufacture and maturation as follows:

| **Stage** | **Description/Sampling time** |
|---|---|
| Contamination | milk before addition of rennet |
| Moulding | approx. 3h |
| Draining | 7h30min |
| Draining | 12h after addition of rennet |
| Draining | 24h |
| Prior to salting | 48h (before salting) |
| Needling | 10 days (entry into cave – piercing) |
| End of first refining | 30 days (wrapping in tin foil) |
| Storage | 3 months of refining |
| Storage | 6 months of refining |

The levels of inoculation ranged from $10^3$-$10^5$ cfu/ml, and reached between $10^5$-$10^7$ before numbers started to decline until total disappearance at 90 days. Enterotoxins A and C were not detected at any stage. It was concluded that conditions in ewe's milk and Roquefort cheese are not conducive to enterotoxin production.

## 5.6 Blue Vein Cheese Consumption in Australia

Blue vein cheese is not a commonly consumed food in Australia, with only approximately 0.5 % of respondents from the 1995 Australian National Nutrition Survey[16] (13,858 respondents) consuming Blue vein type cheese (Table 3).

From data prior to 1997 when Roquefort cheese was permitted for sale in Australia, imports of Roquefort cheese did not exceed 10 tonnes per annum compared with imports of all speciality cheeses of 8,000 tonnes per annum. It therefore accounted for 0.1% of the imported speciality cheese market at that time.

It is therefore considered that consumption of Roquefort cheese in Australia is likely to be extremely low.

**Table 3: The average consumption of Blue Vein cheese by consumers is 20.9 grams/day**

| Age (years) | No. consumers surveyed | No. consuming blue cheese (% of no. surveyed) | Mean consumer intake of blue vein cheese (g/day) | 95th percentile intake of vein blue cheese (g/day) |
|---|---|---|---|---|
| 2-4 | 583 | 0 (0%) | 0 | 0 |
| 5-12 | 1,496 | 0 (0%) | 0 | 0 |
| 13-18 | 928 | 1 (0.1%) | 71.5 | 71.5 |
| 19-64 | 8,891 | 49 (0.6%) | 20.8 | 67.7 |
| 65+ | 1,960 | 15 (0.8%) | 17.6 | 92.4 |
| TOTAL | 13,858 | 65 (0.5%) | 20.9 | 74.2 |

**NOTE**:
1. Blue vein cheese consumption data were derived from the 1995 Australian National Nutrition Survey (NNS).
2. The consumption figures do not include blue cheese used in recipes.
3. The consumption figures listed below are for **consumers** of blue vein cheese only.
4. For consumption figures shaded in grey, there are insufficient consumers for a statistically robust figure to be derived.

## 5.7 Qualitative Microbiological Risk Assessment

The previous sections provide a descriptive analysis of the major microbial hazards considered in the assessment. There is no internationally agreed methodology or framework for undertaking a qualitative risk assessment for these hazards. Codex[17] and FSANZ[18] have guidelines for the conduct of microbiological risk assessments but they do not provide actual tools that can be used to objectively assess or rank the risk to public health and safety.

---

16 Australian Bureau of Statistics and Department of Health and Family Services (1997). *National Nutrition Survey 1995.* Australian Government Publishing Service, Canberra.

17 CODEX (CAC/GL 30, 1999) Principles and Guidelines for the Conduct of Microbiological Risk Assessment http://www.codexalimentarius.net/web/standard_list.do?lang=en

18 ANZFA, 1996 *Framework for the Assessment and Management of Health Risks in Relation to Food*

In the absence of an internationally agreed tool to qualitatively assess the risk of food-borne hazards associated with the consumption of Roquefort cheese, two approaches have been used to assess the risks (Vanderlinde, 2004). The complete report on the qualitative microbiological risk assessment is at Appendix 2.

The approach adopted involved the use of a semi-quantitative risk assessment tool, the Risk Ranger, proposed by Ross and Sumner (2002), and the development of a qualitative risk assessment framework.

### *5.7.1 Risk Ranger (Ross and Sumner, 2002)*

Risk Ranger was developed by Ross and Sumner (2002) as a tool for risk managers. The model of Ross and Sumner (2002) was applied, using data for the hazards under consideration, to calculate the risk they present to consumers of Roquefort cheese. The risk is calculated based on user inputs as to the severity of the hazard, the likely consumption, effects of processing, etc. The output of the model can be a risk rating from 1 to 100 or an estimate of probability of illness in the consuming population. The general risk ranking generated in this assessment was categorised based on the predicted probability of illness and the risk categories proposed by Voysey (2001), thereby removing any ambiguity regarding the qualitative nature of the assessment. The resulting risk categories in Table 4 do not take into account severity of illness.

A full description of the Ross and Sumner (2002) approach used for semi-quantitatively assessing Roquefort cheese is provided in Appendix 2. The values used in the model are also provided in Appendix 2.

The assumptions used for the inputs into risk ranger regarding the effect of processing and handling on levels of pathogens are derived from:

- the outcomes of a Mediterranean workshop on the estimation of the survival of some hazards in various types of cheeses (Anon, 1998);
- evaluation of the likely effect of processing on the microbiological hazards and challenge studies (Section 5.4 and 5.5); and
- frequency of hazards in Australia raw milk supplies and available data on hazard levels and frequency in French milk.

The probability of illness was calculated using Risk Ranger based on the potential number of cases in the Australian population. The number of consumers eating Roquefort cheese annually was estimated based on the following assumptions:

- 100 g consumed per person per eating event (no data are available on the amount of blue-cheese consumed per serving);
- 12 eating events per year (no data are available on the consumption rate of blue-cheese in Australia); and
- 15 tonnes of product imported into Australia annually (based on previous import rate of Roquefort cheese).

The number of consumers in a year was estimated at 12,500 (15 tonnes ÷ 100g consumed ÷ 12 consumption events per year).

The risk categories obtained using Risk Ranger are given in Table 4.

**Table 4: Ranking of hazards potentially associated with Roquefort cheese**

| Hazard | General Risk Ranking |
|---|---|
| *Campylobacter jejuni* | Negligible |
| *Staphylococcus aureus* (enterotoxin) | Low |
| *Listeria monocytogenes* | Very Low |
| *Escherichia coli* (EHEC) | Very Low |
| *Salmonella* | Low |
| *Brucella melitensis* | Negligible |
| *Coxiella burnetii* | Negligible |

While Risk Ranger can account for severity of disease in calculating a risk rating, the general risk ranking categories used for potential hazards in Roquefort cheese (Table 4) were based only on the number of cases of disease predicted.

The risk ranking for *Listeria* and EHEC was calculated based on an at-risk individual[19] consuming a portion of Roquefort cheese. Those members of the populations considered not to be at risk are unlikely to become ill from consuming the number of organisms likely to be present in Roquefort cheese at the time of consumption. The number of individuals in this category was estimated at 2,500 *i.e.* 20 percent of the consuming population of 12,500.

Using the Risk Ranger model, consumption of Roquefort cheese, represents a low to negligible likelihood of illness to consumers in the general population.

### *5.7.2 Development of a Qualitative Framework*

A model based on the Codex principles for microbiological risk assessment was developed by Food Science Australia as a tool to assist in the evaluation of the risk of microbiological hazards in Roquefort cheese. The framework takes into consideration three components of risk assessment: hazard characterisation, exposure assessment and risk characterisation.

Each hazard was categorised on the level of exposure required to give a significant probability of disease and severity of the disease (hazard characterisation module). The exposure module characterises exposure to the hazard based on the likely level of the hazard in the raw product and the effect of processing. The risk characterisation combines the hazard characterisation and exposure modules to give an overall categorisation of the hazard (Table 5).

[19] An individual more susceptible to illness

**Table 5: Risk characterisation categories for hazards associated with Roquefort cheese**

| Hazard | Hazard characterisation module[1] | Exposure module | Risk Characterisation |
|---|---|---|---|
| *Campylobacter jejuni* | Low | Negligible | Negligible |
| *S. aureus* (enterotoxin) | Negligible | Moderate | Low |
| *Listeria monocytogenes* | Negligible | Very Low | Negligible |
| *Escherichia coli* (EHEC) | Moderate | Negligible | Very Low |
| *Salmonella* | Moderate | Negligible | Very Low |
| *Brucella melitensis* | Low | Negligible | Negligible |
| *Coxiella burnetii* | High | Negligible | Low |

[1] The range given for some of the hazards reflects the different outcomes of infection between the general population and those at greater risk. These ranges are carried through to the risk characterisation.

The terms used within each of the modules were adapted from the work of Ross and Sumner (2002). Basically the framework categorises the risk of each hazard by combining information about the hazard (severity and infective dose) with exposure information (prevalence in raw materials and effect of processing).

The model found that consumption of this cheese represents a low to negligible public health and safety risk to consumers in the general population.

### *5.7.3 Findings of the Qualitative Microbiological Risk Assessment*

The two tools produced similar risk ratings for the seven microbiological hazards considered in this evaluation (Table 5). The process of manufacturing Roquefort cheese results in a substantial or complete reduction of the hazards so they represent a **low** to **negligible** public health and safety risk to consumers in the general population.

**Table 5: Comparison of the risk characterisation results using the two assessment tools**

| Hazard | Risk Ranger | Risk Characterisation Framework |
|---|---|---|
| *Campylobacter jejuni* | Negligible | Negligible |
| *S. aureus* (enterotoxin) | Low | Low |
| *Listeria monocytogenes* | Very Low | Negligible |
| *Escherichia coli* (EHEC) | Very Low | Very Low |
| *Salmonella* | Low | Very Low |
| *Brucella melitensis* | Negligible | Negligible |
| *Coxiella burnetii* | Negligible | Low |

Some of the differences in the risk ratings in Table 4 are due to the estimated exposure of the hazard. Risk Ranger assigns zero to the exposure for hazards that are eliminated during processing *i.e. Brucella melitensis*, *Coxiella burnetii* and *Campylobacter jejuni*, whereas the hybrid risk framework only assigns a category *i.e.* negligible. If hazards are eliminated from the cheese during processing and/or storage they pose no risk to the consumer.

# 6 Discussion

A review of food-borne illness outbreaks associated with raw milk cheeses found that Roquefort cheese has not been implicated in any outbreaks of food-borne illness.

During Roquefort cheese manufacture, several factors are involved in controlling the growth of bacteria including pH, temperature, salt, and water activity or moisture content. While each of these has an effect, it is their combined effect, which influences growth and survival of pathogens in cheese. The process of manufacturing Roquefort cheese makes it unlikely pathogens will survive or proliferate. Challenge studies undertaken by the Institut Pasteur de and the Ecole National Veterinaire support this conclusion.

Blue vein cheese is not a commonly consumed food in Australia. From data prior to 1997 when Roquefort cheese was permitted for sale in Australia, imports of Roquefort cheese accounted for only 0.1% of the imported speciality cheese market at this time. It is therefore considered that consumption of Roquefort cheese in Australia is likely to be extremely low.

The findings from the two qualitative risk assessment models (Risk Ranger and qualitative framework model) found that consumption of this cheese represents a low to negligible public health and safety risk to consumers in the general population.

The process of Roquefort cheese production outlined in the application has been judged to achieve the following:

| Pathogen | Risk associated with Roquefort Cheese |
|---|---|
| *Campylobacter* | *Campylobacter* is unlikely to survive processing and maturation, hence is not considered to be a problem in raw milk cheeses and is a negligible risk. |
| Pathogenic *E. coli* | Very low risk if the level of raw milk contamination with *E. coli* is low. Challenge study demonstrates organism numbers initially increase, but the organism doesn't survive cheese maturation. |
| *Salmonella* | *Salmonella* contamination of raw milk is likely to be very low/low. Challenge study shows inactivation during cheese making and maturation. |
| *Staphylococcus aureus* | Risk from staphylococcal enterotoxin is considered low. Conditional on good control over cheese making, specifically acidification of the curd. Challenge study shows the organism fails to produce enterotoxin in Roquefort cheese. |
| *Listeria monocytogenes* | Very low/negligible risk if the organism is not present in raw milk and there is effective control over cheese making and ripening operations. |
| *Coxiella burnetii* | Risk is low/negligible, although no real control measures for raw milk. Organism unable to survive processing. |
| *Brucella melitensis* | Risk is negligible. Milk is only collected from Brucellosis free herds. Organism doesn't survive the cheese making process. |

The hazards of most concern in Roquefort cheese are, in order of importance, *S. aureus* enterotoxin, *Salmonella*, EHEC and *L. monocytogenes*, but the risk to the general population is considered to be low.

For at-risk consumers EHEC is the hazard posing the greatest risk (low). *Listeria* poses the same risk to at-risk consumers as soft cheeses made from pasteurised milk, based on the assumptions made in this assessment[20].

# 7 Conclusions

During the manufacture of Roquefort cheese, pathogens, if present, would be unlikely to survive or proliferate. Therefore the consumption of Roquefort cheese poses a low risk to public health and safety. This conclusion is supported by the finding that there have been no reported outbreaks of food-borne illness due to the consumption of Roquefort cheese.

Vital for the control of all hazards is the use of raw milk of good microbiological criteria; the application of standard operating procedures (SOPs) and good manufacturing practices (GMPs) during ewe's milk collection and processing; effective implementation of hazard analysis and critical control point (HACCP) plans during cheese manufacture and ripening; and microbiological monitoring of the final product.

Critical steps required to control the pathogens during manufacture can be summarised as follows:

- the microbiological status of the incoming raw milk;
- the rapid acidification of the milk during the initial phase of cheese manufacture (i.e. drop in pH from 6.5 to <5.0 within 6 to 8 hours and then to pH 4.8 within 24 hours);
- desiccation of the curd during subsequent processing stages (i.e. a final water activity of approximately 0.92) ; and
- prolonged ripening (i.e. 90 days).

The conclusions in this evaluation are based on information supplied by the Applicant, including the challenge studies; the review by Food Science Australia; and scientific literature and they confirm:

- Roquefort cheese is an unfavourable medium for the elaboration of *S. aureus* enterotoxin;
- the cheese making process and subsequent maturation achieves a significant reduction in *Salmonella*, EHEC, *L. monocytogenes* and *S. aureus*; and
- sheep flocks from which the milk is derived are free from *B. melitensis.*

The evaluation determined that:

- *B. melitensis, C. burnetii* and *C. jejuni* are eliminated during cheese making and maturation;
- if low levels of *Salmonella*, EHEC, *Listeria* and *S. aureus* were present in raw milk, conditions during cheese making and maturation make it unlikely they would survive or proliferate; and
- *L. monocytogenes* is unlikely to grow in Roquefort cheese during maturation and subsequent storage.

[20] Note that in existing FSANZ listeria risk management material (the pamphlet ***Listeria and food – advice for people at risk***) at-risk populations are advised to avoid raw milk products and blue cheese.

The uncertainties in this evaluation are largely related to data on the management of the cheese making process (rate of acid production, final pH, and water activity) and the extent to which incoming milk may contain pathogenic bacteria.

## Acknowledgements

FSANZ acknowledges the contribution from Food Science Australia on undertaking the qualitative risk assessment of raw milk Roquefort cheese.

## References

Ammon, A. (1997) Surveillance of enterohaemorrhagic *E. coli* (EHEC) infections and haemolytic uraemic syndrome (HUS) in Europe Eurosurveillance 2 (12) 91-96

Anon (1986) Epidémie de salmonellose due à un fromage à pâte molle Bulletin de l'office fédéral de la santé publique 8 48-49

Anon (1998). Mzcp/Workshop on the Management of Milkborne Zoonoses Surveillance and Control in the Mzcp Countries, Cephalonia Island, Greece, 1-2 April 1998.

Anon (2003). *The Bad Bug Book*. Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, Centre for Food Safety & Applied Nutrition, U.S. Food & Drug Administration. http://www.cfsan.fda.gov/~mow/intro.html

Ash, M. (1987). *Staphylococcus aureus* and staphylococcal enterotoxins. In. *Foodborne Micro-Organisms of Public Health Significance*, 5th ed. pp 313-332. Eds. Hocking, A. D., Arnold, G., Jenson, Newton, K and Sutherland, P., AIFST Inc, Sydney.

Azadian, B. S., Finnerty, G. T., and Pearson, A. D. (1989) Cheese-borne Listeria meningiitis in immunocompetent patient Lancet 15 (February 11) 322-323

Berri, M, K. Laroucau and A. Rodolakis (2000). The detection of Coxiella burnetii from ovine genital swabs, milk and faecal samples by the use of single touchdown polymerase chain reaction. Vet Microbiology, 72: 285-293

Bille, J. (1990) Epidemiology of human listeriosis in Europe with special reference to the Swiss outbreak. In *Foodborne Listeriosis* (eds Miller, A.L. Smith, J.L & Somkuti, G) London. Elsevier. 71-74

Black, R. E., Levine, M. M., Blaser, M. J., Clements, M. L. and Hughes T. P. (1993). Studies of *Campylobacter jejuni* infection in volunteers, pp. 13. In A. D. Pearson, M. B. Skirrow, B. Rowe, J. R. Davies and D. M. Jones (eds). *Campylobacter* II. Public Health Laboratory Services, London.

Bone, F. J., Bogie, D., and Morgan-Jones, S. C (1989) Staphyloccoccal food poisoning from sheep milk cheese Epidemiology and Infection 103 449-458

Buchanan, R. L., Damert, W. G., Whiting, R. C., van Schothorst, M. (1997). Use of epidemiologic and food survey data to estimate a purposefully conservative dose-response relationship for *Listeria monocytogenes* levels and incidence of listeriosis. Journal of Food Protection, 60, 918-922.

Buchanan, R. L., Smith, J. L. and Long W. (2000). Microbial risk assessment: dose-response relations and risk characterization. International Journal of Food Microbiology 58, 159–172.

CDC (2000) Outbreak of *Escherichia coli* 0158:H7 infection associated with eating fresh cheese curds - Wisconsin, June 1998 MMWR 49 (40) 911-913

CDC (2001) Outbreak of Listeriosis associated with homemade Mexican-style cheese - North Carolina, October 2000 - January 2001 MMWR 50 (26) 560-562

Cody, S. H., Abbott, S. L., Marfin, A. A, Schulz, B. et al. (1999) Two outbreaks of multidrug-resistant *Salmonella* serotype Typhimurium DT104 infections linked to raw-milk cheese in Northern California The Journal of the American medical Association 281 (19) 1805-1810

Curnow, J. (1994) E. coli 0157 phage type 28 infections in Grampian Communicable Disease Report Weekly 28 (1)

De Buyser, M. L., Janin, F., and Dilasser, F. (1985) Contamination of ewe cheese with *Staphylococcus aureus*: study of an outbreak of food poisoning. In: Jeljaszewicz, J. (Ed), The Staphylococci, Zbl Bakt. Supp. 14. Gustav Fisher Verlag, Stuttgart, 677-678

De Buyser, M. D., Dufour, B., Marie, M. and Lafarge, V. (2001). Implication of milk and milk products in foodborne disease in France and in different industrialised countries. International Journal of Food Microbiology, 67, 1-17.

de Valk, H., Delarocque-Astagneau, E., Colomb, G., Ple, S. et al. (2000) A community-wide outbreak of Salmonella enterica serotype Typhimurium infection associated with eating a raw milk soft cheese in France Epidemiol Infect 124 (1) 1-7

D'Aoust, J. Y. (1994). *Salmonella* and the international food trade. Int. J. Food Microbiol., 24:11-31.

D'Aoust, J. Y., Warburton, D. W., Sewell, A. M. (1985). *Salmonella typhimurium* phage-type 10 from cheddar cheese implicated in a major Canadian foodborne outbreak. Journal of Food Protection, 48:1062-1066.

Davis, J. G. (1976). Cheese. Volume III – Manufacturing Methods. Churchill Livingstone, London.

Deschenes, G., *et al*. (1996). Cluster of cases of haemolytic uraemic syndrome due to unpasteurised cheese. Pediatric Nephrology, 10:203-205.

Desenclos, J-C., Bouvet, P., Benz-Lemoine, E., Grimont, F., Desqueyroux, H., Rebiere, I., Grimont, P. A. (1996). Large outbreak of *Salmonella enterica* serotype paratyphi B infection caused by a goats' milk cheese, France, 1993: a case finding and epidemiological study. British Medical Journal, 312:91-94.

Desmarchelier P. D and Fegan, N. (2003). Enteropathogenic *Escherichia coli*. In. *Foodborne Microorganisms of Public Health Significance*, 6th ed. pp 267-310, Ed A. D. Hocking et al., AIFST Inc., Sydney.

Desmarchelier, P. M., Grau, F. H. (1997). *Escherichia coli*. In. *Foodborne Micro-Organisms of Public Health Significance*, 5th ed. pp 231-264. Eds. Hocking, A. D., Arnold, G., Jenson, Newton, K and Sutherland, P., AIFST Inc, Sydney.

Ellis, A., Preston, M., Borczyk, A., Miller, B.et al. (1998) A community outbreak of *Salmonella berta* associated with a soft cheese product Epidemiology and Infection 120 29-35

European Commission (2003) Opinion of the Scientific Committee on veterinary measures relating to public health on Staphylococcal enterotoxins in milk products, particularly cheeses http://europa.eu.int/comm/food/fs/sc/scv/out61_en.pdf

Fox, P. E., Guinee, T. P., Cogan, T. M., and McSweeney, P. L. H. Fundamentals of cheese science. 2000. Maryland, Aspen Publishers, Inc.

Godfroid, J and Kasbohrer, A. (2002). Brucellosis in the European Union and Norway at the turn of the twenty-first century. Veterinary Microbiology, 90, 135-145.

Goulet, V., Jacquet, C., Vaillant, V., Rebiere, I. *et al*. (1995) Listeriosis from consumption of raw-milk cheese Lancet 345 1581-1582

Grimont, P. A and Bouvet, P. (1991) Les salmonelles et les shigelles en 1990 en France Bulletin Epidémiologique Hebdomadaire 25 102-

Haeghebaert, S. *et al*. (2003). Two outbreaks of Salmonella Enteritidis phage type 8 linked to the consumption of Cantal cheese made from raw milk , France 2001. Eurosurveillance Monthly, 8, (7-8): 151-156

Hedberg, C. W., Korlath, J. A., D'Aoust, J. Y., White, K. E., Schell, W. L., Miller, M. R., Cameron, D. N., MacDonald, K. L., Osterholm, M. T. (1992). A multistate outbreak of *Salmonella* Javiana and *Salmonella* Oranienburg infections due to consumption of contaminated cheese. Journal of the American Medical Association. 268:3203-3207.

Health Canada (2003). First documented outbreak of *Listeria monocytogenes* in Quebec 2002. Canada Communicable Disease Report, 29, (21): 181-186

Huchot, A., Bohnert, M., Cerf, O., Farrokh, C., and Lahellec, C. (1993) Does cheese made of raw milk represent a public health problem? A review of international epidemiological data Dairy Fed. 48 F-doc 223 supplement.

ICMSF (1996a). *Campylobacter*. In. *Micro-organisms in Foods 5. Microbiological specifications of Food Pathogens.* pp. 45-65. Blackie Academic & Professional, London.

ICMSF (1996b). *Salmonella.* In. *Micro-organisms in Foods 5. Microbiological specifications of Food Pathogens.* pp. 217-264. Blackie Academic &Professional, London.

ICMSF (1996c). *Staphylococcus aureus.* In. *Micro-organisms in Foods 5. Microbiological specifications of Food Pathogens*. pp. 299-333. Blackie Academic &Professional, London.

ICMSF (1996d). *Listeria monocytogenes.* In. *Micro-organisms in Foods 5. Microbiological specifications of Food Pathogens*. pp. 141-182. Blackie Academic &Professional, London.

ICMSF (1998). Milk and Dairy Products. In. *Micro-organisms in Foods 6. Microbial Ecology of Food Commodities*. pp. 521-576. Blackie Academic &Professional, London.

IDF (1980). Behaviour of pathogens in cheese. Bull. Int. Dairy Fed., 122.

Infuso, A., Vaillant, V., and Desenclos, J. C. (1997) Epidémie de salmonellose à Salmonella enterica sérotype Dublin, France, november-décembre 1996. Institut de Veille Sanitaire, Saint-Maurice, France, Mai 1997 13-

Jacquet, C., Saint-Cloment, C., Brouille, F., Catimel, B., and Rocourt, J (1998) La listeriose humaine en France en 1997, données du Centre National de Référence des Listeria. Bulletin Epidémiologique Hebdomadaire 33 142-143

Johnson, E. A., Nelson, J. H., Johnson, M. (1990). Microbiological safety of cheese made from heat-treated milk, Part II. Microbiology. Journal of Food Protection, 53:519-540.

Kourilova, J. and Kultan, V (1990) Epidemiology of *Campylobacter jejuni/coli* Mikrobiologie, Imunologie, 39 43-49

Laporte, E., J. P. Guiraud, J. P. Reverbel (1992). Antimicrobial action associated to Roquefort cheese technology: influence of the *Penicillium roqueforti* strain. Sciences des Aliments., 12 (4):729-741.

Leclerc, V. *et al.* (2002). Pathogens in meat and milk products: surveillance and impact on human health in France. Livestock Production Science, 76, 195-202.

Loncarevic, S., M. L. Danielsson-Tham and W. Tham (1995). Occurrence of *Listeria monocytogenes* in soft and semi-soft cheese in retail outlets in Sweden. Int. J. Food Microbiol., 26:245-250.

MacDonald, K. L., and others (1985). A multistate outbreak of gastrointestinal illness caused by enterotoxigenic *Escherichia coli* in imported semisoft cheese. Journal of Infectious Diseases, 151:716-20.

Maguire, H., Boyle, M., Lewis, M. J., Pankhurst, J.et al. (1991) A large outbreak of food poisoning of unknown aetiology associated with Stilton cheese Epidemiology and Infection 106 (3) 497-505

Maguire, H., Cowden, J., Jacob, M., Rowe, B., Roberts, D., Bruce, J., and Mitchell, E. (1992) An outbreak of Salmonella dublin infection in England and Wales associated with a soft unpasteurized cows' milk cheese Epidemiology and Infection 109 (3) 389-396

Marrie, T. J. (2003). *Coxiella burnetii* pneumonia. European Respiratory Journal, 21, 713-719.

Maurin, M. and Raoult, D. (1999). Q Fever. Clinical Microbiological Reviews, 12, 518-533.

Mead, P. S. and Griffin, P. M. (1998). *Escherichia coli* O157:H7. The Lancet Volume: 352, Issue: 9135, October 10, 1207-1212.

Meng, J., Doyle, M., Zhao, T. and Shao, S. (2001). Enterohaemorrhagic *Escherichia coli*. In. *Food Microbiology: Fundamental and Frontiers* 2nd edit. pp 193-214 (eds). Doyle, M., Beuchat, L. R., Montville, T. J. ASM Press, Washington.

Mèndez Martinez, C., Páez Jimènez, A., Cortés Blanco, M., Salmoral Chamizo, E.et al. (2003). Brucellosis outbreak due to unpasteurized raw goat cheese in Andalucia (Spain), January - March 2002 Eurosurveillance 8 (7) 164-168

Montanaro, C, Pavone, R., Zaccarelli, M., Ascenzo, E.et al. (1989) Incidence of pathogenic *E. coli* strains in milk and milk products Acta Veterinaria, Yugoslavia, 39 127-135

Nielsen, E. M. , Engberg, J., Madens, M. (1997). Distribution of *Campylobacter jejuni* and *C. coli* from Danish patients, poultry, cattle and swine. FEMS Immunology and Medical Microbiology. 19:47-56.

O'Donnell, E. T. (1995). The incidence of *Salmonella* and *Listeria* in raw milk from farm bulk tanks in England and Wales. Journal of the Society of Dairy Technology, 48:25-29.

Oberhelman, R. A., Taylor, D. N. (2000). *Campylobacter* infections in developing countries, pp 139-153, In. *Campylobacter,* 2nd ed., (Eds. I. Nachamkin, and M. J. Blaser), ASM Press, Washington DC.

Papageorgiou, D. K. and E. H. Marth. (1989a). Fate of *Listeria monocytogenes* during the manufacture, ripening and storage of Feta cheese. J. Food Protect., 52 (2), 82-87.

Papageorgiou, D. K. and E. H. Marth. (1989b). Fate of *Listeria monocytogenes* during the manufacture and ripening of Blue cheese. J. Food Protect., 52 (7): 459-465.

Rampling, A. (1996). Raw milk cheeses and *Salmonella*. Brit. Med. J., 312:67-68.

Ross, T and Sumner, J. (2002). A simple, spreadsheet-based, food safety risk assessment tool. International Journal of Food Microbiology, 77, 39-53.

Rousset, E.; Russo, P.; Pépin, M.; Raoult, D. (2001). Épidémiologie de la fièvre Q animale. Situation en France. Medecine et Maladies Infectieuses Volume: 31, Supplement 2, March, 2001: 233-246

Spahr, U. and B. Url. (1994). Behaviour of pathogenic bacteria in cheese – A synopsis of experimental data. Bull. Int. Dairy Fed.: 298, 2-16.

Tissot-Dupont, H., Raoult, D., Brouqui, P., Janbon, F., Peyramond, D., Weiller, P.J., et al (1992). Epidemiologic features and clinical presentation of acute Q fever in hospitalized patients: 323 French cases. Am J Med 93:427-434

Voysey, P. (2001). *Microbiological Risk Assessment.* In. *Hot Topics in Food Microbiology*. Campden & Chorleywood Food Research Association Group, 6-7 September 2001.

Wallace R. B. (2003). *Campylobacter*. In. *Foodborne Microorganisms of Public Health Significance*, 6th ed. pp 267-310. Ed. A. D. Hocking et al., AIFST Inc., Sydney.

# Appendix 1

# Hazard Characterisation

FSANZ acknowledges the contribution of Food Science Australia in providing information for incorporation in the following hazard characterisations.

Each of the hazards identified as being of concern were characterised under the headings organism, disease, infective dose, epidemiology and effect of cheese making on pathogens.

## *Campylobacter jejuni* and *Campylobacter coli*

### (a) Organism

*C. jejuni* is a Gram-negative, curved and highly motile rod. It is a micro-aerophilic organism growing best in atmospheres of 5% $O_2$ and 10% $CO_2$. The organism appears to be very fragile, and is sensitive to environmental stress *e.g.* aerobic atmospheres, drying, heating, disinfectants, acidic conditions etc). There is debate over its sensitivity to stress, with some researchers reporting that the organism enters a viable (infectious) but non-culturable state.

*Campylobacter* is the leading cause of bacterial diarrhoeal disease in most Western countries. *C. jejuni* and *C. coli* are the most common *Campylobacter* spp. associated with human diarrhoeal disease. The clinical disease of both is indistinguishable and most laboratories do not differentiate between the species so the ratio of illness due to each species is not clear.

In the USA it is estimated that 1-3% human cases are due to *C. coli* (Oberhelman and Taylor, 2000) and in a study in Denmark 6% of campylobacteriosis cases over 12 months were caused by *C. coli* (Nielsen *et al*., 1997). Due to its predominance in human infection, most information on foods relates to *C. jejuni.*

### (b) Disease

Infection with *C. jejuni* usually results in watery diarrhoea, which may contain blood. Other symptoms include fever, abdominal pain, nausea, headaches and muscle pain. The illness is generally self-limiting with an onset of symptoms 2-5 days after ingestion of the contaminated food or water. Illness generally lasts 7-10 days, but relapses can occur in up to 25% of cases. Long-term sequelae have been reported resulting in Guillan-Barré syndrome.

### (c) Infectious dose

The infective dose of *C. jejuni* is considered to be small. Human feeding studies suggest that around 500 cells in milk may be sufficient to cause illness in some individuals, while in others greater numbers are required (Anon, 2003; Black *et al.*, 1983; ICMSF, 1996a). Volunteer human feeding studies suggest that host susceptibility plays an important role in likelihood of disease. The mode of pathogenicity of *C. jejuni* is not completely understood, but it produces a heat-labile toxin that may cause diarrhoea.

### (d) Epidemiology

Birds and animals are the main reservoir of *C. jejuni/coli* and they are found in the intestinal tract of a wide range of healthy domesticated animals. *C. jejuni* is found in cattle and sheep, while *C. coli* is more often found in pigs and birds and is less likely to be a contaminant of sheep or cow's milk than *C. jejuni*. The organisms are found in the faeces of these animals and in cattle they can cause low-grade or subclinical mastitis although infrequently. The role of *C. jejuni* in sheep mastitis is unknown.

Milk may be contaminated from faecal material or *Campylobacter* may be shed in the milk itself, as is the case when the animal has clinical or subclinical mastitis due to *Campylobacter* infection. Campylobacters have been isolated from 1-6% raw milk samples (Wallace, 2003). Raw or inadequately pasteurised milk is the most frequently identified vehicle of foodborne human infection with *C. jejuni* (ICMSF, 1996a).

No records were found linking campylobacteriosis to the consumption of cheese, and no information is available on the role of cheese in the epidemiology of campylobacteriosis. In an investigation of foodborne disease outbreaks in France, De Buyser *et al*. (2001) did not consider *Campylobacter*, suggesting that there is little evidence of an association between raw milk products and campylobacteriosis or a lack of information.

### (e) Effect of Cheese making

Campylobacters are unlikely to grow in milk or cheese, as their growth requires reduced oxygen tension and temperatures between 32-45ºC. Even during fermentation and curd formation, when the temperature is >32ºC, growth is unlikely or at most slight. In addition, Campylobacters do not survive well under slightly acidic conditions or in the presence of >2% salt (ICMSF, 1996a).

Conditions during Roquefort cheese manufacture would be lethal to these organisms and they would not be expected to survive.

## *Escherichia coli*

### (a) Organism

*E. coli* are gram-negative rods motile by flagella, or non-motile, and facultatively anaerobic. The EHEC strain O157:H7 can be differentiated from other *E. coli* by its inability to ferment sorbitol and by the presence of specific virulence markers. *E. coli* can grow at temperatures from 7-45ºC, although growth at 7ºC is very slow.

Pathogenic *E. coli* associated with foodborne disease are grouped into specific pathotypes based mainly on their virulence characteristics, mechanisms of pathogenicity and clinical syndromes: enteropathogenic (EPEC), enterotoxigenic (ETEC), enteroinvasive (EIEC), diffuse-adhering (DAEC), enteroaggregative (EAEC) and enterohaemorrhagic (EHEC) (Desmarchelier and Fegan, 2003).

The pathogenic *E. coli* strains of most concern are enterohaemorrhagic *E. coli* (EHEC) and Shiga toxin producing *E. coli* (STEC). The aetiology of other pathogenic strains *i.e.* enteropathogenic *E. coli* (EPEC) is not well understood.

Most pathogenic *E. coli* are not readily distinguishable from generic strains using traditional culture techniques. They need to be differentiated based on the presence of known virulence markers or to a limited extent by serotyping.

**(b) Disease**

Of the pathotypes of *E. coli*, the EHEC have become the most important foodborne type, in particular those belonging to the serotype O157:H7. This is mainly due to the severity of the disease and the high mortality rate in young children.

EHEC infection may be asymptomatic or associated with a range of symptoms including mild diarrhoea, severe haemolytic colitis (HC), haemolytic uraemic syndrome (HUS) and death (Meng *et al*., 2001). Only a proportion of those infected may develop HUS (2-7%) and for these patients the mortality rate is between 5-10%. The most severe clinical symptoms are normally seen in children and the elderly. Other pathogenic *E. coli i.e.* Shiga toxigenic *E. coli* (STEC) has been associated with disease from consumption of contaminated food.

**(c) Infectious dose**

The infective dose of most pathogenic *E. coli* is not clearly defined. However, the dose of EHEC required to cause human illness is considered to be very low with fewer than 50 cells believed to be sufficient to cause disease (Mead and Griffin, 1998). The infective dose of EHEC is believed to be similar to *Shigella* spp. and dose response models have been developed that are based on feeding trials undertaken with *S. dysenteriae*.

**(d) Epidemiology**

The epidemiology is not clear for all of these pathotypes. Human carriers are believed to be a principal reservoir and source of EPEC, EIEC and ETEC strains involved in human illness. The intestinal tract of ruminants including cattle and sheep is an important reservoir of EHEC.

There is insufficient data of each pathotypes' behaviour in foods and data for non-pathogenic strains are used unless a pathotype is known to behave differently. EHEC in particular are distinguished from the other *E. coli* pathotypes, as some EHEC strains are able to tolerate mildly acidic conditions in foods.

Pathogenic *E. coli* have been the cause of foodborne illness where cheeses have been implicated as the source of infection. These have included EIEC isolated from Brie and Camembert, ETEC associated with consumption of Brie and EHEC implicated directly or indirectly with consumption of a variety of cheeses including semi-soft cheese, cheese curds, goat cheese and Lancashire cheese (a semi-hard cheese) (MacDonald *et al*., 1985; Deschenes *et al*., 1996; Desenclos *et al*., 1996; Desmarchelier and Grau, 1997). The source of the pathogens may have been the raw milk used in the cheese manufacture (EHEC), food handlers (EIEC, ETEC, EHEC) or water used in the manufacturing process (EIEC).

Shiga toxin-producing *E. coli* (STEC) of which EHEC is a sub-group are found in the faeces of healthy cattle, sheep and goats (Reviewed in Desmarchelier and Fegan, 2003). Milk can become contaminated at collection or from the milking parlour environment and O157 EHEC have been isolated from raw cow's milk on farm and from bulk raw milk tankers (summarised in Meng *et al*., 2001; Desmarchelier and Fegan, 2003).

Bacterial numbers in raw milk is expected to be very low, particularly with co-mingling of milk in bulk containers. EHEC infection has been reported following consumption of raw cow's milk or milk contaminated post-pasteurisation (summarised in Meng *et al*, 2001; Desmarchelier and Grau, 1997).

**(e) Effect of Cheese making**

Shiga toxin producing *E. coli* (STEC) have been responsible for a number of cheese related outbreaks. The main strains of concern are EHEC. These strains have been found in sheep, although their prevalence in France is not known.

Increases in pathogenic *E. coli* have been reported during the first 24 hours of Feta cheese manufacture (1-2 logs, final pH 4.3-5.0), although no *E. coli* was detected after 5-days storage at 22ºC (>8-log reduction; Spahr and Url, 1993). Similar increases in *E. coli* would be expected in Roquefort cheese.

The behaviour of EHEC in cheese may be similar to *Salmonella*, although EHEC strains have been shown to behave differently to *Salmonella* in other foods *i.e. E. coli* O157:H7 is generally considered to be more acid resistant that *Salmonella*. As the infective dose for *E. coli* O157:H7 is low, small numbers present in the final product are of concern. Low levels of *E. coli* are achieved by Good Hygienic Practice on farm.

***Salmonella spp.***

**(a) Organism**

*Salmonella* is a Gram-negative rod-shaped, motile (exceptions *S.* Gallinarum and *S.* Pullorum), non-sporeforming and facultatively anaerobic bacterium. *Salmonella* will grow on food at temperatures from 7-45ºC. Although growth has been reported at temperatures below 7ºC, this is generally accepted as the lower limit of growth on foods. Salmonellae are generally recognised by serovar (serotype) names.

**(b) Disease**

Acute symptoms of infection include nausea, vomiting, abdominal cramps, minimal diarrhoea, fever, and headache with an onset 6-48 hours after consuming contaminated foods. Acute symptoms may last for 1-2 days or may be prolonged, depending on host factors, ingested dose, and strain characteristics. Chronic sequelae have been identified and include arthritic symptoms that may follow 3-4 weeks after onset of acute symptoms.

**(c) Infectious dose**

Serovars vary in their pathogenicity, hence the infective dose cannot easily be determined. For example, some serovars commonly found in animals and animal products are rarely associated with human disease *i.e. S.* Sofia.

Using human volunteers for infectious dose studies it has been found that $10^7$ salmonellae were required to have a significant likelihood of causing disease (ICMSF, 1996b). However, for highly virulent serovars, as few as 15-20 cells can cause disease. Infectious dose is influenced by factors such as the immuno-status of the consumer and the nature of the food matrix e.g. fatty foods protect *Salmonella* from the action of stomach acids.

Cheese implicated in salmonellosis outbreaks has been found to contain low numbers, 0.36-9.3 cells/100 grams (D'Aoust *et al*., 1985) and 0.36-4.3 cells/100 grams (Hedberg *et al*., 1992).

**(d) Epidemiology**

Human salmonellosis associated with the consumption of cheese made from unpasteurised milk has long been recognised (D'Aoust, 1994; Rampling, 1996; FSANZ, 2004).

Salmonellae can be found in the intestinal tract of most warm and cold-blooded animals. In cattle and sheep, the bacterium is carried by both healthy and diseased animals and is transmitted in the faeces. *Salmonella* can enter milk by faecal contamination or by contamination of equipment. Even under good hygienic conditions *Salmonella* can be expected to be found in milk from time to time.

*Salmonella* has been isolated frequently from raw milk (Johnson *et al*., 1990). In the US, 4.7% of milk in 678 tankers was positive. In a study of raw milk in bulk tanks in the UK in 1995, 0.36% of the tanks sampled were contaminated (O'Donnell, 1995).

Both milk and milk products such as cheddar cheeses and Vacherin cheese have been implicated in outbreaks of salmonellosis (Johnson *et al*., 1990). The source of contamination is primarily the raw milk contaminated via the udder and teats and maybe via systemic infection and workers. Milk can also be contaminated post-pasteurisation. Product may be further contaminated via the factory environment and food handlers during processing.

**(e) Effect of Cheese making**

During the initial stages of cheese manufacture, salmonellae can grow (Spahr and Uhr, 1994). Growth will stop when the pH falls below about 5. Once the pH has fallen to 4.8 there will be little chance of growth of pathogens and death will commence. *Salmonella* did not survive in blue cheese with a pH of 5.3 (IDF, 1980).

During maturation the numbers of salmonellae will decrease, with the rate of decline dependent on the temperature and pH. As the pH of the cheese increases salmonellae are better able to survive.

Random end-product testing has been shown to be ineffective in detecting *Salmonella* contamination (Desenclos *et al*., 1996), as it is notoriously insensitive as a method of detecting intermittent contamination with pathogens. It is not clear if testing every production batch offers greater protection. The infective dose of *Salmonella* in cheese has been reported to be as low as 0.36 cells per 100g (D'Aoust, 1994 and Hedberg *et al*., 1992). If 5 x 25g samples are collected from every batch and tested there is only a 30% chance of detecting a pathogen when present at 0.36 cfu/100g (Figure 1).

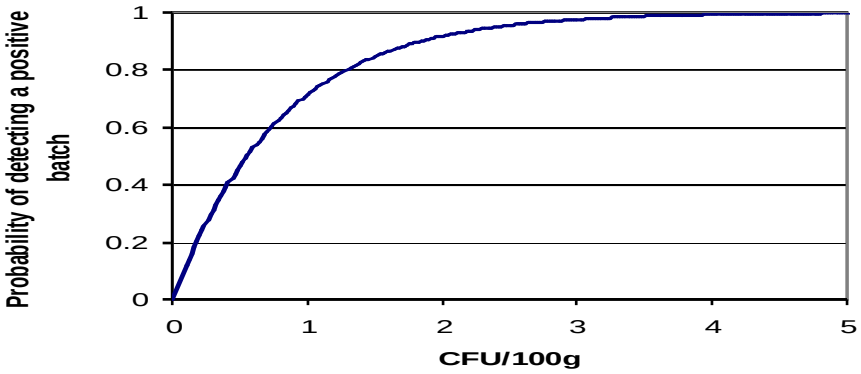



**Figure 1: Probability of detecting a positive batch at various concentrations of pathogenic bacteria in the batch at the time of sampling (5 x 25g samples).**

Control of *Salmonella* in Roquefort cheese is due mostly to reducing the level of contamination of the raw material and preventing growth of the organisms in raw milk by effective temperature control during transportation and storage. Control of *Salmonella* in raw milk is achieved through good hygienic practices on-farm and this is verified through monitoring for *Salmonella* in milk used for production.

## *Staphylococcus aureus*

### (a) Organism

*S. aureus* is a spherical, Gram-positive bacterium. Some strains are capable of producing a highly heat-stable toxin that causes illness in humans. High numbers of staphylococci (>$10^5$ cfu/mL) are required for the production of sufficient enterotoxin to cause disease. The staphylococcal enterotoxins are thermally stable and if toxin is present in the raw milk, active toxin will remain after thermal processing (ICMSF, 1996c) such as pasteurisation.

*S. aureus* can grow over a temperature range of 7-48ºC although significant enterotoxin production occurs over a more restricted range *i.e.* between 10-48ºC with optimum production at 35-40ºC and pH of 6.0-7.0. Production is also influenced by the salt concentration.

Raw milk that is not cooled rapidly or stored correctly will support growth and possible toxin production. At 10ºC there is a long lag time (>20h) and when growth commences it is very slow (ICMSF, 1996c). *S. aureus* will grow over a wider range of $a_w$ values than other pathogens *e.g.* 0.83-0.99, however the rate of growth is significantly slowed below 0.94.

### (b) Disease

Disease is caused by the ingestion of preformed *S. aureus* enterotoxin. The onset of food poisoning symptoms is usually rapid and in many cases acute, depending on individual susceptibility to the toxin, the amount of contaminated food eaten, the amount of toxin in the food ingested, and the general health of the victim.

The most common symptoms are nausea, vomiting, retching, abdominal cramping, and prostration. Some individuals may not always demonstrate all the symptoms associated with the illness. In more severe cases, headache, muscle cramping, and transient changes in blood pressure and pulse rate may occur. Recovery generally takes two days, however, it is not unusual for complete recovery to take three days and sometimes longer in severe cases.

**(c) Infectious dose**

A toxin dose of less than 1.0 microgram in contaminated food will produce symptoms of staphylococcal intoxication (Anon, 2003). This toxin level is reached when *S. aureus* populations exceed 100,000 per gram.

**(d) Epidemiology**

*S. aureus* occurs in the mucous membranes and on the skin of most healthy, warm-blooded animals, including man and food animals (ICMSF, 1996c). *S. aureus* may be shed into milk in large numbers (up to $10^5$ colony forming units per ml) by animals having mastitis before any clinical symptoms are shown. The bacterium is also a common cause of wound and skin infections in personnel including food handlers and farm workers.

Milk usually becomes infected via the animal host or food handlers during processing. Outbreaks of staphylococcal intoxication have been attributed to dairy products including cheeses such as Swiss style cheeses (*e.g*. Emmental, Gruyere and Swiss), raw milk cheddar, Colby and cheese curd (Johnson *et al.*, 1990). These outbreaks resulted from poor process control, contamination from infected workers, contaminated starter cultures and use of contaminated water. Enterotoxin production can occur in the raw milk before processing or during cheese production. Enterotoxins have been shown to persist in cheese for several years (IDF, 1980). *S. aureus* was by far the most frequent pathogen associated with outbreaks from milk and milk products in France (85.5%) (De Buyser *et al.*, 2001).

Consumption of cheese made from raw sheep-milk has been recognised as the cause of a number of outbreaks of staphylococcal food-poisoning (Bone *et al.*, 1989). *S. aureus* is frequently found in raw milk (ICMSF, 1998), with shedding rates of $10^5$ cfu/ml even in subclinical cases of mastitis.

**(e) Effect of Cheese making**

Outbreaks of foodborne staphylococcal intoxication attributed to cheese have resulted largely from poor process control and contaminated or ineffective starter cultures. Proper raw milk handling and storage, and rapid acid production during acidification of cheese are important controls over this organism during cheese manufacture.

*S. aureus* will increase during curd formation due to cell growth and syneresis, although the organism is generally considered to be a poor competitor. It is possible that 4-5 generations of growth will occur, although toxin formation is unlikely (IDF, 1980).

The risk from staphylococcal enterotoxin is dependent on initial levels of *S. aureus* in raw milk and the amount of growth occurring. However challenge studies show that *S. aureus* is not detectable in cheese at the end of maturation and that no toxin has been formed. Nevertheless large number of *S. aureus* in milk at the start of processing may be a concern.

*S. aureus* will likely only be a concern if fermentation fails or if high loads are present in the milk at the time of manufacture. Rapid pH fall is the critical control point for restricting pathogen growth and toxin production in the cheese during the early stages of production.

Boer and Kuik (1987) examined 256 samples of blue vein cheeses (Roquefort, Danablu, and Gorgonzoloa) and found that *S. aureus* was always present at numbers less than 100 cfu/g. Tatini *et al*. (1973) studied the production of enterotoxin A in blue cheese, and could not detect enterotoxin in any lots, even when large inocula ($>10^6$ cfu./ml) were used and *S. aureus* populations reached of $10^7$ cfu/g of cheese, or when a complete starter failure was induced by bacteriophage action.

The existing data suggest that cheeses ripened with internal mould activity are very hostile environment for *S. aureus*. This may be due to the combined inhibitory effect of *Penicillium* spp. and starter bacteria (Tatini *et al*., 1973; Meyrand and Vernozy-Rozand, 1999).

Staphylococcal enterotoxin will not be affected by processing but growth of *Staphylococcus* is required for the production of sufficient toxin to cause disease. Maintaining the cold chain from farm to processing and monitoring the fermentation process will ensure that growth does not occur and hence toxin is not formed; also testing of end product for toxin will give additional assurance of product safety.

## *Listeria monocytogenes*

### (a) Organism

*L. monocytogenes* is a Gram-positive, non-sporeforming, motile bacterium that can grow at refrigeration temperatures. It has been isolated from numerous species including humans. It can be found in soil, silage, and other environmental samples.

*L. monocytogenes* is resistant to freezing and drying, and is more heat resistant than Gram negative foodborne pathogens ($D_{65}$=100sec). *Listeria* is capable of growing on foods under refrigerated storage and has similar growth requirements to lactic acid bacteria. Growth can occur at 0ºC in foods of neutral pH, although the growth rate is slow (62-131 hours; ICMSF, 1996d). Because of its slow growth rate at refrigeration temperatures (compared to *Pseudomonas* spp.), *Listeria* is not a concern on fresh aerobically stored meat.

*Listeria* is tolerant of low $a_W$ and pH conditions found in most processed foods that require chilled storage, and can grow in these foods. *Listeria* cannot generally grow under conditions that render a product shelf stable *i.e*. pH<5.0 or $a_W$ <0.9. Chilled foods that are of concern are those in which *Listeria* can grow and that have an extended shelf-life *i.e*. soft cheeses, processed meats, pâté.

### (b) Disease

Most *L. monocytogenes* infections occur in people with suppressed immune systems *i.e*. the aged, pregnant women and their foetuses, cancer patients, AIDS sufferers etc. The onset of more severe symptoms is usually preceded by flu-like symptoms including persistent fever. Recently less severe symptoms such as nausea, vomiting, and diarrhoea have been reported. Such gastrointestinal symptoms have been epidemiologically associated with use of antacids, although the significance of this is unclear.

The onset of severe disease is variable and can range from a few days to several weeks. The onset time to gastrointestinal symptoms is probably greater than 12 hours.

Listeriosis is clinically defined when the organism is isolated from blood, cerebrospinal fluid, or an otherwise normally sterile site *e.g.* placenta, foetus. The manifestations of listeriosis include septicaemia, meningitis, encephalitis, and intrauterine or cervical infections in pregnant women, which may result in spontaneous abortion (2nd/3rd trimester) or stillbirth.

**(c) Infectious dose**

While there is a generally lack of consensus on the number of cells required to give a significant probability of infection, it is thought to be relatively high *i.e.* >10,000 cells. The pathogenicity of *Listeria* is believed to vary with the strain. Serotypes 4b and to a lesser extent 1/2a and 1/2b account for most cases of disease worldwide. Some studies have shown that the risk of disease from foods contaminated occasionally with <100 cells/g is low, even in susceptible populations (Buchanan *et al*., 1997). The probability of infection is determined by a number of factors *i.e.* the number of cells consumed, host specific factors, the type of food and the pathogenicity of the strain.

**(d) Epidemiology**

The ability of the organism to grow at temperatures as low as 0ºC in some foods permits multiplication under refrigeration conditions. It is also ubiquitous in the environment of food production facilities.

*L. monocytogenes* has been associated with foods such as raw milk, pasteurised fluid milk, cheese (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats, and raw and smoked fish (ICMSF, 1996d).

*L. monocytogenes* is carried by milk producing animals and can cause disease in these hosts. Hence *Listeria* is frequently detected in raw milk, and it is able to grow in chilled milk. Because *Listeria* is commonly found in the processing environment it is a hazard for all cheese manufacturing processes as a post-processing contaminant, and not just those plants utilising unpasteurised milk.

Soft and semi-soft mould ripened cheeses are higher risk as they have a water activity and pH that allows *L. monocytogenes* to grow to large numbers even when stored chilled (ICMSF, 1998). Cheeses such as Brie de Meaux (France) have caused disease outbreaks (Goulet, *et al*., 1995).

**(e) Effect of Cheese making**

While *L. monocytogenes* is primarily considered an environmental contaminant, raw milk cheeses are more often contaminated than cheeses manufactured using pasteurised milk (Loncarevic *et al*., 1995). The combination of entrapment of cells in the curd and their growth means that the population of *L. monocytogenes* in 1-day-old cheese would be expected to be 10-100 times that in the raw milk (Papageorgiou and Marth, 1989). At salting, the combination of low pH and decreased water activity will prevent further growth and viable cell numbers will start to decrease.

In Roquefort cheese, the pH will rise during mould ripening. Because of the low water activity of the cheese, growth is unlikely to occur until the pH is near 6. Combined with low storage temperatures (0-2ºC), any growth will be slow.

In experimental Blue cheese, made with *P. roqueforti* and which contained average values of 4.5% salt and 38.9% water, no growth of *L. monocytogenes* occurred at the pH values reached at the end of aging *i.e*. pH 5-6 (Papageorgiou and Marth, 1989). The water activity of Roquefort cheese is 0.92 at the end of maturation (data from Applicant).

## *Coxiella burnetii* (Q-fever)

### (a) Organism

Q fever is a zoonotic disease caused by *C. burnetii*, a species of rickettsiae that is distributed globally. Because the disease is rare and possibly underreported, scientists cannot reliably assess how many cases of Q fever occur worldwide. Many human infections are sub-clinical.

*C. burnetii* is a Gram-negative like (will not stain) coccobacillus than is an obligate intracellular microorganism (will not grow in foods or outside host cells). *C. burnetii* is able to form spore like structures which may explain its long survival in soils and the environment (Marrie, 2003).

### (b) Disease

Only about half of all people infected with *C. burnetii* show signs of clinical illness. Most acute cases of Q fever begin with the sudden onset of one or more of the following: high fever, severe headache, general malaise, myalgia, confusion, sore throat, chills, sweats, non-productive cough, nausea, vomiting, diarrhoea, abdominal pain, and chest pain. Fever usually lasts for 1 to 2 weeks. Weight loss can occur and persist for some time.

Thirty to fifty percent of patients with symptomatic infection will develop pneumonia. Additionally, a majority of patients have abnormal results on liver function tests and some will develop hepatitis. In general, most patients will recover to good health within several months without any treatment. The mortality rate in patients with acute Q fever is 1-2%.

Chronic Q fever, characterized by infection that persists for more than 6 months is uncommon but is a much more serious disease. Patients who have had acute Q fever may develop the chronic form as soon as 1 year or as long as 20 years after initial infection. A serious complication of chronic Q fever is endocarditis, generally involving the aortic heart valves, less commonly the mitral valve. Most patients who develop chronic Q fever have pre-existing valvular heart disease or have a history of vascular graft. Transplant recipients, patients with cancer, and those with chronic kidney disease are also at risk of developing chronic Q fever, as many as 65% of persons with chronic Q fever may die of the disease.

The incubation period for Q fever varies depending on the number of organisms that initially infect the patient. Infection with greater numbers of organisms will result in shorter incubation periods. Most patients become ill within 2-3 weeks after exposure. Those who recover fully from infection may possess lifelong immunity against re-infection.

### (c) Infectious dose

Infection of humans usually occurs by inhalation of the organisms from air that contains airborne barnyard dust contaminated by dried placental material, birth fluids, and excreta of infected herd animals (aerosols). Humans are often very susceptible to the disease, and very few organisms (as little as 10) may be required to cause infection.

Ingestion of contaminated raw milk or raw milk products has been suggested as a route of transmission, however no hard evidence is available and no information on the number of organisms required for infection is available.

### (d) Epidemiology

Cattle, sheep, and goats are the primary reservoirs of *C. burnetii*. Infection has been noted in a wide variety of other animals, including other species of livestock and in domesticated pets. *C. burnetii* does not usually cause clinical disease in these animals, although when it does infection may result in abortion in goats and sheep.

Organisms are excreted in milk, urine, and faeces of infected animals. Large amounts of *C. burnetii* may be shed in the milk of cows and to a lesser extent sheep, although it is likely that ingestion of contaminated milk is a minor route for human infection (Maurin and Raoult, 1999). Most importantly, during birthing the organisms are present in high numbers within the amniotic fluids and the placenta. *C. burnetii* can survive for long periods in the environment and is resistant to heat, drying, and many common disinfectants.

Q fever is fairly common in France, especially in the south, with the incidence rate estimated at 50 cases per 100,000 inhabitants per year (Maurin and Raoult, 1999). The incidence rate in Australia was estimated at between 3.11 and 4.99 cases per 100,000 inhabitants per year between 1991 and 1994 (Maurin and Raoult, 1999). Hospital morbidity data (Australian Institute of Health and Welfare; www.aihw.gov.au) for 2001-2002 indicate a case rate of 1.3 cases per 100,000. No information on the current incidence rate in France was available.

Seroprevalence surveys of sheep in France found on average 5% of animals have antibodies for *C. burnetii* (Rousset *et al*., 2001). *C. burnetii* has been recovered from 50% of milk samples collected from infected ewes in France (Berri *et al*., 2000). Clinical cases of disease have increased in France from 1 in 1982 to 107 in 1990 (Tissot-Dupont, 1992), with the majority of cases presenting with hepatitis (61.9%). Development of hepatitis has been linked with intraperitoneal exposure to *C. burnetii i.e.* oral exposure, rather than exposure to contaminated aerosols. The significance of this is not clear, although consumption of raw milk and raw milk cheeses were identified as possible risk factors (Tissot-Dupont, 1992). The French authorities maintain that infection with *C. burnetii* is primarily through contaminated aerosols.

### (e) Effect of Cheese making

*C. burnetii* is not considered in food safety programs for Roquefort cheese except that milk from diseased animals cannot be use in the manufacture of Roquefort cheese. Animals infected with *C. burnetii* may not show overt signs of clinical infection.

Nevertheless, *C. burnetii* is likely to be of low risk, as it is reported not to survive the Roquefort cheese manufacturing process (Anon, 1998). Other raw milk products in France may be more important sources of disease.

***Brucella melitensis***

**(a) Organism**

*B. melitensis* is an extremely small gram negative coccobacilli. It is a facultatively anaerobic intracellular pathogen.

**(b) Disease**

Brucellosis in humans is characterised by fever and prolonged illness resulting in loss of vitality and ability to work. The economic cost of hospitalisation and lost earnings globally is substantial. The severity of the symptoms varies with species with infection by *B. melitensis* the most severe. The incubation period is generally long (1-2 months), after which the onset of illness may be acute or slow. The symptoms can last for days to months and can be debilitating, although the case fatality rate is very low (except in cases of *B. melitensis* endocarditis). Chronic sequelae have been reported including sacroiliitis, hepatic disease, endocarditis, colitis and meningitis.

**(c) Infectious dose**

Little is known about the number of cells required to cause infection, it is however thought to be low.

**(d) Epidemiology**

Australia is free of *B. abortus* in cattle due to eradication programs and *B. melitensis* does not occur in Australian sheep. Little is known about the prevalence in Australian goats although no cases have been reported in humans. *B. suis* has been isolated from wild pig populations but is an uncommon form of human disease although possible cases have been noted.

As well as causing human disease, brucellosis in livestock causes heavy economic losses from abortions, sterility, decreased milk production, veterinary attendance and the cost of culling infected animals. However, the impact of the disease in small ruminants is greater in terms of the adverse effects it may have on human health and the traditional products produced from sheep and goat milk.

Transmission in generally via the consumption of raw milk or raw milk cheeses. When milk is pasteurised before consumption or processing, transmission due to consumption is rare. Infection in these cases is due to contact with placental tissues or vaginal secretions from infected animals.

*B. melitensis* is usually found in France with other species less common (Leclerc *et al.*, 2002). Infections in the human population are seasonal with the majority of cases located in the south of France, with cheese frequently implicated in cases of disease (Leclerc *et al.*, 2002). France was not officially *B. melitensis* free (ObmF) in 2002 (Godfroid and Kasbohrer, 2002), although 70% of holdings were listed as ObmF.

The majority of non-ObmF holding were located in the south of France where the incidence of disease was also greatest. An annual monitoring program is carried out to monitor the status of *B. melitensis* in France (Godfroid and Kasbohrer, 2002). The significance of the geographical distribution of *B. melitensis* in relation to the manufacture of Roquefort cheese is not clear. The French government, in their submission to FSANZ, specify that milk from brucellosis positive herds is not used for manufacturing Roquefort cheese.

FOOD SCIENCE AUSTRALIA
A JOINT VENTURE OF CSIRO AND THE VICTORIAN GOVERNMENT

Australian Food Safety Centre of Excellence
Food Safety: the essential ingredient

Ref: 108297

# Qualitative Risk Assessment of Raw Milk Roquefort Cheese

# Final Report

**Mr Paul Vanderlinde**
Food Science Australia
Tel: (07) 3214 2038
Fax: (07) 3214 2002
E-mail: Paul.Vanderlinde@csiro.au

An Australian Food Safety Centre of Excellence Initiative

Prepared for:
**Food Standards Australia New Zealand**
October, 2004

## Qualitative Risk Assessment of Raw Milk Roquefort Cheese

The purpose of conducting a risk assessment is to provide appropriate scientific information on risks. In some cases where data are limited a risk assessment may not be needed or may not be possible, and a less extensive evaluation (e.g. limited to an exposure assessment or a hazard characterisation) may be more appropriate. When considered appropriate a risk assessment provides an objective assessment of relevant scientific knowledge to aid risk manager in making informed decision. In order to conduct a risk assessment the purpose and scope must be clearly defined and throughout the assessment there should be good communication between risk managers, risk assessors, and other relevant parties e.g. industry and consumers.

The outcome of a risk assessment is an estimation of risk but more importantly a risk assessment defines the events leading to consumption. This allows risk managers to evaluate different stages in the farm-to-fork continuum for their effect on the final risk. Using this information risk managers can see where appropriate interventions can be applied to ensure an appropriate level of consumer protection.

### *Introduction*

Importation of raw milk cheeses into Australia has been the subject of considerable interest for a number of years. The position adopted by risk managers has been based on equivalence i.e. the safety of these products should be the same as for cheeses manufactured from pasteurised milk. In practice however, risk management discussions have been based on the concept of ensuring an appropriate level of protection (ALOP) for the Australian consumer.

Most of the hazards found in raw milk cannot be completely eliminated by the cheese making process, therefore raw milk cheeses, in most cases, will potentially pose more of a risk to consumers than cheeses manufactured from pasteurised milk. What needs to be considered however is if the risk is acceptable? The risk from post-pasteurisation contamination, particularly by pathogen such as *Listeria monocytogenes*, will similar for both pasteurised and raw milk cheeses.

The following paper identifies some of the important microbiological hazards found in raw milk and looks at the fate of those hazards during the manufacture of Roquefort cheese. A qualitative risk assessment of the microbiological hazards is undertaken and the hazards posing the greatest risk discussed in terms of controls in place to mitigate them. The impact of the importation of raw milk cheeses on animal health is not considered. The approach taken follows the Codex guidelines for the conduct of microbiological risk assessment i.e. Hazard Identification, Hazard Characterisation, Exposure Assessment and Risk Characterisation.

### *Roquefort cheese*

Roquefort cheese is a semi-hard blue-vein variety manufactured in the south of France from sheep milk. The name Roquefort is restricted by designation of origin and can only be given to cheese made from unpasteurised and curdled ewe's milk; it must be cylindrical in shape and measure 18 to 20 cm across and from 8.5 to 11.5 cm high; weigh from 2.5 to 3 kg; be a veined paste; sprinkled with spores of *Roqueforti Penicillium*; be neither pressed or pasteurised; be fermented and salted, with a moist crust; ripened for at least 90 days, and contain at least 52% fat after total desiccation and at least 55% dry matter.

***Hazard identification***

All microbiological pathogens associated with dairy animals, human handlers, equipment and the environment may be accidental contaminants of milk. Pathogens typically associated with raw milk include *Coxiella burnetii, Brucella* spp. (*B. melitensis* for goat and sheep milk), *Salmonella* spp., *Yersinia enterocolitica, Campylobacter jejuni*. *Listeria monocytogenes,* enterotoxigenic *Staphylococcus aureus* and pathogenic *Escherichia coli* (ICMSF, 1998).

Animals with mastitis may shed high numbers of bacteria into their milk at the time of collection. *S. aureus, Streptococcus agalactiae, Strep. dysgalactiae, Strep. uberis, E. coli* and *Actinomyces pyogenes* are the organisms most commonly associated with mastitis (ICMSF, 1998). *L. monocytogenes* and *Salmonella* have also been implicated. Animals that are sick may also shed other organisms in their milk, including, *Mycobacterium* spp., *Brucella* spp., *L. monocytogenes, Salmonella* or *C. burnetii.* Excretion of pathogens into milk is not the only source of bacterial contamination. Direct faecal contamination of the milk at the time of collection can lead to contamination by a range of organisms i.e. *Salmonella, C. jejuni,* pathogenic *E. coli* and *Y. enterocolitica.* Such indirect contamination at low levels is very difficult to eliminate and these organisms are occasional contaminants of raw milk.

There has been some concern over the transfer of viruses via milk, however there are no viral zoonosis that are of concern and therefore viruses are not considered in this hazard analysis.

Raw milk may also contain mycotoxins, in particular aflatoxin $M_1$. The presence of toxin is the result of metabolic hydroxylation of aflatoxin $B_1$. The issues in relation to viral particles and mycotoxins are not covered in this report.

For the purposes of this report the following agents have been identified as the principal hazards of concern.

- *Campylobacter jejuni/coli*
- Enterotoxigenic *Staphylococcus aureus*
- *Listeria monocytogenes*
- pathogenic *Escherichia coli* (EHEC)
- *Salmonella*
- *Brucella melitensis*
- *Coxiella burnetii.*

***Hazard Characterisation***

Each of the hazards identified previously as being of concern will be characterised in the following section under the headings organism, disease, infective dose and epidemiology. It is recognised that the term infective dose is no longer fashionable and that modern theory is centred on ‘single hit’ or non-threshold models for dose response (Buchanan et al, 2000 ) i.e. a single cell has the capability of causing disease. Nevertheless it is still recognised that some hazards need to be present in larger numbers than others for there to be a significant likelihood of disease.

***Campylobacter jejuni/coli***

**Organism:** *Campylobacter jejuni* and *C. coli* are the most common *Campylobacter* spp. associated with human diarrhoeal disease. The clinical disease of both is indistinguishable and most laboratories do not differentiate between the species so that the ratio of illness due to each species is not clear.

In the USA it is estimated that 1-3% human cases are due to *C. coli* (Oberhelman and Taylor, 2000) and in a study in Denmark 6% of campylobacteriosis cases over 12 months were caused by *C. coli* (Nielsen et al, 1997). Due to the predominance in human infection of *C. jejuni*, most information in foods relates to this species.

*C. jejuni* is a Gram-negative curved and highly motile rod. It is a micro-aerophilic organism (only grows at reduced oxygen levels) growing best in atmospheres comprising 5% $O_2$ and 10% $CO_2$. It appears to be very fragile, and is sensitive to environmental stresses (e.g. aerobic atmospheres, drying, heating, disinfectants, acidic conditions etc). There is some debate over the sensitivity of the bacteria to stress, with some researchers believing that the organism enters a viable (infectious) but non-culturable state. *Campylobacter* is the leading cause of bacterial diarrhoeal disease in most Western countries.

**Disease:** Infection with *C. jejuni* usually results in watery diarrhoea, which may contain blood. Other symptoms can include fever, abdominal pain, nausea, headaches and muscle pain. The illness is generally self-limiting with onset of symptoms 2-5 days after ingestion of the contaminated food or water. Illness generally lasts 7-10 days, but relapses can occur in up to 25% of cases. Long term sequelae have been reported i.e. Guillan-Barré syndrome.

**Infectious dose:** The infective dose of *C. jejuni* is considered to be small. Human feeding studies suggest that around 500 cells in milk may be sufficient cause illness in some individuals, while in others greater numbers are required (Anon, 2003; Black et al, 1983; ICMSF, 1996a). Volunteer human feeding studies suggest that host susceptibility plays an important role in determining the likelihood of disease. The mode of pathogenicity of *C. jejuni* is not completely understood, but it does produce a heat-labile toxin that may cause diarrhoea.

**Epidemiology:** Birds and animals are the main reservoir of *C. jejuni/coli* and they are found in the intestinal tract of a wide range of healthy domesticated animals. *C. jejuni* is found in cattle and sheep, while *C. coli* is more often found in pigs and birds and is less likely to be a contaminant of sheep or cow's milk than *C. jejuni*. The organisms are found in the faeces of these animals and in cattle they can cause low-grade or subclinical mastitis although infrequently. The role of *C. jejuni* in sheep mastitis is unknown.

Milk may be contaminated from faecal material or *Campylobacter* may be shed in the milk itself, as is the case when the animal has clinical or subclinical mastitis due to *Campylobacter* infection. Campylobacters have been isolated from 1-6% raw milk samples (Wallace, 2003). Raw or inadequately pasteurised milk is the most frequently identified vehicle of foodborne human infection with *C. jejuni* (ICMSF, 1996a). No record was found linking campylobacteriosis to the consumption of cheese. No information is available as to the role of cheese in the epidemiology of campylobacteriosis.

In an investigation of foodborne disease outbreaks in France, Buyser et al (2001) did not consider *Campylobacter* suggesting that there is little evidence of an association between raw milk products and campylobacteriosis or a lack of information.

**Pathogenic *Escherichia coli***

**Organism:** Pathogenic *E. coli* associated with foodborne disease are grouped into specific pathotypes based mainly on their virulence characteristics, mechanisms of pathogenicity and clinical syndromes: enteropathogenic (EPEC), enterotoxigenic (ETEC), enteroinvasive (EIEC), diffuse-adhering (DAEC), enteroaggregative (EAEC) and enterohaemorrhagic (EHEC) (Desmarchelier and Fegan, 2003).

The epidemiology is not clear for all of these pathotypes. Human carriers are believed to be a principal reservoir and source of EPEC, EIEC and ETEC strains involved in human illness. The intestinal tract of ruminants including cattle and sheep is an important reservoir of EHEC. Most pathogenic *E. coli* are not readily distinguishable from generic strains using traditional culture techniques. They need to be differentiated based on the presence of known virulence markers or to a limited extent by serotyping. *E. coli* are gram-negative rods motile by flagella, or non-motile, and facultatively anaerobic. The EHEC strain O157:H7 can be differentiated from other *E. coli* by its inability to ferment sorbitol and by the presence of specific virulence markers. *E. coli* can grow at temperatures from 7-45 $^{0}$C, although growth at 7 $^{0}$C is very slow.

**Disease:** Of the pathotypes of *E. coli*, the EHEC have become the most important foodborne type, in particular those belonging to the serotype O157:H7. This is mainly due to the severity of the disease and the high mortality rate in young children. EHEC infection may be asymptomatic or associated with a range of symptoms including mild diarrhoea, severe haemolytic colitis (HC), haemolytic uraemic syndrome (HUS) and death (Meng et al, 2001). Only a proportion of those infected may develop HUS (2-7%) and for these patients the mortality rate is between 5-10%. The most sever clinical symptoms are normally seen in children and the elderly. Other pathogenic *E. coli* i.e. Shiga toxigenic *E. coli* (STEC) has been associated with disease from consumption of contaminated food.

**Infectious dose:** The infective dose of most pathogenic *E. coli* is not clearly defined. However, the dose of EHEC required to cause human illness is considered to be very low with fewer than 50 cells believed to be sufficient to cause disease (Mead and Griffin, 1998). The infective dose of EHEC is believed to be similar to *Shigella* spp. and dose response models have been developed that are based on feeding trials undertaken with *Shigella dysenteriae*.

**Epidemiology:** There is insufficient data of each pathotypes' behaviour in foods and data for non-pathogenic strains are used unless a pathotype is known to behave differently. EHEC in particular are distinguished from the other *E. coli* pathotypes, as some EHEC strains are able to tolerate mildly acidic conditions in foods.

Pathogenic *E. coli* have been the cause of foodborne illness where cheeses have been implicated as the source of infection. These have included EIEC isolated from Brie and Camembert, ETEC associated with consumption of Brie and EHEC implicated directly or indirectly with consumption of a variety of cheeses including semi-soft cheese, cheese curds, goat cheese and Lancashire cheese (a semi-hard cheese) (MacDonald, 1985; Deschenes et al., 1996; Desenclos et al., 1996; Desmarchelier and Grau, 1997).

The source of the pathogens may have been the raw milk used in the cheese manufacture (EHEC), food handlers (EIEC, ETEC, EHEC) or water used in the manufacturing process (EIEC).

Shiga toxin-producing *E. coli* (STEC) of which EHEC is a sub-group are found in the faeces of healthy cattle, sheep and goats (Reviewed in Desmarchelier and Fegan, 2003). Milk can become contaminated at collection or from the milking parlour environment and O157 EHEC have been isolated from raw cow's milk on farm and from bulk raw milk tankers (summarised in Meng et al, 2001; Desmarchelier and Fegan, 2003). The number of bacteria present in raw milk is expected to be very low, particularly with the co-mingling of milk in bulk containers. EHEC infection has been reported following the consumption of raw cow's milk or milk contaminated post-pasteurisation (summarised in Meng et al, 2001; Desmarchelier and Grau, 1997).

***Salmonella***

**Organism:** *Salmonella* is a Gram-negative rod-shaped, motile bacterium (notable exceptions *S.* Gallinarum and *S.* Pullorum), non-sporeforming and facultatively anaerobic. *Salmonella* will grow on food at temperatures from 7-45 $^0$C. Although growth has been reported at temperatures below 7 $^0$C this is generally accepted as the lower limit of growth on foods. Salmonellae are generally recognised by serovar (serotype) names. Some serovars are host adapted e.g. *S.* Typhi is host specific for humans and does not infect other species. The most commonly isolated *Salmonella* are of subspecies I (*S. enterica* subsp. *enterica*).

**Disease:** Acute symptoms of infection can include nausea, vomiting, abdominal cramps, minimal diarrhoea, fever, and headache. Chronic sequelae have been identified and include arthritic symptoms which may follow 3-4 weeks after onset of acute symptoms. Onset of disease may occur 6 to 48 hours after consumption of contaminated foods. Acute symptoms may last for 1 to 2 days or may be prolonged, depending on host factors, ingested dose, and strain characteristics.

**Infectious dose:** Serovars vary in their pathogenicity. Some serovars can cause disease in animals or appear asymptomatic. Some serovars commonly found in animals and animal products are rarely associated with human disease i.e. *S.* Sofia. Because of this the infective dose cannot easily be determined. For some serovars as few as 15-20 cells can cause disease, depending on the immunostatus of the consumer and the food matrix. Using human volunteers for infectious dose studies it has been found that $10^7$ salmonellae were required to have a significant likelihood of causing disease (ICMSF, 1996b). Outbreaks involving water, which has a minimal retention time in the stomach, and fatty or buffered foods, which protect organisms from the action of stomach acids, have been shown to result from ingestion of far fewer numbers of salmonellae (ICMSF, 1996b). Cheese implicated in salmonellosis outbreaks has been found to contain low numbers, 0.36-9.3 cells/100 grams (D'Aoust et al, 1985) and 0.36-4.3 cells/100 grams (Hedberg et al, 1992).

**Epidemiology:** Salmonellae can be found in the intestinal tract of most warm and cold blooded animals. In cattle and sheep the bacterium are carried by both healthy and diseased animals and are transmitted in the faeces and hence can contaminate raw milk. Food handlers may also excrete the organisms during infection and convalescence and a small percentage become carriers. *Salmonella* has been isolated frequently from raw milk (Johnson et al, 1990). In the US, 4.7% of milk in 678 tankers was positive.

In a study of raw milk in bulk tanks in the UK in 1995, 0.36% of the tanks sampled were contaminated (O'Donnell, 1995). Both milk and milk products such as cheddar cheeses and Vacherin cheese have been implicated in outbreaks of salmonellosis (Johnson et al, 1990). The source of contamination is primarily the raw milk contaminated via the udder and teats and maybe via systemic infection and workers. Milk can also be contaminated post-pasteurisation. Product may be further contaminated via the factory environment and food handlers during processing.

***Staphylococcus aureus***

**Organism:** *Staphylococcus aureus* is a spherical bacterium (coccus) which on microscopic examination appears in pairs, short chains, or bunched, grape-like clusters. These organisms are Gram-positive. Some strains are capable of producing a highly heat-stable protein toxin that causes illness in humans. High numbers of staphylococci ($>10^5$ CFU/mL) are required for the production of sufficient heat stable enterotoxins to cause disease. The staphylococcal enterotoxins are thermally stable and if toxin is present in the raw milk active toxin will remain after normal thermal processing (ICMSF, 1996c). *S. aureus* can grow over a temperature range of 7-48$^0$C although significant enterotoxin production occurs over a more restricted range. Enterotoxin production occurs between 10-48$^0$C with optimum production occurring at 35-40$^0$C and at a pH of 6.0-7.0. Production is also influenced by the salt concentration. Raw milk that is not cooled rapidly or stored correctly will support growth and possible toxin production. At 10ºC there is a long lag time (>20h) and when growth commences it is very slow (ICMSF, 1996c). *S. aureus* will grow over a wider range of $a_w$ values than other foodborne pathogens e.g. 0.83-0.99, however the rate of growth is significantly slowed at values less than 0.94.

**Disease:** Disease is caused by the ingestion of toxin and not by the ingestion of *S. aureus* itself. The onset of symptoms in staphylococcal food poisoning is usually rapid and in many cases acute, depending on individual susceptibility to the toxin, the amount of contaminated food eaten, the amount of toxin in the food ingested, and the general health of the victim. The most common symptoms are nausea, vomiting, retching, abdominal cramping, and prostration. Some individuals may not always demonstrate all the symptoms associated with the illness. In more severe cases, headache, muscle cramping, and transient changes in blood pressure and pulse rate may occur. Recovery generally takes two days, however, it us not unusual for complete recovery to take three days and sometimes longer in severe cases.

**Infectious dose:** A toxin dose of less than 1.0 microgram in contaminated food will produce symptoms of staphylococcal intoxication (Anon, 2003). This toxin level is reached when *S. aureus* populations exceed 100,000 per gram.

**Epidemiology:** *S. aureus* occurs in the mucous membranes and skin of most healthy warm-blooded animals, including man and food animals (ICMSF, 1996c). In food animals the organism may be shed into milk in subclinical cases of mastitis at levels up to $10^5$ CFU/mL. The bacterium is also a common cause of wound and skin infections in personnel including food handlers and farm workers. Milk usually becomes infected via the animal host or food handlers during processing. Outbreaks of staphylococcal intoxication have been attributed to dairy products including cheeses such as Swiss style cheeses (e.g. Emmental, Gruyere and Swiss), raw milk cheddar, Colby and cheese curd (Johnson et al, 1990). These outbreaks have resulted from poor process control, contamination from infected factory workers, contaminated starter cultures and use of contaminated water.

Enterotoxin production can occur in the raw milk before processing or during cheese production. Enterotoxins have been shown to persist in cheese for several years (IDF, 1980). *S. aureus* was by far the most frequent pathogen associated with outbreaks from milk and milk products in France (85.5%) (Buyser et al, 2001).

***Listeria monocytogenes***

**Organism:** *Listeria monocytogenes* is a Gram-positive motile bacterium that does not produce spores and can grow at refrigeration temperatures (down to 0 $^0$C). It has been isolated from numerous species including humans. It can be found in soil, silage, and other environmental samples. *L. monocytogenes* is resistant to freezing and drying, and is more heat resistant than other Gram negative foodborne pathogens ($D_{65}$=100sec). *Listeria* is capable of growing on foods under refrigerated storage and has similar growth requirements to lactic acid bacteria. Growth can occur at 0 $^0$C in foods of neutral pH, although the growth rate is slow (62-131 h; ICMSF, 1996d). Because of its slow growth rate at refrigeration temperatures (compared to *Pseudomonas* spp.), *Listeria* is not a concern on fresh aerobically stored meat. *Listeria* is tolerant of $a_W$ and pH conditions found in most processed foods that require chilled storage, and can grow in these foods. *Listeria* cannot generally grow under conditions that render a product shelf stable i.e. pH<5.0 or $a_W$ <0.9. Chilled foods that are of concern are those in which *Listeria* can grow and that have an extended shelf-life i.e. soft cheeses, processed meats, pâté.

**Disease:** Listeriosis is clinically defined when the organism is isolated from blood, cerebrospinal fluid, or an otherwise normally sterile site (e.g. placenta, fetus). The manifestations of listeriosis include septicaemia, meningitis, encephalitis, and intrauterine or cervical infections in pregnant women, which may result in spontaneous abortion (2nd/3rd trimester) or stillbirth. Although some cases occur in individuals without any predisposing condition, most *L. monocytogenes* infections occur in people with suppressed immune systems i.e. the aged, pregnant women and their foetuses, cancer patients, AIDS sufferers etc. The onset of more severe symptoms is usually preceded by flu-like symptoms including persistent fever. Recently less severe symptoms such as nausea, vomiting, and diarrhoea have been reported. Such gastrointestinal symptoms have been epidemiologically associated with use of antacids, although the significance of this is unclear. The onset of severe disease is variable and can range from a few days to several weeks. The onset time to gastrointestinal symptoms is probably greater than 12 hours.

**Infectious dose:** While there is a generally lack of consensus on the number of cells required to give a significant probability of infection it is thought to be relatively high i.e. >10,000 cells. The pathogenicity of *Listeria* is believed to vary with the strain. Serotypes 4b and to a lesser extent 1/2a and 1/2b account for most cases of disease worldwide. Some studies have shown that the risk of disease from foods contaminated occasionally with <100 cells per g is low, even in susceptible populations (Buchanan et al, 1997). The probability of infection is determined by a number of factors i.e. the number of cells consumed, host specific factors, the type of food and the pathogenicity of the strain.

**Epidemiology:** *L. monocytogenes* has been associated with foods such as raw milk, supposedly pasteurised fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish. Its ability to grow at temperatures as low as 0 $^0$C in some foods permits multiplication under refrigeration conditions.

*L. monocytogenes* is carried by milk producing animals and can cause disease in these hosts. It is also ubiquitous in the environment of food production facilities. *L. monocytogenes* has been linked to numerous foods associated with outbreaks including coleslaw, pate, frankfurters, jellied pork tongue and raw milk and cheese (ICMSF, 1996d). *Listeria* is frequently detected in raw milk and is able to grow in properly chilled milk. Because *Listeria* is commonly found in the processing environment it is a hazard for all cheese manufacturing processes, not just those utilising unpasteurised milk, as a post-processing contaminant. Generally foods that allow growth of *Listeria* during storage are of greater risk.

***Brucella melitensis***

**Organism:** *B. melitensis* is an extremely small gram negative coccobacilli. It is a facultatively anaerobic intracellular pathogen.

**Disease:** In humans the disease is characterised by fever and prolonged illness resulting in loss of vitality and ability to work. The economic cost of hospitalisation and lost earnings globally is substantial. The severity of the symptoms varies with species with infection by *B. melitensis* the most severe. The incubation period is generally long (1 to 2 months), after which the onset of illness may be acute or slow. The symptoms can last for days to months and can be debilitating, although the case fatality rate is very low (except in cases of *B. melitensis* endocarditis). Chronic sequelae have been reported including sacroiliitis, hepatic disease, endocarditis, colitis and meningitis.

**Infectious dose:** Little is known about the number of cells required to cause infection, it is however thought to be low.

**Epidemiology:** Australia is free of *B. abortus* in cattle due to eradication programs and *B. melitensis* does not occur in Australian sheep. Little is known about the prevalence in Australian goats although no cases have been reported in humans. *B. suis* has been isolated from wild pig populations but is an uncommon form of human disease although possible cases have been noted.

As well as causing human disease, brucellosis in livestock causes heavy economic losses from abortions, sterility, decreased milk production, veterinary attendance and the cost of culling infected animals. However, the impact of the disease in small ruminants is greater in terms of the adverse effects it may have on human health and the traditional products produced from sheep and goat milk. Transmission in generally via the consumption of raw milk or raw milk cheeses, when milk is pasteurised before consumption or processing transmission due to consumption is rare. Infection in these cases is due to contact with placental tissues or vaginal secretions from infected animals.

*B. melitensis* is usually found in France with other species less common (Leclerc et al, 2002). Infections in the human population are seasonal with the majority of cases located in the south of France, with cheese frequently implicated in cases of disease (Leclerc et al, 2002). France was not officially *B. melitensis* free (ObmF) in 2002 (Godfordand and Kasbohrer, 2002), although 70% of holdings were listed as ObmF. The majority of non-ObmF holding were located in the south of France where the incidence of disease was also greatest. An annual monitoring program is carried out to monitor the status of *B. melitensis* in France (Godfroid and Kasbohrer, 2002). The significance of the geographical distribution of *B. melitensis* in relation to the manufacture of Roquefort cheese is not clear.

The French government, in their submission to FSANZ, specify that milk from brucellosis positive herds is not used for manufacturing Roquefort cheese.

***Coxiella burnetii* (Q-fever)**

**Organism:** Q fever is a zoonotic disease caused by *Coxiella burnetii,* a species of rickettsiae that is distributed globally. Because the disease is rare and possibly underreported, scientists cannot reliably assess how many cases of Q fever actually occur worldwide. Many human infections are sub-clinical. *C. burnetii* is a Gram-negative like (will not stain) coccobacillus than is an obligate intracellular microorganism (will not grow in foods or outside host cells). *C. burnetii* is able to form spore like structures which may explain its long survival in soils and the environment (Marrie, 2003).

**Disease:** Only about half of all people infected with *C. burnetii* show signs of clinical illness. Most acute cases of Q fever begin with the sudden onset of one or more of the following: high fever, severe headache, general malaise, myalgia, confusion, sore throat, chills, sweats, non-productive cough, nausea, vomiting, diarrhoea, abdominal pain, and chest pain. Fever usually lasts for 1 to 2 weeks. Weight loss can occur and persist for some time. Thirty to fifty percent of patients with symptomatic infection will develop pneumonia. Additionally, a majority of patients have abnormal results on liver function tests and some will develop hepatitis. In general, most patients will recover to good health within several months without any treatment. The mortality rate in patients with acute Q fever is 1 to 2%.

Chronic Q fever, characterized by infection that persists for more than 6 months is uncommon but is a much more serious disease. Patients who have had acute Q fever may develop the chronic form as soon as 1 year or as long as 20 years after initial infection. A serious complication of chronic Q fever is endocarditis, generally involving the aortic heart valves, less commonly the mitral valve. Most patients who develop chronic Q fever have pre-existing valvular heart disease or have a history of vascular graft. Transplant recipients, patients with cancer, and those with chronic kidney disease are also at risk of developing chronic Q fever, as many as 65% of persons with chronic Q fever may die of the disease.

The incubation period for Q fever varies depending on the number of organisms that initially infect the patient. Infection with greater numbers of organisms will result in shorter incubation periods. Most patients become ill within 2-3 weeks after exposure. Those who recover fully from infection may possess lifelong immunity against re-infection.

**Infectious dose:** Infection of humans usually occurs by inhalation of the organisms from air that contains airborne barnyard dust contaminated by dried placental material, birth fluids, and excreta of infected herd animals. Humans are often very susceptible to the disease, and very few organisms (as little as 10) may be required to cause infection. Ingestion of contaminated raw milk or raw milk products has been suggested as a route of transmission, however no hard evidence is available and no information on the number of organisms required for infection is available.

**Epidemiology:** Cattle, sheep, and goats are the primary reservoirs of *C. burnetii*. Infection has been noted in a wide variety of other animals, including other species of livestock and in domesticated pets. *C. burnetii* does not usually cause clinical disease in these animals, although when it does infection may result in abortion in goats and sheep. Organisms are excreted in milk, urine, and faeces of infected animals.

Large amounts of *C. burnetii* may be shed in the milk of cows and to a lesser extent sheep, although it is likely that ingestion of contaminated milk is a minor route for human infection (Maurin and Raoult, 1999). Most importantly, during birthing the organisms are present in high numbers within the amniotic fluids and the placenta. *C. burnetii* can survive for long periods in the environment and is resistant to heat, drying, and many common disinfectants.

Q fever is fairly common in France, especially in the south, with the incidence rate estimated at 50 cases per 100,000 inhabitants per year (Maurin and Raoult, 1999). The incidence rate in Australia was estimated at between 3.11 and 4.99 cases per 100,000 inhabitants per year between 1991 and 1994 (Maurin and Raoult, 1999). Hospital morbidity data (Australian Institute of Health and Welfare; www.aihw.gov.au) for 2001-2002 indicate a case rate of 1.3 cases per 100,000. No information on the current incidence rate in France was available.

**Qualitative Risk Assessment**

The issue of how to do a qualitative risk assessment is really unresolved. No detailed framework for qualitative risk assessment has been published anywhere in the world. A number of organisations, including Codex and FSANZ, have guidelines for the conduct of microbiological risk assessments but they do not provide actual tools that can be used to assess risk. The FAO/WHO has commenced work in this area but a framework is not yet available.

Without an accepted tool to qualitatively assess the risk of foodborne hazards we are left with two options, use a semi-quantitative tool, such as that proposed by Ross and Sumner (2002), or develop a qualitative framework ourselves. The later offers flexibility the former recognition and greater acceptance in the scientific community. For the purposes of this qualitative risk assessment both approaches were used. The model of Ross and Sumner (2002) was applied to the data we have for the hazards under consideration and their fate during the manufacture of Roquefort cheese. The output of the assessment was categorised to remove any confusion as to the qualitative nature of the assessment. A second purely qualitative framework was developed based on the Codex principles for conducting microbiological risk assessments. The following sections detail the work undertaken and highlight the results, comparing the outputs from the two approaches.

*Background*

Attempts have been made to estimate the risk of some of the disease agents mentioned in the previous sections. At a meeting to discuss milk-borne zoonoses in the Mediterranean region, delegates categorised the risk posed by a number of zoonotic disease agents (Anon, 1998). Table 1 shows some of the hazards considered at this meeting and the risk categories put forward for both the general population and at-risk individuals. An indication of possible sequelae and the effect of pasteurisation are also given.

**Table 1: Risk rating for infection to humans of some pathogenic agents found in milk and milk products (Anon, 1998).**

| Organism | Risk for | | Sequelae * | Effect of Pasteurisation |
|---|---|---|---|---|
| | Healthy | At-risk | | |
| *Brucella melitensis, B. abortus* | Mild | Severe | + | + |
| *Mycobacterium tuberculosis, M. bovis* | Severe | Frequently lethal | | + |
| *Campylobacter jejuni* | Mild | Moderate | + | + |
| *Coxiella burnetii* | Severe | Severe | | + |
| *Escherichia coli* (EHEC) | Mild | Frequently lethal | + | + |
| *Listeria monocytogenes* | Mild | Frequently lethal | | + |

EHEC=Enterohaemorrhagic *E. coli*.

* It is not clear what blanks mean in the context of sequelae. It is assumed that no sequelae are known to occur.

Clearly the risk from these agents is greatly increased in immunocompromised individuals. The significance of this in the case of Roquefort cheese is not clear as there is no information specifically linking at-risk groups to the consumption of this product. It is unlikely that infants will be exposed to Roquefort cheese however the aged may be at greater risk as they may be a greater consumer of this type of product. Blue vein cheese appears in the new FSANZ *Listeria* pamphlet. Unlike the previous version in its current form the pamphlet targets all vulnerable (susceptible) populations and will hopefully reach non-pregnant as well as pregnant at risk consumers.

Another outcome from the Mediterranean workshop was an estimation of the survival of some of these agents in various types of cheese (Table 2 - taken directly from the report). Of particular interest are the results for semi-hard cheeses i.e. the classification in which Roquefort cheese is most likely to fall.

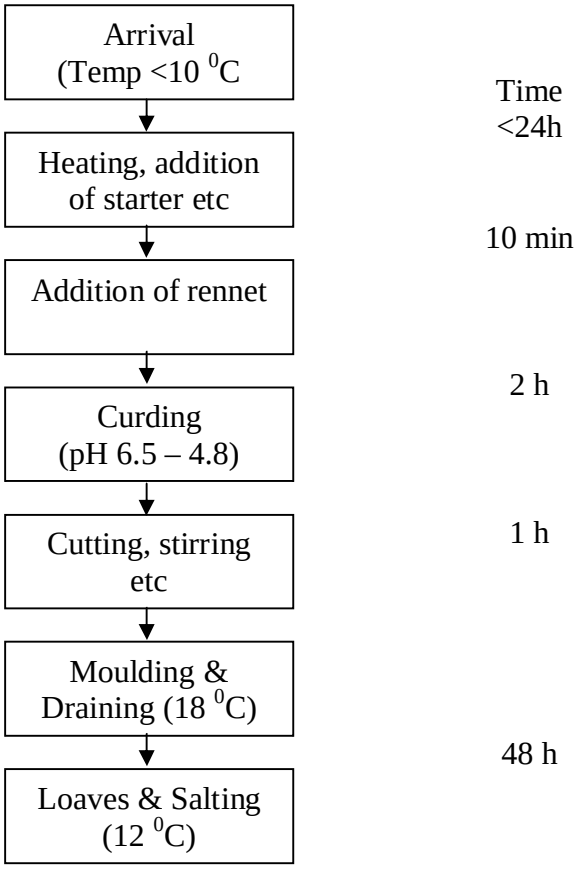
**Table 2: The duration of survival of agents listed in Table 1 in various categories of cheese (Anon, 1998).**

| | **≤14 d** | | | **≤60 d** | | **>60 d** |
|---|---|---|---|---|---|---|
| **Organism** | **fresh** | **soft acid** | **soft not acid** | **Semi-hard** | **hard** | **butter** |
| *Brucella melitensis, B. abortus* | S | S | S | N | N | |
| *M. tuberculosis, M. bovis* | S | S | S | S | S | S |
| *Campylobacter jejuni* | N | N | N | N | N | N |
| *Coxiella burnetii* | S | S | S | N | N | S |
| *Escherichia coli* (EHEC) | S | + | ++ | S | S | S |
| *Listeria monocytogenes* | + | + | ++ | (+) | N | N |

N=no survival or growth; S=survival; +/++=growth

The science behind the observations in Table 2 was not referenced in the report and no published data have been found. It is however encouraging that some of the hazards considered in the current risk assessment i.e. *C. jejuni*, *B. melitensis* and *C. burnetii* are reported not to survive the cheese making process. For the purposes of the risk assessment it is assumed, due to lack of any other available information, that these hazards are eliminated from the cheese during production and maturation.

The growth of survival of other hazards i.e. *Salmonella*, pathogenic *E. coli*, *L. monocytogenes* and *S. aureus* will be dependent on the conditions in the cheese during production and maturation. A schematic of the cheese making process is shown in Figure 2. No data on the




time frame for each production stage were provided. The overall time to complete all stages in Figure 2 is 10-days. Loaves are salted for 5-days at 10 $^0$C.

**Figure 2: Flow diagram for the manufacture of Roquefort cheese. Only stages up to maturation are shown.**

Rapid pH fall is the critical control point for restricting pathogen growth and toxin production in the cheese during the early stages of production. Initially conditions are ideal for bacterial growth and some growth of *Salmonella*, *E. coli*, *S. aureus* and *L. monocytogenes* would be expected. The warming of the milk to 30 $^0$C will increase the likelihood of growth as this is near the optimum temperature for growth of most enteric pathogens. The pH of the milk falls to below 5.5 in the first 6 h and to below 5 in the first 24h. This will be sufficient to restrict the growth of *Staphylococcus* and prevent the formation of enterotoxin. Most enteric pathogens (*Salmonella*, *E. coli* and *Listeria*) will grow poorly at 5.5 and should not grow at pH values less than 5. During the initial stages of processing it is not unusual for numbers of enteric pathogens to increase (10 to 100-fold), due some growth and concentration of cells in the curd as water is removed (whey).

After salting pathogen growth is unlikely and numbers generally decrease, with the rate of decrease being proportional to the final pH. *Listeria* may grow if the pH rises to values near pH 6; growth is more likely to occur near or on the surface of cheese. The longer bacteria are held under conditions not supporting their growth the greater will be the reduction in their numbers. Therefore cheeses with long maturation periods are generally safer then fresh cheeses (i.e. those with short or no maturation period).

Challenge studies undertaken by French processors of Roquefort cheese demonstrate that enteric pathogens and *Staphylococcus* numbers are reduced during processing (see Annex 27 in the original import assessment documents and more detailed documents provided by the French authorities). In these challenge studies *E. coli* O157 was inoculated into milk and enumerated during processing using CT-SMAC. This media is inhibitory and one might expect the number of cells recovered on the agar to be lower than the number that might have been recovered using a less inhibitory media. However, no *E. coli* O157 were detected using enrichment techniques at or after 70 days i.e. not detected in 100 g. Therefore the likely reduction in *E. coli* O157 might be in the order of 5-logs.

In a similar challenge study (documents supplied by FSANZ), *Staphylococcus aureus* numbers were reduced by more than 3-logs during the first 20 days of processing. There was an increase (~2-log) in *S. aureus* numbers during the early stages of production, before the pH had fallen to below 5. Interestingly the pH of the cheese rose during the later stages of maturation (175 days) to just above pH 6. Previously the French government had stated that the pH of Roquefort cheese did not rise during the later stages of maturation. The pH of cheese in all challenge studies was greater than 6 at the end of the trial. The general pattern was for *L. monocytogenes* numbers to decrease slowly during maturation. However, *L. monocytogenes* could survive in cheese for 175 days. There was a suggestion of a slight increase in numbers at day 175, in cheese inoculated with ~25 CFU/g of *L. monocytogenes.* This "increase" corresponded to a rise in pH. *L. monocytogenes* was not detected in cheese slices, packaged and stored for 3 months. If packaged slices are indicative of product exported to Australia then *L. monocytogenes* does not appear to grow and presents a low risk.

*Risk Ranger (Ross and Sumner, 2002)*

Risk Ranger was developed by Ross and Sumner (2002) as a tool for risk managers. The spreadsheet based model calculates the risk of a hazard in a food based on user inputs as to the severity of the hazard, the likely consumption, effects of processing etc. The output of the model is a rating from 1 to 100. Because of the lack of qualitative data on the hazards associated with Roquefort cheese, the output from Risk Ranger was categorised based on the predicted probability of illness and the risk categories put forward by Voysey (2001, see Appendix 1 for examples of the risk categories used). The probability of illness was calculated from Risk Ranger based on the number of cases in the Australian population. The number of consumers eating Roquefort cheese annually was estimated based on the following assumptions:

- 100 g consumed per person per eating event (no data are available on the amount of blue-cheese consumed per serving)
- 12 eating events per year (no data are available on the consumption rate of blue-cheese in Australia)
- 15 tonnes of product imported into Australia annually (based on previous import rate of Roquefort cheese)

The number of consumers in a year was estimated at 12,500 (15 tonnes ÷ 100g consumed ÷ 12 consumption events per year). The risk categories obtained are given in Table 3; a full description of the values entered into risk ranger to obtain these estimates is given in Appendix 2 and definitions for the various input variables i.e. severity of hazard are summarised in Appendix 3.

**Table 3: Risk ranking of hazards likely to be associated with Roquefort cheese manufactured from raw milk.**

| Hazard | General Risk rating |
|---|---|
| *Campylobacter jejuni* | Negligible |
| *Staphylococcus aureus* (enterotoxin) | Low |
| *Listeria monocytogenes* | Very Low |
| *Escherichia coli* (EHEC) | Very Low |
| *Salmonella* | Low |
| *Brucella melitensis* | Negligible |
| *Coxiella burnetii* | Negligible |

While risk ranger accounts for severity of disease in calculating a risk rating, the categories in Table 3 are based only on the number of cases of disease predicted. Obviously five cases of salmonellosis may, depending on the hosts underlying health, be less of a concern then five cases of infection by EHEC. The risk ranking for *Listeria* and EHEC was calculated based on an at-risk individual consuming a portion of Roquefort cheese, given that healthy people are not likely to become ill from consuming the number likely to be present in Roquefort at the time of consumption. The number of individuals in this category was estimated at 2,500 i.e. 20% of the consuming population of 12,500 (see Appendix 2 for more details).

There may be arguments for changing some of these ratings but at the present time this is the best that can be done with the data supplied from the French government and the literature. In general it has been assumed that the process of manufacturing Roquefort cheese results in a substantial or complete reduction of the hazards under consideration. Staphylococcal enterotoxin will not be affected by processing but growth of *Staphylococcus* is required for the production of sufficient toxin to cause disease. Maintaining the cold chain from farm to processing and monitoring the fermentation process will ensure that growth does not occur and hence toxin is not formed; also testing of end product for toxin will give additional assurance of product safety.

*Development of a Qualitative framework*

A model based on the Codex principles for microbiological risk assessment was developed as a tool to assist in the evaluation of the risk of microbiological hazards in Roquefort cheese. This framework considers three of the four components of risk assessment, hazard characterisation, exposure assessment and risk characterisation. Hazard characterisation categorises each hazard based on the level of exposure required to give a significant probability of disease and the severity of the disease. The exposure module characterises exposure to the hazard based on the likely level of the hazard in the raw product and the effect of processing. This assumes no change in the hazard over time in the product. The risk characterisation takes the two previous modules and combines them to give an overall categorisation of the hazard.

The terms within each of the modules were adapted from the work of Ross and Sumner (2002) (see Appendix 3); the frame work is shown in Figure 3. Basically the framework categorises the risk of each hazard by combining information about the hazard (severity and infective dose) with exposure information (prevalence in raw materials and effect of processing).

Table 4 lists the risk categories obtained, for each of the hazards under consideration, when the framework detailed in Figure 3 was applied to the manufacture of Roquefort cheese from raw sheep milk. Risk rankings, obtained using Risk Ranger, are given for comparison. A detailed example of how the risk category was assigned for EHEC is given in Appendix 4. Briefly, EHEC was judged to be a mild hazard (for normal consumers) with a reported minimum infective dose of <10, receiving a hazard characterisation rating of moderate for these consumers. Exposure to EHEC was rated as minimal based on a low prevalence (rare) in the raw material and a 99% reduction during manufacture. The overall risk rating for EHEC (for the normal population) was very low. Details of the assumption used for assigning risk categories for the other hazards under consideration are given in Appendix 5.

**Table 4: Risk categories for hazards likely to be associated with Roquefort cheese; calculated using the framework proposed in Figure 3**

| Hazard | Hazard [1] | Exposure [2] | Risk Characterisation | Risk Ranger |
|---|---|---|---|---|
| *Campylobacter jejuni* | Low | Negligible | Negligible | Negligible |
| *Staphylococcus aureus* (enterotoxin) | Negligible | Moderate | Low | Low |
| *Listeria monocytogenes* | Negligible | Very Low | Negligible | Very Low |
| *Escherichia coli* (EHEC) | Moderate | Negligible | Very Low | Very Low |
| *Salmonella* | Moderate | Negligible | Very Low | Low |
| *Brucella melitensis* | Low | Negligible | Negligible | Negligible |
| *Coxiella burnetii* | High | Negligible | Low | Negligible |

[1] The range given for some of the hazards reflects the different outcomes of infection between the general population and those at greater risk. These ranges are carried through to the risk characterisation.
[2] Based on challenge studies and the outcomes of the Mzpc workshop (1998).

Some of the differences in the risk ratings in table 4 are due to the estimated exposure of the hazard. Risk Ranger assigns zero to the exposure for hazards that are eliminated during processing i.e. *Brucella melitensis*, *Coxiella burnetii* and *Campylobacter jejuni*, whereas the risk framework in Figure 3 only assigns a category i.e. negligible. If hazards are eliminated from the cheese during processing and/or storage they pose no risk to the consumer.

Whichever tool is used a similar risk rating is obtained. The hazards (hazards eliminated from the product during processing are not considered) of most concern are, in order of importance, *Staphylococcus* enterotoxin, *Salmonella*, EHEC and *Listeria monocytogenes*. For at-risk consumers EHEC would be the hazard posing the greatest risk (Low). *Listeria* poses a Very Low risk even for at-risk consumers, based on the assumptions made in this assessment. Control of all these hazards must be ensured using SOPs and GMPs during milk collection and processing.

**Colour code**

High
Moderate
Low
Very Low
Negligible

**Hazard characterisation**

| | Consequences of exposure | | | |
|---|---|---|---|---|
| **"Infective dose"** | Minor | Mild | Moderate | Severe |
| <10 | | | | |
| 10 -100 | | | | |
| 100 - 1,000 | | | | |
| >10,000 | | | | |

**Exposure assessment**

| | Effect of processing | | | | | |
|---|---|---|---|---|---|---|
| **Raw product contamination** | Eliminates | 99% reduction | 50% reduction | No effect | 10 fold increase | 1000 fold increase |
| Rare (1:1,000) | | | | | | |
| Infrequent (1%) | | | | | | |
| Sometimes (10%) | | | | | | |
| Common (50%) | | | | | | |
| Always (100%) | | | | | | |

**Risk Characterisation**

| | Severity of Hazard | | | | |
|---|---|---|---|---|---|
| **Exposure** | Negligible | Very Low | Low | Moderate | High |
| Negligible | | | | | |
| Very Low | | | | | |
| Low | | | | | |
| Moderate | | | | | |
| High | | | | | |

**Figure 3: Qualitative framework for categorising hazards associated with Roquefort cheese manufactured from raw milk.**

*Control of major hazards (SOPs and GMPs)*

In general all of the hazards considered in this study are controlled either as part of the plants HACCP program i.e. *Listeria* and Staphylococcal enterotoxin or through the application of SOPs and GMPs. Milk is only collected from Brucellosis free herds and a herd where abortions have been noted is excluded from milk collection for a period of one year (personnel communication with French authorities). High rates of abortion in sheep have been attributed to infection with *B. melitensis* and to a lesser extent *C. burnetii*. On going testing of herd status for *B. melitensis* is also undertaken by the French authorities. No controls are in place for *C. burnetii*, although ingestion is unlikely to be a significant source of disease. Both *B. melitensis* and *C. burnetii*, along with *C. jejuni*, are reportedly eliminated from semi-hard cheeses during processing and maturation. If this is the case they should not pose a risk to consumers of Roquefort cheese.

Hazards such as EHEC and *Salmonella* are controlled in animals through monitoring of raw milk and on-farm programs, although contamination of the raw milk from time to time is unavoidable. Challenge studies have demonstrated that these hazards are reduced or eliminated during the manufacturing process. Testing of final product for generic *E. coli* (using the criteria in the Australian *Food Standards Code*) offers further assurance that the level of EHEC in the final product is very low. The survival of *Listeria* after maturation is possible. Testing of each batch gives some assurance that the level of contamination is low. Growth of *Listeria* on Roquefort cheese is unlikely unless the pH rises to levels above 6.0. This has been documented in some batches.

**Conclusions**

It is unlikely that the importation of Roquefort cheese will pose a significant risk to Australian consumers. Critical assumptions/uncertainties impacting on this assessment are:

- Elimination of *B. melitensis, C. burnetii* and *C. jejuni* during processing and maturation.
- Freedom of flocks from *B. melitensis.*
- 3-log or more reduction in *Salmonella*, EHEC, *Listeria* and *Staphylococcus*.
- Insufficient growth of *S. aureus* to form enough enterotoxin to cause disease.
- Inability of *Listeria* to grow on Roquefort during maturation and subsequent storage.

Several of these assumptions have been addressed by the French authorities. FSANZ needs to be confident in the guarantees put forward by the French if they are to allow the importation of Roquefort cheese into Australia. Of particular importance is any rise in pH during manufacture. While challenge studies support the assumption that growth does not occur, it is not clear if samples were analysed from cheese as it would be exported to Australia. The only samples found to be negative for *L. monocytogenes* after the end of maturation were packaged cheese 'slices'. As a precaution FSANZ should investigate the possibility of restricting imports to cheese with a pH of <6.0 at the time of shipping.

*References*

Anon (1998). Mzcp/Workshop on the Management of Milkborne Zoonoses Surveillance and Control in the Mzcp Countries, Cephalonia Island, Greece, 1-2 April 1998.

Anon (2003). *The Bad Bug Book*. Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, Centre for Food Safety & Applied Nutrition, U.S. Food & Drug Administration. http://www.cfsan.fda.gov/~mow/intro.html

Ash, M. (1987). *Staphylococcus aureus* and staphylococcal enterotoxins. In. *Foodborne Micro-Organisms of Public Health Significance*, 5th ed. pp 313-332. Eds. Hocking, A. D., Arnold, G., Jenson, Newton, K and Sutherland, P., AIFST Inc, Sydney.

Black, R. E., Levine, M. M., Blaser, M. J., Clements, M. L. and Hughes T. P. (1993). Studies of *Campylobacter jejuni* infection in volunteers, pp. 13. In A. D. Pearson, M. B. Skirrow, B. Rowe, J. R. Davies and D. M. Jones (eds). *Campylobacter* II. Public Health Laboratory Services, London.

Buchanan, R. L., Damert, W. G., Whiting, R. C., van Schothorst, M. (1997). Use of epidemiologic and food survey data to estimate a purposefully conservative dose-response relationship for *Listeria monocytogenes* levels and incidence of listeriosis. Journal of Food Protection, 60, 918-922.

Buchanan, R. L., Smith, J. L. and Long W. (2000). Microbial risk assessment: dose-response relations and risk characterization. International Journal of Food Microbiology 58, 159–172.

Buyser, M. D., Dufour, B., Marie, M. and Lafarge, V. (2001). Implication of milk and milk products in food-borne disease in France and in different industrialised countries. International Journal of Food Microbiology, 67, 1-17.

D'Aoust, J. Y., Warburton, D. W., Sewell, A. M. (1985). *Salmonella typhimurium* phage-type 10 from cheddar cheese implicated in a major Canadian foodborne outbreak. Journal of Food Protection, 48:1062-1066.

Deschenes, G., and others (1996). Cluster of cases of haemolytic uraemic syndrome due to unpasteurised cheese. Pediatric Nephrology, 10:203-205.

Desenclos, J-C., Bouvet, P., Benz-Lemoine, E., Grimont, F., Desqueyroux, H., Rebiere, I., Grimont, P. A. (1996). Large outbreak of *Salmonella enterica* serotype paratyphi B infection caused by a goats' milk cheese, France, 1993: a case finding and epidemiological study. British Medical Journal, 312:91-94.

Desmarchelier P. D and Fegan, N. (2003). Enteropathogenic *Escherichia coli*. In. *Foodborne Microorganisms of Public Health Significance*, 6th ed. pp 267-310, Ed A. D. Hocking et al., AIFST Inc., Sydney.

Desmarchelier, P. M., Grau, F. H. (1997). *Escherichia coli*. In. *Foodborne Micro-Organisms of Public Health Significance*, 5th ed. pp 231-264. Eds. Hocking, A. D., Arnold, G., Jenson, Newton, K and Sutherland, P., AIFST Inc, Sydney.

Godfroid, J and Kasbohrer, A. (2002). Brucellosis in the European Union and Norway at the turn of the twenty-first century. Veterinary Microbiology, 90, 135-145.

Hedberg, C. W., Korlath, J. A., D'Aoust, J. Y., White, K. E., Schell, W. L., Miller, M. R., Cameron, D. N., MacDonald, K. L., Osterholm, M. T. (1992). A multistate outbreak of *Salmonella* Javiana and *Salmonella* Oranienburg infections due to consumption of contaminated cheese. Journal of the American Medical Association. 268:3203-3207.

ICMSF (1996a). *Campylobacter*. In. *Micro-organisms in Foods 5. Microbiological specifications of Food Pathogens*. pp. 45-65. Blackie Academic & Professional, London.

ICMSF (1996b). *Salmonella*. In. *Micro-organisms in Foods 5. Microbiological specifications of Food Pathogens*. pp. 217-264. Blackie Academic &Professional, London.

ICMSF (1996c). *Staphylococcus aureus*. In. *Micro-organisms in Foods 5. Microbiological specifications of Food Pathogens*. pp. 299-333. Blackie Academic &Professional, London.

ICMSF (1996d). *Listeria monocytogenes*. In. *Micro-organisms in Foods 5. Microbiological specifications of Food Pathogens*. pp. 141-182. Blackie Academic &Professional, London.

ICMSF (1998). Milk and Dairy Products. In. *Micro-organisms in Foods 6. Microbial Ecology of Food Commodities*. pp. 521-576. Blackie Academic &Professional, London.

IDF (1980). Behaviour of pathogens in cheese. Bulletin, Document 122.

Johnson, E. A., Nelson, J. H., Johnson, M. (1990). Microbiological safety of cheese made from heat-treated milk, Part II. Microbiology. Journal of Food Protection, 53:519-540.

Leclerc, V. and others (2002). Pathogens in meat and milk products: surveillance and impact on human health in France. Livestock Production Science, 76, 195-202.

MacDonald, K. L., and others (1985). A multistate outbreak of gastrointestinal illness caused by enterotoxigenic *Escherichia coli* in imported semisoft cheese. Journal of Infectious Diseases, 151:716-20.

Marrie, T. J. (2003). *Coxiella burnetii* pneumonia. European Respiratory Journal, 21, 713-719.

Maurin, M. and Raoult, D. (1999). Q Fever. Clinical Microbiological Reviews, 12, 518-533.

Mead, P. S. and Griffin, P. M. (1998). *Escherichia coli* O157:H7. The Lancet Volume: 352, Issue: 9135, October 10, 1207-1212.

Meng, J., Doyle, M., Zhao, T. and Shao, S. (2001). Enterohaemorrhagic *Escherichia coli*. In. *Food Microbiology: Fundamental and Frontiers* 2nd edit. pp 193-214 (eds). Doyle, M., Beuchat, L. R., Montville, T. J. ASM Press, Washington.

Nielsen, E. M. , Engberg, J., Madens, M. (1997). Distribution of *Campylobacter jejuni* and *C. coli* from Danish patients, poultry, cattle and swine. FEMS Immunology and Medical Microbiology. 19:47-56.

O'Donnell, E. T. (1995). The incidence of *Salmonella* and *Listeria* in raw milk from farm bulk tanks in England and Wales. Journal of the Society of Dairy Technology, 48:25-29.

Oberhelman, R. A., Taylor, D. N. (2000). *Campylobacter* infections in developing countries, pp 139-153, In. *Campylobacter*, 2nd ed., (Eds. I. Nachamkin, and M. J. Blaser), ASM Press, Washington DC.

Ross, T and Sumner, J. (2002). A simple, spreadsheet-based, food safety risk assessment tool. International Journal of Food Microbiology, 77, 39-53.

Voysey, P. (2001). *Microbiological Risk Assessment.* In. *Hot Topics in Food Microbiology*. Campden & Chorleywood Food Research Association Group, 6-7 September 2001.

Wallace R. B. (2003). *Campylobacter*. In. *Foodborne Microorganisms of Public Health Significance*, 6th ed. pp 267-310. Ed. A. D. Hocking et al., AIFST Inc., Sydney.

## Appendix 1

**Risk categories and associated probability ranges, examples for each category and associated probability estimates are also given.**

| Term used | Probability Range | Example | Probability Estimate |
|---|---|---|---|
| High | >1:100 | Transmission of HIV from mother to child | 1:6 |
| Moderate | 1:100 – 1:1,000 | Lung cancer from smoking 10 cigarettes a day | 1:200 |
| Low | 1:1,000 – 1:10,000 | Death from a road accident | 1:8,000 |
| Very low | 1:10,000 – 1:100,000 | Homicide | 1:100,000 |
| Minimal | 1:100,000 – 1:1M | Death from accident on railway | 1:500,000 |
| Negligible | <1:10M | Hit by lightning | 1:10M |

**Appendix 2: Values entered into risk ranger to obtain the risk categories given in Appendix 1.**

| | Pathogen | *Campylobacter* | *Brucella* | *Staphylococcus* | *Salmonella* | *Listeria* | EHEC | *Coxiella* |
|---|---|---|---|---|---|---|---|---|
| Risk ranger input[21] | | | | | | | | |
| 1 | Hazard severity | Minor | Moderate | Mild | Moderate | Severe | Severe | Mild |
| 2 | Susceptibility | General | General | General | General | Very | Very | General |
| 3 | Frequency of consumption | Monthly | Monthly | Monthly | Monthly | Monthly | Monthly | Monthly |
| 4 | Proportion of population consuming | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| 5 | Size of population | 12,500 | 12,500 | 12,500 | 12,500 | 2,500 (20%) | 2,500 (20%) | 12,500 |
| 6 | Proportion of raw product contaminated | 10% | 0.1% | 1% | 1% | 1% | 1% | 1% |
| 7 | Effect of processing | Eliminates | Eliminates | No Effect | 99% reduction | 50% reduction | 99% reduction | Eliminates |
| 8 | Potential for cross-contamination | No | No | No | No | 1% | No | No |
| 9 | Effective post processing controls | NA | NA | NA | NA | NA | NA | NA |
| 10 | Potential increase in hazard | 0 | 0 | 100 fold | 0 | 100 fold | 0 | 0 |
| 11 | Effect of preparation | No Effect | No Effect | No Effect | No Effect | No Effect | No Effect | No Effect |
| Probability of illness | | 0 | 0 | $3.3x10^{-6}$ | $3.3x10^{-6}$ | $9.8x10^{-5}$ | $9.8x10^{-5}$ | 0 |
| Risk ranking | | 0 | 0 | 52 | 57 | 69 | 69 | 0 |
| Estimated total number of cases | | 0 | 0 | 15 | 15 | 3 | 3 | 0 |

[21] Definitions for input variables are given in Ross and Sumner (2002) and summarised in Appendix 3.

# Appendix 3: Magnitude of values assigned in risk ranger for input variables

| **1. Hazard Severity** | |
|---|---|
| SEVERE hazard - causes death to most victims | 1 |
| MODERATE hazard - requires medical intervention in most cases | 0.01 |
| MILD hazard - sometimes requires medical attention | 0.001 |
| MINOR hazard - patient rarely seeks medical attention | 0.0001 |

| **2. How susceptible is the consumer ?** | |
|---|---|
| GENERAL - all members of the population | 1 |
| SLIGHT - e.g., infants, aged | 5 |
| VERY - e.g. neonates, very young, diabetes, cancer, alcoholic etc | 30 |
| EXTREME - e.g., AIDS, transplants recipients, etc. | 200 |

| **3. Frequency of Contamination** | |
|---|---|
| Rare (1 in a 1000) | 0.001 |
| Infrequent (1 per cent) | 0.01 |
| Sometimes (10 per cent) | 0.1 |
| Common (50 per cent) | 0.5 |
| All (100 per cent) | 1 |

| **4a. Effect of Process** | |
|---|---|
| The process RELIABLY ELIMINATES hazards | 0 |
| The process USUALLY (99% of cases) ELIMINATES hazards | 0.01 |
| The process SLIGHTLY (50% of cases) REDUCES hazards | 0.5 |
| The process has NO EFFECT on the hazards | 1 |
| The process INCREASES (10 x) the hazards | 10 |
| The process GREATLY INCREASES (1000 x ) the hazards | 1000 |

| **6. How effective is the post-processing control system?** | |
|---|---|
| Pre-YMT | 1 |
| CONTROLLED - mostly reliable systems in place (3-fold increase) | 3 |
| NOT CONTROLLED - no systems, untrained staff (10 -fold increase) | 10 |
| Post YMT | 100000000 |
| NOT RELEVANT - level of risk agent does not change | 1 |

| **7. How much increase is required to reach an infectious or toxic dose?** | |
|---|---|
| none | 1 |
| slight (10 fold increase) | 0.1 |
| moderate (100-fold increase) | 0.01 |
| significant (10,000-fold increase) | 0.0001 |

| **8. Frequency of Consumption** | |
|---|---|
| daily | 365 |
| weekly | 52 |
| monthly | 12 |
| a few times per year | 3 |

| **9. Proportion of Consuming Population** | |
|---|---|
| all (100%) | 1 |
| most (75%) | 0.75 |
| some (25%) | 0.25 |
| very few (5%) | 0.05 |

**4b. Effect of Preparation for Meal**

| | |
|---|---|
| Meal Preparation RELIABLY ELIMINATES hazards | 0 |
| Meal Preparation USUALLY ELIMINATES (99%) hazards | 0.01 |
| Meal Preparation SLIGHTLY REDUCES (50%) hazards | 0.5 |
| Meal Preparation has NO EFFECT on the hazards | 1 |

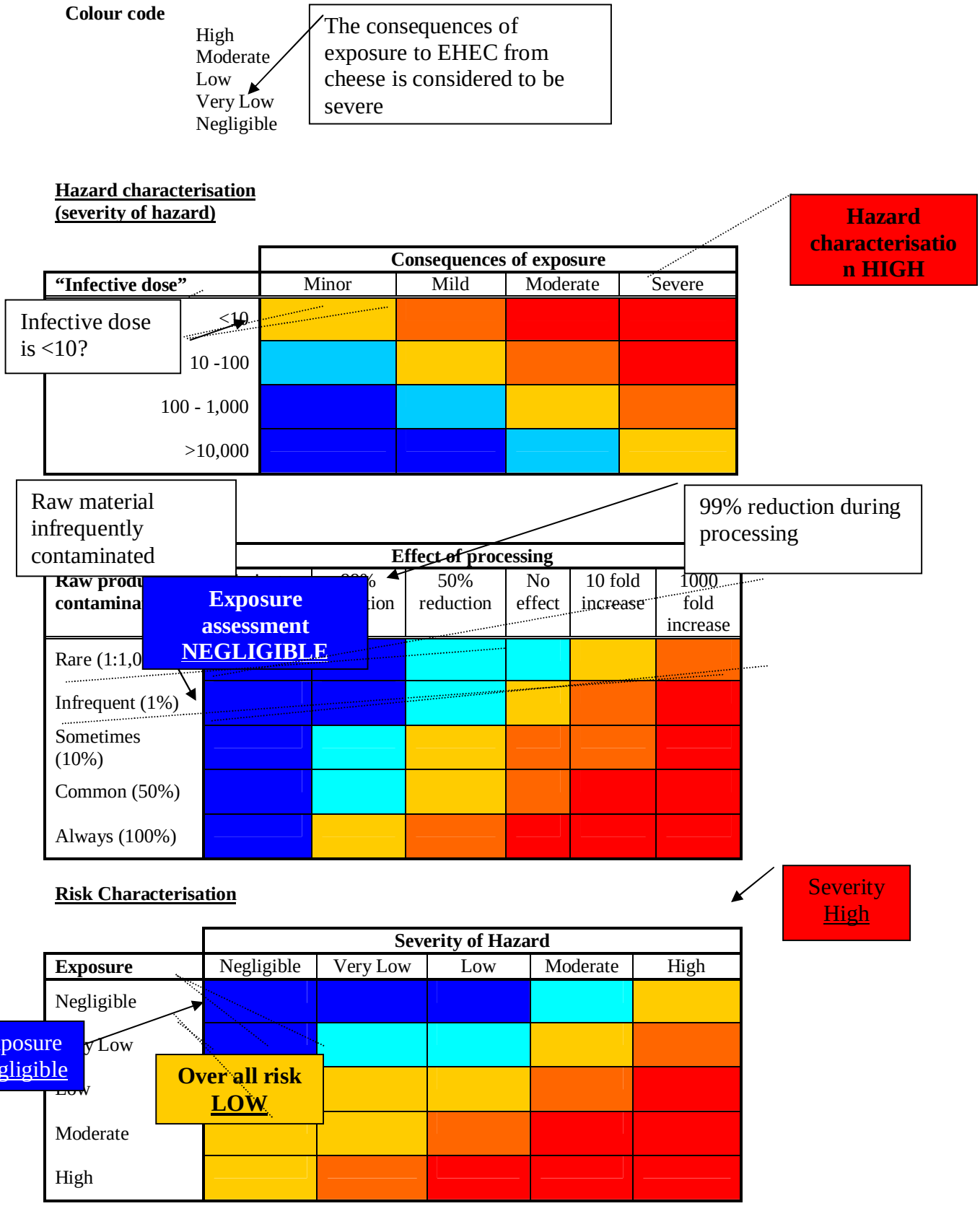
**5. Is there potential for recontamination ?**

| | |
|---|---|
| NO | 0 |
| YES - minor (1% frequency) | 0.01 |
| YES - major (50% frequency) | 0.5 |

**10. Size of Consuming Population**

| | |
|---|---|
| Australia | 19500000 |
| ACT | 321000 |
| New South Wales | 6595000 |
| Northern Territory | 198000 |
| Queensland | 3595000 |
| South Australia | 1547000 |
| Tasmania | 491000 |
| Victoria | 4847000 |
| Western Australia | 1905000 |
| OTHER | 12500 |

**Appendix 4: Detailed example of risk categorisation of EHEC in raw milk Roquefort cheese**



**Appendix 5: Assumptions used for assigning risk categories for hazards in Roquefort cheese**.

| Hazard | Infective dose | Consequences of exposure | Severity of hazard | Raw product contamination | Effect of processing | Exposure | Risk characterisation |
|---|---|---|---|---|---|---|---|
| *Campylobacter jejuni* | 100-1,000 | Mild | Very Low | Infrequent (1%) | Eliminates | Negligible | Negligible |
| *Staphylococcus aureus* | >10,000 | Mild | Negligible | Sometimes (10%) | No Effect | Moderate | Low |
| *Listeria monocytogenes* | >10,000 | Mild | Negligible | Infrequent (1%) | 50% Reduction | Very Low | Negligible |
| *Escherichia coli* (EHEC) | <10 | Mild | Moderate | Rarely (1:1,000) | 99% Reduction | Negligible | Very Low |
| *Salmonella* | 10-100 | Moderate | Moderate | Infrequent (1%) | 99% Reduction | Negligible | Very Low |
| *Brucella melitensis* | 10-100 | Mild | Low | Rarely (1:1,000) | Eliminates | Negligible | Negligible |
| *Coxiella burnetii* | <10 | Severe | High | Rarely (1:1,000) | Eliminates | Negligible | Low |

**ATTACHMENT 3**

## Review of Safety Control Measures implemented by the Confederation of Roquefort Producers and enforced by the French Government

## EXECUTIVE SUMMARY

The microbiological safety of Roquefort cheese is managed by control and/or regulatory oversight of processes at various stages during milk production, storage and transport and cheese manufacture and maturation.

The Review of safety control measures implemented by the Confederation of Roquefort Producers and enforced by the French Government was undertaken to examine the framework in place in France to support the safe production of Roquefort cheese. This involved the examination of:

- Infrastructure including legislation (e.g. food law and enforcement) and administration (e.g. organisation of national/regional authorities, enforcement systems).
- Program design, implementation and monitoring (including documentation, decision criteria and audit).
- Specific process-related requirements e.g. HACCP plans and product-related requirements e.g. microbiological limits.

This review was undertaken as a desk audit of the documentation provided by the Applicant (the French Government). This information included:

- European Council and Commission Directives;
- French regulations and Ministerial orders;
- Guide of Good Manufacturing Practices (Confederation of Ewe Milk producers and Roquefort Producers);
- selected data on inspections and audits:
- generic HACCP Plans: raw milk production and production, ripening and packaging of cheese; and
- general internal inspection plan implemented throughout the chain from ewe livestock farms up to the final marketing of Roquefort.

The hygiene controls imposed in France on sheep milk production and processing of Roquefort cheese are legislated in France through several key regulations (Ministerial Orders). These orders identify on-farm activities that must be managed and are consistent with the Codex Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57, 2004). The Codex Code applies to all products derived from milk including raw milk cheeses.

The Codex *Code of Hygienic Practice for Milk and Milk Products* states that it *does not mandate or specify the use of any one set of controls to be used, but leaves it up to those responsible for assuring the safety of the finished product to choose the most appropriate set of control measures for the particular situation. There are a wide variety of raw milk products, most of which are cultured products such as cheeses.*

*The range of moisture content, pH and salt content (among other parameters) in these products will have varying degrees of impact on any potential microbiological hazards that may be present in the milk used for their manufacture. The degree to which the inherent characteristics of the product (or process used to manufacture the product) will control the hazard should guide the extent to which these potential hazards need to be prevented or controlled during primary production.*

In addition, to assist producers and manufacturers, French Ministerial Orders have been translated into a **Guide of Good Manufacturing Practices for the Production of Ewe's milk in the manufacture of Roquefort.** (Confédération Générale des Producteurs de lait de Brebis et des Industriels du Roquefort). The Confederation Guide summarises the current on-farm regulations and sets out the hygienic practices required for the production of quality milk.

Compliance with French Regulations and Confederation Guidelines is monitored by French Government Officials, the Confederation and cheese producers themselves. In addition, there are incentives and sanctions for producers to ensure compliance with Regulations and Guidelines.

Inspectors from the Departmental Veterinary Services Directorates (DDSV) and the Departmental Competition, Consumerism and Fraud Investigation Directorates (DDCCRF) monitor and verify the safety of foodstuffs in the market place. Inspections focus on relevance and proper implementation of procedures for the control of critical points identified throughout the manufacturing process. As part of their work they routinely inspect manufacturers of Roquefort cheese.

A HACCP plan was submitted for the manufacture of Roquefort cheese. The HACCP plan is general in nature and relies heavily on microbiological testing to ensure the safety of the final product. A full analysis of the HACCP plan as submitted by the applicant was conducted by Food Science Australia.

All hazards considered potentially significant in Roquefort cheese are subject to management through on-farm systems and the application of HACCP-based control during processing. This is in combination with the application of standard operating procedures (SOPs) and good manufacturing practice (GMP) as determined and controlled by the Confederation of Roquefort Producers.

The system of regulating the safety of raw milk and subsequently Roquefort cheese manufacture is considered comprehensive and adequate. Sanctions against producers and manufacturers that fail to meet the requirements of the Ministerial Orders and the requirements of the Confederation of Roquefort Producers are severe.

The regulatory system is consistent with the Codex Code of Hygienic Practice for Milk and Milk Products.

# 1 Introduction

An application from the French Government (Ministry of Agriculture, Food, Fisheries and Rural Affairs) seeks to amend Standard 2.5.4 - Cheese of the *Australia New Zealand Food Standards Code* (the Code) to permit the sale of Roquefort cheese. Roquefort cheese is a semi-hard cheese manufactured from raw sheep milk. Over the past four years, selected raw milk cheeses have been permitted in Australia, following scientific evaluations of their safety. These evaluations have been based on equivalence determinations, and have resulted in permission to import gruyere, Sbrinz, and Emmental cheeses from Switzerland and specific extra hard raw milk grating cheeses. These permissions reflect the capacity of regulatory systems and/or processing conditions to produce cheeses of equivalent food safety to those made from pasteurised or thermised milk.

# 2 Roquefort Cheese

Blue or blue-veined cheeses are a class of semi-hard cheeses characterised by the growth of *Penicillium roqueforti*, in fissures throughout the cheese. Blue cheeses tend to be strong in flavour and aroma, both of which intensify with aging.

# 3 Scope of the Review

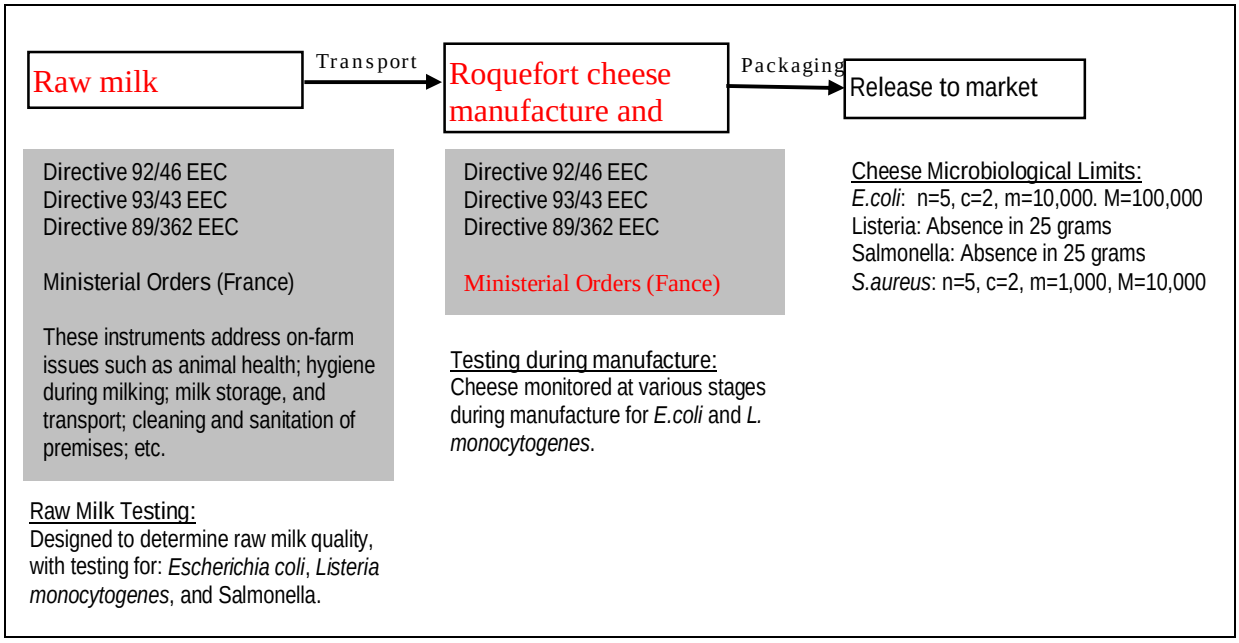
The safety of Roquefort cheese is influenced by a combination of factors, including on-farm control of animal health; on-farm production hygiene; the microbiological status of the incoming raw milk; the rapid acidification of the milk during the initial phase of cheese manufacture; desiccation of the curd during subsequent stages; prolonged ripening; and microbiological testing of the final product before release to the market.

The purpose of the review was to evaluate the regulatory environment under which ewe's milk is produced and Roquefort cheese manufactured. This review was undertaken in the form of a desk audit of documentation provided by the applicant.

Roquefort cheese is produced under a regulatory environment that involves European Union Directives which have been transposed into French Government Ministerial Orders, combined with microbiological testing of raw material and the final product.

Verification of Control Measures implemented by the Confederation of Roquefort Producers and enforced by the French Government and results of routine monitoring and testing will be a subsequent process to this review. Verification of these measures will be substantiated by an on-site audit to be overseen by AQIS, with technical input from FSANZ, and the results of the audit will be incorporated into the Final Assessment Report.

Regulatory control mechanisms and testing regimes in place for Roquefort cheese may be summarised graphically as follows:




# 4 Desk Audit of the Control Infrastructure for Roquefort Cheese

The microbiological safety of Roquefort cheese is managed by control and/or regulatory oversight of a combination of conditions and factors at various stages during milk production, storage and transport and cheese processing and maturation.

In this part of the evaluation, FSANZ undertook a desk audit of the documentation provided by the Applicant. This information included:

- European Council and Commission Directives;
- French regulations and Ministerial orders;
- Guide of Good Manufacturing Practices (Confederation of Ewe Milk producers and Roquefort Producers);
- Selected data on inspections and audits:
- Generic HACCP Plans: raw milk production and production, ripening and packaging of cheese;
- Curd acidification curve;
- General internal inspection plan implemented throughout the chain from ewe livestock farms up to the final marketing of Roquefort; and
- Challenge studies for selected bacterial pathogens.

## 4.1 Regulatory Control over Safety of Raw Milk and Roquefort Cheese

Official control of foodstuffs in France requires compliance with Ministerial Orders, which embrace European Union Directives that have been transposed into French law. Specific regulations include the following:

**Table 1: Selected regulations covering milk and milk products**

| **European Union** | **Selected Details of Content** |
|---|---|
| Commission Directive 89/362/EEC 26 May 1989 General conditions of hygiene in milk production holdings | ▪ Production holdings – general conditions and upkeep<br>▪ Equipment - general conditions and upkeep<br>▪ General hygiene of milking operations |
| Commission Directive 92/46/EEC (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 | ▪ Health rules<br>▪ Microbiological criteria<br>▪ Managing non-compliance<br>▪ Packaging, labelling and traceability |
| Council Directive 93/43/EEC (14 June 1993) on the hygiene of foodstuffs, including the use of HACCP principles to ensure adequate safety procedures are identified, implemented, maintained and reviewed | ▪ Basic principles for design of premises<br>▪ Qualifications and training of staff |
| Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 | Outlines general principles and requirements of food law, establishes the European Food Safety Authority and lays down procedures in matters of food safety, including:<br>▪ Separation of risk assessment and risk management<br>▪ Traceability and incident alert system |
| **French Government** | |
| Ministerial Order of 30 December 1993<br>(J.O. No. 8 of 11 January 1994) | ▪ Requirements relating to premises, equipment and operation of milk collection or standardization centres and of establishments involved in the treatment or processing of milk or milk-based products.<br>▪ Critical control points are identified and monitored. |
| Ministerial Order of 18 March 1994<br>(J.O. No. 91 of 19 April 1994) | ▪ Hygiene of milk production and collection. |
| Ministerial Order of 30 March 1994<br>(J.O. No. 93 of 21 April 1994) | ▪ Microbiological criteria that drinking milk and milk-based products must satisfy in order to be placed on the market |
| Ministerial Order of 28 June 1994<br>(J.O. No. 176 of 31 July 1994) | ▪ Identification and sanitary approval of establishments placing on the market animal foodstuffs or foodstuffs of animal origin and on health marking. |
| Ministerial Order of 2 March 1995<br>(J.O. No. 82 of 6 April 1995) | ▪ Approval of milk collection, standardization or treatment centres and of establishments involved in the processing of milk or milk-based products |
| Decree of 22 January 2001<br>(J.O. No. 21 of 25 January 2001) | ▪ Relating to the protected designation of origin of Roquefort cheese |
| Regulation (14 May 2001) | Regarding the Decree for the Protected designation of origin of Roquefort cheese |

European Union Council Directive 92/46/EEC of 16 June 1992 lays down health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products (Table 2). Annex A of the Directive outlines specific requirements for the collection, transportation and processing of milk for the purposes of manufacturing cheese (including

raw milk cheese). These requirements focus on hygiene during these stages and include microbiological criteria for raw milk intended for cheese manufacture.

**Table 2: Summary of Directive 92/46/EEC**

| | |
|---|---|
| **Chapter 1:** | **Animal health requirements** – officially free of brucellosis; absence of symptoms of infectious diseases communicable to humans through milk; absence of residues of prohibited substances, etc |
| **Chapter 2:** | **Hygiene of holding** – conditions of animal housing, hygiene, cleanliness, and health of animals; hygiene conditions for milking, handling, cooling, and storing; structure of premises; etc |
| **Chapter 3:** | **Hygiene in milking** – cooling to ≤8ºC immediately after milking and further chilled to ≤6ºC if milk is not collected daily; hygiene of premises, equipment and tools; staff hygiene; and production hygiene. |
| **Chapter 4:** | **Standards** – raw sheep's milk:<br>Plate count: 500,000/ml (at 30ºC)<br>*S. aureus*: n=5, c=2, m=500, M=2,000 |

The extent to which Directive 92/46/EEC is transposed into French law was assessed by a Food and Veterinary Office (European Commission) mission to France from 14-18 June 1999. The results of the mission were favourable and are published on the European Commission website (http://europa.eu.int/comm/food/fs/inspections/vi/reports/france/vi_rep_fran_1112-1999_en.html). The conclusions were:

- transposition of Directive 89/362/EEC into French law appears to be satisfactory; and
- the standards set out in Directive 92/46/EEC also appear to have been transposed satisfactorily

Minor points were raised and a list of recommendations provided to the French authorities.

Under Article 9 of Council Directive 92/46 EEC, there is the capacity to issue limited derogations from specific community health rules for raw milk. For example, under Council Directive 92/46 EEC (Annex A, Chapter 3,) and Ministerial Order of 18 March 1994 (Chapter III, Article 9) milk on farm must be cooled to ≤8ºC immediately after milking and further chilled to ≤6ºC if milk is not collected daily. However a dispensation granted by the Ministry of Agriculture and Fisheries requires that milk temperatures both at the farm and during transportation must not exceed 10ºC. Under the Decree (Appellation d'Origine Contrôlée Roquefort, 14 May 2001: Article 5) milk temperature should not exceed 10ºC during storage and transportation, and where farms are remote, milk used in the manufacture of Roquefort cheese may be stored for up to 38 hours at a temperature of 4ºC.

## 4.2 Control of Raw Milk

### *4.2.1 Regulation and Guidelines*

Raw milk in France is controlled by Ministerial Orders listed in Table 1. These orders identify on-farm activities that must be controlled and managed, and are consistent with the Codex Alimentarius Commission Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57, 2004).

The Codex Code of Hygienic Practice for Milk and Milk Products contains guidelines relating to the area and premises for milk production, animal health, general hygienic practice on farm and hygienic milking. The Code applies to all products derived from milk including raw milk cheeses.

The Codex Code of Hygienic Practice for Milk and Milk Products states that it:

> *does not mandate or specify the use of any one set of controls to be used, but leaves it up to those responsible for assuring the safety of the finished product to choose the most appropriate set of control measures for the particular situation. There are a wide variety of raw milk products, most of which are cultured products such as cheeses. The range of moisture content, pH and salt content (among other parameters) in these products will have varying degrees of impact on any potential microbiological hazards that may be present in the milk used for their manufacture. The degree to which the inherent characteristics of the product (or process used to manufacture the product) will control the hazard should guide the extent to which these potential hazards need to be prevented or controlled during primary production*.

To assist producers and manufacturers, these requirements have been translated into a **Guide of Good Manufacturing Practices for the Production of Ewe's milk in the manufacture of Roquefort.** (Confédération Générale des Producteurs de lait de Brebis et des Industriels du Roquefort). The Guide summarises the current on-farm regulations and sets out the hygienic practices required for the production of quality milk.

The guide specifies the following technical constraints that the milk:

- be rich and well-balanced in the amounts of protein, fat and minerals it contains;
- have a characteristic microbial flora;
- contain no microorganisms detrimental to manufacture nor pathogenic microorganisms;
- have as few somatic cells as possible;
- contain no chemical residues, contaminants or drugs; and
- have been subjected to no adulteration and no contamination by a foreign milk.

In addition the guidelines outline the risks from both microbiological and chemical contamination on-farm.

The regulations and guidance provided in the guidelines is summarised in Table 3.

The principles and guidelines in the Codex Code of Hygienic Practice for Milk and Milk Products have been incorporated into both European Union and French Legislation and the Confederation's ***Guide of Good Manufacturing Practices for the Production of Ewe's milk in the manufacture of Roquefort***. Table 4 compares the Guidelines within the Codex Code of Hygienic Practice for Milk and Milk Products with French Legislation for the control of primary production of raw milk.

**Table 3: Summary of the Guide of Good Manufacturing Practices for the Production of Ewe's milk in the manufacture of Roquefort and supporting French Regulation**

| FARM INPUTS | ON-FARM REGULATIONS | CONFEDERATION GUIDELINES |
|---|---|---|
| **Milking hygiene** | | |
| Milking premises | *Ministerial Order of 18 March 1994 on the hygiene of milk production and collection*<br>**Chapter II –** Hygiene at the production holding<br>**Article 7:** Special conditions applying to milk treatment rooms and premises where milk is stored | Sets out the conditions of hygiene at the milking premises and gives guidance on how this is achieved. |
| Milking premises | *Ministerial Order of 18 March 1994 on the hygiene of milk production and collection*<br>**Chapter III –** Hygiene of milking, storing and collection operations<br>**Article 10:** Equipment hygiene | Sets out the conditions of hygiene at the milking premises for equipment used in milking and gives guidance on how this is achieved. |
| Milking operation | ***Ministerial Order of 18 March 1994 on the hygiene of milk production and collection***<br>**Chapter III –** Hygiene of milking, storing and collection operations<br>**Article 8:** Milking hygiene | Provides guidance on preventing contamination, during milking, and on correct operation and maintenance of milking machine, including cleaning. |
| Personnel | ***Ministerial Order of 18 March 1994 on the hygiene of milk production and collection***<br>**Chapter III –** Hygiene of milking, storing and collection operations<br>Article 11: Staff hygiene<br>*Ministerial Order of 10 March 1977 on the state of health and hygiene of personnel involved* | Provides guidance on staff hygiene |
| **Hygiene at the production holding** | | |
| Hygiene at the production holding | ***Ministerial Order of 18 March 1994 on the hygiene of milk production and collection***<br>**Chapter II –** Hygiene at the production holding<br>**Article 5:** General conditions applying to premises used for animal housing, milking and storage of milk | Provides guidance on the general requirements for premises at the production holding |
| Sheep shed | ***Ministerial Order of 18 March 1994 on the hygiene of milk production and collection***<br>**Chapter II –** Hygiene at the production holding<br>**Article 6:** Special conditions with respect to animal housing premises | Provides guidance on the design, cleaning, sanitisation, of housing |
| Feed storage | | Provides guidance on feed storage |
| Care of animals | **Article 2:** State of health of animals | Provides guidance on purchase of animals, mastitis, and treatment of mastitis |
| **Environment** | | |
| Organisation and maintenance of surroundings | | Provides guidance on farm access, maintenance of farm surroundings, and pest control |
| Use of water | *Directive 93/43/EEC of 14 June 1993 on hygiene of food stuffs*<br>**Annex – Chapter VII**: Water supply | |
| Farm refuse | ***RURAL CODE – Sanitary control*** | Provides guidance on storage of manure, disposal |

| | | |
|---|---|---|
| | Chapter II – **Regarding the quartering of dead animals**<br>**Article 264** (L. no 75-13436 of 31 December 1975) | of dead animals and refuse |

**Table 4: Comparison of Codex Code of Hygienic Practice for Milk and Milk Products with French Legislation for the control of primary production of raw milk**

| **Codex** | **Codex Code of Hygienic Practice -** guidelines for on-farm inputs | **Guide to on-farm requirements* - consistency with Codex Guidelines and supporting French Legislation** | |
|---|---|---|---|
| Environmental Hygiene<br>Section 3.1 | Suitability of water | ٦ | *Ministerial Order of 18 March 1994 on the hygiene of milk production and collection*<br>Chapter II – Hygiene at the production holding<br>Article 7: Special conditions applying to milk treatment rooms and premises where milk is stored<br>*Directive 93/43/EEC of 14 June 1993 on hygiene of food stuffs*<br>Annex – Chapter VII: Water supply |
| Hygienic Production of Milk<br>Section 3.2<br>Areas and premises for Milk Production<br>Section 3.2.1 | Design and layout animal holding areas<br>Cleanliness animal holding areas<br>Design and layout milking areas | ٦ | *Ministerial Order of 18 March 1994 on the hygiene of milk production and collection*<br>Chapter II – Hygiene at the production holding<br>Article 5: General conditions applying to premises used for animal housing, milking and storage of milk<br>Article 6: Special conditions with respect to animal housing premises<br>Article 7: Special conditions applying to milk treatment rooms and premises where milk is stored |
| Animal Health<br>Section 3.2.2 | Disease status<br>General health of animal<br>Isolation of sick animals<br>Identification of animals<br>Correct use of milking equip<br>Hygiene of milking<br>Mgt of animal holding areas<br>Registration of herds | ٦ | *Ministerial Order of 18 March 1994 on the hygiene of milk production and collection*<br>Chapter I – Animal health requirements<br>Article 2: State of health of animals<br>*Ministerial Order of 28 June 1994 on the identification and sanitary approval of establishments placing on the market animal foodstuffs or foodstuffs of animal origin and on health marking*<br>Chapter II – Approval<br>Article 3 |
| General Hygienic Practice<br>Section 3.2.3 | Codex Code of Practice on Good Animal Feeding (under development)<br>Storage of fermented feeds<br>Design silage silos<br>GMP production | ٦ | No regulation<br>Guidelines provided<br>Good Ensilage Practice Guide is referred to |
| Hygienic Milking<br>Section 3.2.4 | Personnel hygiene<br>Animal hygiene (e.g. clean teats etc)<br>Cleaning and disinfection milking vessels and equipment<br>Milk Equipment design | ٦ | *Ministerial Order of 18 March 1994 on the hygiene of milk production and collection*<br>Chapter II – Hygiene at the production holding<br>Article 7: Special conditions applying to milk treatment rooms and premises where milk is stored<br>Chapter III – Hygiene of milking, storing and collection operations<br>Article 11: Staff hygiene<br>*Ministerial Order of 10 March 1977 on the state of health and hygiene of personnel involved*<br>Chapter III- Hygiene of milking, storing and collection operations |
| Handling storage and transport of milk<br>Section 3.3<br>Milking Equipment<br>Section 3.3.1 | Design<br>Cleaning and disinfection<br>Periodic verification of equipment | ٦ | *Ministerial Order of 18 March 1994 on the hygiene of milk production and collection*<br>Chapter III – Hygiene of milking, storing and collection operations<br>Article 10: Equipment hygiene |
| Storage Equipment<br>Section 3.3.2 | Design<br>Cleaning and disinfection | ٦ | *Ministerial Order of 18 March 1994 on the hygiene of milk production and collection*<br>Chapter III – Hygiene of milking, storing and collection operations<br>Article 10: Equipment hygiene |

| **Codex** | **Codex Code of Hygienic Practice -** guidelines for on-farm inputs | **Guide to on-farm requirements* - consistency with Codex Guidelines and supporting French Legislation** | |
|---|---|---|---|
| Premises for, and Storage of Milk and Milking-Related Equipment Section 3.3.4 | Suitable milk refrigeration equip<br>Water<br>Protection from vermin<br>Design for easy cleaning<br>Separation animals & milking areas | √ | Milk collected daily and kept at no more than 10°C. |
| Collection, Transport and Delivery Procedures and Equipment Section 3.3.4 | Personnel hygiene<br>Hygienic training | √ | *Ministerial Order of 30 December 1993 requirements relating to the premises, equipment and operation of milk collection centres and establishments involved in the treatment or processing of milk or milk-based products*<br>Title II – Requirement relating to hygiene of operations<br>Chapter 1 – Control of hygiene<br>Article 14<br>Chapter IV - Staff hygiene<br>Article 22 |
| Documentation and Record Keeping Section 3.4 | | √ | *Ministerial Order of 30 December 1993 requirements relating to the premises, equipment and operation of milk collection centres and establishments involved in the treatment or processing of milk or milk-based products*<br>Title II – Requirement relating to hygiene of operations<br>Chapter 1 – Control of hygiene<br>Article 13 |

* Confederation ***Guide of good manufacturing practices for the production of ewe's milk in the manufacture of Roquefort***

### *4.2.2 Compliance with Regulations and Guidelines*

Compliance with French Ministerial Orders and Confederation Guidelines is monitored by French Government Officials, the Confederation and the cheese producers. Government oversight of the food sector is managed by the General Directorate for Food (Direction Générale de l'Alimentation - DGAL) of the Ministry of Agriculture, Food Fisheries and Rural Affairs (Ministre de la Agriculture, de l'Alimentation, de la Pêche et des Affaires Rurales - MAAPAR).

In addition, there are incentives and sanctions for producers to ensure milk complies with national regulations and the Confederation Guidelines.

Official inspections require separate testing (plate count and somatic cell counts) of raw milk using samples taken at random from each holding, with the obligation to immediately notify Government Veterinary Services of DGAL if maximum limits for the plate count and somatic cell count have been reached (Ministerial Order of 18 March 1994 on the hygiene of milk production and collection - Articles 15 and 16).

Private veterinary officers are required to report the disease status of flocks. The Ministerial Order of 18 March 1994 (on *amending the list or reputedly contagious animal diseases*) specifies that raw milk can only be derived from ewes recognised as free from brucellosis. Hence milk is only collected from brucellosis free herds. Any herd where abortions have been noted is excluded from milk collection for a period of one year (Advice obtained from French authorities). On going testing of herd status for *B. melitensis* is also undertaken by the French authorities, with serum tests for ovine brucellosis undertaken at intervals laid down by a Ministerial Order of 13 October 1998.

All farm holdings are audited by the Confederation and an obligation is imposed on livestock farmers to ensure that their facilities are compliant with requirements. Failure to do so will result in their holdings being downgraded. A copy of the Hygiene Compliance Audit is attached as Appendix 2.

Every breeder is encouraged to put in place a somatic cell plan, and this becomes compulsory when cell counts exceed 800,000 cells per ml. Payments to producers of ewe's milk is based on incoming raw milk meeting specific standards for somatic cell count, total plate count, coliforms, absence of antibiotics and absence of *L. monocytogenes*. Penalties (sanctions) exist for milk that fails to meet specifications *e.g.* once the somatic cell count exceeds 800,000 cells/ml suppliers are penalised and receive a reduced payment for their milk. Where *L. monocytogenes* is found in milk, it is downgraded and leads to withholding of payment.

Low bacterial counts and low somatic cell counts are the key indicators of milk quality and as their numbers increase there is a higher risk of contamination of milk and cheese with pathogens. Notwithstanding public health considerations, high bacterial and somatic cell counts also impact negatively on cheese yield and on quality, and this diminishes consumer acceptability. There are unmistakable public health and commercial incentives to reduce these counts.

In addition, self-inspection by producers is required by the Confederation. French authorities do not monitor milk transportation, but such inspections are performed by producers and Confederation.

### *4.2.3 Non-compliance*

Ewes are culled if the Somatic Cell Count, Californian Mastitis Test (CMT) or mammary lesions are unsatisfactory. Various corrective measures and sanctions are implemented if animal husbandry practices are non-compliant.

If ewes test positive for brucellosis, government veterinary services intervene as defined by legislation.

### *4.2.4 Control of Critical Control Points*

Under the Ministerial Order of 30 December 1993 (Title II: Chapter I, Article 13), operators of establishments collecting milk must monitor hygienic conditions. This includes identifying and monitoring critical control points and keeping records.

The Applicant has submitted a generic HACCP plan addressing the production and collection of ewe's milk. The document titled ***Risk analysis, Identification of Critical Control Points and Implementation of Corrective Measures*** is attached as Appendix 1.

The HACCP plan lists risks in the production of raw milk, identifying specific hazards such as pathogenic microorganisms (*Salmonella* spp. and *L. monocytogenes*), hazards indicating contamination (*E. coli and S. aureus*), and other microbiological hazards (total coliforms, standard plate count, butyric spores, and presence of somatic cells). The plan also identifies risks of contamination during milking and farm storage of ewe's milk.

The HACCP plan provides details of preventative measures employed by producers, and documents critical limits, surveillance procedures and corrective actions for the identified hazards.

Risks associated with *Salmonella* spp. and *L. monocytogenes* are managed by checks and surveillance of premises, animals and drinking water. The HACCP plan sets critical limits of absence in 25 ml of milk for both *Salmonella* spp. and *L. monocytogenes* according to a Pathogen Plan. The documentation indicates that ewe's milk is checked daily for both *Salmonella* spp. and *L. monocytogenes.*

### *4.2.5 Discussion on the control of raw milk*

The documentation indicates that the French authorities and the ewe's milk industry have a well documented system in place for controlling the hygienic production of raw milk.

Compliance with Confederation guidelines, combined with Government regulation, inspection oversight and industry testing should ensure the microbiological status of the incoming raw milk will not compromise the safety of the cheese making process.

However, on-site demonstration of compliance with all the components of this system is needed to confirm that the systems as described are operational and functioning effectively.

## 4.3 Control over the Roquefort cheese manufacturing process

Council Directive 93/43/EEC (14 June 1993) defines food hygiene (Article 2) and requires food businesses to ensure that food is produced hygienically (Article 3). Food business operators must identify critical control points (CCPs) and identify and implement control strategies based on HACCP principles. The definition of food businesses includes all businesses preparing or processing foodstuffs, and includes cheese manufacturers.

The French Ministerial Order of 30 December 1993, concerning the conditions of installation, equipment and operation of centres for the collection or standardisation of milk and facilities treating and processing milk and milk-based products, requires food businesses to ensure food is produced hygienically, and includes monitoring and checking of critical control points. The manufacturers of Roquefort cheese are required to put in place a system that addresses critical control points and undertakes monitoring. Compliance with this requirement was demonstrated by the provision of a generic HACCP plan for the manufacture of Roquefort cheese (Attached in Appendix 3 - ***Downstream HACCP Plan***).

Specific manufacturing parameters for Roquefort cheese are not specified by either French or EEC standards.

### *4.3.1 HACCP*

The HACCP plan submitted for the manufacture of Roquefort cheese is general in nature. While it does not specifically list the hazards that were identified in the hazard analysis step, it broadly describes the types of hazards that may arise at stages during cheese making and chain *e.g.* contamination of milk by equipment, proliferation of bacteria, etc. The HACCP plan demonstrates that the major food safety hazards considered in the scientific evaluation are addressed.

The HACCP plan also describes preventive measures, critical limits, surveillance procedures and corrective measures.

The safety of Roquefort cheese is obtained through adherence to good manufacturing practices that cover cheese making steps such as acidification, syneresis, salting, and ripening and maturation. Critical factors impacting on the safety of the final products include milk temperature during transportation and storage, milk temperature during curd formation, the extent and rate of pH fall during fermentation, salting, and the temperature and period of ripening and maturation. While the HACCP plan requires manufacturers to demonstrate real time control of processing *e.g.* visual checks on cleaning and sanitation, monitoring of pH and temperatures, etc, microbiological monitoring of raw milk, curd and cheese is the prime means by which the safety of this product is achieved.

The HACCP plan indicates that microbiological testing is carried out at the following stages in the cheese making process:

**Table 5: Microbiological testing at stages in the cheese making process**

| **Processing stage** | ***Listeria*** | ***Salmonella*** | ***Staphylococcus*** | **Coliforms** | ***E. coli*** |
|---|---|---|---|---|---|
| Raw milk - each production batch | + | +[1] | +/-[2] | | |
| Coagulation/Stirring | + | | | + | |
| Moulding | + | | | + | |
| Turning out | + | | | + | |
| Salting | + | | | + | |
| Needling | + | | | + | |
| Sealing/packaging | + | | | + | |
| Ripening/Storage | + | + | + | | + |
| Removal of foil/cutting/packaging | + | | | + | |

[1] Testing not mandatory
[2] Systematic testing not carried out

The HACCP plan indicates that the pH of the milk or curd is measured at 3 hours, 6 hours and days 1, 2, 5 and 90 of the cheese making process. A critical limit of pH 4.8 for 5-days has been set but no corrective actions are mentioned, except for a stepped up inspection schedule for slow acidification vats. This schedule is not defined. Effective acidification is necessary to prevent the potential outgrowth of pathogens such as *E. coli, S. aureus, L. monocytogenes* and *Salmonella* spp., and while pH monitoring would confirm the viability of the starter culture, microbiological testing initiated at the coagulation/stirring, moulding, turning out and salting stages demonstrates these organisms have not proliferated at the expense of a slow or non-viable starter.

Temperature is presumably monitored at stages during production, but this is not well documented in the HACCP plan. Data on temperature variations at various stages of cheese making should be pursued at the on-site audit stage *i.e.* raw milk receival, storage etc.

While the HACCP plan states that *Listeria* should not be present in raw milk used in Roquefort cheese manufacture, screening of raw milk may not always provide results in sufficient time to remove non-complaint milk from the Roquefort production chain.

If *Listeria* is detected in milk after processing has commenced the product is not discarded or heat treated, but each batch is tracked and subjected to a more intensive surveillance plan.

The HACCP documentation provided by the applicant is an overview and is heavily weighted towards prevention of contamination by *L. monocytogenes* and coliforms. This is a reflection of the limited number of CCPs associated with the manufacture of cheese from unpasteurised milk. During on-site audit, it will be necessary to access and review actual HACCP plans in selected Roquefort cheese making plants.

FSANZ invited Food Science Australia to analyse the HACCP plan submitted by the applicant. The results of this analysis are summarised in Table 6.

**Table 6: Analysis of the Roquefort HACCP program (Food Science Australia, 2004)**

| Question | Observations |
|---|---|
| Does the HACCP plan identify all hazards associated with the manufacture of Roquefort cheese? | HACCP Plan was only provided and therefore it is not clear if hazards not mentioned were considered.<br>*C. burnetii* was not considered. |
| Are all critical control points identified | Yes - for the hazards specified |
| Is monitoring (both parameter and frequency) of critical control points appropriate for the control of the hazards | No real record of the frequency of monitoring for parameters such as pH and temperature. |
| Do the documented corrective actions effectively address variances from the critical limits | No - corrective actions are not quantitative or decisive in nature (they are presented in the form of corrective measures).<br>Corrective measures usually take the form of increased surveillance, *i.e.* no corrective action given for non-compliance with required milk temperature.<br>The ***more-intensive surveillance plan*** for slow fermenting batches in not clearly specified and appears to be the same as routine surveillance. |
| Do the corrective actions fully consider the implications of a situation where monitoring indicates loss of control at a critical control point | This is critical for pH during fermentation.<br>Corrective measures do not include identification of the source of the fermentation failure. |
| Is the HACCP plan effectively supported by pre-requisite programs (e.g. cleaning and sanitation, pest control, personal hygiene) | It would appear so, although little information is supplied on pre-requisite programs. More information is required on programs in place on-farm. |
| Is there a requirement for industry to implement a HACCP plan and comply with associated French and EC regulations | Yes - HACCP in mandated and inspections are undertaken.<br>The frequency on internal inspections is provided.<br>External audits are undertaken at least once a year, more frequently if problems occur. |
| Actual compliance with the HACCP plan and associated French and EEC regulations | No evidence of actual compliance with HACCP requirements is given.<br>Certification is removed if the processor is non-compliant, but no data is provided. |

### *4.3.2 Microbiological testing*

The national reference laboratory used for testing and analysis of milk and milk based products is AFSSA (Agence Française de Sécurité Sanitaire des Aliments) based at Maisons-Alfort, Paris, and is the European Commission reference laboratory for milk and milk-based products as described in Directive 92/46/EEC.

This laboratory is also the national reference laboratory for milk and milk-based products.

Routine test laboratories include:

- Public test laboratories run by local government. These laboratories carry out, in the capacity of service providers, official testing requested by veterinary agencies as part of their official inspection activities and in the context of the national monitoring and inspection programme. They also carry out self-inspection testing for enterprises and producers.

- Inter-branch milk laboratories (LIAL) managed by the milk industry as a whole and approved by the Prefects of the "département" where they are based. The LIASLs perform tests required by law for the verification of composition and quality-linked payment for milk. They may also test for brucellosis (ring test on milk) and perform some of the tests specified in self-inspection programmes put in place by milk industry professionals.

- Private laboratories, which are either totally independent or set up internally in milk industry enterprises. They are accredited in many cases, carry out routine testing (pH, total counts, surface tests, detection of pathogenic organisms, etc) as part of self-testing programmes put in place by industry, in addition to all the specific testing for milk-based products imposed by official standards.

A summary of microbiological testing in the production of Roquefort cheese is listed in Table 5.

Incoming raw milk is tested on a batch by batch basis for *Listeria, E. coli* and *Salmonella*. Testing for *S. aureus* is not routinely carried out or required by French regulation. French legislation only requires testing of ewe's milk for plate counts (Ministerial Order 18 March 1994):

Plate count <1,000,000 total plate count/ml at 30ºC

Final products are analysed for coliforms, *E. coli*, *S. aureus*, *L. monocytogenes*, and *Salmonella*. With the exception of the *E. coli* standard, French standards for Roquefort cheese are similar to standards required of Australian cheese. Five 25g samples are analysed in both standards. The sample frequency for Roquefort cheese is 5 per batch (Personal communication).

The French Ministerial Order 30 March 1994 in compliance with the requirements of directive 92/46/EEC requires blue veined cheese made from raw milk or thermised milk to meet the following criteria on leaving the establishment:

| | | | | |
|---|---|---|---|---|
| *L. monocytogenes* | Absence in 25 g, | | n = 5 | c = 0 |
| *Salmonella* spp. | Absence in 25 g | | n = 5 | c = 2 |
| *S. aureus* | n = 5 | c = 2 | m = 1,000 | M = 10,000 |
| *E. coli* | n = 5 | c = 2 | m = 10,000 | M = 100,000 |

The Australian guidelines for the microbiological examination of ready-to-eat foods recognise levels of *S. aureus* above $10^3$ as unsatisfactory. The French standards allow 2 of 5 samples to be between $10^3$ and $10^4$ cfu/g.

**Table 7: Internal Microbiological Inspection Procedures for Roquefort**

| Production Stage | Tests | Targets | Frequency |
|---|---|---|---|
| **FARM** | Somatic cells<br>Butyric spores<br>*Listeria*<br>Total coliforms<br>MG, MP | Cf. milk payment scale<br><br>Absence/ml<br>Cf. milk payment scale | 3/month<br>2/month from December to April<br>Silage: 1/batch of ewes for milking<br>3/month<br>4/month |
| Milk collection/ Tanker | *L. monocytogenes*<br>Total coliforms/*E. coli* | Absence/ml | Daily<br>1day/2 |
| Dairy | *Listeria*<br>*Salmonella*<br>*E. coli*<br>Total coliforms | Absence/25 ml<br>Absence/25 ml | Daily |
| Cave | *L. monocytogenes*<br>*Salmonella* spp<br>*S. aureus*<br>*E. coli* | Absence/25g<br>Absence/25g<br><100/g<br><100/g | 1/batch |
| Packaging | *L. monocytogenes*<br>*Salmonella* spp<br>*S. aureus*<br>*E. coli* | Absence/25g<br>Absence/25g<br><100/g<br><100/g | 1/batch |

### *4.3.3 Compliance with Regulations*

Inspectors from the Departmental Veterinary Services Directorates (DDSV) and the Departmental Competition, Consumerism and Fraud Investigation Directorates (DDCCRF) monitor and verify the safety of foodstuffs in the market place.

Inspections focus on relevance and proper implementation of procedures for the control of critical control points identified throughout the manufacturing process. As part of their work they routinely inspect manufacturers of Roquefort cheese.

The frequency of inspection is determined on the basis of:

- perceived risk (Roquefort cheese is included in the same category as pasteurised butter and yoghurt);
- production volume;
- manufacturer's sanitary control plan; and
- inspector's assessment of the factory.

Inspections are supplemented by official samples taken for the purpose of testing finished products. Such samples maybe taken at any stage in the manufacture of milk-based product or its distribution up to the use-by date.

Veterinary inspections are carried out at least once per annum, and more frequently if problems arise, or if there are modifications being made to the plant (Personal communication). This is in-line with current criteria for determining the audit frequency of Australian food processing establishments.

As well as the French inspection programs, EU inspection bodies undertake periodic audits of the French system. These are performed by EU Community inspection bodies, typically as missions by the Food Veterinary Office (FVO). The most recent audit focused on the French alert system. There are no third party audit results addressing the production of ewe's milk or the manufacture of Roquefort cheese. However the implementation in France of the provisions contained in directive 92/46/EEC of 16 June 1992 have led to several inspection missions by the FVO. The main objectives of these missions have been to verify:

- correct transfer to national legislation of the provisions laid down by Community directives;
- satisfactory performance by veterinary authorities;
- satisfactory reliability of test laboratories; and
- adherence of industry professionals to regulatory requirements.

The results from the mission to France to France from 14-18 June 1999 (Report No. XXIV/112/99) to assess application of Directive 92/46/EEC laying down the health rules for the production and placing on the market of milk and milk-based products results were favourable. The report found:

- transposition of Directive 89/362/EEC into French law satisfactory;
- transposition of standards set out in Directive 92/46/EEC transposed satisfactorily;
- inspection staff competent, motivated and well trained;
- most veterinary services implemented; and
- HACCP principles correctly applied to establishments inspected including farms.

Although the report did make some recommendations for improvement, this report was conducted over 5 years ago.

#### *4.3.4 Non compliance*

Raw milk found to be positive for *L. monocytogenes* prior to manufacture is diverted to pasteurisation and individual farm samples are analysed to trace the source of contamination. Industry data suggests that only one positive sample was found in 2003.

Documentation provided by the Applicant also mentions that if raw milk is found to be positive for *Salmonella*, *L. monocytogenes* or *S. aureus* after the start of the manufacturing, that batches are monitored. Milk and cheese loaves which do not meet *Listeria* criteria are diverted to make pasteurised products (feta, or pressed and processed cheeses).

In the event of an unsatisfactory result in testing for *L. monocytogenes* or *Salmonella* spp. the veterinary authorities for the territorial "département where the production establishment is based must be informed. The batch is considered unfit for human consumption and must be removed from the human food chain and market distribution channels. Procedures and control of critical productions points are intensified, and veterinary authorities are kept informed of corrective measure implemented and intensified production monitoring arrangements.

In the event of an unsatisfactory result in testing for *S. aureus* or *E. coli*, veterinary authorities for the territorial "département: where the production establishment is based must be informed. Any breach of the threshold 'M' imposed by the standard for levels of *S. aureus* automatically entails testing to detect possible presence of enterotoxins, and will automatically lead to the batch involved being withdrawal from the market . Procedures for monitoring and control of critical production points must be intensified and veterinary authorities again are kept informed.

It is clear that plants that do not meet EU certification requirements lose their certification and cannot produce cheese e.g. *L. monocytogenes* present in manufacturing plant. Approval is resumed when corrective measures have adequately been put in place.

On-site audit will permit the integrity of these systems for controlling non-compliant product to be confirmed.

### *4.3.5 Discussion on control of the manufacturing process*

A review of the documentation demonstrates that the industry and French authorities have a well documented system of controls for the manufacture of Roquefort cheese.

While there are some gaps in the data presented, the on-site audit will assist in addressing these issues. For example details on the frequency of testing, the method of handling and addressing non-conformances, and evidence of the type of data retained by Roquefort cheese manufacturers will be collected. An on-site audit will verify that recommendations made by the EC Mission have been implemented.

## 5 Conclusions

All hazards considered potentially significant in Roquefort cheese are subject to management through on-farm systems and the application of HACCP-based control during processing. This is in combination with the application of standard operating procedures (SOPs) and good manufacturing practice (GMP) as determined and controlled by the Confederation of Roquefort Producers.

The system of regulating the safety of raw milk and subsequently Roquefort cheese manufacture is considered comprehensive and adequate. Sanctions against producers and manufacturers that fail to meet the requirements of the Ministerial Orders and the requirements of the Confederation of Roquefort Producers are severe.

The regulatory system is consistent with the Codex Code of Hygienic Practice for Milk and Milk Products.

Verification of control measures implemented by the Confederation of Roquefort Producers and enforced by the French Government and results of routine monitoring and testing will be a subsequent process to this review (undertaken as an on-site audit). The audit will be overseen by AQIS, with technical input from FSANZ, and the results will finalise the scientific evaluation and review of the application and be incorporated into the Final Assessment Report.

## Acknowledgements

FSANZ acknowledges the contribution from Food Science Australia in undertaking a review of the documentation and the HACCP plan provided by the French Government, and providing comments and advice.

## References


Codex Alimentarius Commission Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57, 2004) http://www.codexalimentarius.net/web/standard_list.do?lang=en

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

Confédération Générale des producteurs del lait de Brebis et des Industriels du Roquefort '*Guide of Good Manufacturing Practices for the Production of Ewe's milk in the manufacture of Roquefort*'.

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.

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).

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

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.

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 ;

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.

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.

Report Summary in respect of a Food and Veterinary Office mission to France from 14-18 June 1999 to assess application of Directive 92/46/EEC laying down the health rules for the production and placing on the market of milk and milk-based products.
http://europa.eu.int/comm/food/fs/inspections/vi/reports/france/vi_rep_fran_1112-1999_en.html

**APPENDIX 1**

# HACCP plan for the production of ewe's milk

GENERAL CONFEDERATION OF ROQUEFORT

RISK ANALYSIS, IDENTIFICATION OF CRITICAL POINTS AND IMPLEMENTATION OF CORRECTIVE MEASURES

| Stage | Causes | | Preventive measures | Critical limits | Surveillance procedure | Corrective actions |
|---|---|---|---|---|---|---|
| **PRODUCTION OF RAW MILK** | Risks linked to pathogenic germs | 1) *Salmonella spp* | - Good hygiene practice<br>- Checks on water quality<br>- Checks on livestock feed<br>- Compliance with conditions for hygiene | Absence in 25 ml of milk | - Tests on water<br>- Pathogen Plan (A*nnexe 18*) | - Water from public supply network<br>- Sorting to remove defective milk<br>- Elimination of healthy carriers of pathogens<br>- Measures to prevent entry of poultry into breeding buildings |
| | | 2) *Listeria monocytogenes* | - Quality of livestock feed (checks on silage)<br>- Hygiene in premises<br>- Proper mulching | Absence in 25 ml of milk | - Pathogen Plan (A*nnexe 18*) | - Change in livestock feed<br>- Disinfection of buildings<br>- Elimination of healthy carriers of pathogens<br>- Sorting to remove defective milk |
| | Risks linked to germs indicating contamination | 1) *E. Coli* | - Surveillance of safety of drinking water<br>- Hygiene in premises<br>- Proper mulching<br>- Detection of ewes suffering from mammitis<br>- Control of drying off<br>- Veterinary follow-up on livestock | < 500 /ml | - Tests on water<br>- Individual Cell Counts (ICC)<br>- Individual "coli" counts | - Water from public supply network<br>- Cell-count programme(*Annexe 22*)<br>- Rejection of ewes with chronic mammitis and high ICCs, as well as ewes with udder defects<br>- Control of drying off |
| | | 2) *Staphylococcus aureus* | - Detection of ewes suffering from mammitis<br>- Detection of wounds<br>- Control of drying off | < 100 /ml | - Surveillance of mammitis<br>- Surveillance of wounds | - Rejection of ewes suffering from mammitis and ewes with udder wounds<br>- Control of drying off |
| | Other microbiological risks (total coliforms, standard plate count, butyric spores, cells | | - Good hygiene practice | Cross-industry chart (*Annexe 17*) | - Checks on milk quality (microbiological tests) | - Cleaning and disinfection of the tank room, milking machine, and tank<br>- Review of feed distribution procedures |

| Stage | Causes | Preventive measures | Critical limits | Surveillance procedure | Corrective actions |
|---|---|---|---|---|---|
| | Defective hygiene on the holding and in its environment | - Good hygiene practice<br>- Good maintenance of sheep pen, milking room, dairy, lock room and surroundings, and feed storage | - Visual inspection<br><br>- Combat against pest infestation | - Audit of holding (*Annexes 19 and 20*)<br>- Checks on safety of drinking water (tests)<br>Feed tests | - Completion of modification works within imposed time period. Feed rejection. |
| **MILKING** | - Contamination by animals<br>- Contamination by equipment<br>- Contamination by the milker<br>- Contamination by the environment | - Checks on animals<br>- Cleaning and disinfection of the milking machine<br>- Checks on the milking machine<br>- Personal hygiene and good health of the milker<br>- Rational design of the milking room (sheltered from external sources of contamination) | - Tests to determine milk quality (limit levels for plate count, coliforms, butyric spores, cells, absence of antibiotics, absence of *Listeria monocytogenes*) | - Udder examination<br>Daily or periodic tests<br><br>- Tests on water quality<br>Inspection by CRA (Crop Relations Agent)<br><br>- Checks on effectiveness of cleaning and disinfection procedures | - Selection of animals<br>- Replacement of worn components<br>- Review of milking practices<br>- Treatment of local water supply or connection to public supply network<br>- Checks on the effectiveness of cleaning and disinfecting practices of equipment and premises<br>- Disinfection of milker's hands |
| **FARM STORAGE** | - Contamination or germ growth due to equipment | - Maintenance of milk tank - Thermometer calibration<br>- Satisfactory cleaning and disinfection procedures | - Tank temperature<br>4 - 8° C<br>- Speed of cooling<br>- Visual inspection | - Checks on conservation temperature<br>- Reductase test at dairy factory<br>- Checks on effectiveness of cleaning and disinfection procedures | - Reconditioning or replacement of equipment<br>If temperature > 10°C or resazurin test + in less than 10 min, ∏ rejection of milk |

**APPENDIX 2**

**Hygiene Compliance Audit plan**

***GENERAL ROQUEFORT CONFEDERATION***

***HYGIENE COMPLIANCE AUDIT***

## DETAILS OF AGRICULTURAL HOLDING

**PRODUCER CODE: ……. INSEE identification number: …….……**

**NAME: ……..… NAME OF HOLDING: ……..……..**

**ADDRESS: ……..…….**

**CHEESE DAIRY: …….……. UAA (CAP DECLARATION): …….……**

**MILK INSPECTION: NO π YES π**

**IF YES, INSPECTING BODY……. CLO π CLS π AT π**

**AREA OF SHEEP-PEN: …… LYING AREA: ……**

**NUMBER EWES PRESENT AT LAMBING: ……**

**OTHER PRODUCTION: ……**

*PRODUCER UNDERTAKINGS*

ON FIRST VISIT: **I the undersigned, (name)……, hereby undertake to ensure due compliance on the points found to be unsatisfactory by (date)**
**……..**

Done at (location) …… ……., on (date) ……

Signature of producer:

ON SECOND VISIT: I the undersigned, (name) ……., hereby undertake to ensure due compliance on the points found to be unsatisfactory by (date one month later) _____ . If the modifications have not been completed, my milk production will be downgraded on each litre in an amount equal to the difference between my Class I price and my Class II price as from that date. The downgrading will continue to apply until due completion of the modifications.

Done at (location) …… ……., on (date) ……

Signature of producer:

# DESCRIPTION OF PRODUCTION CONDITIONS

| CRITERIA | STANDARDS | First Visit OVERVIEW OF EXISTING CONDITIONS | | Second Visit IMPLEMENTATION OF MODIFICATIONS | | Third Visit COMPLETION OF MODIFICATIONS | | Fourth Visit FURTHER PERIOD FOR MODIFICATIONS | | Observations ① |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | |
| Inspectors | Hygiene Officer | | | | | | | | | |
| | ARC: Crop Liaison Off. | | | | | | | | | |
| 1 – SHEEP-PEN | | | | | | | | | | |
| Area per animal | 1.2 sq. metre | | | | | | | | | |
| Condensation | None | | | | | | | | | |
| Ammonia odour | Absent | | | | | | | | | |
| Straw bedding | Satisfactory, laid down daily | | | | | | | | | |
| Cleanliness of drinking troughs | Water clear | | | | | | | | | |
| Disinfection of drinking troughs | Weekly | | | | | | | | | |
| Disinfection and elimination of insects in buildings | Yearly | | | | | | | | | |
| 2 – MILKING PARLOUR | | | | | | | | | | |
| Connection with sheep-pen | Separate | | | | | | | | | |

| CRITERIA | STANDARDS | First Visit OVERVIEW OF EXISTING CONDITIONS | | Second Visit IMPLEMENTATION OF MODIFICATIONS | | Third Visit COMPLETION OF MODIFICATIONS | | Fourth Visit FURTHER PERIOD FOR MODIFICATIONS | | Observations ① |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | |
| Condition of flooring | Cleanable material Resistance to thermal shock and impact | | | | | | | | | |
| Cleaning and disinfection of flooring | Immediately after milking | | | | | | | | | |
| Drainage of liquids and washing water | Central channel bottom and livestock platforms inclined toward drain | | | | | | | | | |
| Condition of walls | Cleanable | | | | | | | | | |
| External surfaces of milking machine | Clean | | | | | | | | | |
| Ambient environment | Dry | | | | | | | | | |
| Products and other items | None | | | | | | | | | |
| Cleaning & disinfection of milking machine | Immediately after milking | | | | | | | | | |
| Water supply point | In central channel | | | | | | | | | |
| Ceiling | No water ingress | | | | | | | | | |
| Inspection of milking equipment | Annual inspection | | | | | | | | | |

| CRITERIA | STANDARDS | First Visit OVERVIEW OF EXISTING CONDITIONS | | Second Visit IMPLEMENTATION OF MODIFICATIONS | | Third Visit COMPLETION OF MODIFICATIONS | | Fourth Visit FURTHER PERIOD FOR MODIFICATIONS | | Observations ① |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | |
| 3 – DAIRY | | | | | | | | | | |
| Connection with milking parlour | No more than 1 door | | | | | | | | | |
| Floor material | Smooth & washable | | | | | | | | | |
| Wall material | Smooth & washable | | | | | | | | | |
| Method for cleaning and disinfecting flooring | Hosing down | | | | | | | | | |
| Method for cleaning and disinfecting walls | Hosing down | | | | | | | | | |
| Cleaning and disinfection of milk tank | Immediately after draining | | | | | | | | | |
| Description of flooring | Floor well drained and waste trap fitted | | | | | | | | | |
| Drainage | Sufficient slope to trap | | | | | | | | | |
| Materials permitted to be stored on premises | Cleaning products for the milking equipment and milk tank | | | | | | | | | |

| CRITERIA | STANDARDS | First Visit OVERVIEW OF EXISTING CONDITIONS | | Second Visit IMPLEMENTATION OF MODIFICATIONS | | Third Visit COMPLETION OF MODIFICATIONS | | Fourth Visit FURTHER PERIOD FOR MODIFICATIONS | | Observations ① |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | |
| Cleaning products for use | If officially approved | | | | | | | | | |
| Authorised equipment | Milking equipment | | | | | | | | | |
| Ceiling | No water ingress | | | | | | | | | |
| Lighting | Adequate | | | | | | | | | |
| Air ventilation | Upper and lower ventilation openings with mosquito screen | | | | | | | | | |
| 4 – VESTIBULE AREA | | | | | | | | | | |
| Existence | Strongly recommended if premises renovated Obligatory when premises newly built | | | | | | | | | |
| Storage facilities | Cloakroom Veterinary products kept in cupboard | | | | | | | | | |
| Water supply | Wash basin with hot and cold water | | | | | | | | | |
| 'Water quality | If from public supply: OK Other supply: to be tested | | | | | | | | | |

| CRITERIA | STANDARDS | First Visit OVERVIEW OF EXISTING CONDITIONS | | Second Visit IMPLEMENTATION OF MODIFICATIONS | | Third Visit COMPLETION OF MODIFICATIONS | | Fourth Visit FURTHER PERIOD FOR MODIFICATIONS | | Observations ① |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | |
| 5 – SURROUNDING AREA | | | | | | | | | | |
| Loading and turning area for milk tanker | Stabilised Free of obstructions Dry | | | | | | | | | |
| Location of manure pit | Sufficiently distant from dairy and points of passage of tanker and livestock | | | | | | | | | |
| 6 – TREATMENT OF RUN-OFF WATER AND LIQUOR | | | | | | | | | | |
| Run-off water | Treatment | | | | | | | | | |
| Silage liquor | Spreading on land | | | | | | | | | |
| Manure liquor | Spreading on land | | | | | | | | | |
| 7 - SUNDRY | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| 8 - OVERALL ASSESSMENT | | | | | | | | | | |
| | | | ② | | ② | | | | | |

| CRITERIA | STANDARDS | First Visit OVERVIEW OF EXISTING CONDITIONS | | Second Visit IMPLEMENTATION OF MODIFICATIONS | | Third Visit COMPLETION OF MODIFICATIONS | | Fourth Visit FURTHER PERIOD FOR MODIFICATIONS | | Observations ① |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | Satisfactory | Unsatis. | |
| **SIGNATURES** (according to outcome: satisfactory or unsatisfactory) | Producer | | | | | | | | | |
| | Hygiene Officer | | | | | | | | | |
| | ARC – Crop Liaison Officer | | | | | | | | | |

OBSERVATIONS: ……
……
……
……
……
……
……

Criteria and standards highlighted in white on black are mandatory.

① Tick (✓) the modifications the producer undertakes to carry out.

② If the state of the holding is unsatisfactory, undertaking given by the producer on P1 to be filled in and signed.

*Document produced in 3 copies: Producer – ARC – General Roquefort Confederation*

**APPENDIX 3**

## HACCP plan for manufacture of Roquefort cheese

GENERAL CONFEDERATION OF ROQUEFORT

## HAZARD ANALYSIS, CRITICAL CONTROL POINT IDENTIFICATION AND IMPLEMENTATION OF CORRECTIVE MEASURES – DOWNSTREAM HACCP PLAN

| Stage | Hazards / Critical Control Points | Preventive measures | Critical limits | Surveillance procedures | Corrective measures |
|---|---|---|---|---|---|
| | - Contamination of the milk<br>- by the tanker<br>- by the equipment used<br>- by the environment<br><br>- Temperature rise in the milk during journey | - Dairy surroundings to be clean and well drained<br><br>- Cleaning and disinfection schedule for the tanker and milk transfer lines<br><br>- Training of personnel<br>Transport to be done in heat-insulated tankers | - Absence of coliforms in rinse water<br><br>- Milk temperature < 10 °C | - Visual checks on areas at risk<br><br>- Verification of proper functioning of CIP (Cleaning In Place) system (concentration, flow rate , temp.)<br>- Tests for coliforms in rinse water | - Stepped up cleaning and disinfection procedures |

| Stage | Hazards / Critical Control Points | Preventive measures | Critical limits | Surveillance procedures | Corrective measures |
|---|---|---|---|---|---|
| TRANSPORT & TANKER COLLECTION | - Contamination of the tanker or storage tanks when contaminated milk is collected during a round subject to contamination | - Test for *Listeria monocytogenes* in the milk mix in each tanker or storage tanks | - Absence of *Listeria monocytogenes* | - Tests for *Listeria monocytogenes* on each tanker or each collection round | - Milk to be sorted (*non-compliant milk to be removed from the Roquefort production chain*)<br>- Identification of livestock farmer and ewe through milking batch<br>- Holding involved to be audited<br>- Holding to be reintegrated into the milk collection system only when test results negative on two consecutive days |
| | - Contamination of milk<br>- by the tanker<br>- by the equipment used<br>- by the environment | - Dairy surroundings to be clean and well drained<br><br>- Cleaning and disinfection schedule for the truck and milk transfer lines<br><br>- Training of personnel | - Absence of coliforms in rinse water | - Visual checks on areas at risk<br><br>- Verification of proper functioning of CIP (Cleaning In Place) system (concentration, flow rate, temp.)<br>- Tests for coliforms in rinse water | - Stepped up cleaning and disinfection procedures (immediate surroundings of facility, tanker, equipment) |

| Stage | Hazards / Critical Control Points | Preventive measures | Critical limits | Surveillance procedures | Corrective measures |
|---|---|---|---|---|---|
| RECEPTION<br><br>STORAGE / COOLING | - Contamination of milk by *Listeria monocytogenes* or *Salmonella sp* | - Sorting of collection rounds<br>- Preventive measures on livestock holding | - Absence of *Listeria monocytogenes* and *Salmonella sp* | - Systematic tests for *Listeria monocytogenes* and *Salmonella sp*<br>- Random tests for *Staphylococcus aureus* | - If the results are known prior to production the milk is to be sent through to pasteurisation-based production<br>- If the results are known only after production of the cheese, the production batches must be tracked<br>- *More intensive surveillance plan* |
| PREPARATION OF MILK PLACING IN VAT / INOCULATION | - Contamination by the equipment used<br>- Contamination by the system<br>- Contamination by ingredients: ferments, rennet, *Penicillium roqueforti* | - Cleaning and disinfection schedule<br>- Good hygiene practice in preparing ferments<br>- Required specifications to be agreed with supplier | - Absence of coliforms<br>- Compliance with agreed specifications | - Absence of coliforms and *Listeria monocytogenes* in rinse water<br><br>- Test report form for each batch | - Verification of correct operation of CIP system (concentration, pressure, temp.)<br>- Verification of compliance with good hygiene practice and training of personnel<br>- Complaints to be investigated and suppliers audited |
| COAGULATION STIRRING | - Contamination by handling procedures<br><br>- Contamination by equipment used | - Clean clothing<br>- Clean hands<br>- Personnel training<br><br>- Good cleaning and disinfection practice | - Clean smocks, footwear and caps to be worn<br><br>- Absence of coliforms and *Listeria monocytogenes* | - Visual checks<br><br>- Monitoring of coliforms on hands<br><br>- Monitoring of coliforms and *Listeria monocytogenes* | - Stepped up checks on cleaning<br>- Stepped up cleaning and disinfection<br>- Renewed awareness raising / training for personnel |
| MOULDING | - Contamination by handling procedures<br><br>- Contamination by equipment used | - Clean clothing<br>- Clean hands<br>- Personnel training<br><br>- Good cleaning and disinfection practice | - Clean smocks, footwear and caps to be worn<br>- Absence of coliforms on hands<br><br>- Absence of coliforms and *Listeria monocytogenes* | - Visual checks<br><br>- Monitoring of coliforms on hands<br>(no coliforms to be present)<br><br>- Monitoring of coliforms and *Listeria monocytogenes* | - Stepped up checks on cleansing of hands and awareness raising / training for personnel<br><br>- Stepped up cleaning and disinfection |

| Stage | Hazards / Critical Control Points | Preventive measures | Critical limits | Surveillance procedures | Corrective measures |
|---|---|---|---|---|---|
| DRAINING | - Proliferation of bacteria due to incorrect acidification | - Good practice in the production of the ferments<br><br>- Verification of acidification capacity of ferments used | - pH of curd (5 days below 4.8)<br><br>- Optimised milk / ferment coupling | - Monitoring of pH levels (cf. plot in *Annexe 24*) | - Stepped up inspection schedule for slow acidification vats |
| TURNING OUT | - Contamination by handling procedures<br><br>- Contamination by equipment used | - Clean clothing<br>- Clean hands<br>- Personnel training<br><br>- Good cleaning and disinfection practice | - Clean smocks, footwear and caps to be worn<br>- Absence of coliforms on hands<br><br>- Absence of coliforms and *Listeria monocytogenes* | - Visual checks<br><br>- Monitoring of coliforms on hands<br><br>- Monitoring of coliforms and *Listeria monocytogenes* | - Stepped up checks on cleansing of hands and renewed awareness raising / training for personnel<br><br>- Stepped up cleaning and disinfection |
| SALTING | - Contamination by handling procedures<br><br>- Contamination by equipment used | - Clean clothing<br>- Clean hands<br>- Personnel training<br><br>- Good cleaning and disinfection practice | - Clean smocks, footwear and caps to be worn<br>- Absence of coliforms on hands<br><br>- Absence of coliforms and *Listeria monocytogenes* | - Visual checks<br><br>- Monitoring of coliforms on hands<br><br>- Monitoring of coliforms and *Listeria monocytogenes* | - Stepped up checks on personnel<br>- Stepped checks on cleaning<br>- Renewed awareness raising / training for personnel<br>- Stepped up cleaning and disinfection |
| STORAGE | - Proliferation of bacteria due to break in cold chain<br><br>- Contamination by environment | - Clean clothing<br>- Maintenance and upkeep of refrigeration system<br><br>- Detection of microbial build-up in storage facilities<br>- Pest control plan | - Clean smocks, footwear and caps to be worn<br>- Temp: between 2°C and + 6°C<br>- Stable relative humidity levels<br>- Bait, insect traps | - Visual checks<br><br>- Recording thermometers and hygrometers<br><br>- Visual checks + and regular visits to be made by outside approved pest control companies | - Stepped up checks on personnel<br>- Repairs to refrigeration systems<br>- Regulated ventilation<br><br>- More intensive pest control plan |

| Stage | Hazards / Critical Control Points | Preventive measures | Critical limits | Surveillance procedures | Corrective measures |
|---|---|---|---|---|---|
| TRANSPORT | - Contamination by handling procedures | - Clean clothing<br>- Clean hands<br>- Personnel training | - Clean smocks, footwear and caps to be worn<br>- Absence of coliforms | - Visual checks<br><br>- Monitoring of coliforms on hands | - Stepped up checks on negligent personnel<br><br>- Stepped up cleaning and disinfection and<br>- Awareness raising / training for personnel |
| NEEDLING | - Contamination by handling procedures<br><br>- Contamination by equipment used | - Clean clothing<br>- Clean hands<br>- Personnel training<br><br>- Good cleaning and disinfection practice | - Clean smocks, footwear and caps to be worn<br><br>- Absence of coliforms<br><br>- Absence of coliforms and *Listeria monocytogenes*<br>- Needling order of cheese (batches subject to more intensive surveillance should be processed last) | - Visual checks<br>- Monitoring of coliforms on hands<br><br>- Monitoring of coliforms and *Listeria monocytogenes* on equipment | - Stepped up checks on personnel<br>- Stepped up cleaning and disinfection and<br>- Awareness raising / training for personnel<br>- Surveillance based on traceability system |
| ENTRY TO FERMENTING CELLAR | - Contamination by handling procedures | - Clean clothing<br>- Clean hands<br>- Personnel training | - Clean smocks, footwear and caps to be worn<br><br>- Absence of coliforms | - Visual checks<br><br>- Monitoring of coliforms on hands | - Stepped up checks on personnel<br>- Stepped up cleaning and disinfection<br>- Renewed awareness raising / training for personnel |
| TINFOIL COVERING (SEALING)<br><br>PACKAGING | - Contamination by handling procedures<br><br>- Contamination by equipment used<br><br>- Contamination by packaging | - Clean clothing<br>- Clean hands<br>- Personnel training<br>- Good cleaning practice<br>- Required specifications to be defined with supplier | - Clean smocks, footwear and caps to be worn<br><br>- Absence of coliforms *and Listeria monocytogenes*<br><br>- Total absence of soiling | - Visual checks<br><br>- Monitoring of coliforms on hands<br><br>- Monitoring of coliforms and *Listeria monocytogenes*<br>- Visual checks on reception and when placed in store | - Stepped up checks on personnel<br>- Stepped up cleaning and disinfection<br>- Renewed awareness raising / training for personnel<br>- Stepped up protection when cheese placed in store |

Milk which is detected as non-compliant at D+1 (for *Listeria monocytogenes* or *Salmonella sp*) is sent through to a pasteurisation facility for use in the manufacture of a product other than Roquefort. Any product made with non-compliant milk is placed under close surveillance and any finished product non-compliant for *Listeria monocytogenes*, *Salmonella sp*, *Escherichia coli*, or which contains the *Staphylococcus aureus* exterotoxin is eliminated.

| Stage | Hazards / Critical Control Points | Preventive measures | Critical limits | Surveillance procedures | Corrective measures |
|---|---|---|---|---|---|
| RIPENING / STORAGE | - Proliferation of bacteria due to break in cold chain | - Maintenance and upkeep of refrigeration system | - Temp: between 2°C and + 6°C<br>- Relative humidity levels | - Recording thermometers and hygrometers | - Repairs to refrigeration systems<br>- Regulated ventilation |
| | - Contamination by *Listeria monocytogenes, Salmonella sp*, *E. coli*. *Staphylococcus aureus* of batches sent through for packaging | - Inspection required for release at end of ripening period<br>*Only compliant batches to be sent through for packaging* | - Absence of *Listeria monocytogenes*<br>- Absence of *Salmonella sp*<br>- *E. coli* < 100 /g (*for batches to be shipped to Australia*)<br>- *Staphylococcus aureus* < 100/g (*for batches to be shipped to Australia*) (minimum of 5 samples to be taken per batch) | - Testing for *Listeria monocytogenes*, *Salmonella sp*, *E. coli*. and *Staphylococcus aureus* in all fermenting cellars<br>- *Special sorting procedure for batches intended for shipment to Australia in terms of E. coli and Staphylococcus aureus criteria* | - Destruction of non-compliant batches (presence of *Listeria monocytogenes* or breach of maximum permitted level of any other potentially pathogenic bacterium) |
| TRANSPORT | - Contamination by handling procedures | - Clean clothing<br>- Clean hands<br>- Personnel training | - Absence of coliforms | - Visual checks<br>- Monitoring of coliforms on hands | - Stepped up cleaning and awareness raising / training for personnel |

| Stage | Hazards / Critical Control Points | Preventive measures | Critical limits | Surveillance procedures | Corrective measures |
|---|---|---|---|---|---|
| REMOVAL OF TINFOIL COVERING (UNSEALING) CUTTING REPACKAGING | - Contamination by handling procedures<br><br>- Contamination by equipment used | - Clean clothing<br>- Clean hands<br>- Personnel training<br><br>- Good cleaning and disinfection practice | - Clean smocks, footwear and caps to be worn<br><br>- Absence of coliforms<br><br>- Absence of coliforms *and Listeria monocytogenes* | - Visual checks<br><br>- Monitoring of coliforms on hands<br><br>- Monitoring of coliforms and *Listeria monocytogenes* | - Stepped up cleaning and awareness raising / training for personnel<br><br>- Stepped up cleaning and disinfection |
| CUTTING PACKING | - Contamination by handling procedures<br>- Contamination by equipment used | - Clean hands<br>- Personnel training<br>- Good cleaning and disinfection practice | - Absence of coliforms *and Listeria monocytogenes* | Monitoring of coliforms on hands<br><br>- Monitoring of coliforms and *Listeria monocytogenes* | - Stepped up cleaning and disinfection and<br>- Renewed awareness raising / training for personnel |

**ATTACHMENT 4**

# SUMMARY OF THE REQUIREMENTS OF THE FRENCH MINISTERIAL ORDERS

| | **Ministerial Order of 18 March 1994 on the hygiene of milk production and collection** | |
|---|---|---|
| | Chapter 1 – Animal health requirements | For ewes - milk must be collected from animals free from brucellosis. Animals must show no signs of disease or present with any wounds (e.g. to udder) likely to affect milk.<br>Milk is excluded from collection, treatment, processing and sale if it does not comply with stipulated conditions. |
| | Chapter 2 – Hygiene at the production holding | - covers general conditions applying to premises used for animal housing, milking and storage as well as more detailed conditions applying to milk treatment rooms and premises where milk is stored. |
| | Chapter 3 – Hygiene of milking, storing and collecting operations | Milking hygiene – general requirements<br>Storage of milk – prescribes temperature of storage until collection (8°C or lower if not collected within 2 hours of milking; 6°C or lower if not collected every day). Temperature during **transportation** must not exceed 10°C.<br>Equipment hygiene – general requirements<br>Staff hygiene – general requirements (including hand washing, location of washing facilities).<br>(**Note:** Ministerial Order of 10 March 1977 covers the state of health and hygiene of personnel involved in handling foods of animal origin. Any person with a transmissible disease; known carriers of Salmonella, Shigella, E. coli, presumed pathogenic Staphylococci; carriers of vegetative or cystic form of amoeba, tapeworms or helminthiases, not permitted to be involved in milk handling operations). |
| | Chapter 4 – Standards to be met | Criteria for goat and ewe's milk:<br>Raw goat or ewe's milk intended for the manufacture of raw-milk products whose manufacturing processes do not include any heat-treatment must satisfy the following criteria:<br>Plate count 30°C: < 500 000<br>*Staphylococcus aureus* (per ml): m=500; M=2000; n=5; c=2<br><br>Compliance with requirements checked by random sampling during collection and holding (Staphylococcus may be further checked during receival of raw milk at treatment or processing establishment).<br><br>Possible derogations from microbiological criteria may be granted (Minister of Agriculture and Fisheries). |

| | | |
|---|---|---|
| | **Ministerial Order of 28 June 1994 on the identification and sanitary approval of establishments** | |
| | Chapter 1 - Identification | Establishments involved in the preparation, treatment, handling or storage of animal foodstuffs or foodstuffs of animal origin should be identified by a number given by the Director of Veterinary Services. |
| | Chapter 2 - Approval | An establishment, as part of the approval process must submit a number of documents. These include plans and description of the establishment; the cleaning and disinfecting program; the pest control program; staff training programs, and the analysis of critical control points. The Director of Veterinary Services grants sanitary approval is granted when the establishment can demonstrate compliance with the sanitary requirements (appropriate to the product) relating to the premises, equipment and operation. |
| | Chapter 3 – Health Mark | This chapter specifies how the Community (EC) health mark should be used/displayed. |
| | | |
| | **Ministerial Order of 2 March 1995 on the approval of milk collection, standardization or treatment centres and of establishments involved in the processing of milk and milk based products** | |
| | Chapter 1 - Approval | This Order refers to the provisions of the Ministerial order of 28 June 1994. Chapter 1 stipulates that, for sanitary approval, documentation must be provided which:<br>▪ provides the latest results of the establishment's own checks performed on raw materials and foodstuffs placed on the market<br>▪ the name of the laboratory performing the tests |
| | Chapter 2 – Health Mark | This chapter stipulates that drinking milk and milk-based products placed on the market by an approved establishment must bear the EC health mark and outlines how this ark should be displayed. |
| | Chapter 3 – Final provisions | Includes requirements for appropriate documentation to accompany products placed on the market and traceability requirements. |
| | | |
| | **Ministerial order of 30 December 1993 on requirements relating to the premises, equipment & operation of milk collection centres and establishments involved in the treatment or processing of milk or milk-based products** | |
| | Article 1 - Definitions | |
| | Title 1 – Requirements relating to the premises & equipment of establishments<br>Chapter 1 - Principles<br>Chapter 2 - Premises<br>Chapter 3 - Equipment | Prescribes requirements for the layout of food premises and equipment relating to the hygienic production of food (e.g. use of wet and dry areas; premises/floors/walls/ceiling easy to clean and disinfect; waste water disposal) Includes pest control, the provision of hand washing facilities, storage facilities and toilet facilities. |

| | | |
|---|---|---|
| | Title 2 – Requirements relating to hygiene of operation<br>Chapter 1- Control of hygiene | Requirements specified within this Chapter include:<br>▪ identifying critical control points<br>▪ monitoring and checking of CCPs<br>▪ the keeping of written records (to be kept for a period of at least 2 years)<br>▪ the taking of samples to check effectiveness of process and compliance with standards<br>▪ the implementation of a food hygiene staff training program |
| | Chapter 2 – General hygiene requirements relating to premises and equipment | ▪ requirement to keep floors, walls, ceilings, partitions well maintained and clean<br>▪ no animals in storage and manufacturing facilities<br>▪ eradication of pests<br>▪ use of potable water<br>▪ conditions under which manufacturing, wrapping and packaging operations may be performed in the same room<br>▪ premises, equipment, tools and tanks used for milk can be only used for the preparation of drinking milk and milk-based products |
| | Chapter 3 – Cleaning and Disinfecting | ▪ use of approved products<br>▪ frequency of cleaning rooms, utensils, containers and equipment<br>▪ cleaning and disinfection of containers and tanks used for transporting raw milk |
| | Chapter 4 – Staff hygiene | General hygiene requirements including suitable clothing and head coverings; hand washing; covering of skin wounds; prohibition of smoking, spitting, eating or drinking on premises. |
| | Title III – final provisions | A derogation from provisions relating to construction of premises may be granted to establishments that manufacture cheeses with a maturation period of 60 days or more (if conforming with provisions would be detrimental to traditional characteristics) |
| | | |

| | | |
|---|---|---|
| | **Ministerial Order of 30 March 1994 on the microbiological criteria that drinking milk and milk-based products must satisfy in order to be placed on the market** | |
| | Articles 1 - 5 | - provide definitions and conditions for testing |
| | Annex A – Microbiological criteria for drinking milk | Sampling plans for a number of microorganisms are provided for drinking milk – raw, pasteurised and UHT |
| | Annex B –<br>1. Microbiological criteria for cheeses | Sampling plans for a number of microorganisms are provided for several cheese categories including hard cheeses (from heat treated and raw/thermised milk); soft cheeses (from heat treated and raw/thermised milk); blue-veined cheeses (from heat treated and raw/thermised milk<br><br>For Blue-veined cheeses made from raw or thermised milk, the following criteria are stipulated:-<br>*Listeria monocytogenes*: Absence in 25g (n=5, c=0)<br>*Salmonella spp*: Absence in 25g (n=5, c=0)<br>*Staphylococcus aureus*: n=5, c=2, m=1000, M=10 000<br>*Escherichia coli*: n=5, c=2, m=10 000, M=100 000 |
| | Annex B –<br>2. Other milk based products | Sampling plans for a number of microorganisms are provided for various milk-based products including milk powder and other powdered milk- based products. |
| | Article 5 | Derogations to meeting the microbiological criteria for cheese may be granted by the Minister for Agriculture and Fisheries to establishments manufacturing products with traditional characteristics - only if compliance with those criteria would be detrimental to the manufacture of the product. |

**Attachment 5.**

# AUSTRALIAN QUARANTINE AND INSPECTION SERVICE (AQIS) ASSESSMENT OF OFFICIAL INSPECTION AND CERTIFICATION SYSTEM - ROQUEFORT CHEESE

**30 March – 8 April 2005**


**Executive Summary**

Part 1 of this report deals with Government to Government certification. The government to government certification will become the primary risk management approach for ongoing control of the safety and compliance of Roquefort cheese, should the FSANZ board approved the application.

This part concludes that the French inspection and certification system can provide Australia confidence that Roquefort cheese, certified by French authorities, will meet Australian requirements that are described in the proposed draft standard.

Part 2 of this report describes the actual audit process from which the conclusions on the acceptability of the French system were drawn. This part includes a report on all elements of cheese manufacture, from farm through manufacturing and packaging of the final product.

Part 2 notes several audit findings, which were drawn to the attention of French authorities. All findings were noted and the majority were already in the process of correction. None of these findings affected the overall conclusion of the audit.

The audit conclusions were that the manufacture of Roquefort could reliably meet the requirements stipulated in the proposed draft standard.

# PART 1
# CERTIFICATION

## INTRODUCTION

In January 2002 an Australian company sought to import Roquefort cheese. The consignment was held by AQIS on the basis that the cheese did not meet the extant requirements stipulated in the Australia New Zealand Food Standards Code (the Code). AQIS was obliged to consider the cheese as "failing food" as it did not comply with the Code, which requires that milk and milk products for cheese production must be heat-treated and stipulated as acceptable are:

- pasteurisation (e.g. holding at a temperature of at least 72ºC for no less than 15 seconds); and
- thermisation (e.g. holding at a temperature of at least 62ºC for no less than 15 seconds) combined with a minimum storage period of 90 days.

Following the rejection of the cheese in 2002, the French Government (Ministry of Agriculture, Food, Fisheries and Rural Affairs) applied to Food Standards Australia New Zealand for a variation to the Code with the aim of ensuring that such cheese would comply with the Code.

Upon receipt of such an application there are requirements according to the Food Standards Australia New Zealand Act (1991), which must be conducted by FSANZ. The Draft Assessment report, 23 March 2005 (DAR) is integral to that process.

Related to the application the French authorities requested that AQIS enter into a certification arrangement to cover the compliance of Roquefort cheese with the Code, as an alternative to routine testing upon arrival in Australia.

Part 1 of this report of the audit deals with the French official inspection and certification system that oversees the production of Roquefort cheese (30 March to 8 April 2005). The report presents the findings in respect of the internationally agreed criteria for assessment of official inspection and certification systems operating in exporting countries as outlined in Codex *"Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Control Systems"* CAC/GL 26-1997.

## AQIS ROLE

AQIS is responsible for the administration and implementation of the *Imported Food Control Act (1992)* (The Act). AQIS achieves this through a mix of border inspection of food according to the risk presented to public health and foreign government certification arrangements where these can be shown to be reliable.

AQIS's responsibilities within the Act that are particularly relevant to the importation of Roquefort Cheese include:

- Assessing imported food for compliance with the *Australia New Zealand Food Standards Code* and fitness for human consumption

- Developing and maintaining certification arrangements with exporting country governments.

## AQIS IMPLEMENTATION OF THE FOOD STANDARDS CODE.

AQIS currently has two mechanisms for implementation of the Code.

### Border inspection and analysis

Where certification arrangements have not been negotiated AQIS samples and analyses products for compliance with the relevant standard at rates according to the risk category of the particular product. Risk products (which includes soft and some semi-hard cheeses) are not released unless they comply with standards.

### Certification arrangements

AQIS encourages the implementation of controls over food production at the earliest point in production, and notes that this is particularly important in the case of raw milk cheese. AQIS is able to recognise controls implemented by official systems in exporting countries that aim to ensure safety of particular products. If AQIS is confident that the system is in place and can deliver an appropriate level of confidence (i.e. can assure compliance with the appropriate standard), then goods certified by the authority in the exporting country will be accepted with minimum testing upon arrival in Australia.

Certification arrangements can be negotiated where an exporting country can assure AQIS that its official inspection and certification systems are at least equivalent to that in Australia. Criteria examined are summarised here. Details are presented in Attachment 1 to this report:

- Legislation
- Competent authority
- Assessment of control programs
- Inspection staff: facilities and training
- Laboratories
- Verification of inspection and certification systems

## DESCRIPTION OF SYSTEM UNDER WHICH ROQUEFORT CHEESE IS PRODUCED

The manufacture of Roquefort cheese is controlled by a combination of strict industry and government controls.

## INDUSTRY CONTROLS

The industry controls are implemented by the General Confederation of Ewes Milk Producers and Roquefort Manufacturers (The Confederation). The Confederation has strong influence over the hygiene of milk production through payment incentives based on milk quality. The Confederation sets conditions for the production and transport of milk including time and temperature, which make significant contribution to the milk quality. The Confederation also provides veterinary and agriculture extension officers to assist farmers to maintain flock quality and milk quality.

While there is a strong monetary incentive for farmers to comply with industry requirements, there is also strong "status" incentive. There are more willing suppliers of milk for Roquefort cheese industry than there is demand. An informal system of "licensing" milk producers exists and the opportunity to supply manufacturers for the Roquefort market is keenly sought. The "licence" to supply for Roquefort cheese is not necessarily inherited or purchased. It is ongoing quality of milk supplied that determines whether a farm will have rights to supply milk for Roquefort manufacture.

There are seven companies producing Roquefort cheese:

- Fromageries Occitanes
- Papillon
- Société
- Vernières
- Gabriel Coulet
- Carles
- Combes

Cheese making plants of these seven companies are located in different places of Aveyron, but all of them have their ripening caves, cutting and packing plants located in Roquefort village.

The cheese manufacturing companies operate under commercial, Confederation and government controls.

Commercial controls are implemented through compliance with international quality management systems, such as ISO 9000 which are audited by accredited certification bodies. In addition, some of the larger Roquefort manufacturers meet major commercial customers requirements, primarily large European retailers, which demand compliance with defined food safety management systems. Similar to international quality management systems, these are audited by bodies external to the Roquefort manufacturers.

Confederation controls at manufacturing stage include implementation of Roquefort origin requirements. These requirements must be met by manufacturers to enable application of the "red ewe" identifying label. Some of these requirements have direct effect on food safety - for example the requirement for curdling of milk to take place within 48 hours of milking.

## GOVERNMENT CONTROLS - ASSESSMENT OF THE OFFICIAL SYSTEM

### LEGISLATION

The criteria for assessment includes examination of the existence of relevant legislation. In the case of Roquefort cheese, the relevant French legislation (an adoption of EU directives) forms part of the Draft standard.

- *The Ministerial Order of 30 December 1993 on requirements relating to the premises, equipment and operation of milk collection or standardization centres and of establishments involved in the treatment or processing of milk or milk-based products*
- *The Ministerial Order of 18 March 1994 on the hygiene of milk products and collection*

- *The Ministerial Order of 30 March 1994 on the microbiological criteria that drinking milk and milk based products must satisfy in order to be placed on the market*
- *The Ministerial Order of 28 June 1994 on the identification and sanitary approval of establishments placing on the market animal foodstuffs or foodstuffs of animal origin and on health marking*
- *The Ministerial Order of 2 March 1995 on the approval of milk collection, standardization or treatment centres and of establishments involved in the processing of milk and milk-based products*

Other legislation relevant to the control system includes Decree of 22 January 2001 relating to the protected designation of origin of Roquefort Cheese, and certain derogations from the European Commission Decision of April the 25th 1997 and a French notification in the French Republic Official Journal specifying the list of milk products with traditional characteristics.

The French official system has detailed legislation covering the production of Roquefort cheese.

**COMPETENT AUTHORITY**

**The Ministry of Agriculture, Food, Fishery and Rural Affairs** (*Ministère de l'Agriculture, de l'Alimentation, de la Pêche et de la Ruralité*) is the French national ministry responsible for food inspection and certification.

The arm of the Ministry which is responsible for food is the **Department of General Directorate for Food (DGAL)**, The role, function and funding of DGAL is the competent authority for risk management through its functions related to enforcement, surveillance and control.

Other Ministries have a role in risk management, including the Ministry of Public Health and the Ministry of Trade and Consumers. The French Agency for Food Safety is a body engaged in risk assessment functions related to food. DGAL has links with these agencies and coordinates activities accordingly.

DGAL administers operational functions through the **Departmental Directions of Veterinary Services (DDSV)**. There is a DDSV in each of France's 100 "departments", and they hold responsibility for food hygiene services, animal health services and environment services. The DDSV that oversees production of Roquefort cheese is the Aveyron department, based in Rodez. The role and function of the DDSV includes ensuring food safety and security, and the Aveyron DDSV covers the production of Roquefort cheese.

The French official system has competent authority with the ability and systems in place to implement legislation covering the production of Roquefort cheese.

**ASSESSMENT OF CONTROL PROGRAMS**

AQIS examined in detail the programs in place to control the safety of Roquefort cheese (see Part 2 for detailed audit report). The DDSV operates programs to cover:

- residues of agricultural and veterinary chemicals;
- animal health;
- raw milk quality; and
- food safety programs implemented by manufacturing establishments.

**Agricultural and veterinary chemicals**

The DDSV participates in national and EU wide program for monitoring pesticide levels in milk. The sampling is based on the volume of production and analysis for organochlorine, organophosphate pesticides, antibiotics, chloramphenicol, sulphonamides, ivermectin, benzimidazoles are taken. Samples are tested at Government reference laboratory.

**Animal health system**

All farms supplying milk for Roquefort cheese production are under supervision by the DDSV. They must be registered by the DDSV and subject to a minimum number of veterinary checks for animal health purposes.

*Brucellosis*

Aveyron is officially brucellosis free. This means that OIE stipulations (*every three years, a minimum of 50 animals from each farm must be tested and no confirmed positives found*) are met in Averyron. In fact, brucellosis sampling and testing is done more frequently in Aveyron than is required by OIE, with each farm tested annually. Records are maintained on a national database.

Other animal health issues

All animal deaths on farm must be reported to DDSV. Carcasses are investigated for Transmissible Spongiform Encephalopathies (TSE) and then disposal occurs at Government approved premises.

In the case of sheep dairy farms that supply milk for Roquefort production, comprehensive records on animal health including veterinary treatments, breeding, transport to and from the farm and animal treatments must be kept by the farmers. As noted above the Confederation provides at least monthly veterinary services, focussing advice on prophylaxis, particularly prevention of diarrhoeic diseases, worm control and vaccination (against clostridial diseases and scabby mouth, which is a differential diagnosis for foot and mouth disease and bluetongue.) Privately employed vets undertaking work of this type must be approved by the DDSV and are formally contracted to perform the tasks.

Farms are required to regularly clean and disinfect animal holding pens and maintain appropriate facilities for the isolation and treatment of sick animals.

The record keeping systems related to animal health on all farms is standardised by the Confederation as part of the quality management of the production of Roquefort.

The Confederation undertakes 6 ‘controls’ per year, where they verify records and consolidate them into a single format that includes all information on animal health, as well as feed purchases, animal movements and genetic testing relevant to the particular farm.

**On farm hygiene**

On farm hygiene related to the collection, holding and transport of milk is covered by French Ministerial Order of 18 March 1994. There is also a Code of Good Practice which is implemented by the Confederation that relates to hygiene and sanitation on farm. The audit concluded that the current on farm practices implemented to meet both industry and official requirements are adequate to ensure milk production and storage is achieved with the minimum of contamination.

While the audit concluded that current practices are adequate, the team observed that there is currently no official requirement for on farm documented food safety programs. In the new EU Regulations (No. 852, 853 and 854) to be implemented by DDSV during 2006, there will be a need for an 'on farm hygiene package'. The implementation of these Regulations will provide enhanced confidence in the system, as the actual practices now implemented by the farm operators will be documented and readily available for audit purposes.

**Cheese making**

The cheese making is performed in technologically advanced premises staffed by suitably qualified and experienced people working to legislated and other commercial requirements. All plants have HACCP plans which are regularly updated. While approximately 14 days of cheese maturation occurs in caves, where normal food manufacture premise conditions are not applied, the controls and checks of the cheese entering the cave maturation and the controls and checks following this period provides sufficient confidence that Australian requirements can be met.
The audit details can be found in Part 2 of this report.

| |
|---|
| The French official system has control programs that cover on farm through production and storage of Roquefort cheese. |

**INSPECTION STAFF: FACILITIES AND TRAINING**

Inspection staff employed by DDSV as a minimum, have appropriate experience and training. The majority of food inspection staff are formally trained in food science and where appropriate veterinary science.

Private veterinary services are used to conduct some official functions. Where this is the case, the practitioners must have contracts with DDSV.

Facilities for conducting audits and record keeping for all aspects of inspection functions are excellent and are being increasingly automated. The "SIGAL" system contain all records of each establishment and each intervention (Government audit, follow-up visit etc), is recorded on the system. The system holds all reports on audits, officers involved, results of audit. The system is being upgraded and all correspondence between DDSV and the establishment will soon be included and available for information of officers.

| |
|---|
| The French official system has inspection staff and facilities that provide the ability of the official system to implement legislation covering the production of Roquefort cheese. |

## LABORATORIES

Laboratories used are a mix of private (establishment owed), accredited Department laboratories and national public reference accredited laboratories. Where processing decisions need to be made quickly, rapid analyses are conducted in-house. This is the case, for example, the disposition of the milk in vats due for processing. Many of these labs are accredited to the French organization Comité Français d' Accréditation (COFRAQ), which is the Australian NATA equivalent. A decree to be implemented by end of 2005 will mandate accreditation of all the laboratories.

The audit of the laboratory component of the Roquefort manufacture concluded that the laboratories used to provide objective measure of compliance with microbiological and chemical limits are satisfactory.

## VERIFICATION OF SYSTEMS

The DDSV internal review processes are not formalised, however EU procedures include review of food safety programs that operate in France. The issue of possible inconsistency of implementation of official food safety programs between Departments was raised by the audit team. This was acknowledged by DGAL officials and there is currently work underway to strengthen system verification. However, the Australian team noted that the many elements of the official system are incorporated in the external audits that are undertaken by commercial certification bodies, which provides added confidence in the French official system.

The French official system currently has informal verification applied through commercial bodies and EU oversight.

## CERTIFICATION

It is one of the roles of DGAL and the DDSVs of respective Departments to provide certification as required for food products.

The system operating for intra Europe trade requires coding system on food packages that identifies the source (city and premise) and therefore the competent authority under which the product was manufactured. This coding system attests to conformance with EU requirements.

Where specific requirements (i.e. beyond EU requirements) are demanded by importing authorities outside the EU, the French system can deliver appropriate attestations. The EU maintains a data base that holds all current import requirements of trading partners. This database is accessible to the relevant authorities within the EU including Rodez DDSV staff.

The ability of the French Government to certify that Roquefort cheese meets the Australian proposed draft standard depends to a large extent on the existence of a traceability system of the product. For example, the proposed draft Australian standard requires that Roquefort cheese should be made from milk that was shown to be free of *Listeria monocytogenes.*

The system that is in place for Roquefort cheese production is able to trace each step in the production chain from the farm forward. As each vat is checked for *Listeria monocytogenes,* it is possible for the French systems to identify and thus certify for Australian purposes cheese made from *Listeria monocytogenes* free milk. This was objectively demonstrated as some customers demand similar requirements to Australia.

A draft certificate was prepared for the Australian delegation and further discussions will take place in respect of the final form of the certification. These discussions will involve Australian Quarantine staff with a view to developing a single certificate for Australia.

| |
|---|
| The French official system has the ability to provide meaningful certification for the particular attestations that Australia requires. |

**CONCLUSION**

The audit findings in relation to the overall capacity of the French official inspection and certification system to deliver Roquefort Cheese that complies with the Australian proposed requirements, shows that the system is in place, and capable of identifying and delivering only cheese that meets Australian requirements.

**FUTURE ACTION**

The development of a Government to Government certification arrangement for Roquefort cheese importation will progress if the FSANZ Board accept the recommendations of the Final Assessment Report and the Ministerial Council does not seek a review of the Boards decision.

- The issues that will then need to be considered by AQIS include:
- Information exchange for issues raised during the audit
- Scope and form of certification
- Development of Memorandum of Understanding between AQIS and DGAL.

# PART 2

## AUDIT OF MILK PRODUCTION AND ROQUEFORT CHEESE MANUFACTURE

### SUMMARY

This review was conducted to assess the integrity of the French system for controlling food safety issues and compliance to the legislated standards in France. The audit was conducted between 30 March and 8 April 2005.

The audit reviewed all facets of Roquefort cheese production and the government management of these systems. The audit team found that the condition and quality of operations in the industry and in government systems were of a high standard.

Some areas of concern were identified during the review, and these were discussed with the French government through the Ministry and the Aveyron Department. In nearly every case, these issues had already been identified and action was underway to rectify them. Some of these actions relate to the issue of a Decree in late 2005 and a hygiene package to be implemented on 1 January 2006.

### AUDIT PROGRAM

The audit program was designed to ensure that management of Roquefort cheese production by Government and industry were assessed. All processes relating to the production of Roquefort Cheese were reviewed from the sheep farming and milking to manufacture and packaging of the cheese.

The audit team consisted of Edwina Mulhearn (Lead Auditor), Peggy Douglass (AQIS and Delegation Leader), Bill Turner (DFAT and animal health technical expert), Deon Mahoney (FSANZ and technical expert), and Katherine West (AQIS).

The audit itinerary is listed as Attachment 2 to this report. The audit team reviewed both government regulatory control and industry activities as outlined below:

**Government**

*(a) National – General Directorate for Food (DGAL), Ministère de L'agriculture, de L'alimentation, de la Pêche et de la Ruralité*

A meeting was held with DGAL on 30 March 2005 to discuss the audit program and to familiarise the audit team with the French system of controls relating to Roquefort cheese production. The meeting was attended by Dr Monique Eloit, Deputy Director General, DGAL.

An exit meeting on 8 April provided DGAL with a summary of the audit team's findings.

*(b) Department (Regional) - Departmental Veterinary Services Directorates (DDSV) de l'Averyon.*

A meeting with DDSV was held on 31 March 2005 where the Department provided information to the team on its activities relating to animal health and food safety. The team was able to review documentation and records.

On 3 April 2005 the audit team observed a DDSV auditor perform a routine audit at a range of Roquefort processing and storage sites. DDSV staff attended visits to all sites and were able to assist the audit team with information regarding their activities and responsibilities.

An exit meeting on 7 April provided DDSV with a summary of the audit team's findings.

**Industry**

*(a) Confédération Générale des Producteurs de lait de brebis et des industriels de Roquefort (The Confederation).*

The Confederation provided a presentation to the audit team outlining the requirements of Roquefort manufacture, its philosophies and control systems. This included standards, penalties and payment systems and their ongoing research and development activities.

The audit team spent the majority of their time in Aveyron Department inspecting and auditing operations involved in milk production and cheese making.

*(b) Sheep dairies* (élevages)

Seven sheep dairies were visited as part of the audit. Visits focused on animal health controls and general milking operations and hygiene.

*(c) Cheese making, maturation and packaging*

There are seven companies producing Roquefort cheese and the audit team visited six of these reviewing various operations:

- Les Fromageries Occitanes - Cheesemaking, caves and cutting and packing
- Papillon - Cutting and packing
- Société - Cheesemaking (2 sites) and caves
- Vernières - Cheesemaking
- Gabriel Coulet - Cutting and packing
- Carles - Caves, cutting and packing

The one company not reviewed, Combes, accounts for less than 0.1% of total Roquefort production.

During the audits, the audit team examined the following mix of operations:

- Cheese making (laiterie) - 4 factories visited.
- Cheese maturation (caves and cold storage) - 3 caves visited and two maturation facilities.

- Cheese cutting and packing (centre de conditionnement) - 4 packaging facilities visited.

**AUDIT FINDINGS**

**Government Management**

France is divided into 100 Departments, and a DDSV is located in each Department to address veterinary and food safety issues. These Departments are responsible for food production from "Farm to Fork", ensuring safe products ***'without damage without hurt'***. Specific issues addressed by DDSV include:

- Food safety and security;
- Control of residues and contamination in food chain;
- Control of use of veterinary medicines;
- Tracking of animals and animal products; and
- Control and certification of animals and products of animal origin.

*Area of concern: There is no national review system to ensure consistency between the 100 Departments.*

**Farm controls**
The main focus of the Department on the sheep dairies is on animal health.

Brucellosis testing:

- Conducted on 50+ animals in every flock in the Department each year - records sighted.
- Flocks are issued with a Brucellosis clearance certificate.
- Presumptive +ve results are acted upon – no stock movement is allowed however milk is still collected and used for cheese production. Sighted letters to farmers on occasions where presumptive +ve results identified by auditors.
- There have been no confirmed positive Brucellosis results for ewes in the department since the program commenced. The last positive results were in 1998 in cattle and 1994 in goats.

Other animal health controls and monitoring:

- For all on-farm animal deaths, carcasses must pass through an official (government contracted) disposal system. This system incorporates testing of all carcasses for EST. Carcasses are disposed of through burning.
- All abortions must be notified and are tested to determine the cause.
- Flock identification systems are in-place.
- Currently 1% of farms are reviewed on-site annually by the DDSV.
- Department veterinary officers monitor records and use of pharmaceuticals on milking animals.

On-farm food safety requirements:

- There is no requirement for on-farm HACCP. French Ministerial Order 28/6/94 does not apply to farms.

*Area of concern: Department visits on-farm do not cover non-animal health food safety issues.*

**Processor controls**

- All wholesale processors of food must comply with the French Ministerial Order 28/6/94. These requirements include:

    - Analysis of CCPs
    - Declaration that water is potable or attestation that it is linked to a public water supply
    - Hygiene and sanitation program
    - Pest control
    - Staff training program

- All processors are audited annually by Department staff.

During the review, the delegation was able to observe a DDSV Officer conducting audits at a Laiterie (cheesemaking facility), caves and centre de conditionnement (cheese maturation, cutting and packing facilities). During the audit process, the officer showed confidence and knowledge of food safety systems and legislated requirements, and performed her duties under difficult circumstances (with at least 10 observers).

Sighted audit report from same premises dated 27 May 2004. The report addressed facility construction, hygiene, capacity of site and interim controls. A response was received from the company indicating corrective action in line with their 3 year investment plan.

Documentation observed at the Rodez office included processor agreements with Roquefort manufacturers and the DDSVs independent testing of Roquefort cheese conducted during 2004, 85 samples were tested. Testing included *Listeria monocytogenes, Salmonella, Staphylococcus* and total coli.

*Area of concern:*

- *Company response to findings from DDSV audit conducted in May 2004 did not adequately address issues raised. While DDSV responded that the issues must be controlled in the interim, a further response should have been obtained from the company.*
- *The Laiterie laboratory was not accredited and is not reviewed by DDSV, however test results from this laboratory provide in-process verification of milk and cheese being pathogen free.*

**SHEEP DAIRIES**

Seven sheep dairies were visited by members of the delegation.

In all cases sheep were housed in clean stalls with straw bedding; as the audit was conducted in early spring the ambient day temperatures were still often colder than 10°C.

Milking equipment was consistently a herringbone set up with a separate milk storage room. The milk storage was in refrigerated vats with digital temperature indicators and programmed clean-in-place systems. There was no evidence of plate coolers being used.

*Areas of concern identified during the audit:*

- *There is no food safety program or documented systems in place on farm.*
- *The milk should be held under factory type conditions from the point of leaving the ewe, as there is no later heat treatment to control potential contamination. The hygiene of milk rooms was not quite up to that standard.*

***Dairy: Le Payssel – 1 April 2005***

The farmer was milking 550 ewes twice daily, with approximately 750 litres of milk collected daily.

This farm participates in a flock recording system conducted by a private accredited organisation on a monthly basis.

- Test results sighted:
    - Somatic cell count: 250,000 cells
    - Total Count: 1,500 cfu/ml
- Minimal treatments with antibiotics:
    - Mastitis – ewe is segregated, treated and then culled
    - Pneumonia or injury – ewe is treated and isolated for specified withholding period
- Young ewes are vaccinated against Q fever.
- Milk room was found to be clean and tidy, however there was straw residue in the milk bowl.

***Dairy: Gaec de Vignots – 1 April 2005***

- Milking 385 ewes though usually 440.
- Milk in tank 7.3$^{o}$C at time of audit. The second milking was in progress.
- Test results sighted:
    - Total count: 17,000 cfu/ml
    - Somatic cell count: 237,000 cells
    - Coliforms: 10 and 20 cfu/ml
- Results for 2004 campaign were sighted, and indicated no positive results for *Salmonella* or *Listeria monocytogenes.* The maximum SCC result was 566,000.

- Sighted records of ewe treatments.
- Sighted evidence of Brucellosis free status.

***Dairy: Gaec de Camargues – 5 April 2005***
***Dairy: Caec des Rougiers de Gazel – 5 April 2005***
***Dairy: Gaec de Mas de Jean – 5 April 2005***

All three farms had comprehensive records on animal health, including births and deaths, animal movements on and off the farm and animal treatments. Two of the farms employed the same vet, who made at least monthly calls, focussing advice on prophylaxis, particularly prevention of diarrhoeic diseases, worm control and vaccination (against clostridial diseases and scabby mouth, which is a differential diagnosis for foot and mouth disease and bluetongue). Vets undertaking work of this type must be approved by the DDSV.

All the farms regularly cleaned and disinfected animal holding pens and had appropriate facilities for the isolation and treatment of sick animals.

The record keeping systems on all farms is standardised by the Confederation – they undertake 6 'controls' per year, where they verify records and consolidate them into a single format that includes all information on animal health, as well as feed purchases, animal movements and genetic testing.

There were no written procedures for the cleaning and sanitation of tanks and milking equipment, except on one farm, where the farmer had a written procedure just in case 'something happened to him and someone else had to take over the milking.'

All three farms had automatic cleaning systems, with some small variation in approach (for example, one had three cycles, another five and another had eight cycles). The basic approach was the same - two cleanings per day (after each use) alternating between acidic and basic cleaning compounds. The addition of the sanitising agent was manual in one case - the farmer had to add the compound before starting the machine. In the other two cases, the agent was pumped from a container. There was an alarm system on the machines to indicate if the product ran out and needed replacement. On at least one machine, details from each cycle were maintained in the control unit for thirty days - only the service company can access these records and they are used to provide a record of operation in the event that there is any dispute regarding the effectiveness of the equipment.

The rooms that housed the milk vats showed a varying degree of hygiene – in one there was a very dirty light fitting overhanging the milk vat. However, the vat was closed and the risk to the product appeared minimal. There was no indication that hygiene lapses threatened the quality or safety of the milk.

*Sanitation verification*

There was no verification testing of sanitation of tanks and milking equipment undertaken by any of the dairies visited. When we questioned whether this was undertaken, we were told that there was no need - poor sanitation of the vats would lead to poor quality milk, meaning the farmer would not get paid for the milk.

*Antibiotic testing results*

No antibiotic testing results are kept on farm. We were assured that the milk was tested for antibiotics daily by the 'laiterie' and records of these checks were maintained there.

*Separation of rooms*

In all three dairies, there was clear separation between the milking room and the storage room. Hand washing facilities were available.

*Records of milk temperature at pick up*

All three milk vats looked at had temperature gauges on the side, clearly indicating that they milk was within specifications (less than 10 degrees Celsius). This equipment is subject to regular calibration and checking by an independent servicer and a government body responsible for weights and measures.

However, there are no records maintained of milk temperature at collection. When asked, we were told that if the milk did not meet specifications, the driver would not pick it up and the farmer would not get paid for it (i.e. there is incentive to ensure that the product is cooled to the required temperature). The consistently satisfactory microbiological analysis of the milk per tanker provided the audit team with the objective evidence that contamination and growth of bacteria was minimised. Given that the controls measures to minimise growth of bacteria are temperature control and low initial contamination it is reasonable to assume that control of temperature of the milk during transport is achieved.

***Dairy: Gaec de Balcon des Grands- Causses – 6 April 2005***

- Milking 388 ewes and supplying Papillon. The ARC (Agent relation culture) auditor from Papillon attended the visit.
- A Confederation report for this élevage dated 15/4/03 was available. The report included a penalty for non-compliance. It was noted in the 2003 audit that the windows in the milk room should be screened and it was also recommended that detergent should not be stored in the milk room. During the delegations audit both of these issues were observed as not rectified.
- Milking commenced at approximately 7.30am and finished at 9.30 at the time of the audit visit the milk temperature was 8.6°C. Papillon requires that milk be <10°C at the time of pickup in accordance with the specification in the Roquefort Decree. Collection was expected to occur at 11.00am.
- The cleaning program for the milk tank is to rotate acid and alkali washes daily. There is no documented procedure for milking or cleaning practices.
- Test results sighted:

    - Total count: 9,000 and 13,000 cfu/ml
    - Somatic cell count: 300,000 and 400,00 cells
    - Coliforms: 10 cfu/ml

- The milking machines are certified annually, and the last inspection occurred in January 2005. This inspection assessed the cleaning system, operation of the machine including vacuum and pulsation and condition of rubber ware.

- The Brucellosis declaration was sighted and dated as valid until June 2005.
- Records of ewe treatment with veterinary medicines are being recorded. This documentation has recently been improved to include the date ewes return to milking.

***Dairy: Gaec du Puech de la Lande – 6 April 2005***

- Milking 380 ewes and supplying Societé cheesemaking plant at Requista.
- Milk vat cleaning cycle reviewed – programmed to rinse, alkali wash for 15 minutes with a warm water sanitise. Water used is from the town supply. At the time of the audit the vat was empty and appeared clean with an evident chlorine smell.
- At the time of audit the milk room was found to have some dirt residue on the floor. Otherwise the bails and milk room were satisfactory.
- Milk temperature is set to be 6 - 8°C.
- An ARC farm inspection report was available dated March 2005. This contained a notation in relation to environmental issues (not food safety) all other components of the inspection were found to be satisfactory.
- Sighted a certificate in relation to disposal of an animal. The list of ewes indicates the cause of death as bloat or other sickness.
- Test results sighted:

    - Total count: 22,000 - 27,000 cfu/ml
    - Coliforms: <10 - 20 cfu/ml
    - Somatic cell count: 361,000 - 621,000 cells

- There are 4 test results indicated on each monthly report. Reports indicate that the milk is graded as Super A.

**CHEESE MAKING**

All factories were found to be clean, tidy and in good condition.

HACCP systems sighted appeared to be well developed and implemented. Most facilities are audited by a number of customers, such as Tesco's and Marks & Spencer, as well as government audits.

All facilities had stringent dress codes for both staff and visitors. The delegation was supplied with plastic disposable coats, shoe covers and hats. Jewellery was required to be removed and hands were washed.

Records of food safety control measures were sighted including:

- Microbiological testing of farm milk and cheese through the production process was found to be extensive and in accordance with HACCP systems.
- Monitoring of pH over the first 24 hours of cheese manufacture is conducted to verify the initial drop in pH in accordance with system controls.

*Areas of concern identified in cheese making facilities included:*

- *Unsealed entry points for service lines in external walls*

- *Glass thermometers present in cheese setting area. These thermometers were held within metal guards.*
- *Splintering wood in cheese shelves with evidence of physical contamination on cheese rounds.*
- *Presence of excessive condensate on ceilings and dripping from pipework, as well as inadequate diversion of evaporator condensate from cheese handling areas.*
- *Cheese and mineral residues on cheese hoops. Cleaning efficiency appears to be impeded by the water condition, which may be rectified with the correct chemical usage.*

***Société, Saint Affrique – 1 April 2005***

- Processed around 150,000 litres of milk/day producing between 10,000 – 13,000 x 3 kg cheeses.
- Each milk tanker is tested for antibiotics, *Listeria monocytogenes* and total count.
- The branding process used to ensure traceability of cheese was observed. This involves branded of each cheese with it's batch code, so that each round is individually traceable though the system until cutting.

***Les Fromageries Occitanes, Montlaur – 4 April 2005***

- Staff are provided with dedicated uniforms.
- Hazard Audit Tables and procedures reviewed.
- Procedures for farm milk pick up sighted. Reviewed tanker results for *L. monocytogenes, S. aureus, E. coli, Salmonella* and inhibitory substances. Followed through trace back to farm where a failure indicated corrective action as per the standard.
- Procedures for isolation and control of product identified as testing positive for *Listeria monocytogenes* were assessed.
- Pest control procedures reviewed, sighted map of rodent bait stations, contractor reports, fumigation and chemical data sheets.
- Calibration procedure reviewed, sighted records, generally internal verification. Handheld thermometers verified monthly, fixed thermometers every 3 months with an annual external calibration of the standard thermometer.

***Société, Requista – 5 April 2005***

- Facility has had HACCP systems since 1997, with HACCP + ISO9001 since 2001 independently certified by AFAQ.
- Data from raw milk collection is recorded on a microchip including milk temperatures and time of pickup, which is downloaded at the factory.
- While the factory was found to be generally clean and tidy, it was observed that cheese hoops were scoured and had product and mineral residue evident after completion of cleaning cycle.
- Condensate was present throughout the facility - receival, cheesemaking, cheese holding and turning areas.
- The audit report from May 2004 was sighted, the results indicated were good.

- No reported problems with slow vats over the past 6 years – monitoring indicated pH in the range of 4.85-5.05 in 24 hours. If the pH was above 5.0 at 24 hours, production was tested for *S. aureus.*

***Vernières, Villefranche-de-Panat – 6 April 2005***

Vernières is a family business producing about 4% of the total Roquefort cheese production, however 45% of their outputs enters export markets in the United States, United Kingdom, the Netherlands, Spain, and Germany.

Milk is sourced from 71 suppliers in a 20 kilometre from the processing plant. Somatic cell counts average 400,000 cells during the campaign.

- Older processing facility, but clean and well maintained
- Cheese inoculated and set in closed vats (typically Roquefort cheese is made in open vats)
- HACCP plan reviewed and selected activities audited - all issues addressed correctly
- The results of testing milk from incoming tankers for *L. monocytogenes* are typically not always available before the commencement of cheese making – processors follow their documented system, and this was confirmed during the audit
- pH is measured at the start of cheese making, then at 5 hours, 21 hours, 48 hours and before salting. No slow vats observed
- Some issues with access to and screening of the receival area – direct access from the truck unloading apron means that flies gain easy access into the receival area. Also noted by DDSV at the time of the audit.

**CAVES**

All caves visited were located in Roquefort. The caves form part of the traditional maturation phase of Roquefort cheese, which must be stored for a minimum of 2 weeks in the caves. The condition of the caves does not comply with standard requirements for food storage facilities; caves walls, floors and ceilings were roughly finished, unsealed, mouldy and damp often to the point of dripping. Shelving was damp and mouldy wood though the wood was generally in good condition.

The caves are audited by the DDSV and are required to have an analysis of CCPs and procedures in accordance with the Ministerial Orders. Testing of cheese to verify it is not contaminated occurs at a number of points post cave storage.

All caves had screened adits plus pest control programs (involving insectocutors, bait stations, etc) maintained by private contractors. Companies had various programs for monitoring the cave environment. For example, the Gabriel Coulet company would sample various points in the caves and materials for *L. monocytogenes* at regular intervals (weekly).

Caves visited included:
***Les Fromageries Occitanes, Roquefort Sur Soulzon – 4 April 2005***
***Société, Roquefort Sur Soulzon – 5 April 2005***
***Vernières, Roquefort Sur Soulzon – 6 April 2005***
***Carles, Roquefort Sur Soulzon – 6 April 2005***

## CHEESE CUTTING AND PACKING

All factories cutting and packaging Roquefort cheese were found to be clean, tidy and in good condition.

HACCP systems sighted appeared to be well developed and implemented. Most facilities are audited by a number of customers, such as Tesco's and Marks & Spencer, as well as government audits.

Cheese ripening was found to be well in excess of the minimum 90 days stated in the Decree, some product is stored for 9 months prior to sale due to the seasonal nature of production.

Testing for $A_w$ of the cheese is not conducted, however all facilities were monitoring salt and moisture content of the product.

***Papillon, Roquefort – 1 April 2005***

- Factory uses a segregated clean room processing system.
- Processing includes an automated cheese wash, cut and pack. Staff conduct a visual inspection and trim cheese.
- Packing lines are cleaned at every production break.
- Product has a 3-month best before code.
- A positive release system is in place to ensure that all product on the market meets company standards.

***Les Fromageries Occitanes, Roquefort – 4 April 2005***

- This facility has ISO certification.
- Reviewed hygiene and sanitation programs, sighted cleaning records, equipment condition records and pest monitoring and controls.
- A thorough review of traceability records was undertaken by DDSV auditor.
- Calibration system and records for scales and metal detector reviewed.
- The company has an accredited laboratory at Saint Mamet which participates in an inter-laboratory comparison program quarterly. Cheese and environmental samples are tested at this laboratory.
- Temperature records for cheese at factory and caves sighted, cheese storage temperatures in caves 6 – 13°C.
- Sighted Pest Control records for Conditionnement (maturation) facility.
- Company laboratory records show compliance to the EU standards and also LFO (Laiterie Fromageries Occitanes) standard which is higher and forms the clearance system. Cheese batches making the higher standard are marked with a green dot. Those complying with the EU standards are marked with a blue dot.
- *E. coli* results for the days packaging showed 1/10 were <10 cfu/g, however later in the season there is stated to be a 95% compliance to the <10 cfu/g standard. This was supported by a review of results from the 2004 campaign.
- Additional records sighted:

    - Medical records for all staff;
    - Mandatory and optional training records;

- Water test results;
- Environmental *Listeria monocytogenes* monitoring records; and
- Calibration.

***Société, Roquefort – 5 April 2005***

- Maturation for Société occurs at a separate storage site in Roquefort.
- All cheese cutting and packing occurs in a clean room system. This area may be observed through windows from offices, de-crating areas and walkways.
- The clean rooms may be completely stripped for cleaning with equipment moved to a wash-up area allowing pressure hosing and foaming of equipment. All equipment examined in this facility was found to be very clean.
- Construction issues identified had been identified by the company with action plans developed and being implemented.
- Cleaning procedures are documented and are available to staff with simple wall charts. Auto dosing of detergents, monitoring of concentration every 6 weeks by chemical supplier, with internal laboratory testing if concerns are raised by staff.
- Traceability system reviewed. There is an automated system in place for the cheese store using transponders which track each trolley of cheese and will not allow dispatch of cheese which has not been cleared. Cheese coding indicates the Laiterie where the cheese was produced, date of manufacture and batch e.g. SA 1115 indicates manufactured at Saint Affrique on 11/1, Batch 5. Batch coding traced through the computer system to verify accuracy of codes.
- Plant uses water derived from the public water system – the local authority monitors the water every 2 months. Full analysis is completed 6 times/year, and microbiological testing is performed weekly by the company.
- Microbiological testing by the company follows documented procedures using standard French methods. Validation tests are performed, and the company is involved in comparative analyses with other laboratories (under supervision of Association Française de Normalisation, AFNOR)
- Each tanker of raw milk (for cheese making) is tested using PCR – the results (+ve or – ve) is known before cheese making commences in three quarters of all tanker loads. Where cheese making has commenced, follow-up testing is done on batches and they are segregated throughout cheese making and maturation.
- Testing for *L. monocytogenes* in cheese after maturation is performed according to the reference method described in the French NF EN ISO 11290-1 standard

***Gabriel Coulet, Roquefort – 6 April 2005***

- Reviewed system for identifying and segregating non-compliance batches; *Listeria* positive cheese is processed last and are identified by being stored in different coloured crates and stored in an area segregated from other cheeses in a separate cool room and cave. There was no *Listeria* positive cheese on-site at the time of the visit however, the dedicated area was sighted and found to be empty.
- The documented HACCP system was reviewed and associated records sighted.
- The facility is working towards compliance to the BRC (British Retail Consortium) standard and the International Food Standard (IFS) developed in Germany for food retailers.

- The company is currently audited by Tesco, and supplies this company with Roquefort cheese meeting requirements such as <10 *E. coli*/gram.
- The packaging area applies a positive air pressure to minimise the ingress of contaminants.

***Carles, Roquefort – 6 April 2005***

- Short inspection of this cave and conditionnement facility. This company is responsible for approximately 0.1% of Roquefort production.
- The packaging area was compact, clean and well maintained. All staff were suitably attired for food handling.
- This facility adopts a traditional approach to Roquefort production, to the extent of propagating the *Penicillium roqueforti* for addition to the cheese. This is done in the caves by inoculating bread.

**AUDIT CONCERNS**

Major areas of concern identified by the auditors were:

1. The DDSV system does not require documented food safety plans on farm, hence an audit of this facet of the farm operations is not easily undertaken.

*DGAL advised that a set of measures will be implemented as a hygiene package on 1 January 2006. This is in accordance with 3 EU regulations (852, 853 & 854). This is a consequence of the Food Law 2002 which allows application of full chain approach, from "farm to fork". Controls to be implemented include guidelines for hygienic practices.*

2. There is currently no formal internal audit processes to ensure consistency between Departments or staff within the Aveyron DDSV.

*DGAL has been developing internal audit systems, also in accordance with the EU regulations. The audit team also noted that the Australian system does not demand consistent implementation of systems across State jurisdictions, nevertheless asked to be informed of the structure and processes of the system when it is implemented.*

3. Non-accredited laboratories conduct some critical raw material (milk) and product monitoring. These laboratories are not reviewed by the DDSV and are not currently required to have testing verification systems in place.

*DGAL has been considering this issue and has drafted a Decree to be implemented at the end of 2005. This Decree is expected to require the notification of laboratories involved in food testing and the compulsory accreditation of these laboratories by the French Committee for Accreditation. The audit team also recognised that the requirements in Australia do not extend to demanding NATA accreditation for all laboratories used in food processing.*

**AUDIT CONCLUSIONS**

The audit team found that the systems in place for the production of Roquefort cheese to be sophisticated and well implemented and capable of delivering safe cheese that meets Australian requirements.

Farms have adopted detailed recording systems to ensure compliance with the Roquefort Decree as well as monitoring animal health and providing good traceability.

Processors including those engaged in cheesemaking, maturation and packaging were all found to have well documented systems to comply with agreements with the DDSV. The processing areas were found to be clean and well maintained.

The condition of the caves do not comply with the standards which would be expected in Australian storage facilities, however these caves form an essential part of the process for the development of Roquefort cheese. Monitoring of the cave environment and product subsequent to cave storage ensures that there is minimal risk of contamination of product, and identification of product should it become contaminated.

Government monitoring by the DDSV was found to be well implemented particularly in relation to animal health testing and records and the auditing of manufacturers.

**ACKNOWLEDGEMENTS**

The Audit Team wishes to acknowledge the support of DGAL and DDSV and the Australian Embassy in France for organising the audit program and facilitating open and effective review of all operations concerning sheep milk production and Roquefort cheese making.

**ATTACHMENT 1**

## CRITERIA FOR ASSESSMENT OF FOREIGN FOOD INSPECTION SYSTEMS.

These criteria are based on work of CCFICS (CAC/GL 26-1997) adapted for the specific purpose of Australia assessing the competence of a foreign country's export food inspection system. A food inspection and certification system that can meet these criteria will be considered for a government to government certification arrangement with Australia. The arrangement will allow food certified by the competent authority in the foreign country to be accepted in Australia with minimal point of entry testing.

In some instances these arrangements may be equivalence arrangements, where the outcomes of the inspections systems deliver an equivalent food safety outcome that is delivered by the systems in place in Australia.

**DEFINITIONS (**CAC/GL 26-1997)

*Audit* is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

*Certification* is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

*Equivalence* is the capability of different inspection and certification systems to meet the same objectives.

*Inspection* is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

*Official accreditation* is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services.

*Official inspection systems and official certification systems* are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.

*Officially recognized inspection systems and officially recognized certification systems* are systems which have been formally approved or recognized by a government agency having jurisdiction.

*Requirements* are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.

*Risk analysis* is a process consisting of three components: risk assessment, risk management and risk communication.

*Risk assessment* is a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization.

*Risk management* is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. [5]

*Risk communication* is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties. [5]

## LEGISLATION

The assessment of foreign certification systems will include judgment of existing legislation for food control.

The legislation must:

- be documented and may include acts, regulations, requirements or procedures covering the protection of public health, the protection of consumers and conditions of fair trading
- provide the competent authority with enforcement powers
- allow for control at all stages of the production manufacture storage and transportation
- if separate from domestic legislation, be able to distinguish export from domestic production.
- provision (as appropriate) for the registration of establishments or listing of certified processing plants, establishment approval, licensing or registration of traders, equipment design approval, penalties in the event of non-compliance and coding requirements.

The foreign country seeking an arrangement must provide objective evidence that the competent authority has the ability to enforce legislation.

## COMPETENT AUTHORITY

Role, function and funding of the competent authority must be defined. The particular products that are covered by the competent authority should be defined.

Where different authorities may also have jurisdiction over some parts of the food chain, or be competing for control, the documentation provided should clarify these aspects.

## ASSESSMENT OF CONTROL PROGRAMS

The competent authority will have control programs in place that are based on precise objectives and appropriate risk analysis. The elements of the control program must be documented including methods and techniques.

The elements of a control program that will be assessed include:

- inspection;
- sampling and analysis;
- provisions for recall of product
- checks on hygiene, including personal cleanliness and clothing;
- written and other records including the process to issue certificates;
- results of any verification systems operated by export establishments;
- audit program of establishments by the national competent authority;
- verification that the control program is meeting the stated objectives.

Assessment will also cover administrative procedures in place to ensure that controls by the inspection system are carried out:

- regularly in proportion to risk;
- where non-compliance is suspected;
- in a co-ordinated manner between different authorities, if several exist.

Appraisal of controls will assess whether the following are adequately covered:

- establishments, installations, means of transport, equipment and material;
- raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs;
- semi-finished and finished products;
- materials and objects intended to come into contact with foodstuffs;
- cleaning and maintenance products and processes, and pesticides;
- processes used for the manufacture or processing of foodstuffs;
- the application and integrity of health, grading and certification marks;
- preserving methods;
- labelling integrity and claims.

**INSPECTION STAFF: FACILITIES AND TRAINING.**

Inspection staff should have access to adequate facilities and equipment to undertake inspection as defined by the control system. The status of inspection staff will be considered to assess the impartiality and the mechanisms to ensure that no conflict of interest arises in the food inspection services conducted.

**Facilities**

Assessment of the control system implemented by the foreign country will include

- adequacy of the inspectorate against the size and scope of the control system
- transport and communication facilities
- data collection and record retrieval systems which cover inspection results and follow-up action
- administrative support.

**Training and expertise**

The training and qualification of inspection staff will be appraised.
Inspection staff must be trained in the skills required to implement the control system. For example if the food control system depends on establishments utilizing HACCP, inspection staff must be sufficiently skilled to assess the effectiveness of the HACCP programs in place.

Training must extend to record maintenance and documentation required by the system, for example training in procedures to ensure the authenticity and validity of certificates at all the relevant stages and to prevent fraudulent certification.

**Laboratories**

The appraisal will assess whether:

- laboratories are evaluated and/or accredited under officially recognized programs
- adequate quality assurance are in place to provide for the reliability of test results
- validated analytical methods are used wherever available
- laboratories are obliged to apply principles of internationally accepted quality assurance techniques to ensure the reliability of analytical results.

**VERIFICATION OF INSPECTION AND CERTIFICATION SYSTEMS**

The national system as a whole should be subject to independent verification that the objectives are consistently met. The extent to which foreign certification authorities have their own system evaluated will be considered by the Australian authorities.

**ATTACHMENT 2**

**Itinerary**

| **Date** | **Meeting or establishment audited** |
|---|---|
| Wednesday 30 March | Entry meeting with DGAL staff in Paris |
| Thursday 31 March | Entry meeting with DDSV Rodez office |
| Friday 1 April | Meeting with Confederation<br>Visit farm :Earl Le Payssel operated by M Bousquet and Gaec des Vignots (M Rivemale) Montlaur<br>Visit conditioning and packaging of Papillon<br>Visit Saint-Affrique factory |
| Monday 4 April | Witness audit of DDSV staff undertaking routine audit of Fromageries Occitanes: factory, caves, and conditioning centre. |
| Tuesday 5 April | Group 1: Audit of factory, caves and conditioning centre of Société des caves<br>Group 2: Audit of 3 farms: Gaec des Camageues; Gaec du Thirondel; and Gaec de Mas de Jean |
| Wednesday 6 April morning | Group 1: Audit of factory of Vernières, Villefranche-de-Panat<br><br>Group 2: Audit of 2 farms: Gaec de Balcon des Grands- Causses and Gaec du Puech de la Lande |
| Wednesday 6 April Afternoon | Conditioning centre of Gabriel Coulet<br>Cave and conditioning of Carles |
| Thursday 7 April | Audit of systems in DDSV office Rodez<br>Exit meeting with DDSV staff |
| Friday 8 April | Exit meeting with DGAL staff in Paris |

## ATTACHMENT 6

## SUMMARY OF SUBMISSIONS

| Organisation | Contact | Issues raised |
|---|---|---|
| Individual | Cameron Jackson | Strongly supports allowing Roquefort into Australia – raises his right to be able to consume such cheeses |
| Individual | Travis Ahearn | Supports the approval of the sale of Roquefort in Australia |
| Individual | Mr F. Boulting | Supports the approval of Roquefort. Raises the issues of:<br>• permitting Australian cheese producers (given appropriate regulatory and inspection systems are in place) to make raw milk specialist cheeses;<br>• product availability and consumer freedom of choice. |
| Food Technology Association of Victoria | David Gill | Supports the amendment to permit the sale of Roquefort cheese |
| Individual | Pamela Koslova | Supports the amendment to permit the sale of Roquefort cheese |
| Australian Specialty Cheesemakers Association | Leanne Bennett-Jones | • Questions the transparency of the FSANZ process and ability to access data on the French HACCP system and outcomes of the audit process<br>• Notes the inconsistency between the provisions proposed for Roquefort and those permitted for domestic production (in particular allowing maturation of cheese in caves).<br>• Is concerned that Roquefort may present health issues in Australia which may negatively impact on the domestic industry (microbiological data and a control procedure must be provided). |

## ATTACHMENT 6

## SUMMARY OF SUBMISSIONS

| Organisation | Contact | Issues raised |
|---|---|---|
| Australian Food and Grocery Council | Kim Leighton | This submission supports the Draft Assessment for A499 and made the following points:<br>• The AFGC agrees with the key issues raised by Dairy Australia at Initial Assessment and noted that the Draft Assessment Report addressed those issues and the concerns raised.<br>• Noted that the proposal is consistent with the position of the AFGC "that properly formulated, scientifically based food safety plans represent the most effective way of ensuring safe food in the food industry".<br>• Recognises that several Australian States permit the sale of unpasteurised goat's milk; that the Code already contains exemptions for the sale of certain hard cheeses and, therefore there is a precedence for the use and sale of raw milk products.<br>• Raises that the permission for imported Roquefort does not extend a similar provision for domestic producers and that this inequity should be addressed through the Dairy Primary Production and Processing Standard. |
| AQIS | Peggy Douglas | This submission deals with the AQIS issues relating to the implementation of the draft variation (Attachment 1 to the DAR).<br>• AQIS is responsible for assessing imported food for compliance with the Code (through border inspection and analysis) and for developing and maintaining certification arrangements with exporting country governments.<br>• Certification arrangements can be negotiated where an exporting country can assure AQIS that its official inspection and certification systems are at least equivalent to Australia. Criteria used include: |

**ATTACHMENT 6**

## SUMMARY OF SUBMISSIONS

| Organisation | Contact | Issues raised |
|---|---|---|
| AQIS cont. | | o Legislation<br>o Competent authority<br>o Assessment of control programs<br>o Inspection Staff: facilities and training<br>o Laboratories<br>o Verification of inspection and certification systems.<br>AQIS provided an assessment of the French system against these criteria, which has been incorporated into the Final Assessment Report.<br><br>In summary, AQIS make the following points:<br>• AQIS concurs with the DAR and considers that compliance of Roquefort cheese with the draft standard would deliver a safe and reliable product for consumption in Australia.<br>• The draft standard should take into account implementation issues, and to this end the Aw specification could be better covered by alternative measures such as salt and moisture specifications.<br>• The existing official system of inspection and certification provides sufficient confidence in the ability of the French officials to certify to Australian specifications.<br>• Should the draft standard be approved by the Ministerial Council, AQIS, with the benefit of objective evidence gained during the recent in situ audit, considers that completion of a certification arrangement with the French authorities would provide the best measure available to ensure that only complying cheese is imported into Australia. |
| Department of Human Services Victoria (DHS) | Victor Di Paola | • Supports Option 2 on the proviso that the audit process verifies that the regulatory system is applied in the manner described by French authorities.<br>• DHS believes that the Draft Assessment comprehensively addresses all relevant human health risks. |

## ATTACHMENT 6

## SUMMARY OF SUBMISSIONS

| Organisation | Contact | Issues raised |
|---|---|---|
| New Zealand Food Safety Authority (NZFSA) | Carol Inkster | • NZFSA note that this is an Australian only standard and that this has been clarified within the DAR<br>• Reaffirms that cheeses for sale in new Zealand must be made in accordance with the new Zealand (Milk and Milk Products Processing) Food Standards 2002.<br>• Trade between New Zealand and the European Union is governed by the *Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products* - it is within that Agreement that New Zealand would establish changes to its position on raw milk.<br>• Strongly supports the location of provisions relating to processing of cheese within Chapter 4 of the Code. |
| Queensland Health – Environmental Health Unit | Gary Bielby | • Accepts the conclusion from the Scientific Evaluation and that all potential hazards are subject to management through on-farm systems and the application of HACCP-based control during processing.<br>• Supports Option 2. |
| Fonterra Co-operative Ltd. | Joan Wright | This submission raises discussion on eight identified areas:<br>• **pH control** – clarification is required as to what is "rapid" acidification (pH < 5 in 6 hours or pH decrease from 6.5 to 4.8 within 24 hours. Decrease within 6 hours would be considered rapid). Management of lactic starter cultures should be considered.<br>• **Seasonal variation** – does seasonal variation (with respect to fat/dry matter) impact the composition of Roquefort, particularly with respect to water activity.<br>• **Challenge studies** – the scientific value of the challenge studies provided by the Institut de Pasteur de Lille is questioned. The information supplied is vague (no direct data provided) and there is no indication that the report has been peer reviewed. |

## ATTACHMENT 6

## SUMMARY OF SUBMISSIONS

| Organisation | Contact | Issues raised |
|---|---|---|
| Fonterra cont. | | • **Cheese storage time and temperature** – raises that the temperature of storage is as important as the time (>90 days) as this impacts on the decrease of pathogen numbers. No assessment of any risks was undertaken through the export/transport/distribution chain.<br>• **Corrective actions** – no information provided on corrective actions will be taken if raw milk quality or acidification, for example, fails the prescribed limits.<br>• ***Mycobacterium avium* subsp. *paratuberculosis* (MAP) in dairy sheep** – raises that Johne's disease (caused by MAP) is widespread in some sheep flocks and that the processing conditions for Roquefort would have not control this. Raises the issue of the transmission of tuberculosis from raw (cow) milk cheese to consumers. **Implications for Australia and New Zealand industry –** the success of the Roquefort application may increase pressure from interested parties to manufacture raw milk cheeses domestically. This issue should be addressed.<br>• **Determination of risk –** raises that the impact analysis has no obvious relevance to food safety. Questions the conclusion that the sale of Roquefort cheese poses a low risk to the public health and safety of Australian consumers based on the importation of 10 tonnes annually. What is the risk to consumers of Roquefort cheese, rather than to the Australian population as a whole. |

## ATTACHMENT 6

## SUMMARY OF SUBMISSIONS

| Organisation | Contact | Issues raised |
|---|---|---|
| NSW Food Authority | Chris Chan | The NSW Food Authority in general supports Option 2 providing adequate control measures are put in place to ensure the safety of the product. The following issues were raised:<br>• **Cave maturation** – there appears to be no corrective action if, through environmental testing, contamination is found in the caves (e.g. Listeria). Additionally, the use of wooden racks is not considered a satisfactory practice.<br>• **pH** – rapid pH drop is highlighted as an important matter to ensure food safety. The drafting requires monitoring of pH but does not require the rapid pH reduction considered important for ensuring safety.<br>• **Salmonella** – the scientific evaluation found the risk of *Salmonella* to be comparable with *L. monocytogenes* however there is no requirement for Salmonella to be not detected in the milk. |
| NSW Food Authority cont. | | • **Storage temperature** – the audit process noted that maturation sometimes occurs at temperatures of –1 to –2 °C, although a critical limit of 2 – 6 °C is specified in the HACCP plan. This should be considered a significant non-compliance. |
| Kim Truong | South Australia Department of Health | SA Health submit that there are no public health and safety issues arising from this application, pending a successful result from the audit process. |

## ATTACHMENT 6

## SUMMARY OF SUBMISSIONS

| Organisation | Contact | Issues raised |
|---|---|---|
| Helen Dornom | Dairy Australia | • **Dairy PPP Standard** – while acknowledging the constraints on FSANZ, Dairy Australia would prefer the development of a Dairy PPP Standard and National framework before an assessment of Roquefort is finalised – an amendment to the Code for Roquefort before a National standard may have unintended consequences. In particular it would be preferable to have a general framework in place than to legislate specific French production methods for a specific cheese with AOC status<br>• **Scientific evaluation** – raises that the conclusion that all hazards considered potentially significant is not consistent with the observations in Table 5. of the report<br>• **Consumer information** – the FSANZ Listeria brochure should specifically include Roquefort<br>• **Risk categorisation** – the scientific evaluation determined that Roquefort would pose a low risk to consumers yet it would be considered a "risk category" food under the Imported Food Inspection Scheme. How is this reconciled?<br>This submission raised a number of questions in relation to the audit process, in particular whether the assumptions supporting the risks for specific pathogens (made at Draft Assessment) were verified, and the on-farm controls over raw milk. |

**ATTACHMENT 7**

# 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.

(b) 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).

(c) 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.

(d) 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.