2-05
23 March 2005

DRAFT ASSESSMENT REPORT

APPLICATION A499

TO PERMIT THE SALE OF ROQUEFORT CHEESE

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 4 May 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

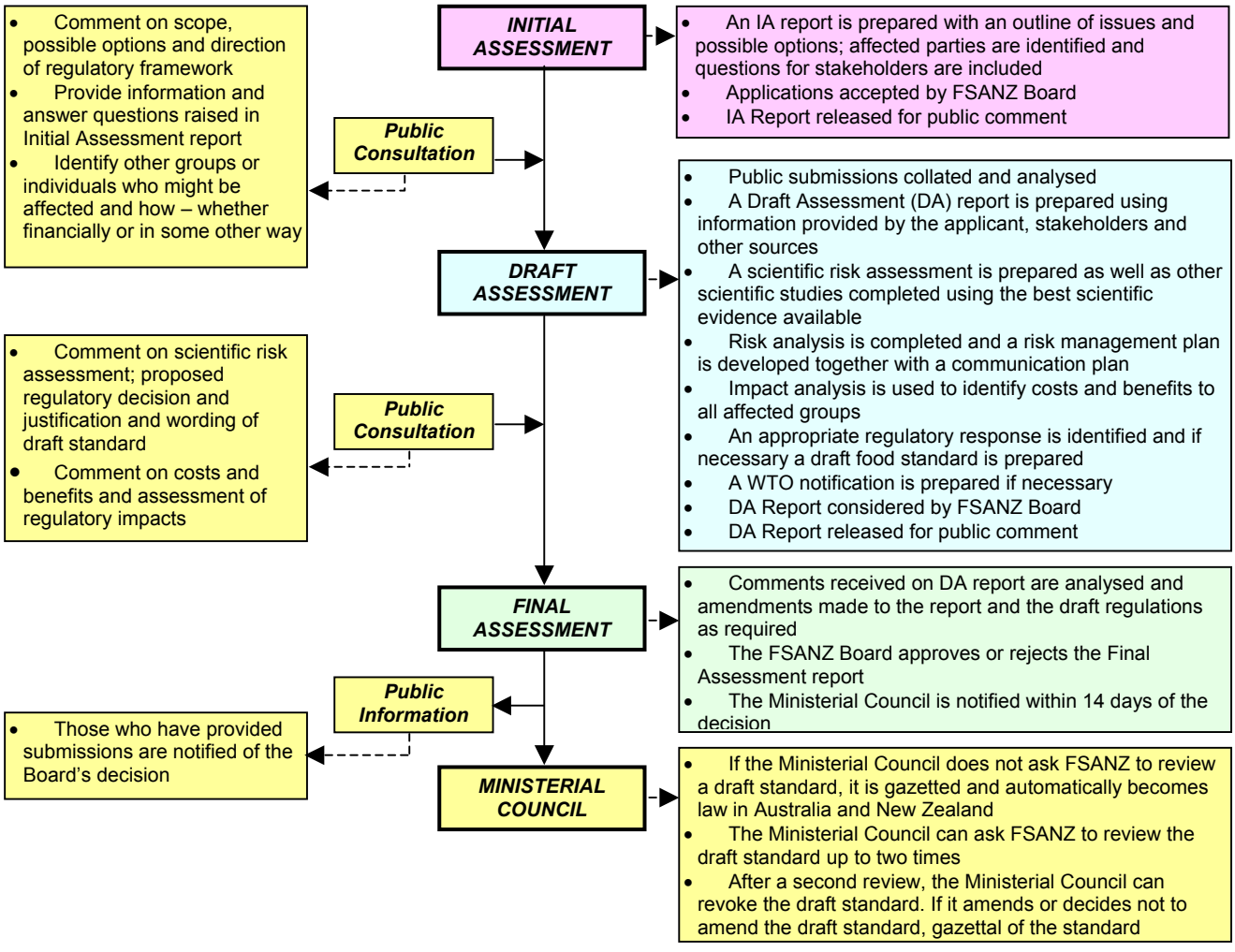
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the 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.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Draft Assessment Report of Application A499; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

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

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

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

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
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Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
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Submissions need to be received by FSANZ by 6pm (Canberra time) 4 May 2005.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

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

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

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Executive Summary 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. A safety assessment of Roquefort cheese production is required in order to permit this cheese.

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.

Relevant Issues

Assessment

The assessment of the safety of Roquefort cheese involves 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, and

3. verification of the implementation of these control measures.

The first two stages of this process have been finalised and have 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.

The third stage of the assessment will comprise an on-site verification of control measures implemented by the Confederation of Roquefort Producers and enforced by the French Government, including results of routine monitoring and testing. This process will be undertaken as an on-site audit, lead by AQIS with technical input from FSANZ. The outcomes of this audit will finalise the assessment of this application.

Risk management measures

Based on the findings of the scientific evaluation and review of safety control measures, an amendment to the Code to permit the sale of Roquefort cheese is proposed. The risk management measures propose the application of a combination of control measures:

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

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

- identification of key processing steps to be controlled, including acidification, water activity and storage time; and

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

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

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

- 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

FSANZ is now seeking public comment in order to assist in assessing this Application at Final Assessment.

Statement of Reasons

At Draft 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.

- 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

An Application (Application A499) has been 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 has been made on behalf of French manufacturers and exporters of Roquefort cheese.

Roquefort cheese is a traditional French blue-veined cheese made from raw[1] ewe's milk 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 to Standard 2.5.4 (Gruyere, Sbrinz and Emmental manufactured in accordance with specified Swiss regulations); or
- exempted from the milk heat treatment requirement (extra hard grating cheeses only).

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.

The information and views raised by the submissions received on the Initial Assessment Report have been considered within this Draft Assessment Report along with scientific, cost-benefit and other analyses. Through this Report, FSANZ now invites stakeholders to comment on the risk management measures proposed for Application A499.

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 the 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 manufacture 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 0 – 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 of equivalent food safety to 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) to be 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 that 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 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. For New Zealand purposes, 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 Milk and milk products	Column 2 **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 Extract from Standard 1.6.1 – Microbiological Limits for Food

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

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

Where:
n = the minimum number of sample units which must be examined from a lot of food
c = the maximum allowable number of defective sample units (the number of samples 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 Products

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.

The Initial Assessment Report[2] for P296 was released for public comment on the 15 December 2004. 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.

[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

The issue of raw milk dairy products is raised within the Initial Assessment Report for P296. 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 all species, and whether these may be produced with appropriate management techniques (by use of, for example, extended ripening or alternative technologies) to ensure a comparable 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.

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].

US regulations[5] require cheese to be pasteurised or, as an alternative treatment, cheeses made from unpasteurised milk require a minimum 60 day aging period. 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 United States 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.

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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

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:
(a)	The milk or the milk from which the cheese or butter was made must be subjected to one of the following heat treatments:
	pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of phosphatase destruction or
	a UHT treatment of 135°C for a minimum of 1 second.
	OR
(b)	The milk from which the cheese was made was not heat treated as above and the milk or the milk from which the cheese or butter was made must originate from a country/zone which meets the OIE requirements for freedom from rinderpest in accordance with Code Article 2.1.4.2.
5	The packaging or immediate container must be stamped with the date of manufacture of the products.
6	Cheese or butter not heat treated in accordance with requirement 4.4(a) will not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture*.
*[Note: For cheese the date of manufacture is the date the curd was set.]	

(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.

[6] France has been listed by the Office International des Epizooties (OIE) as free of foot and mouth disease.

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.

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 approach to equivalence determination;
- consistency of safety requirements in food produced in Australia and, where relevant, New Zealand with food imported from other countries;
- transparency of process; and
- expert and community consultation.

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

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

5.1.3 Assessment for Roquefort cheese

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

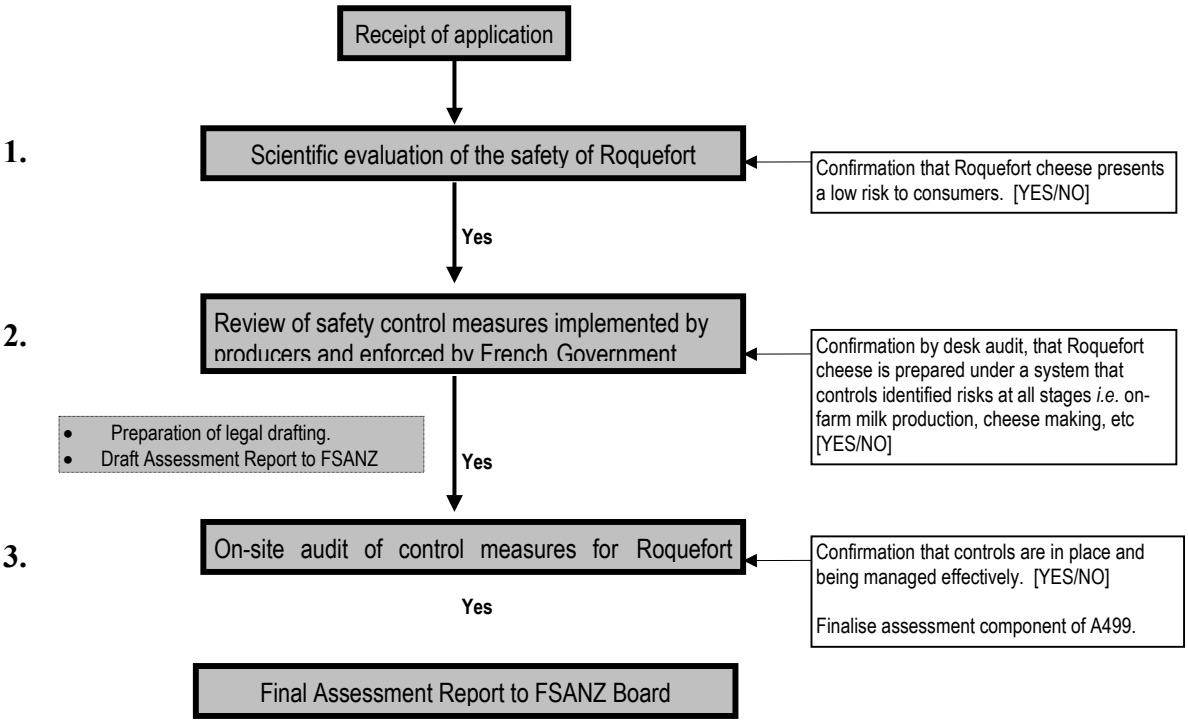
1. A scientific evaluation of the safety of the cheese to examine the effect of the cheese manufacturing processes on selected microbial pathogens (Attachment 2).

2. A review of the regulatory environment and safety control measures under which sheep milk is produced and Roquefort cheese manufactured (Attachment 3).

3. Verification of the implementation of these control measures.

This process is represented below in Figure 1.

Figure 1: Stages of the assessment of Roquefort cheese



5.2 Scientific Evaluation of the Safety 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, 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. However, 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 as follows:

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 that, there have been no reported outbreaks of food-borne illness due to consumption of Roquefort cheese.

Roquefort cheese production was judged to achieve the following effects on 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].

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 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;

[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.

- 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.*

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.

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 review of 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. 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 the treatment or processing of milk or milk-based products. ▪ 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 4.

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 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.

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 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.

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 5.

Table 5: 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. *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). Corrective measures usually take the form of increased surveillance, *i.e.* no corrective action given for non-compliance with required milk temperature. 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. 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. The frequency on internal inspections is provided. 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. 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.

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

5.4 Verification of control measures

Verification of control measures implemented by the Confederation of Roquefort Producers and enforced by the French Government (including the results of routine monitoring and testing) will be undertaken as a subsequent process to this review. This will take the form of an on-site audit.

Issues such as the integrity of pre-requisite programs (see Table 5) will be addressed during this phase of the assessment.

The audit will be undertaken with AQIS supervision and oversight in March 2005. FSANZ will provide technical input into this process. The results of the audit will finalise the evaluation and review of the application and be incorporated into the Final Assessment Report.

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) impose 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.

Hazard	Control measures
S. aureus enterotoxin	**On farm:** • Ministerial Order of 18 March 1994 on the Hygiene of milk Production and Collection - milk derived from healthy animals - criteria for Plate Count at 30 °C - temperature/time requirements for milk storage (≤ 8°C) and transport (≤ 10°C) **Processing and production:** • Ministerial Order of 30 December 1993 - requirement for hazard analysis/identification of critical control points and ongoing monitoring and checking (e.g. HACCP plan)
Salmonella	**On farm:** • Ministerial Order of 18 March 1994 - hygiene requirements for production, holding, milking, storage and collection operations - temperature/time requirements for milk storage (≤ 8°C) and transport (≤ 10°C) **Production and Processing:** • Ministerial Order of 30 December 1993 - requirement for hazard analysis/identification of critical control points and ongoing monitoring and checking (e.g. HACCP plan)
Pathogenic *E. coli*	**On farm:** • Ministerial Order of 18 March 1994 - hygiene requirements for production, holding, milking, storage and collection operations **Processing and production** • Ministerial Order of 30 December 1993 - general hygiene requirements
Listeria monocytogenes	**On farm:** • Ministerial Order of 18 March 1994 - hygiene requirements for production, holding, milking, storage and collection operations **Processing and Production:** • Ministerial Order of 30 December 1993 - general hygiene requirements - 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 six hours to below 5.5 and then below 5.0 after 24 hours.

5.3.4 Water activity

The scientific evaluation highlighted that the final water activity of Aw 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.

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 for *E. coli* in particular is different to that applied in the EU. Roquefort, however, must meet the limits specified in the Code.

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:

- microbiological criterion for *L. monocytogenes* in raw milk;
- the acidification process;
- water activity, 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 pasteurised or thermised milk.

6. Regulatory Options

At Initial Assessment 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. 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 water activity during cheese production; and
- a minimum storage time of Roquefort of 90 days (at a temperature of no less than 2°C)

The draft variation to the Code is at Attachment 1. Specific pH and water activity limits have not been included in the draft variation at this stage but may be included in the drafting at Final Assessment once additional information obtained during the on-site audit can be assessed. Additionally, the sampling plan currently drafted for *L. monocytogenes* in raw ewe's milk may also be amended in light of information obtained during the audit process.

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. The Application is framed in terms of seeking an amendment to the Code to permit the sale of Roquefort cheese in Australia, not in Australia and New Zealand. Thus, it would be consistent with The Application for an Australia only Standard to apply. In addition the New Zealand Food Safety Authority have 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. 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 a blank Dairy PPP Standard in 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. 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).

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 (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 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 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 the 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 dairy industry in the very short term would be unaffected by Option 2 because it does not produce an equivalent 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, of 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 can make an application to FSANZ for permission for similar styles of cheese providing they have supporting information.

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 food 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 the 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

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

- Australian Specialist Cheesemakers' Association
- Food Technology Association of Victoria
- Victoria Department of Human Services
- Queensland Health
- SafeFood Queensland
- Dairy Food Safety Victoria
- Australian and New Zealand Dairy Authorities Standards Committee (ADASC)
- Tasmanian Dairy Industry Authority
- Department of Agriculture, Fisheries and Forestry (DAFF)
- Dairy Australia
- Fonterra
- New Zealand Food Safety Authority
- Fromagent Australia
- F. Mayer Imports
- three from the general public

A summary of the issues raised in these submissions is provided at Attachment 5.

Further consultation 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.

Additionally, 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 the 10 February 2005.

8.1 Issues raised in submissions and other stakeholder consultations

The public consultation process undertaken since Initial Assessment of this application raised a number of issues in relation to the importation and sale of Roquefort cheese in Australia. The major issues raised by stakeholders are presented and discussed below.

8.1.1 Safety and the verification of hygiene controls

The safety evaluation of Roquefort cheese and the review of the legislative and industry controls overriding its production are an integral part of this Draft Assessment Report. The safety evaluation and review of safety control measures is presented in Section 5. As discussed previously verification of the control measures in place will be a subsequent process, undertaken as an on-site audit in France.

8.1.2 Impact on the Australian industry of permitting Roquefort cheese

It was 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.

8.1.3 Australia's approach to geographical indications

Roquefort cheese has AOC status (Appellation-controlled origin, or protected designation of origin) in Europe. This means that the cheese can only be produced in the region surrounding the town of Roquefort-sur-Soulzon in France, under stipulated conditions, in order to be entitled 'Roquefort' cheese in Europe.

Australia's policy on geographical indications is different from the European model. The assessment of this application has primarily been concerned with the safety of Roquefort cheese in which specified geographical boundaries for production have not been a consideration. The name 'Roquefort', for the purposes of this application, is akin to a trademark defining a particular blue vein cheese manufactured from sheep milk in France under specific production and processing conditions.

8.1.4 Transparency of the FSANZ process

The process for amending the Code is prescribed in the 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.

8.1.5 Labelling

Labelling is one of a number of risk management tools used by FSANZ. FSANZ uses labelling in the development of food standards if there is –

- a demonstrated risk to public health and safety; and/or
- a need to ensure the adequacy of information for informed choice; and/or
- the potential for misleading and deceptive conduct.

There is a range of labelling strategies used by FSANZ dependent on the degree of risk. The greater the degree of risk the more prescriptive the labelling strategy required

8.1.5.1 Warning and advisory statements

In certain circumstances, the Code (Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations) requires warning statements or advisory statements to be used on a food label or in association with the display of the food if the food is not required to bear a label. Warning statements and advisory statements are used for different purposes.

Mandatory warning statements are used where the risk to public safety is potentially life threatening and it can be reasonably assumed that the general population or the specific target group is unaware of the potential safety risk. Currently the Code only requires a warning statement for food containing royal jelly. As the scientific evaluation shows that Roquefort cheese can be produced to an equivalent level of safety to blue cheeses made from heat treated milk, a mandatory warning statement cannot be justified.

Mandatory advisory statements are used where the general population or a sub-group of the population is exposed to a health and safety risk but the risk is not life threatening, or when guidance about a food is needed to maintain public health and safety. There are currently mandatory advisory statements for unpasteurised milk and liquid milk products which requires a statement to the effect that the product has not been pasteurised. There are currently no mandatory advisory statements for cheeses produced from unpasteurised milk. The assessment of this application does not support a mandatory advisory statement for Roquefort cheese.

8.1.5.2 Ingredient labelling requirements

Clause 4 of Standard 1.2.4 - Labelling of Ingredients requires that the ingredients in the statement of ingredients be declared using:

- the common name of the ingredient; or
- a name that describes the true nature of the ingredient; or
- where applicable, a generic name set out in the Table to this clause (a generic name is provided for 'cheese')
- (an editorial note is provided stating that the names of ingredients should be sufficiently detailed and accurate to ensure they are not false, misleading or deceptive or likely to mislead or deceive and that the generic names listed may be accompanied by a suitable word or words to further specify the ingredient)

Given these requirements, `unpasteurised sheep (or ewe) milk' should be declared as such in the ingredient list, being a description of the true nature of the ingredient. This is consistent with the Codex requirements[12] for ingredient labelling. Retail packages of Roquefort cheese, in addition to the other labelling requirements of the Code, should display such a declaration on the label. This is a matter that can be checked by AQIS at the border and importers may be required to re-label for sale in Australia as necessary.

8.1.6 Primary Production and Processing Standard for Dairy

A number of submissions raised that it would be preferable to consider the issue of raw milk cheeses 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. 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. Accordingly, the assessment of the Roquefort Application has progressed independently of the Dairy PPP Standard process.

8.1.7 *Implementation*

Stakeholders raised that is was essential that there could be ongoing assurances that Roquefort cheese would be produced safely according to the identified safety controls. To this effect, and in addition to the surveillance of this food under the Imported Food Inspection Scheme, Australia is currently working with France to establish a Government to Government certification agreement for Roquefort cheese. This is discussed further in Section 11.2.

8.1.8 *WTO obligations*

In developing and varying standards FSANZ must have regard to international food standards and notify the WTO of proposed mandatory regulator measures that impact on trade. Australia's obligations under the WTO are discussed below in Section 9.1.

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:

[12] 12 Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev. 1-1991

- 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.

8.2 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 (A499), 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 will be therefore be made in accordance with Australia's obligations under the WTO Sanitary and Phytosanitary Measure (SPS) Agreement. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusions and Recommendations

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

- The conclusion from the Scientific Evaluation of the safety of Roquefort cheese is that the sale of Roquefort cheeses poses a low risk to the public health and safety of Australian consumers.

- In general, 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 standard operating procedures (SOPs) and good manufacturing practice (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.

- 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 proposed drafting for amendment to the Food Standards Code is at **Attachment 1**.

10. Implementation and review

10.1 Imported Food Inspection Scheme

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

The Scheme 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.

10.1.1 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.

(a) 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.

(b) 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.

(c) Random surveillance category

Five percent 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.

10.1.2 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.

10.2 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.

Australia is currently working with France to establish a Government to Government certification agreement for Roquefort cheese. This process will involve an on-site audit using qualified auditors who, on behalf of AQIS, will assess the adequacy of hygiene controls on-farm; the Roquefort cheese production methods and facilities, as well as the official inspection procedures. Australia bases the assessment of food export inspection and certification systems on the Codex Guidelines for the *Design, operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26 – 1997).

A successful on-site audit will result in Australia and France developing a Memorandum of Understanding (MoU) or similar document, which sets out the obligations of each party in respect of the arrangement. This will be based on the Annex of the Codex document *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection Systems* (CAC/GL 34 – 1999).

Australia will continue to verify the food safety of certified 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. Summary of Submissions
6. 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 1.6.2*** *of the Australia New Zealand Food Standards Code is varied by –*

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

Table of Provisions

1 Processing of milk and liquid milk products
2 Deleted
3 Processing of egg products
4 Eviscerated poultry
5 Dried meat
6 Crocodile meat
7 Game meat
8 Fermented comminuted processed meat
9 Production of fermented comminuted meat which has not been cooked
10 Semi-dry heat-treated processed meat

Schedule Methods of analysis

[1.2] *omitting clause 2 and the associated editorial note, substituting –*

2 Deleted

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

[2.1] *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

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

3 Deleted

[3] ***The Australia New Zealand Food Standards Code*** *is varied by inserting after Standard 4.2.1* -

STANDARD 4.2.4

PRIMARY PRODUCTION AND PROCESSING STANDARD FOR DAIRY (AUSTRALIA ONLY)

Purpose and commentary

Table of Provisions

1 Application
2 Interpretation
3 Manufacture of cheese and cheese products

Clauses

1 Application

(1) Reserved

2 Interpretation

(1) Reserved

3 Manufacture 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 subclause 3(2) of this Standard.

(2) Cheese and cheese products specified in Column 1 of the Table to this subclause 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 3(1)(a) of this Standard; and

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

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

Table to subclause 3(2)

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* 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*	(1) The following matters must be monitored and recorded during cheese production: (a) pH during the acidification process; and (b) water activity. (2) Unpasteurised milk for cheese production must meet the following microbiological criteria: *Listeria monocytogenes/2 5ml: n=5, c=0, m=0 where n, c and m have the same meaning as in Standard 1.6.1*. (3) The cheese must be stored at a temperature of no less than 2°C for a period of no less than 90 days from the date of manufacture.

Editorial note:

Cheese under paragraph 3(1)(b) is generally known as 'extra hard grating cheese' – see the Codex International Standard for Extra Hard Grating Cheese (CODEX STAN C-35-1978).

Legislation or documentation will only be listed in the Table to subclause 3(2) 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), 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.

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 foodborne 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 foodborne 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 foodborne 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 foodborne 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 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 foodborne 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 20th 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 foodborne 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 foodborne 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 foodborne 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 foodborne illness are significantly underreported, while cases of sporadic foodborne illness are rarely investigated.

A review of the role of milk and milk products in foodborne 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 foodborne 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, milkborne 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 foodborne 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 milkborne 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 foodborne 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

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*.

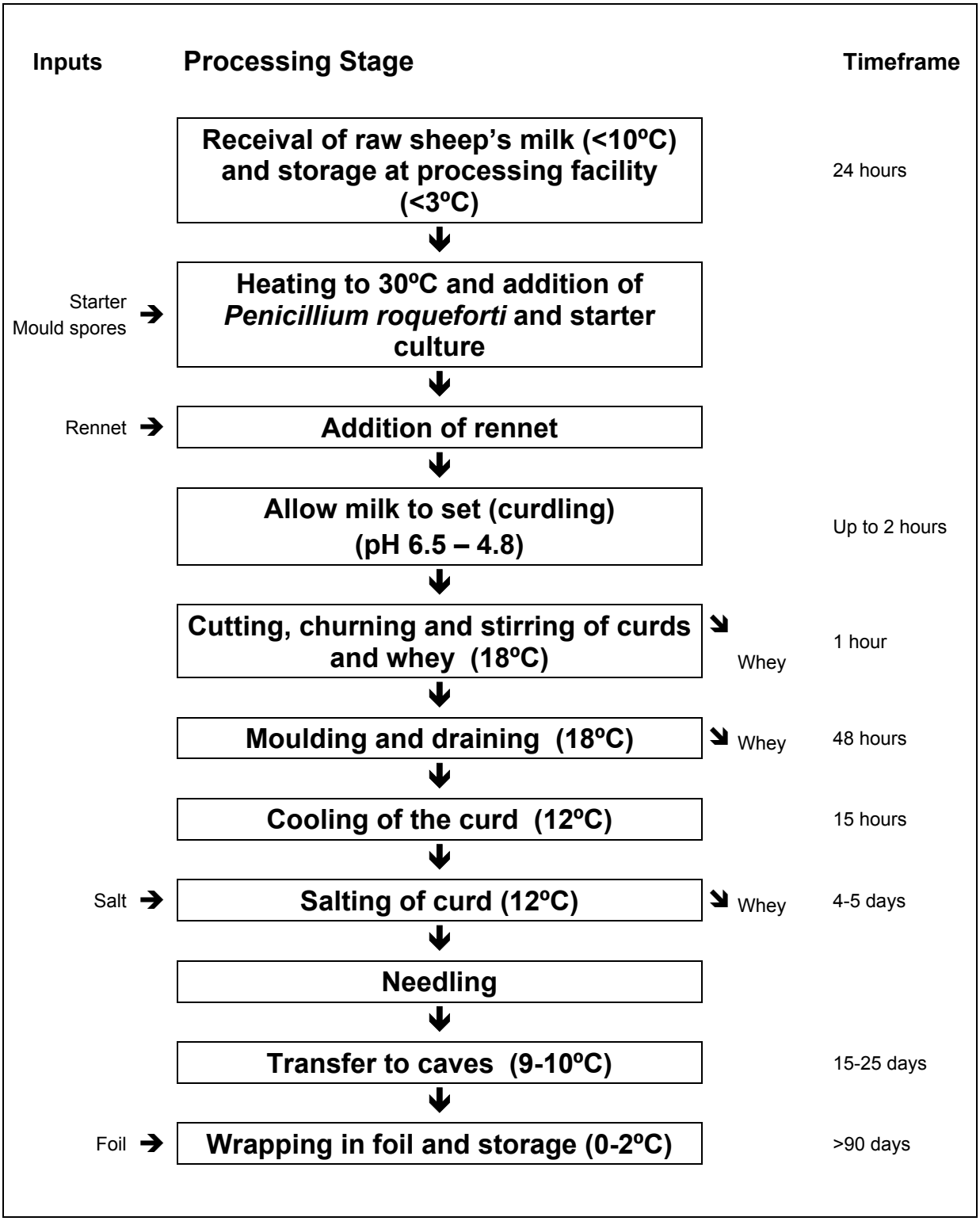


Figure 1: Flow diagram for the manufacture of Roquefort cheese

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[13] detection technique up until 130 days in one sample. In all cases, no *Salmonella* could be detected after 130 days.

[13] 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[14] (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[15] and FSANZ[16] 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.

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

15 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

16 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 foodborne 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[17] 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).

[17] 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 foodborne illness outbreaks associated with raw milk cheeses found that Roquefort cheese has not been implicated in any outbreaks of foodborne 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[18].

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 foodborne 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 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.

[18] 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.

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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 microaerophilic 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).

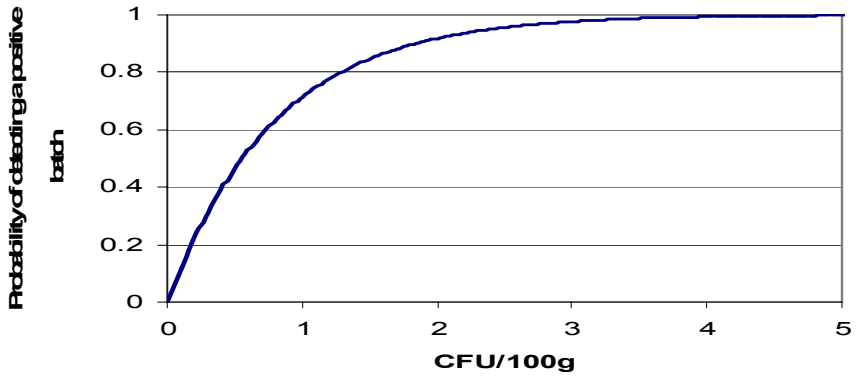

Figure 1: Probability of detecting a positive batch at various concentrations of pathogenic bacteria in the batch at the time of sampling (5 x 25g samples).

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*. Emmenthal, 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.

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Qualitative Risk Assessment of Raw Milk Roquefort Cheese

Final Report

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An Australian Food Safety Centre of Excellence Initiative

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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 microaerophilic 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. Emmenthal, 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 milkborne 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.

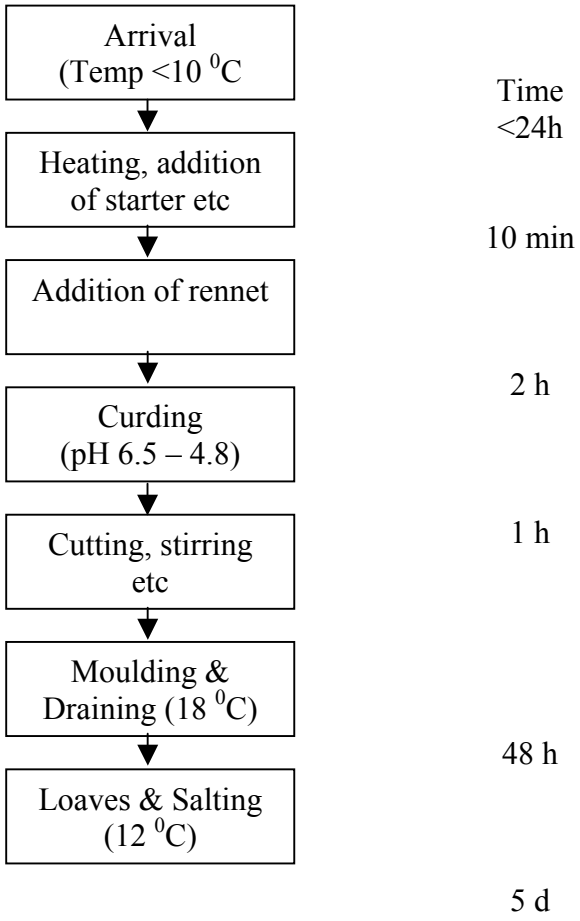

Figure 2: Flow diagram for the manufacture of Roquefort cheese. Only stages up to maturation are shown.

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 and New Zealand 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.

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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[19]								
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

[19] 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

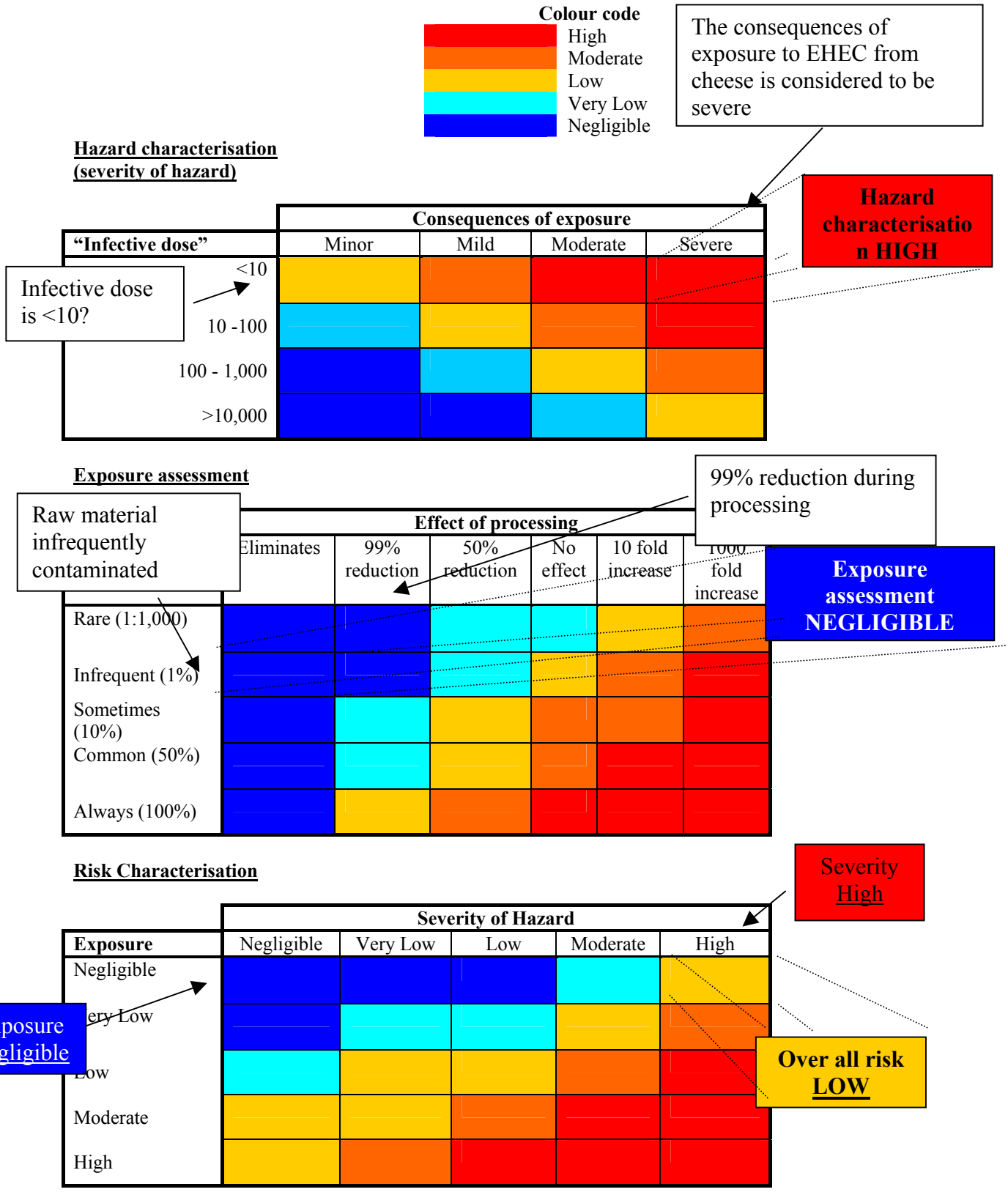
5. Is there potential for recontamination ?

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

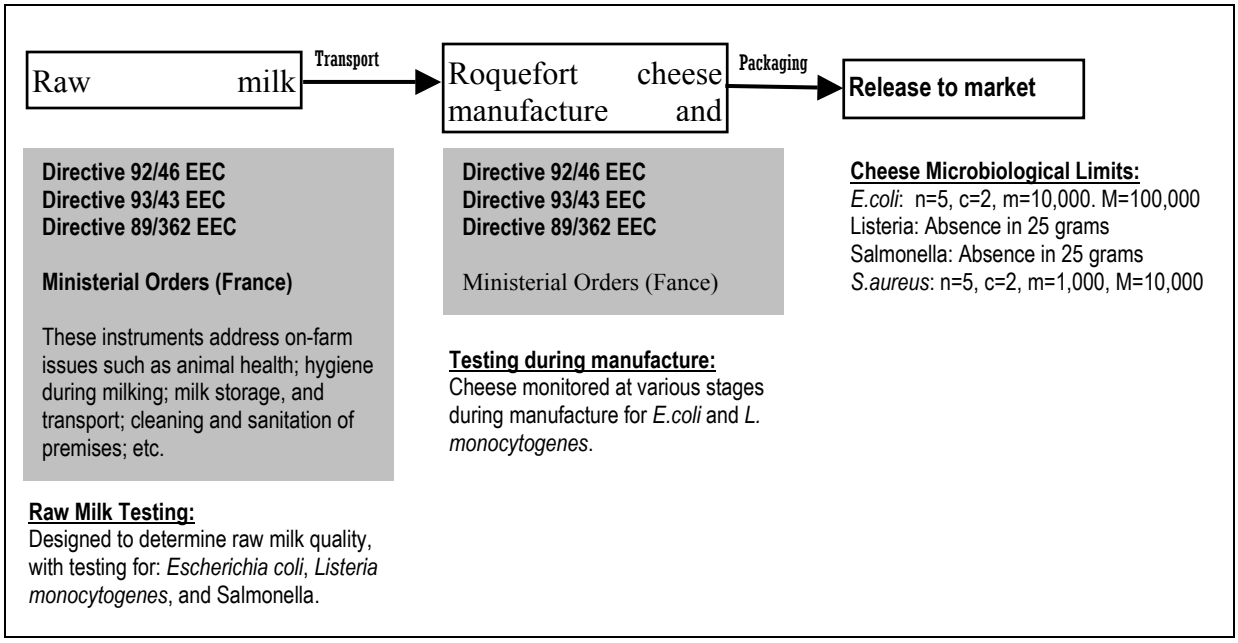
The safety of Roquefort cheese is influenced by a combination of factors, including on-farm control of animal health; on-farm production hygiene; the microbiological status of the incoming raw milk; the rapid acidification of the milk during the initial phase of cheese manufacture; desiccation of the 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 ▪ Equipment - general conditions and upkeep ▪ 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 ▪ Microbiological criteria ▪ Managing non-compliance ▪ 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 ▪ 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: ▪ Separation of risk assessment and risk management ▪ Traceability and incident alert system
French Government	
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 the treatment or processing of milk or milk-based products. ▪ 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

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: Plate count: 500,000/ml (at 30ºC) *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 (Appelation 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* **Chapter II –** Hygiene at the production holding **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* **Chapter III –** Hygiene of milking, storing and collection operations **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*** **Chapter III –** Hygiene of milking, storing and collection operations **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*** **Chapter III –** Hygiene of milking, storing and collection operations Article 11: Staff hygiene *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*** **Chapter II –** Hygiene at the production holding **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*** **Chapter II –** Hygiene at the production holding **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* **Annex – Chapter VII**: Water supply	
Farm refuse	***RURAL CODE – Sanitary control*** Chapter II – **Regarding the quartering of dead animals** **Article 264** (L. no 75-13436 of 31 December 1975)	Provides guidance on storage of manure, disposal 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 Section 3.1	Suitability of water	✓	*Ministerial Order of 18 March 1994 on the hygiene of milk production and collection* Chapter II – Hygiene at the production holding Article 7: Special conditions applying to milk treatment rooms and premises where milk is stored *Directive 93/43/EEC of 14 June 1993 on hygiene of food stuffs* Annex – Chapter VII: Water supply
Hygienic Production of Milk Section 3.2 Areas and premises for Milk Production Section 3.2.1	Design and layout animal holding areas Cleanliness animal holding areas Design and layout milking areas	✓	*Ministerial Order of 18 March 1994 on the hygiene of milk production and collection* Chapter II – Hygiene at the production holding Article 5: General conditions applying to premises used for animal housing, milking and storage of milk Article 6: Special conditions with respect to animal housing premises Article 7: Special conditions applying to milk treatment rooms and premises where milk is stored
Animal Health Section 3.2.2	Disease status General health of animal Isolation of sick animals Identification of animals Correct use of milking equip Hygiene of milking Mgt of animal holding areas Registration of herds	✓	*Ministerial Order of 18 March 1994 on the hygiene of milk production and collection* Chapter I – Animal health requirements Article 2: State of health of animals *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* Chapter II – Approval Article 3
General Hygienic Practice Section 3.2.3	Codex Code of Practice on Good Animal Feeding (under development) Storage of fermented feeds Design silage silos GMP production	✓	No regulation Guidelines provided Good Ensilage Practice Guide is referred to
Hygienic Milking Section 3.2.4	Personnel hygiene Animal hygiene (e.g. clean teats etc) Cleaning and disinfection milking vessels and equipment Milk Equipment design	✓	*Ministerial Order of 18 March 1994 on the hygiene of milk production and collection* Chapter II – Hygiene at the production holding Article 7: Special conditions applying to milk treatment rooms and premises where milk is stored Chapter III – Hygiene of milking, storing and collection operations Article 11: Staff hygiene *Ministerial Order of 10 March 1977 on the state of health and hygiene of personnel involved* Chapter III- Hygiene of milking, storing and collection operations
Handling storage and transport of milk Section 3.3 Milking Equipment Section 3.3.1	Design Cleaning and disinfection Periodic verification of equipment	✓	*Ministerial Order of 18 March 1994 on the hygiene of milk production and collection* Chapter III – Hygiene of milking, storing and collection operations Article 10: Equipment hygiene
Storage Equipment Section 3.3.2	Design Cleaning and disinfection	✓	*Ministerial Order of 18 March 1994 on the hygiene of milk production and collection* Chapter III – Hygiene of milking, storing and collection operations Article 10: Equipment hygiene
Premises for, and Storage of Milk and Milking-Related Equipment Section 3.3.4	Suitable milk refrigeration equip Water Protection from vermin Design for easy cleaning Separation animals & milking areas	✓	Milk collected daily and kept at no more than 10°C.

* Confederation ***Guide of good manufacturing practices for the production of ewe's milk in the manufacture of Roquefort***

Table 4 (continued): 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**	
Collection, Transport and Delivery Procedures and Equipment Section 3.3.4	Personnel hygiene 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* Title II – Requirement relating to hygiene of operations Chapter 1 – Control of hygiene Article 14 Chapter IV - Staff hygiene 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* Title II – Requirement relating to hygiene of operations Chapter 1 – Control of hygiene 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 Péche 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. *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). Corrective measures usually take the form of increased surveillance, *i.e*. no corrective action given for non-compliance with required milk temperature. 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. 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. The frequency on internal inspections is provided. 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. 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 Butyric spores *Listeria* Total coliforms MG, MP	Cf. milk payment scale Absence/ml Cf. milk payment scale	3/month 2/month from December to April Silage: 1/batch of ewes for milking 3/month 4/month
Milk collection/ Tanker	*L. monocytogenes* Total coliforms/*E. coli*	Absence/ml	Daily 1day/2
Dairy	*Listeria* *Salmonella* *E. coli* Total coliforms	Absence/25 ml Absence/25 ml	Daily
Cave	*L. monocytogenes* *Salmonella* spp *S. aureus* *E. coli*	Absence/25g Absence/25g <100/g <100/g	1/batch
Packaging	*L. monocytogenes* *Salmonella* spp *S. aureus* *E. coli*	Absence/25g Absence/25g <100/g <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 - Checks on water quality - Checks on livestock feed - Compliance with conditions for hygiene	Absence in 25 ml of milk	- Tests on water - Pathogen Plan (A*nnexe 18*)	- Water from public supply network - Sorting to remove defective milk - Elimination of healthy carriers of pathogens - Measures to prevent entry of poultry into breeding buildings
		2) *Listeria monocytogenes*	- Quality of livestock feed (checks on silage) - Hygiene in premises - Proper mulching	Absence in 25 ml of milk	- Pathogen Plan (A*nnexe 18*)	- Change in livestock feed - Disinfection of buildings - Elimination of healthy carriers of pathogens - Sorting to remove defective milk
	Risks linked to germs indicating contamination	1) *E. Coli*	- Surveillance of safety of drinking water - Hygiene in premises - Proper mulching - Detection of ewes suffering from mammitis - Control of drying off - Veterinary follow-up on livestock	< 500 /ml	- Tests on water - Individual Cell Counts (ICC) - Individual "coli" counts	- Water from public supply network - Cell-count programme(*Annexe 22*) - Rejection of ewes with chronic mammitis and high ICCs, as well as ewes with udder defects - Control of drying off
		2) *Staphylococcus aureus*	- Detection of ewes suffering from mammitis - Detection of wounds - Control of drying off	< 100 /ml	- Surveillance of mammitis - Surveillance of wounds	- Rejection of ewes suffering from mammitis and ewes with udder wounds - 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 - Review of feed distribution procedures
	Defective hygiene on the holding and in its environment		- Good hygiene practice - Good maintenance of sheep pen, milking room, dairy, lock room and surroundings, and feed storage	- Visual inspection - Combat against pest infestation	- Audit of holding (*Annexes 19 and 20*) - Checks on safety of drinking water (tests) Feed tests	- Completion of modification works within imposed time period. Feed rejection.

Stage	Causes	Preventive measures	Critical limits	Surveillance procedure	Corrective actions
MILKING	- Contamination by animals - Contamination by equipment - Contamination by the milker - Contamination by the environment	- Checks on animals - Cleaning and disinfection of the milking machine - Checks on the milking machine - Personal hygiene and good health of the milker - 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 Daily or periodic tests - Tests on water quality Inspection by CRA (Crop Relations Agent) - Checks on effectiveness of cleaning and disinfection procedures	- Selection of animals - Replacement of worn components - Review of milking practices - Treatment of local water supply or connection to public supply network - Checks on the effectiveness of cleaning and disinfecting practices of equipment and premises - Disinfection of milker's hands
FARM STORAGE	- Contamination or germ growth due to equipment	- Maintenance of milk tank - Thermometer calibration - Satisfactory cleaning and disinfection procedures	- Tank temperature 4 - 8° C - Speed of cooling - Visual inspection	- Checks on conservation temperature - Reductase test at dairy factory - Checks on effectiveness of cleaning and disinfection procedures	- Reconditioning or replacement of equipment 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 ❒ YES ❒

IF YES, INSPECTING BODY……. CLO ❒ CLS ❒ AT ❒

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**									
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									

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 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									

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									
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									

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					
SIGNATURES	Producer									
(according to outcome: satisfactory or unsatisfactory)	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
TRANSPORT & TANKER COLLECTION	- Contamination of the milk - by the tanker - by the equipment used - by the environment - Temperature rise in the milk during journey	- Dairy surroundings to be clean and well drained - Cleaning and disinfection schedule for the tanker and milk transfer lines - Training of personnel Transport to be done in heat-insulated tankers	- Absence of coliforms in rinse water - Milk temperature < 10 °C	- Visual checks on areas at risk - Verification of proper functioning of CIP (Cleaning In Place) system (concentration, flow rate , temp.) - Tests for coliforms in rinse water	- Stepped up cleaning and disinfection procedures
	- 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***) - Identification of livestock farmer and ewe through milking batch - Holding involved to be audited - Holding to be reintegrated into the milk collection system only when test results negative on two consecutive days

Stage	Hazards / Critical Control Points	Preventive measures	Critical limits	Surveillance procedures	Corrective measures
RECEPTION **STORAGE / COOLING**	- Contamination of milk - by the tanker - by the equipment used - by the environment	- Dairy surroundings to be clean and well drained - Cleaning and disinfection schedule for the truck and milk transfer lines - Training of personnel	- Absence of coliforms in rinse water	- Visual checks on areas at risk - Verification of proper functioning of CIP (Cleaning In Place) system (concentration, flow rate, temp.) - Tests for coliforms in rinse water	- Stepped up cleaning and disinfection procedures (immediate surroundings of facility, tanker, equipment)
	- Contamination of milk by *Listeria monocytogenes* or *Salmonella sp*	- Sorting of collection rounds - Preventive measures on livestock holding	- Absence of *Listeria monocytogenes* and *Salmonella sp*	- Systematic tests for *Listeria monocytogenes* and *Salmonella sp* - Random tests for *Staphylococcus aureus*	- If the results are known prior to production the milk is to be sent through to pasteurisation-based production - If the results are known only after production of the cheese, the production batches must be tracked - ***More intensive surveillance plan***
PREPARATION OF MILK PLACING IN VAT / INOCULATION	- Contamination by the equipment used - Contamination by the system - Contamination by ingredients: ferments, rennet, *Penicillium roqueforti*	- Cleaning and disinfection schedule - Good hygiene practice in preparing ferments - Required specifications to be agreed with supplier	- Absence of coliforms - Compliance with agreed specifications	- Absence of coliforms and *Listeria monocytogenes* in rinse water - Test report form for each batch	- Verification of correct operation of CIP system (concentration, pressure, temp.) - Verification of compliance with good hygiene practice and training of personnel - Complaints to be investigated and suppliers audited
COAGULATION STIRRING	- Contamination by handling procedures - Contamination by equipment used	- Clean clothing - Clean hands - Personnel training - Good cleaning and disinfection practice	- Clean smocks, footwear and caps to be worn - Absence of coliforms and *Listeria monocytogenes*	- Visual checks - Monitoring of coliforms on hands - Monitoring of coliforms and *Listeria monocytogenes*	- Stepped up checks on cleaning - Stepped up cleaning and disinfection - Renewed awareness raising / training for personnel

Stage	Hazards / Critical Control Points	Preventive measures	Critical limits	Surveillance procedures	Corrective measures
MOULDING	- Contamination by handling procedures - Contamination by equipment used	- Clean clothing - Clean hands - Personnel training - Good cleaning and disinfection practice	- Clean smocks, footwear and caps to be worn - Absence of coliforms on hands - Absence of coliforms and *Listeria monocytogenes*	- Visual checks - Monitoring of coliforms on hands (no coliforms to be present) - Monitoring of coliforms and *Listeria monocytogenes*	- Stepped up checks on cleansing of hands and awareness raising / training for personnel - Stepped up cleaning and disinfection
DRAINING	- Proliferation of bacteria due to incorrect acidification	- Good practice in the production of the ferments - Verification of acidification capacity of ferments used	- pH of curd (5 days below 4.8) - 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 - Contamination by equipment used	- Clean clothing - Clean hands - Personnel training - Good cleaning and disinfection practice	- Clean smocks, footwear and caps to be worn - Absence of coliforms on hands - Absence of coliforms and *Listeria monocytogenes*	- Visual checks - Monitoring of coliforms on hands - Monitoring of coliforms and *Listeria monocytogenes*	- Stepped up checks on cleansing of hands and renewed awareness raising / training for personnel - Stepped up cleaning and disinfection
SALTING	- Contamination by handling procedures - Contamination by equipment used	- Clean clothing - Clean hands - Personnel training - Good cleaning and disinfection practice	- Clean smocks, footwear and caps to be worn - Absence of coliforms on hands - Absence of coliforms and *Listeria monocytogenes*	- Visual checks - Monitoring of coliforms on hands - Monitoring of coliforms and *Listeria monocytogenes*	- Stepped up checks on personnel - Stepped checks on cleaning - Renewed awareness raising / training for personnel - Stepped up cleaning and disinfection

Stage	Hazards / Critical Control Points	Preventive measures	Critical limits	Surveillance procedures	Corrective measures
STORAGE	- Proliferation of bacteria due to break in cold chain - Contamination by environment	- Clean clothing - Maintenance and upkeep of refrigeration system - Detection of microbial build-up in storage facilities - Pest control plan	- Clean smocks, footwear and caps to be worn - Temp: between 2°C and + 6°C - Stable relative humidity levels - Bait, insect traps	- Visual checks - Recording thermometers and hygrometers - Visual checks + and regular visits to be made by outside approved pest control companies	- Stepped up checks on personnel - Repairs to refrigeration systems - Regulated ventilation - More intensive pest control plan
TRANSPORT	- Contamination by handling procedures	- Clean clothing - Clean hands - Personnel training	- Clean smocks, footwear and caps to be worn - Absence of coliforms	- Visual checks - Monitoring of coliforms on hands	- Stepped up checks on negligent personnel - Stepped up cleaning and disinfection and - Awareness raising / training for personnel
NEEDLING	- Contamination by handling procedures - Contamination by equipment used	- Clean clothing - Clean hands - Personnel training - Good cleaning and disinfection practice	- Clean smocks, footwear and caps to be worn - Absence of coliforms - Absence of coliforms and *Listeria monocytogenes* - Needling order of cheese (batches subject to more intensive surveillance should be processed last)	- Visual checks - Monitoring of coliforms on hands - Monitoring of coliforms and *Listeria monocytogenes* on equipment	- Stepped up checks on personnel - Stepped up cleaning and disinfection and - Awareness raising / training for personnel - Surveillance based on traceability system
ENTRY TO FERMENTING CELLAR	- Contamination by handling procedures	- Clean clothing - Clean hands - Personnel training	- Clean smocks, footwear and caps to be worn - Absence of coliforms	- Visual checks - Monitoring of coliforms on hands	- Stepped up checks on personnel - Stepped up cleaning and disinfection - Renewed awareness raising / training for personnel

Stage	Hazards / Critical Control Points	Preventive measures	Critical limits	Surveillance procedures	Corrective measures
TINFOIL COVERING (SEALING) **PACKAGING**	- Contamination by handling procedures - Contamination by equipment used - Contamination by packaging	- Clean clothing - Clean hands - Personnel training - Good cleaning practice - Required specifications to be defined with supplier	- Clean smocks, footwear and caps to be worn - Absence of coliforms *and Listeria monocytogenes* - Total absence of soiling	- Visual checks - Monitoring of coliforms on hands - Monitoring of coliforms and *Listeria monocytogenes* - Visual checks on reception and when placed in store	- Stepped up checks on personnel - Stepped up cleaning and disinfection - Renewed awareness raising / training for personnel - 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 - Relative humidity levels	- Recording thermometers and hygrometers	- Repairs to refrigeration systems - 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 ***Only compliant batches to be sent through for packaging***	- Absence of *Listeria monocytogenes* - Absence of *Salmonella sp* - *E. coli* < **100** /g (***for batches to be shipped to Australia***) - *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 - ***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)

Stage	Hazards / Critical Control Points	Preventive measures	Critical limits	Surveillance procedures	Corrective measures
TRANSPORT	- Contamination by handling procedures	- Clean clothing - Clean hands - Personnel training	- Absence of coliforms	- Visual checks - Monitoring of coliforms on hands	- Stepped up cleaning and awareness raising / training for personnel
REMOVAL OF TINFOIL COVERING (UNSEALING) **CUTTING** **REPACKAGING**	- Contamination by handling procedures - Contamination by equipment used	- Clean clothing - Clean hands - Personnel training - Good cleaning and disinfection practice	- Clean smocks, footwear and caps to be worn - Absence of coliforms - Absence of coliforms *and Listeria monocytogenes*	- Visual checks - Monitoring of coliforms on hands - Monitoring of coliforms and *Listeria monocytogenes*	- Stepped up cleaning and awareness raising / training for personnel - Stepped up cleaning and disinfection
CUTTING **PACKING**	- Contamination by handling procedures - Contamination by equipment used	- Clean hands - Personnel training - Good cleaning and disinfection practice	- Absence of coliforms *and Listeria monocytogenes*	Monitoring of coliforms on hands - Monitoring of coliforms and *Listeria monocytogenes*	- Stepped up cleaning and disinfection and - 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. 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 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. Equipment hygiene – general requirements Staff hygiene – general requirements (including hand washing, location of washing facilities). (**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: 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: Plate count 30°C: < 500 000 *Staphylococcus aureus* (per ml): m=500; M=2000; n=5; c=2 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). 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: ▪ provides the latest results of the establishment's own checks performed on raw materials and foodstuffs placed on the market ▪ 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 Chapter 1 - Principles Chapter 2 - Premises 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 Chapter 1- Control of hygiene	Requirements specified within this Chapter include: ▪ identifying critical control points ▪ monitoring and checking of CCPs ▪ the keeping of written records (to be kept for a period of at least 2 years) ▪ the taking of samples to check effectiveness of process and compliance with standards ▪ 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 ▪ no animals in storage and manufacturing facilities ▪ eradication of pests ▪ use of potable water ▪ conditions under which manufacturing, wrapping and packaging operations may be performed in the same room ▪ 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 ▪ frequency of cleaning rooms, utensils, containers and equipment ▪ 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 – 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 For Blue-veined cheeses made from raw or thermised milk, the following criteria are stipulated:- *Listeria monocytogenes*: Absence in 25g (n=5, c=0) *Salmonella spp*: Absence in 25g (n=5, c=0) *Staphylococcus aureus*: n=5, c=2, m=1000, M=10 000 *Escherichia coli*: n=5, c=2, m=10 000, M=100 000
	Annex B – 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

SUMMARY OF SUBMISSIONS

Organisation	Contact	Issues raised
Fromagent Australia Pty Ltd	Mr Will Studd	• Trade - the ban on Roquefort is inconsistent with international standards. This cheese is traded internationally without restriction except in Australia and New Zealand. - the ban represents a trade barrier designed to protect domestic producers - there is a need to fulfil WTO obligations and take into account equivalence outcomes as required by the WTO • Domestic regulations - the ban on Roquefort is in breach of COAG guidelines with regard to minimal effective regulation and harmonisation with international standards - the ban reflects a lack of adequate domestic regulations, which have an overly prescriptive focus on input processes rather than equivalence outcomes • Safety - raises a previous deliberation by the Authority in regard to cheeses made from raw milk that states that the implementation of Codes of Practice incorporating HACCP principles significantly reduces public health risks associated with cheese made from unpasteurised milk. - questions the validity of pasteurisation as the only critical control point (CCP). Asserts that starter culture activity should be seen as the CCP. - dependence on mandatory pasteurisation reflects a lack of domestic controls on herd testing and encourages the use of milk of poor microbiological controls.
F. Mayer Imports	Robbie Mayer	This submission reflects the same issues as raised by Fromagent (above).

Australian Specialist Cheesemakers Association	Mr David Brown	• Safety - while HACCP control systems have improved milk quality and hygiene, raw milk and raw milk products still pose a risk, particularly for higher moisture cheeses. - the use of caves as an environment in which to mature cheese presents an uncontrolled microbiological environment and not inline with modern hygienic practices (would not be permitted under Australian regulations). • Unfair commercial advantage - an unlevel playing field favouring Roquefort cheese traders would be created as local producers are not allowed to produce cheese using raw milk nor could other overseas producers of other raw milk cheeses import their products. • Quality - the perception that raw milk cheeses are superior in flavour and character is not supported. Modern cheese technology and ingredients produce more consistent quality cheese using pasteurised milk. ASCA believes that using raw milk in cheese making will be a thing of the past.
Food Technology Association of Victoria Inc.	David Gill	Supports amending the Code to permit the sale of Roquefort cheese.
Individual	John Carleton	This submission supports the sale of Roquefort cheese, noting the use and scientific evidence on this product over a long period of time. The scientific assessment should include an objective comparison between the risks from raw milk and pasteurised milk products, and include a thorough analysis of the manufacturing process and identification of critical control points.
Individual	Susan Rainbow	Supports the sale of Roquefort.

Department of Human Services Victoria	Victor Di Paola	This submission questions the premise that pasteurisation is required to produce a safe cheese – good herd management combined with good manufacturing practice, HACCP and the use of designated starter cultures may well produce safe cheese regardless of pasteurisation. Other issues raised include: - end point testing (the use of end product microbiological standards) is still valid and is currently the basis on which all high risk products are tested - outbreaks of illness associated with cheese have occurred in both cheeses made from raw milk and heat treated milk - there appears to be a different regulatory approach with UCFM products (where mandatory heat treatment is not required) compared to cheese.
Queensland – Public Health Services (with input from QLD Department of Primary Industries and Fisheries)	Kerry Bell	This submission neither supports or opposes the Application - the position of Qld is contingent on the scientific evaluation and the assessment of the documentation provided by the French Government.
Safe Food Queensland	Phil Pond	This submission reserves its position on the application, contingent on the scientific safety evaluation and the assessment of the documentation provided by the French Government.
New Zealand Food Safety Authority (NZFSA)	Carole Inkster	This submission notes that cheeses for sale in New Zealand must be made in accordance with the New Zealand Food Standards 2002 (which require heat treatment of milk) – An application to the NZFSA would need to be made to import Roquefort into NZ. It suggests that the permissions currently for raw milk Emmental, Gruyere & Sbrinz cheeses in Standard 2.5.4 should be placed in Standard 1.6.2 covering Australia only processing requirements.

Individual	Chandanie Weragoda	This submission raises a number of issues in relation to the primary objectives set out in the FSANZ Act. - Soft cheeses made form unpasteurised milk have been associated with many cases of food-borne illness and are a public risk. -There is a lack of consumer awareness of the risks associated with raw milk cheese and no current labelling requirements for such products. - There should be consistency between standards applied domestically and to imported products – what would be the AQIS requirements. - The submission notes the importance of HACCP based systems but questions whether such systems are outcome based but process based. - The Roquefort issue could be addressed within the Primary Production and Processing Standard, which would also provide a more cohesive approach and consider domestic production as well.
Dairy Food Safety Victoria	Joanne Patterson	Dairy Food Safety Victoria would prefer that the assessment of dairy foods made form unpasteurised milk be dealt with generally as part of the development of the Primary Production and Processing Standard for Dairy. The assessment of this application should consider: - The inconsistency in international legislation with respect to raw milk and raw milk cheeses (e.g. microbiological limits) - how will this be addressed in terms of equivalence and conformity with international standards. - The science used in determining equivalence must be robust and transparent. - Validation of the documentation provided as well as verifying the HACCP plan should be critical components of the safety evaluation. - There should be a discussion on the issues concerning labelling. The submission raises that HACCP-based food safety programs have been in operation in Australia since the early 1990's and that Australia does not rely only on pasteurisation to manage bacterial contamination as suggested in the Initial Assessment report.

Tasmanian Dairy Industry Authority (TDIA)	Don Sandman	The TDIA would prefer that the Dairy Primary Production and Processing Standard deal generally with (raw milk) dairy products rather than a case-by-case approach. An assessment of A499 should include: - an equivalence determination using science-based risk assessment that can demonstrate that a level of safety protection equivalent to existing (Australian) controls is achieved; - consideration of the difference between EU microbiological standards and Australian standards; - consideration of a mandatory warning statement.
Australia New Zealand Dairy Authorities' Standards Committee (ADASC)	Joanne Patterson (Chair)	Would prefer that the issue of the manufacture of dairy foods from methods not using pasteurisation/thermisation was progressed through the development of the national Primary Production and Processing Standard for Dairy. The assessment of this application should include: - a robust scientific risk assessment - verification of enforcement and compliance with appropriate standards - consideration of a warning statement in labelling requirements. ADASC questions how a permission for Roquefort cheese while restricting the sale of domestically produced raw milk blue-mould ripened cheeses could be justified.

Dairy Australia	Helen Dornom	Would prefer that a framework for assessing raw milk cheeses be established through the development of a Dairy Primary Production and Processing Standard before progressing this application. A solution for managing raw milk cheeses should be as a whole chain regulatory approach. Other matters raised include: - Australia does not rely on pasteurisation of milk to control specific hazards – the dairy industry has well implemented HACCP based food safety programs. The manufacture of Roquefort should meet the same food safety outcomes and have similar systems in place. - A permission for Roquefort would advantage imported cheese at the expense of the domestic industry - labelling provisions should be discussed as part of the draft assessment - validation and verification of the equivalent system should be demonstrated and specific requirements should be enforceable by AQIS.
Department of Agriculture, Fisheries and Forestry (DAFF) – Food Regulation and Safety	Tom Black	This submission raises the importance of a rigorous scientific evaluation of the safety of Roquefort cheese before any permission is given for its sale. Other matters raised include: - The progress of this assessment should not include any implication that Australia accepts geographical indicators – Roquefort has AOC status under European rules. - Domestic producers are not permitted to manufacture cheese using raw milk. Inconsistencies with certain imported products and domestic production need to be addressed within the development of the Primary Production and Processing Standard for Dairy. - there needs to be clarification on how the microbiological limits for Roquefort cheese will align with those in the Code. - Labelling requirements for raw milk products needs to be considered.
Fonterra	Joan Wright	This submission raises the importance of a rigorous scientific evaluation to assess the food safety risks of Roquefort cheese. It notes that the manufacture (based on the information supplied) involves slow acid production which can result in the outgrowth of contaminant microorganisms, and questions whether the properties of this cheeses would be inhibitory to the growth of pathogens during storage. Incidents of illness associated with raw milk cheeses are supplied.

ATTACHMENT 6

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 Cheese treatment
Emmental, Gruyere or Sbrinz Cheese	Pasteurisation Cheese treatment 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.