Primary Production and Processing Standard for Dairy Products

A guide to Standard 4.2.4 *Primary Production and Processing Standard for Dairy Products*

Part 3: Dairy Processing

Chapter 4 of the Australia New Zealand Food Standards Code (Australia only)

First edition, June 2009

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

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Introduction

What is the purpose of the guide?

This guide to Standard 4.2.4 *Primary Production and Processing Standard for Dairy Products* has been developed by Food Standards Australia New Zealand (FSANZ) as one of its functions under section 13(1)(c) of the *Australia New Zealand Food Authority Act 1991*. It is intended to help with the interpretation of Standard 4.2.4 in Chapter 4 of the *Australia New Zealand Food Standards Code* (the Code). A copy of Standard 4.2.4 is included in this guide at pages 6 to 11.

What is the scope of the guide?

This guide has been developed to help government agencies responsible for enforcing the requirements of Standard 4.2.4 to understand the general intent of individual clauses in the standard. It does this by providing an explanation of individual provisions and includes examples where appropriate. Enforcement officers seeking further clarification of definitions or requirements in the Code should approach the relevant agency in the state or territory.

The guide may also be useful to dairy businesses. It does not specify how dairy businesses must comply with the requirements of the standard but the explanations and examples provided may help them to comply.

What is the legal status of the guide?

The guidance provided in the guide is not legally binding - only the clauses in the standard are legally binding. Persons who are uncertain about the meaning of a clause in Standard 4.2.4 can refer to the explanation in the guide for clarification.

The guide includes examples that may be helpful in explaining the meaning of a clause. However, neither the explanations nor the examples in the guide are legal requirements for dairy businesses. The examples given in this guide are used to illustrate how the clause might apply

Dairy businesses seeking guidance on compliance with the standard should contact their local enforcement agency for advice.

How do I use the guide?

Standard 4.2.4 contains requirements for dairy primary production businesses (Division 2), dairy transport businesses (Division 3) and dairy processing businesses (Division 4). The guide to the standard has been developed in three parts - this is Part 3: Dairy Processing requirements.[1]

1 **The other parts are Part 1: Dairy Primary Production Requirements and Part 2: Dairy Collection and Transport Requirements**

This guide aims to provide an explanation of each clause of the standard that applies to dairy processing businesses (covering Divisions 1 and 4 of the standard). This interpretation, beginning with the definitions in Standard 4.2.4 begins on page 12. A copy of the complete standard is on pages 6 to 11.

The guide provides an explanation of each clause of the standard in the same order in which they appear in the standard. The legal requirements are provided in bold type followed by a description of the intended food safety outcome (or other outcome as appropriate) and an explanation of the requirement, as outlined below.

LEGAL REQUIREMENT

INTENDED OUTCOME

EXPLANATION OF REQUIREMENT

Terms in the standard are explained under the interpretation clauses and the clauses where they are used. An alphabetical listing of defined terms, including applicable definitions from Chapter 2 and Chapter 3, is in the Glossary.

Background

The Australia New Zealand Food Standards Code

FSANZ is a statutory authority that works in partnership with the Australian government, state and territory governments, and the New Zealand government to set food standards. Food standards are contained in the Code, which is divided into chapters:

- Chapter 1 of the Code contains general food standards that apply to all foods (for example labelling)
- Chapter 2 contains compositional standards for particular classes of foods (for example meat and meat products)
- Chapters 3 and 4 contain food safety requirements for the production and processing of food, and requirements for premises and vehicles used for food production. Chapters 3 and 4 do not apply in New Zealand.[2]

The food standards in the Code are incorporated into state, territory and (with exceptions) New Zealand legislation, and are legal requirements on food businesses. Because food standards are given legal effect by state, territory and New Zealand legislation, the Code must be read in conjunction with the relevant legislation.

The Code, and information about the Code, is available on the FSANZ website at <www.foodstandards.gov.au>. Information can also be obtained from the FSANZ Information Officer on (02) 6271 2241, or email <info@foodstandards.gov.au>. Information on the *Food Standard Australia New Zealand Act 1991* can be obtained from www.comlaw.gov.au.

Chapter 4 Primary Production and Processing Standards

In August 2002 the Australia and New Zealand Food Regulation Ministerial Council adopted a whole-of-chain approach to food safety in Australia. FSANZ was given responsibility for developing national food safety requirements for the primary production end of the supply chain—primary production and processing standards—for inclusion in the Code.

Chapter 4 is a new chapter in the Code and includes the standards for primary production and processing of food. FSANZ has developed primary production and processing standards for seafood and dairy products, and is working on standards for poultry meat and eggs.

Primary production and processing standards are developed with regard to the Australia and New Zealand Food Regulation Ministerial Council's *Overarching Policy Guideline on Primary Production and Processing Standards*.[3] FSANZ develops primary production and processing standards using scientific risk analysis and wide consultation with stakeholders. A standards development committee is established for each primary production and processing standard developed. The committee members are representatives from industry, consumer bodies, research organisations and governments.

2 **Information about dairy regulation in New Zealand is available on the New Zealand Food Safety Authority's website at <www.nzfsa.govt.nz>.**

3 **The *Overarching Policy Guideline on Primary Production and Processing Standards* is available on the Food Standards Australia New Zealand website at <www.foodstandards.gov.au> and the Department of Health and Ageing's website at <www.health.gov.au>.**

Standard 4.2.4 Primary Production and Processing Standard for Dairy Products

Standard 4.2.4 Primary Production and Processing Standard for Dairy Products was gazetted on 5 October 2006. There is a two-year implementation period for the standard, which means that dairy businesses were required to comply with the standard from 5 October 2008.

Application dates may vary between states and territories as they enact legislation to apply the standard to dairy businesses.

Standard 4.2.4 sets out a number of food safety requirements for dairy primary production businesses (covering on-farm milk production activities), dairy transport businesses (covering the collection and bulk transport of milk and dairy products) and dairy processing businesses (covering activities up to, but not including, retail). Distribution of dairy products and retail sale activities are covered by the requirements of Chapter 3 of the Code (Standard 3.2.2 and Standard 3.2.3).

Under Standard 4.2.4, dairy businesses are required to control the potential food safety hazards associated with their business by implementing a documented food safety program. Particular measures that should be covered by the food safety program are also specified.

The requirements for dairy primary production businesses, dairy transport businesses and dairy processing businesses are set out in separate divisions of the standard:

- Division 1 — Preliminary
- Division 2 — Dairy primary production requirements
- Division 3 — Dairy collection and transport
- Division 4 — Dairy processing.

This guide covers the requirements for dairy processing businesses (Division 4). Separate guides cover the requirements for Divisions 2 and 3.

Standard 4.2.4

Primary Production and Processing Standard for Dairy Products

Standard 4.2.4

Primary Production and Processing Standard for Dairy Products (Australia Only)

Commenced on 5 October 2008

Purpose and commentary

This Standard sets out a number of food safety requirements, including the implementation of documented food safety programs for dairy primary production, collection, transportation and processing. However, this Standard does not apply to retail sale activities. Chapter 3 of this Code covers retail sale activities.

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Clauses

Division 1 — Preliminary

1 Interpretation

(1) Unless the contrary intention appears, the definitions in Chapters 2 and 3 of this Code apply to this Standard.

(2) In this Standard –

Authority means the State, Territory or Commonwealth government agency or agencies having the legal authority to implement and enforce this Standard.

control measure means a measure that prevents, eliminates or reduces to an acceptable level, a food safety hazard.

dairy primary production means the production of milk or colostrum for further processing for human consumption and includes the keeping, grazing, feeding and milking of animals and the storage of milk on the premises at which the animals were milked.

dairy primary production business means a business, enterprise or activity that involves dairy primary production.

dairy processing includes the manufacture of dairy products.

dairy processing business means a business, enterprise or activity that involves dairy processing.

dairy products include –

(a) milk; and

(b) colostrum; and

(c) liquid milk products; and

(d) cream and thickened cream; and

(e) butter, butter concentrate, buttermilk, concentrated buttermilk, dairy blend, ghee, and anhydrous milk fat (butter oil);

(f) casein, caseinate, and cheese; and

(g) whey, whey cream and concentrated whey cream; and

(h) cultured milk and yoghurt; and

(i) ice-cream and ice-cream mix; and

(j) buttermilk powder, lactose powder, milk sugar, powdered milk, skim milk powder, whey powder, milk protein powder and other milk concentrates.

dairy transport business means a business, enterprise or activity involving the collection and transport of milk from the dairy primary production business to the processing business or the transport of bulk milk or dairy products between dairy processors.

inputs includes any feed, water and chemicals, including agricultural and veterinary chemicals, used in connection with the primary production of milk or colostrum.

2 Application

(1) Subclause 1(2) of Standard 1.1.1 does not apply to this Standard.

(2) This Standard does not apply in New Zealand.

(3) This Standard does not apply to retail sale activities.

Division 2 — Dairy primary production requirements

3 Controlling food safety hazards

A dairy primary production business must control its potential food safety hazards by implementing a documented food safety program.

4 Specific requirements

(1) For clause 3, the control measures must manage the hazards arising from –

(a) inputs; and

(b) the design, construction, maintenance and operation of premises and equipment; and

(c) milking animals; and

(d) persons involved in milking; and

(e) milking practices.

(2) For clause 3, the control measures must also –

(a) include support programs that ensure that premises and equipment are clean and sanitary and that pests are controlled; and

(b) ensure that milk is cooled and stored at a temperature that prevents or reduces the growth of microbiological hazards in the milk; and

(c) ensure that milk for human consumption is only sourced from healthy animals.

5 Tracing

As part of the documented food safety program in clause 3, a dairy primary production business must have a system that enables the tracing of –

(a) inputs; and

(b) animals to be milked; and

(c) the milk produced.

6 Skills and knowledge

A dairy primary production business must ensure that persons undertaking primary production activities have skills and knowledge of food safety and hygiene matters commensurate with their work activities.

Division 3 — Dairy collection and transportation

7 Controlling food safety hazards

A dairy transport business must control its potential food safety hazards by implementing a documented food safety program.

8 Specific requirements

For clause 7, the control measures must manage hazards arising from –

(a) transport vehicles, equipment and containers used in the collection and transport of the milk or dairy product; and

(b) persons engaged in the dairy transport business.

and must include a support program that ensures that the food contact surfaces of transport vehicles, and equipment and containers used in collecting and transporting of the dairy products are clean and sanitary.

9 Product tracing

As part of the documented food safety program in clause 7, a dairy transport business must have a system to identify the immediate supplier and immediate recipient of the dairy product.

10 Time and temperature controls

A dairy transport business must transport dairy products using time and temperature controls that prevent or reduce the growth of microbiological hazards in the product.

11 Skills and knowledge

A dairy transport business must ensure that persons undertaking milk or dairy product collection and transport activities have skills and knowledge of food safety and hygiene matters commensurate with their work activities.

Division 4 — Dairy processing

12 Application

To avoid doubt, Standards 3.2.2 and 3.2.3 apply to the processing of dairy products.

13 Controlling food safety hazards

A dairy processing business must control its potential food safety hazards by implementing a documented food safety program.

14 Product tracing

As part of the documented food safety program in clause 13, a dairy processing business must have a system to identify the immediate supplier of dairy products and ingredients and the immediate recipient of the dairy products.

15 Processing of milk and dairy products

(1) Milk must be pasteurised by –

(a) heating to a temperature of no less than 72°C and retaining at such temperature for no less than 15 seconds; or

b) heating, using any other time and temperature combination of equivalent or greater lethal effect on any pathogenic micro-organisms in the milk; or

(c) using any other process that provides an equivalent or greater lethal effect on any pathogenic micro-organisms;

unless an applicable law of a State or Territory otherwise expressly provides.

Editorial note:

For paragraph 15(1)(c), any other process used would need to be validated by the business and verified by the Authority.

The provision concerning an applicable law of a State or Territory is a temporary one and will be reviewed by FSANZ under another proposal.

(2) Milk processed under paragraph 15(1)(a) must be cooled immediately in a way that ensures that the growth of microbiological hazards in the milk is prevented or reduced.

(3) Dairy products, other than cheese and cheese products, must be processed using –

(a) a heat treatment that uses a combination of time and temperature of equal or greater lethal effect on any pathogenic micro-organisms in the milk product achieved by paragraphs 15(1)(a) or 15(1)(b); or

(b) using any other process that provides an equivalent or greater lethal effect on any pathogenic micro-organisms.

Editorial note:

For paragraph 14(3)(b), any other process used would need to be validated by the business and verified by the Authority.

(4) Dairy products processed under paragraph 15(3)(a) must be cooled immediately in a way that ensures that the growth of microbiological hazards in the product is prevented or reduced.

(5) To avoid doubt, subclause 15(3) does not apply to the processing of dairy products that have been made using milk already processed in accordance with subclause 15(1).

Editorial note:

Dairy products may have a greater fat and/or solids content compared to milk and therefore require a greater time and temperature treatment to achieve an equivalent level of bacterial reduction. Information on equivalent heat treatments to pasteurisation for these products is provided in the "Interpretive Guide" to this Standard.

16 Processing of dairy products to make cheese and cheese products

Milk or dairy products used to make cheese or cheese products must be processed –

(a) in accordance with subclause 15(1); or

(b) by being held at a temperature of no less than 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 processing; or

(c) 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 processing; or

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

Editorial note:

For dairy product distribution, refer to the requirements in Standards 3.2.2 and 3.2.3 on storage and transportation.

Interpretation of Standard 4.2.4 Primary Production and Processing Standard for Dairy Products, Divisions 1 and 3

Division 1 — Preliminary

1 Interpretation

This clause defines the terms used in Standard 4.2.4. In the absence of a definition in the *Australia New Zealand Food Standards Code*, the definition in *The Macquarie dictionary* (latest edition) should be used.

1(1) Unless the contrary intention appears, the definitions in Chapters 2 and 3 of this Code apply to this Standard.

Terms used in Standard 4.2.4 are generally defined within the Code. Definitions for milk and other dairy products are contained in Part 2.5 of Chapter 2. Terms used in relation to food safety requirements are contained in Chapter 3. Terms developed for use specifically in Standard 4.2.4 are defined in the standard.

Definitions in Chapter 2

Part 2.5 of the Code contains compositional standards for dairy products including a number of definitions. Of relevance to Standard 4.2.4 is the definition for milk in Standard 2.5.1.

milk means the mammary secretion of milking animals, obtained from one or more milkings for consumption as liquid milk or for further processing but excludes colostrum.

Milk is the primary commodity to which Standard 4.2.4 applies. This definition establishes that the production, transport and processing of milk for human consumption from all milking animals (for example cow, goat, sheep, buffalo, camel) is covered by the standard.

Milk excludes colostrum and so Standard 4.2.4 refers to colostrum as a separate commodity. No definition for colostrum is provided in the Code.

Definitions in Chapter 3

Definitions in Chapter 3 of the Code that are applicable to Standard 4.2.4 are presented below, along with a reference to where the terms are used in the standard and their intent.

clean means clean to touch and free of extraneous visible matter and objectionable odour.

The definition clarifies that ‘clean’ is not about the microbiological status of the surface, but about what can be assessed by sight, touch and smell. The term ‘clean’ is used in paragraph 4(2)(a) and clause 8.

equipment means a machine, instrument, apparatus, utensil or appliance, other than a single-use item, used or intended to be used in or in connection with food handling and includes any equipment used or intended to be used to clean food premises or equipment.

The intention is to ensure that all equipment that is used in relation to milking, storage and transport activities and in cleaning procedures is covered by the requirements. Equipment is referenced in paragraph 4(1)(b) and subclause 8(a). Single use items are not included as they are regulated under clause 23 of Standard 3.2.2 Food Safety Practices and General Requirements.

food handling operation means any activity involving the handling of food.
Handling of food includes the making, manufacturing, producing, collecting, extracting, processing, storing, transporting, delivering, preparing, treating, preserving, packing, cooking, thawing, serving or displaying of food.

The intention is that all activities involved in dairy primary production, dairy transport and dairy processing operations are covered by the standard. The definition of 'handling' is not restricted to the activities listed. This term is used in clause 5 of Standard 3.2.1, Content of food safety programs.

food safety program means a food safety program that satisfies the requirements of clause 5 of Standard 3.2.1.

Food safety programs are a means for food businesses to identify and control potential food safety hazards. The elements of a food safety program are specified in clause 5 of Standard 3.2.1. Dairy primary production businesses, dairy transport businesses and dairy processing businesses are all required to control their food safety hazards by implementing a documented food safety program. How this requirement applies to dairy processing businesses is explained under clause 13.

hazard means a biological, chemical or physical agent in, or condition of, food that has the potential to cause an adverse health effect in humans.

The intention is that biological, chemical and physical hazards are managed in the food safety program. Clauses 3, 7 and 13 refer to the control of potential food safety hazards. Subclause 4(1) and clause 8 refer to hazards arising at specific steps or processes.

monitoring includes checking, observing or supervising in order to maintain control.

Monitoring is conducted to determine that control is being maintained over identified hazards. The aim of monitoring is to assess whether the control measure(s) chosen to manage a hazard is occurring in practice. This term is used in clause 5 of Standard 3.2.1, Content of food safety programs.

pests includes birds, rodents, insects and arachnids.

The intention is to ensure that the requirements cover all animals that could contaminate food either directly or indirectly. It is not restricted to the animals listed. The term 'pest' is used in paragraph 4(2)(a).

sanitise means to apply heat or chemicals, heat and chemicals, or other processes, to a surface so that the number of micro-organisms on the surface is reduced to a level that –

(a) does not compromise the safety of food with which it may come into contact; and

(b) does not permit the transmission of infectious disease.

Sanitary is the condition of premises and equipment after being sanitised. The term 'sanitary' is used in Standard 4.2.4 in paragraph 4(2)(a) and clause 8.

1(2) In this Standard –

Subclause 1(2) defines a number of terms specifically for use in Standard 4.2.4. These are presented below, along with a reference to where the terms are used in the standard and their intent.

Authority means the State, Territory or Commonwealth government agency or agencies having the legal authority to implement and enforce this Standard.

Each state and territory Food Act (or other Act) specifies the agency responsible for the enforcement of the Act and any regulations or standards referred to in it. The agencies having the legal authority to enforce Standard 4.2.4 will be the same agencies that enforced previous regulations relating to dairy food production and sale in the respective state or territory:

- New South Wales Food Authority
- Safe Food Production Queensland
- Dairy Authority of South Australia
- Dairy Food Safety Victoria
- Tasmanian Dairy Industry Authority
- Department of Health, Western Australia
- Northern Territory Health and Community Services
- ACT Department of Health.

control measure means a measure that prevents, eliminates or reduces to an acceptable level, a food safety hazard.

This clarifies that 'managing the hazards' involves implementing measures that prevent, eliminate or reduce the hazards that may arise. Control measures are required under subclauses 4(1) and 4(2) and clause 8 of Division 2.

dairy primary production means the production of milk or colostrum for further processing for human consumption and includes the keeping, grazing, feeding and milking of animals and the storage of milk or colostrum on the premises at which the animals were milked.

This clarifies the nature of a dairy primary production business and the activities covered by the operation of that business. The intent is that all activities involved in dairy primary production operations are covered by the standard. This covers farm management practices in relation to animal husbandry (keeping), pasture management (grazing) and stock feed supply (feeding), as well as all activities undertaken during the milk or colostrum collection and storage operations.

'Further processing' clarifies that these requirements have been developed specifically for milk that is to undergo subsequent processing. Jurisdictions that permit the production and sale of raw goat milk may apply specific regulatory measures (for example pathogen testing and compliance with requirements) to raw milk producers under their own legislation.

dairy primary production business means a business, enterprise or activity that involves dairy primary production.

Dairy primary production businesses include those that produce milk or colostrum for further processing. The production of milk and the production of colostrum are considered as distinct primary production operations. A business involved in either of these is covered by the requirements of the standard.

Division 2 of the standard specifies requirements for dairy primary production businesses. The definition of 'dairy primary production business' establishes the scope of the businesses that must comply with these requirements.

dairy processing includes the manufacture of dairy products.

This clarifies the nature of a dairy processing business. The definition of dairy processing establishes the scope in terms of the dairy products manufactured by a business rather than the milk processing activities undertaken.

dairy processing business means a business, enterprise or activity that involves dairy processing.

Division 4 of the standard specifies requirements for dairy processing businesses. The definition of 'dairy processing business' establishes the scope of the businesses that must comply with these requirements. Dairy processing businesses are defined in terms of the dairy products they manufacture.

dairy products include –

(a) milk; and

(b) colostrum; and

(c) liquid milk products; and

(d) cream and thickened cream; and

(e) butter, butter concentrate, buttermilk, concentrated buttermilk, dairy blend, ghee, and anhydrous milk fat (butter oil);

(f) casein, caseinate, and cheese; and

(g) whey, whey cream and concentrated whey cream; and

(h) cultured milk and yoghurt; and

(i) ice-cream and ice-cream mix; and

(j) buttermilk powder, lactose powder, milk sugar, powdered milk, skim milk powder, whey powder, milk protein powder and other milk concentrates.

The requirements of Division 4 of the standard apply to those businesses that are involved in the manufacture of the dairy products listed. The list is not exclusive and the intent is that the manufacture of all products derived from milk, including fat and protein derivatives, are covered by the requirements of the standard. This includes products that are normally considered dairy foods but are not specifically listed, such as custards and other dairy desserts (for example products of milk or cream) and dairy dips (for example products of cultured milk and yoghurt or cheese). Dairy products do not include foods that have milk or milk products as an ingredient as compared to being derived from milk.
For example, cheesecake and custard tarts are not included.

Colostrum has been listed separately as the definition of milk excludes colostrum and businesses that produce colostrum for sale are covered by this Standard.

dairy transport business means a business, enterprise or activity involving the collection and transport of milk from the dairy primary production business to the processing business or the transport of bulk milk or dairy products between dairy processors.

Division 3 of the standard specifies requirements for dairy processing businesses. The definition of 'dairy transport business' establishes the scope of the businesses that must comply with these requirements.

Dairy transport businesses include:

- businesses that collect and haul bulk milk from dairy farms to processing facilities or depots
- businesses that transport milk or dairy products such as concentrates or milk powders in bulk between processing facilities

The term 'bulk' clarifies that the product is not packaged or intended for direct sale (retail or wholesale) and is intended for further processing.

inputs includes any feed, water and chemicals, including agricultural and veterinary chemicals, used in connection with the primary production of milk or colostrum.

Inputs are referred to in paragraph 4(1)(a) and discussed under clause 4 Specific requirements.

2 Application

The application clause explains the starting date of the standard and specifies the businesses and business activities that are not required to comply.

2(1) Subclause 1(2) of Standard 1.1.1 does not apply to this Standard.

Subclause 2(1) clarifies that the 12-month transition period under subclause 1(2) of Standard 1.1.1 of the Code does not apply to this standard. Instead, Standard 4.2.4 commences two years from gazettal of the standard. Businesses must comply with Standard 4.2.4 from that date (5 October 2008).

2(2) This Standard does not apply in New Zealand.

Subclause 2(2) clarifies that the standard does not apply to food businesses in New Zealand. While there is an agreement between Australia and New Zealand to establish a joint food standard-setting system for the two countries, the agreement specifically excludes food safety provisions (Chapter 3 and Chapter 4 standards). New Zealand maintains and develops its own food safety regulatory measures. Primary production and processing requirements for the dairy industry in New Zealand are administered by the New Zealand Food Safety Authority. These requirements include the:

- Food Act 1981
- New Zealand (Milk and Milk Products Processing) Food Standards 2002
- Animal Products Act 1999
- Animal Products (Dairy) Regulations 2005
- Animal Products (Dairy Risk Management Programme Specifications) Notice 2005
- Animal Products (Dairy Processing Specifications) Notice 2006
- DPC1 Approved Criteria for General Dairy Processing 2006
- DPC2 Approved Criteria for Farm Dairies 2006
- DPC3 Approved Criteria for the Manufacturing of Dairy Material and Products 2006
- DPC4 Approved Criteria for Storage and Transportation of Dairy Material and Products 2006.

2(3) This Standard does not apply to retail sale activities.

Standard 4.2.4 applies to dairy primary production businesses, dairy transport businesses and dairy processing businesses as defined under clause 1. Subclause 2(3) clarifies that the requirements of the standard do not apply to food businesses undertaking retail sale activities in relation to dairy products.

'Retail sale' refers to direct sale to the public and does not include sale to wholesalers, caterers or to businesses that on-sell. Businesses that manufacture dairy products such as ice-cream, gelato, cheese and dairy desserts, only for retail sale, are not required to comply with Standard 4.2.4. Such businesses may include restaurants, ice-cream shops, cafes etc. However, if these businesses also sell these dairy products to wholesalers, caterers or to other businesses that on-sell, they are required to comply with Standard 4.2.4. Therefore, as soon as a business manufactures dairy products and sells these products to a wholesaler, caterer or to any other businesses that on-sell, they must comply with Standard 4.2.4 irrespective of whether they also sell these products directly to the public.

Examples of activities which are considered to be either retail sale or non-retail sale are provided in Table 1.

Table 1: Examples of retail sale and non-retail sale activities

Business activity	Comment
A business buys in yoghurt (plain) in bulk and flavours it by combining it with different fruit mixes, nuts etc. The yoghurt is displayed in 5 L trays in a refrigerated display cabinet and sold in various sized plastic tubs for immediate consumption by the purchaser.	This is a retail sale activity. The business is not required to comply with Standard 4.2.4.
A business buys in yoghurt (plain) in bulk and flavours it by combining with different fruit mixes. The business packages and distributes this product, under its own brand name, for sale at other premises (e.g. grocery stores, market stores).	This is a non-retail sale activity. The food business is manufacturing flavoured yoghurts to on-sell to other businesses that sell direct to the public. The food business would need to comply with the requirements in the standard for dairy processing businesses.
A gelato business prepares gelato using milk, cream etc. purchased from a dairy distributor. It processes a number of varieties for direct sale to the public both in take home tubs (250ml and 500ml) and for immediate consumption in cones or plastic containers. The business also sells the gelato to a wholesaler.	This business manufactures dairy products for retail and non-retail sale and must therefore comply with Standard 4.2.4.
A restaurant makes its own ice-cream for sale to customers who come to eat at the restaurant.	This is a retail sale activity. The business is not required to comply with Standard 4.2.4.

Division 4 — Dairy processing

12 Application

To avoid doubt, Standards 3.2.2 and 3.2.3 apply to the processing of dairy products.

This application clause confirms the food safety standards that apply to dairy processing businesses

Dairy processing businesses are already required to comply with the requirements of Standard 3.2.2 *Food Safety Practices and General Requirements* and Standard 3.2.3 *Food Premises and Equipment*. Clause 12 has been included to clarify that Standard 4.2.4 is an additional requirement on these businesses and, 'to avoid doubt', they must also comply with Standard 3.2.2 and Standard 3.2.3.[4]

13 Controlling food safety hazards

A dairy processing business must control its potential food safety hazards by implementing a documented food safety program.

The safety of dairy products is best ensured through the systematic identification and control of hazards throughout the production chain.

Food safety program

Standard 3.2.1 *Food Safety Programs*[5] defines a food safety program to mean one that satisfies clause 5 of that standard. Clause 5 states that a food safety program must:

(a) systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business

(b) identify where, in a food handling operation, each hazard identified under paragraph (a) can be controlled, and the means of control

c) provide for the systematic monitoring of those controls

d) provide for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control

e) provide for the regular review of the program by the food business to ensure its adequacy

4 Guidance on the requirements of Standards 3.2.2 and 3.2.3 is provided in Safe Food Australia – A Guide to the Food Safety Standards, available on the FSANZ website at <www.foodstandards.gov.au>

5 FSANZ has developed A guide to Standard 3.2.1 Food Safety Programs, which provides an explanation of the intent of all clauses contained in Standard 3.2.1. This guide is available on the FSANZ website at <www.foodstandards.gov.au>

f) provide for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program.

Clause 5 of Standard 3.2.1 provides for the following elements to be included in a food safety program:

- food handling operations of the business
- potential food safety hazards
- control measures
- monitoring activities
- corrective actions
- review of the program
- record keeping.

These elements are discussed separately in the sections below.

The food safety program may be developed by the dairy processing business or by an external consultant and may use templates or guideline documents developed by the enforcement agency.

Dairy processing business may already have developed Hazard Analysis and Critical Control Point (HACCP) systems. HACCP was developed in the 1960s in the United States by the Pillsbury Company for the National Aeronautics and Space Administration, to ensure the safety of the food provided for the astronauts. The international reference to HACCP is specified with the Codex Alimentarius Commission's (Codex)[6] *Basic Texts on food hygiene, third edition*[7]. The elements of a Food Safety Program specified in clause 5 of Standard 3.2.1 are based on the principles of HACCP set out within the *Codex Basic texts on food hygiene*. Therefore, dairy processing businesses that already have HACCP systems in place should meet the requirements of clause 5 of Standard 3.2.1.

Food handling operations

Clause 5(a) of Standard 3.2.1 requires that the food safety program must **systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the business**. A systematic approach to identifying potential hazards can be demonstrated through the use of a flow diagram that clearly identifies the key steps and activities undertaken, in order of operation.

A dairy processing business may manufacture a range of dairy products, involving different processing steps. As potential hazards need to be identified in all food handling operations of the business, flow diagrams should be constructed for each product/manufacturing process the business undertakes. A generic flow diagram outlining the key steps involved in packaged milk manufacture is illustrated in Figure 1.

6 **Codex was created in 1963 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop international food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme.**

7 **For a copy of this document, see www.codexalimentarius.net under 'Official standards'-'Special publications'.**

At each step involved in the manufacture of a product there are inputs and associated activities that need to be considered to identify potential hazards that may be 'reasonably expected to occur'. At the pasteurisation step, for example, in order to eliminate pathogens in the raw milk and prevent the milk being recontaminated:

- the equipment design and operation need to be effective
- effective cleaning and sanitising need to have occurred
- potable water must be used
- personnel should have the skills and knowledge to enable them to competently operate and monitor the equipment.

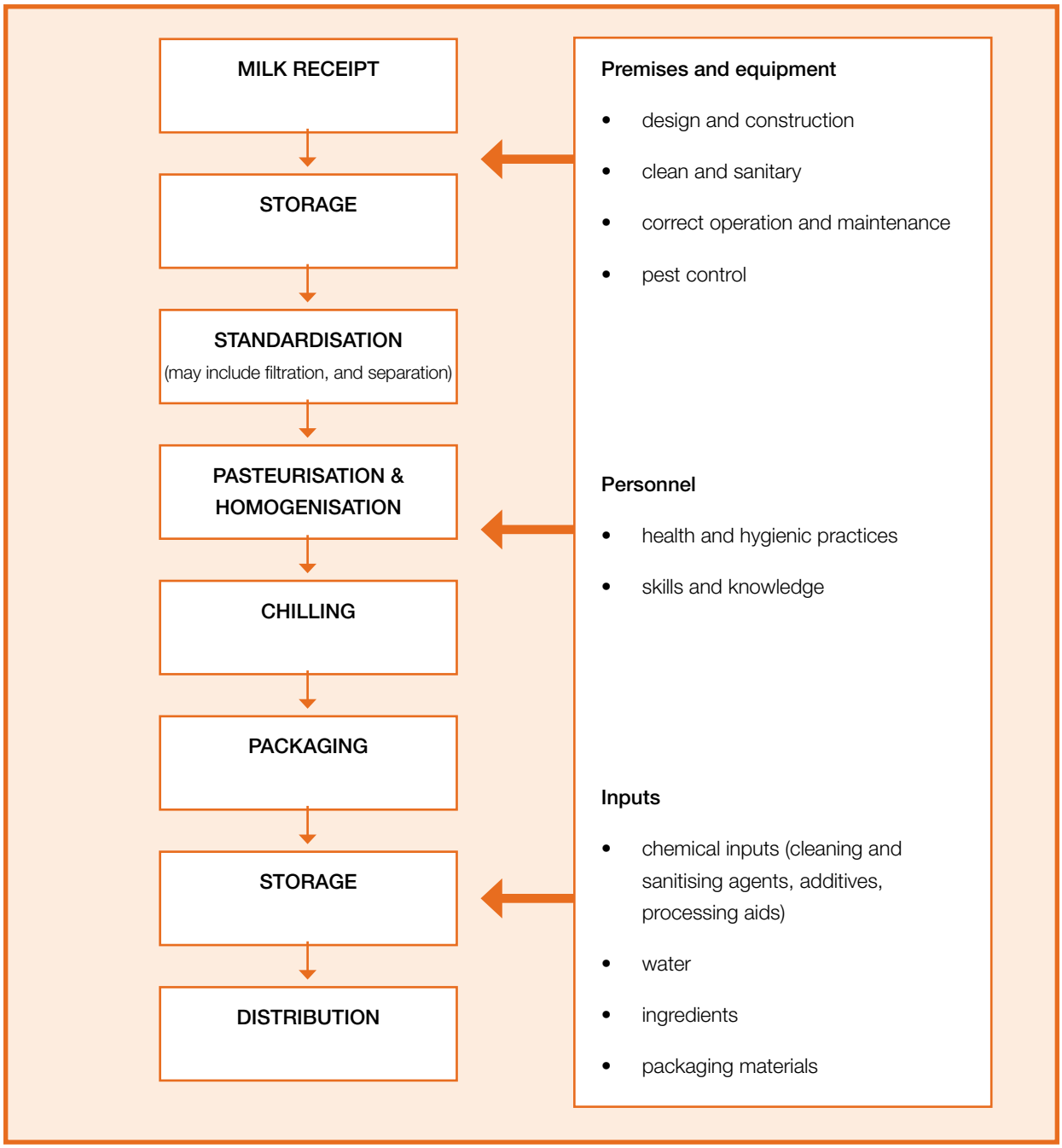

Figure 1: Key steps involved in packaged milk processing

Food safety hazard

A 'hazard' is defined in Standard 3.1.1 as 'a biological, chemical or physical agent in, or condition of, food that has the potential to cause an adverse health effect in humans'. Examples of these hazards are listed below.

Microbiological

- Food poisoning bacteria such as *Salmonella* spp., *Escherichia coli, Listeria monocytogenes, Staphylococcus aureus, Cronobacter sakazakii, Bacillus cereus*
- Foodborne viruses such as hepatitis A and noroviruses
- Foodborne parasites such as *Cryptosporidium parvum* and *Giardia lamblia*
- Toxin-producing moulds such as *Aspergillus flavus*, which produces aflatoxin.

Chemical

- Cleaning and sanitising agents – chemical residues remaining on food contact surfaces, equipment and/or containers may contaminate milk.
- Agricultural and veterinary chemicals - agricultural and veterinary chemical residues must be within the limits specified within Standard 1.4.2 Maximum Residue Limits, of the Food Standards Code. If a limit for a residue is not listed, there must be no detectable residue of that agricultural or veterinary chemical in that food, in this instance milk.
- Contaminants – contaminants must be within the maximum levels specified within Standard 1.4.1 *Contaminants and Natural Toxicants*, of the *Food Standards Code*. If a maximum level is not specified for a contaminant in a food, the level of the contaminant should be kept as low as reasonably achievable.

Physical

- Foreign matter such as glass, metal, plastic, insects, mites, adhesive dressings, packaging materials, rat droppings.

It is only necessary for potential hazards to be identified if they are 'reasonably expected to occur', that is, that the hazard is foreseeable, typical or likely to occur in association with dairy manufacturing activities.

Control measures

Clause 5(b) of Standard 3.2.1 requires that the food safety program must **identify where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control**. Hazards can be controlled by support programs (discussed below) or by a particular measure undertaken at a specific step in the production chain. The controls included in the food safety program (alone or collectively) must effectively prevent, eliminate or reduce the hazard to a safe and acceptable level. For chemical hazards, for example, an acceptable level may mean that there are no residues arising from the use of cleaning and sanitising chemicals that can result in the contamination of milk or dairy products. An acceptable level for microbiological hazards may mean the absence of specific pathogens or that coliform or total plate counts are within acceptable limits.

Clause 15 of Standard 4.2.4 specifically requires that the processing of milk and dairy products includes pasteurisation or an equivalent process to eliminate any pathogenic micro-organisms that may have been present in the incoming milk. This control measure is also specified under clause 16 for the processing of cheese and cheese products in addition to other control measures (e.g. pH, organic acid content, storage time and temperatures, water activity) that collectively provide an acceptable level of safety. These processing requirements for dairy products are covered in more detail under Clauses 15 and 16.

Controlling hazards through support programs

Hazards that are common across a number of steps within a business's operations are normally controlled through the use of support programs. For example, a cleaning and sanitation program may be applied across a number of steps to minimise contamination by microbiological hazards from premises and equipment. Instead of repeating the controls for each of these steps, the controls can be set out in a cleaning and sanitising program. Support programs include:

- cleaning and sanitising program (addresses microbiological, physical and chemical hazards arising from premises and equipment)
- maintenance program (addresses microbiological, physical and chemical hazards arising from operational failures to premises and equipment)
- pest control program (addresses microbiological and physical hazards arising from pests)
- staff health and hygiene program (addresses microbiological and physical hazards that arise from personnel involved in processing operations)
- calibration of equipment (ensures equipment being used to measure parameters critical to food safety are operating effectively).

The above list of support programs is not exhaustive and businesses may have other support programs such as 'waste disposal'. Businesses may also have programs that are related to taking corrective actions such as 'rework and disposal of product' and 'hold and release systems' and verification such as 'testing' programs.

To ensure support programs are effective in controlling the hazards identified, they must be monitored and corrective action must be taken if the support program is not being followed. The monitoring and corrective actions for each support program can be described within the support program itself.

Cleaning and sanitising program

A cleaning and sanitising program is a system that the business has in place to ensure that premises and equipment are effectively cleaned and sanitised at the appropriate times and using the appropriate chemicals and cleaning equipment and at appropriate dosage levels.

The cleaning and sanitising program must be documented within the food safety program and should include the following information:

- the cleaning and sanitising procedures for the premises and equipment
- frequency of cleaning
- personnel responsible for each task
- cleaning equipment, chemicals (including concentrations, temperature and flow rates) and method to be used
- records to indicate that cleaning was carried out (for example daily check list)
- corrective actions to be taken and records of these actions when they occur.

Maintenance program

A maintenance program is a system the business has in place to ensure that there is a planned and documented approach to the ongoing maintenance of premises and equipment. This preventative approach reduces the likelihood of equipment failure during manufacturing operations and also minimises contamination of product from faulty or deteriorating structures or equipment.

The maintenance program should be documented within the food safety program and should include the following information:

- the maintenance procedures for premises and equipment
- records to indicate that maintenance procedures have been followed
- corrective actions to be taken if maintenance procedures have not been followed

Outside of the scheduled maintenance program, maintenance issues may arise at any time and need to be dealt with. A record of any such maintenance should be kept, identifying the following information:

- date maintenance issue was identified
- description of maintenance issue
- date maintenance issue was or will be rectified.

Pest control program

A pest control program is a system that the business has in place to ensure that storage areas, manufacturing areas, equipment etc. are kept free from pests[8] as much as practicable. This should cover both preventative measures (e.g. removing potential harbourage sites) and eradication measures.(e.g. physical or chemical removal). It is important that any pest control measures themselves do not pose a risk of contamination to dairy products.

The pest control program should be documented within the food safety program and include:

- the procedures describing the pest control measures to be put in place including any chemicals used
- monitoring activities to be undertaken (for example inspecting for pest activity)
- the frequency of monitoring
- records to show that pest control activities have been carried out (for example inspection reports)
- corrective actions to be taken and records of these actions when they occur.

Health and hygiene program

Food handlers can be a direct source of contamination if good hygienic practices are not followed or if they are suffering from a foodborne illness and are engaged in food handling activities where there is a reasonable likelihood of contamination. Division 4 of Standard 3.2.2 *Food Safety Practices and General Requirements* specifies the health and hygiene requirements on food handlers and food businesses to ensure the safety and suitability of food.[9] The measures a dairy processing business has in place in relation to health and personal hygiene practices must be documented in the food safety program under a health and hygiene program or policy.

8 **Pests include birds, rodents, insects, arachnids or any other animal that could contaminate milk or dairy products directly or indirectly. Pests can carry pathogenic organisms that can contaminate the dairy product or equipment and may also cause physical contamination with hair, urine, faeces or their body, in whole or part.**

9 **Further information on these requirements is provided in Safe Food Australia – A guide to the food safety standards (January 2001), available on the FSANZ website at www.foodstandards.gov.au.**

Personal hygiene practices are measures that food handlers take to avoid contaminating milk or dairy products or any equipment likely to be in contact with milk or dairy products. Contamination could occur from foreign objects, microorganisms or chemicals that are transferred through direct contact with milk or dairy products or as a result of contaminating surfaces that come into contact with the product.

The personal hygiene practices that food handlers are expected to follow must be documented in the food safety program. This could include, for example:

- a hand washing policy (for example, how and when hands are to be washed and dried)
- rules regarding clothing , hair and jewellery
- where on the premises eating/smoking is or is not permitted
- avoiding unnecessary contact with the product
- requirements for covering cuts and wounds.

Personnel with symptoms of foodborne illness, or know that they are suffering from or are carriers of a foodborne disease, must not be involved in activities where there is a reasonable likelihood they could contaminate food. Symptoms of foodborne illness include diarrhoea, vomiting, sore throat with fever, fever or jaundice. Foodborne diseases that can be transmitted via food contaminated by infected handlers include gastroenteritis, hepatitis A, salmonellosis and campylobacter enteritis.

The procedures to be followed when food handlers involved in food handling activities have symptoms of or are suffering from a foodborne illness should be documented in the food safety program. This could cover, for example:

- what to do about personnel working if they report that they are unwell
- which illnesses or conditions mean a person is unable to undertake particular activities.

Calibration of equipment

To ensure that equipment used to measure parameters critical to food safety (e.g. temperature, flow rate, duration etc.) is accurate, it needs to be routinely calibrated. The food business should identify all measuring equipment critical to food safety, how this equipment is calibrated, how frequently calibration is carried out and the specifications used. Records kept for calibrated equipment should detail:

- tests conducted on the equipment
- date of calibration
- equipment calibrated
- who performed the calibration
- results and accuracy of calibration.

Controlling hazards at a production step

Hazards specific to a production step are normally controlled at that step. For example, the hazard of microbiological pathogens, in raw milk, is generally controlled by heat treatment using specified time and temperatures (required under clause 15) at a specified step in production. Other controls may include specified limits of moisture level, acidity (pH), water activity or processes such as sterilisation of packaging. The food safety program should clearly identify the measure(s) applied to control the identified hazards at each step of production, including the specific parameters that should be met.

Validation of controls

Validation is the action taken by the business to confirm that the controls in place are effective in controlling the hazards (that is, they prevent, eliminate or reduce a food safety hazard to an acceptable level).

Some controls for food safety hazards may be specified in legislation (for example pasteurisation temperatures and times). Alternatively, control measures may be provided within industry guidelines or standards (for example retort time and temperatures for canned products). Such controls are recognised by the relevant state or territory enforcement agency and do not need to be validated by the business. However, where a business puts in place its own procedures or processes, these must be validated for their effectiveness in preventing or eliminating a particular hazard.

Once control measures have been validated to confirm that they are effective in controlling the hazards, they may need to be re-validated if there are any changes to the operations that could affect the effectiveness of that control. For example, the introduction of new or different types of equipment, new product formulations or processes. Where re-validation is needed, it must confirm that the hazard is still being controlled by the changed process.

Monitoring

Clause 5(c) of Standard 3.2.1 requires that the food safety program must **provide for the systematic monitoring of those controls**. Monitoring is defined in Standard 3.2.1 as including 'checking, observing or supervising in order to maintain control'. The aim of monitoring is to assess whether the control chosen to manage a hazard is occurring in practice.

The food safety program must indicate how each control measure will be monitored. This includes support programs. Examples of monitoring are:

- measuring temperatures, pH, water activity etc.
- checking time/temperature charts, logs or readouts
- inspecting storage areas for pest activity
- observing that cleaning procedures are being followed.

For each monitoring action, the food safety program must indicate:

- what monitoring is to be done
- who will do the monitoring
- when the monitoring is to be done (for example every 2hours, every batch, daily, weekly, etc.).

The recording of monitoring activities is covered separately on page 27 under 'Record keeping'.

Corrective action

Clause 5(d) of Standard 3.2.1 requires that the food safety program must **provide for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control**. If monitoring finds that the control in place to manage a hazard is either not working or is not being followed, corrective action must be taken. A corrective action generally consists of two stages.

First, immediate action needs to be taken for any product that may now be unsafe or unsuitable because the hazard is not under control. For example, if monitoring (through checking time/temperature read out from the pasteuriser) shows that the critical limits have not been met, the business will need to follow the corrective action specified in the food safety program. Such corrective actions may include disposal or reprocessing of the product.

Second, there needs to be an investigation into the probable cause of the 'loss of control' of the hazard so that steps can be taken to make sure this incident does not happen again. For example, an immediate investigation into why the pasteuriser was not performing to specifications and adjusting the process (including any maintenance required) to ensure it is back in control. Changes may be required to the food safety program arising from the investigation.

All corrective actions should be documented in the food safety program.

Review of the program

Clause 5(e) of Standard 3.2.1 requires that the food safety program must **provide for the regular review of the program by the food business to ensure its adequacy**. A review ensures that the food safety program is meeting its objective of controlling all potential food safety hazards that are reasonably likely to occur at each step of production.

A review is necessary because activities of food businesses are not static; they change over time (for example, when new equipment is purchased). When changes take place that affect the food safety program, the food business must review the plan immediately, regardless of when the next review is scheduled.

There are two parts to a review: **validation** and **verification.**

Validation

Validation is the action taken by the business to confirm that the controls in place are effective in controlling the hazards (that is, they prevent, eliminate or reduce a food safety hazard to an acceptable level).

A food safety program needs to be validated before it is implemented to confirm whether the control measures chosen will be effective. Therefore, when control measures are being determined during the development of the food safety program, these control measures need to be validated. This is discussed under 'Validation on control' on the previous page.

However, ongoing validation of the food safety program by the business must also be conducted as part of its review. This needs to include the following checks:

- all potential hazards that are reasonably expected to occur have been identified
- the controls in place are effective. While controls may have been validated when the program was first developed, any changes to these controls or the introduction of new controls need to be validated as part of the overall program.

Verification

Verification is the action taken by the business to confirm that the practices and procedures in the food safety program are happening.

Verification of a food safety program needs to occur after it has been implemented to check that it is operating as it should. The business must check that control measures (including support programs), monitoring activities, corrective actions and record-keeping are actually happening in practice. Examples of verification actions include:

- checking of food processing operations to ensure that all activities of the business are covered by the food safety program
- scheduled sampling and analysis of product
- examination of the records and documents kept to ensure they are being completed correctly, including the recording of any non-conformances and subsequent corrective action taken

- observing whether personnel are complying with measures in the food safety program (for example, in relation to hygiene practices such as hand-washing, use of foot baths, protective clothing etc.)

The food safety program must include information about the review of the program, such as:

- the person or persons in the business responsible for the review

Those involved should be familiar with the food safety program and operations of the business, and should have the authority to check records and act on the outcomes.

- when the review is to be carried out

A full review of the entire food safety program should be conducted routinely. The enforcement agency may determine when a full review is to be conducted (for example, every year or two years). However, a more frequent review may be necessary, particularly where a loss of control is discovered (for example a non-conformance) or there is a change in the operations of the business. In this case the review need only be on the sections of the food safety program affected.

- the scope of the review

The scope should describe the food handling operations covered by the review, procedures and records to be checked, and whether any equipment is due for calibration checks.

- the records of the review to be kept

Subclause 5(f) of Standard 3.2.1 requires the food safety program to include appropriate record-keeping procedures. These records should include information on the review. For example, they should indicate who carried out the review, dates of reviews and their scope and outcomes, including action to correct any non-conformances.

Record keeping

Clause 5(f) of Standard 3.2.1 requires that the food safety program must **provide for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program**.

The food safety program must nominate what records will be kept and the business must keep these records. At a minimum, records must be kept for:

- monitoring actions
- corrective actions
- all reviews of the program.

These records must be 'appropriate', that is, they must provide sufficient information to show that the business is complying with the food safety program. Records must be legible and indicate:

- what the record relates to
- who made the record
- the date and, where relevant, the time the record was made
- the result of what is being recorded
- any action taken as a result of the recording such as a corrective action

The food safety program needs to document how long records will be kept for. This period may be mandated by the state/territory or commonwealth enforcement agency. If the enforcement agency does not specify a minimum time, all records need to be kept at least until the food safety program has been externally audited, either by a second[10]- or third-party[11] auditor.

Documenting the program

Clause 13 requires the food safety program to be documented. The food safety program must be a written document, in English, and be kept on the premises. The Commonwealth *Electronic Transactions Act 1999* also allows records and documents to be kept in an electronic form. An auditor or enforcement officer will need to see the food safety program, either in writing or on a computer system readily available on the premises, to be satisfied that this program contains the information required in clause 5 of Standard 3.2.1.

One way to document the requirements of a food safety program is to tabulate them. For each step in the business's food handling operations the potential hazards, corresponding controls, monitoring of those controls, corrective action and required records can be set out in columns. This is illustrated in Table 2 below.

Table 2: Hazards, control, monitoring, corrective action and records set out in a table

Key step in food operation	Comment			
Pasteurisation	Microbiological (survival of pathogenic microorganisms)	Milk is to be pasteurised to a temperature of at least 72°C for at least 15 seconds.	**What** Check time/temperature readouts **Who** Person in charge of shift **When** Each batch **Records** Time/temperature readouts (may be electronic)	Where possible, adjust times/temperatures to meet control specifications. If fault cannot be fixed, stop production. Inadequately pasteurised milk to be discarded if delay exceeds nominated time. Investigate possible cause of problem. **Records** Record action taken.

Documents may also include:

- product specifications
- processing procedures or methods
- supporting information such as chemical or microbiological test results.

10 **A second party audit is an audit conducted by a government-employed or government-contracted auditor.**
11 **A third-party audit is an audit conducted by an independent certified auditor. These auditors are certified by private companies that themselves have been accredited by the Joint Accreditation System of Australia and New Zealand.**

The business should include the following information in their food safety program:

Details of the business

- business name and licence, registration, or accreditation information where applicable
- name of proprietor(s) (this means the person(s) or company that owns the business)
- contact details of the business.

Responsible persons

- a list of all key personnel (for example managers or supervisors) and their roles and functions in relation to the food safety program. This includes the person(s) responsible for the overall implementation of the food safety program.

Such a list ensures that all key roles and functions are covered and that all staff understand their responsibilities. It also provides an early indication of the need to review the list should staff leave the business or operations change.

Development of the food safety program

- a brief description of how the food safety program was developed, for example whether the food business used a government-provided template, industry quality assurance program, external consultants, or developed the program in-house.

Auditing of the food safety program

- information on how often the food safety program is required to be audited and who will be conducting the audit. This is based on information obtained from the relevant authority.

The business may also want to identify the relevant local government enforcement agency responsible for monitoring the activities of the business, and up-to-date contact details for contact officers within this agency.

14 Product tracing

As part of the documented food safety program in clause 13, a dairy processing business must have a system to identify the immediate supplier of dairy products and ingredients and the immediate recipient of the dairy products.

Product tracing contributes to the effectiveness of control measures by enabling the source and distribution of the product to be identified at a specified stage in production.

Clause 14 requires that dairy processing businesses must include a tracing or traceability system as part of their food safety program for dairy products and ingredients used. The intent is to trace the movement one step backwards (immediate supplier) and one step forward (immediate recipient). A traceability system should provide dairy processing businesses with the necessary information to carry out corrective actions if hazards arise.

The 'immediate supplier' is the business that has provided the dairy product or ingredient (including any food additive) used in processing to the dairy processing business.

The 'immediate recipient' is the business that purchases the processed dairy product from the dairy processing business, that is, the 'immediate customer'.

The traceability system the business has in place must be documented in the food safety program. This includes any procedures for identifying suppliers, customers and products and the records kept.

Traceability records

Traceability records enable businesses to identify and locate product if a food safety problem arises. Examples of such records include:

- name and address of suppliers and a description of the dairy products or ingredients supplied
- name and addresses of customers and a description of the dairy products supplied to them
- date of transaction or delivery
- volume or quantity of dairy products or ingredients received and dairy products supplied
- batch or lot numbers and other markings that will assist with identification.

Product recall

Clause 12 of Standard 3.2.2 Food Safety Practices and General Requirements specifies:

> A food business engaged in the wholesale supply, manufacture or importation of food must:
>
> (a) have in place a system to ensure the recall of unsafe food;
>
> (b) set out this system in a written document and make this document available to an authorised officer on request; and
>
> (c) comply with this system when recalling unsafe food.

This clause requires wholesale suppliers, manufacturers and importers to have a recall system. A recall system is the procedures and arrangements that a food business uses to ensure that unsafe food can be retrieved from the food supply chain.

Traceability is an essential element of a recall system. A food business must be able to identify which batches of its product, and the quantity, have gone where. Food businesses must keep records for the products they manufacture and ensure that records are easy to follow and are kept readily available. The records should:

- contain complete and up-to-date histories of all batches of products, from starting materials to the finished products
- allow for determination of the use and disposal of all raw materials and bulk products
- provide adequate details of customers to whom the end product has been sold or distributed.

If detailed records are kept, the extent of the recall may be minimised i.e. where product segregation can be demonstrated and records reflect the segregation.

For assistance in relation to this requirement, businesses can refer to the FSANZ *Food Industry Recall Protocol – A guide to conducting a food recall and writing a food recall plan* (6th edition, September 2008)[12].

15 Processing of milk and dairy products

Pasteurisation or an equivalent process can ensure the safety of milk and dairy products by reducing to safe levels any pathogenic micro-organisms that may be present in the raw milk.

Clause 15 specifies that the processing of milk and dairy products must include a pasteurisation step or equivalent treatment to pasteurisation to reduce any pathogenic micro-organisms that may be present in the raw milk to a safe level. The processing requirements for liquid milk and dairy products (other than cheese), are specified under separate subclauses. Dairy processing businesses must comply with the processing controls specified. The food safety program should document the processing controls used by the business, including time, temperature or other specifications, monitoring, corrective actions and supporting records.

(1) Milk must be pasteurised by –

(a) heating to a temperature of no less than 72°C and retaining at such temperature for no less than 15 seconds; or

Paragraph 15(1)(a) specifies the minimum time/temperature parameters for High Temperature Short Time (HTST) pasteurisation treatment of milk. Processing businesses must ensure that liquid milk is treated to at least 72°C for 15 seconds or demonstrate that an equivalent time and temperature process has been met as specified under paragraph 15(1)(b) below.

12 **This guide is available from the FSANZ website, www.foodstandards.gov.au under 'Food matters'-'Food recalls'.**

(b) heating, using any other time and temperature combination of equivalent or greater lethal effect on any pathogenic micro-organisms in the milk; or

Paragraph 15(1)(b) allows for alternative time and temperature treatments of milk, other than the 72°C for 15 seconds specified above, provided an equivalent or greater lethal effect on pathogenic micro-organisms is achieved. For example batch pasteurisation of milk at 63°C for 30 minutes would provide an equivalent lethal effect. Other heat treatments equivalents to 72°C for 15 seconds for milk and other dairy products are provided in Appendix 2. The figures provided are minimum holding times at the lowest allowable temperature. Processing businesses may employ higher temperatures or times to provide a greater lethal effect, depending on product specifications and other factors. In the case of Ultra Heat Treatment (UHT) of milk, for example, temperatures of at least 132ºC must be used to achieve commercial sterility.

(c) using any other process that provides an equivalent or greater lethal effect on any pathogenic micro-organisms;

Paragraph 15(1)(c) allows for the processing of milk using alternative technologies to heating. Such alternative technologies could include:

- microfiltration
- high pressure processing
- pulsed electric field
- ultrasonication.

The process or combination of processes used must achieve an equivalent lethal effect on any pathogenic micro-organisms that may be present to that provided by heating specified in paragraphs 15(1)(a) and 15(1)(b). The editorial note following clause 15 clarifies that such a process *would need to be validated by the business and verified by the Authority*.

The Codex Alimentarius Commission has developed guidelines for the validation of food safety control measures[13] for industry and governments. These guidelines outline a number of approaches to validation that may be used individually or in combination, including:

- reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure
- scientifically valid experimental data that demonstrate the adequacy of the control measure
- collection of data during operating conditions in the whole food operation
- mathematical modelling

The process of validating the control measure outlined in the Codex guidelines includes the following steps:

- decide on the approach or combination of approaches
- define the parameters and decision criteria [14] that will demonstrate that a control measure or combination of control measures, if properly implemented, is capable of consistently controlling the hazard to the specified outcome
- assemble relevant validation information and conduct studies where needed
- analyse the results

13 **Codex Alimentarius Commission, Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 – 2008), www.codexalimentarius.net.**

14 **Decision criteria should take into account the uncertainty and variability associated with the validation methodology and the performance of the control measure or combination of control measures.**

- document and review the validation.

Following validation, the Authority would need to verify that the results obtained demonstrate that an equivalent or greater lethal effect on pathogenic micro-organisms is achieved by that process as achieved by the pasteurisation of milk at 72°C for 15 seconds.

unless an applicable law of a State or Territory otherwise expressly provides.
This provision is temporary until a national review of raw milk permissions is undertaken. It allows for State and Territory jurisdictions to permit the sale of milk that has not been processed in accordance with sub clause 15(1) (e.g. raw or unpasteurised milk).

(2) Milk processed under paragraph 15(1)(a) must be cooled immediately in a way that ensures that the growth of microbiological hazards in the milk is prevented or reduced.

The cooling requirement specified under sub-clause 15(2) is to ensure that the HTST pasteurisation process specified under paragraph 15(1)(a) includes an immediate cooling step. Most foodborne pathogens do not grow at temperatures of 5ºC or below. Cooling milk immediately to or below this temperature will prevent or reduce bacterial growth and any bacterial toxin production.

(3) Dairy products, other than cheese and cheese products, must be processed using

(a) a heat treatment that uses a combination of time and temperature of equal or greater lethal effect on any pathogenic micro-organisms in the milk product achieved by paragraphs 15(1)(a) or 15(1)(b); or

Paragraph 15(3)(b) requires that dairy products other than liquid milk (captured under sub-clause 15(1)) have also undergone a pasteurisation process. The heat treatment used must provide an equivalent or greater lethal effect on any pathogenic micro-organisms that may be present as that achieved on liquid milk under paragraph 15(1)(a) and 15(1)(b).

The Editorial note following clause 15 notes that *dairy products may have a greater fat and/or solids content compared to milk and therefore require a greater time and temperature treatment to achieve an equivalent level of bacterial reduction*. Equivalent heat treatments for other dairy products depend on a number of factors including fat content, solids content, particle size etc. Dairy products containing elevated levels of fats or solids such as ice-cream mixes, cream and yoghurt, generally require higher time/temperature combinations than 72ºC for 15 seconds, in order to compensate for the protective effect of fat and solids on pathogenic micro-organisms. Other heat treatment equivalents to 72°C for 15 seconds for dairy products are provided in Appendix 2, based on fat content, particle size and total solids content.

(b) using any other process that provides an equivalent or greater lethal effect on any pathogenic micro-organisms.

Paragraph 15(3)(b) allows for the processing of dairy products using alternative technologies to heating. This is discussed above under paragraph 15(1)(c).

(4) Dairy products processed under paragraph 15(3)(a) must be cooled immediately in a way that ensures that the growth of microbiological hazards in the product is prevented or reduced.

The cooling requirement specified under sub-clause 15(4) is to ensure that the heat treatment process required under paragraph 15(3)(a) includes an immediate cooling step. Most foodborne pathogens do not grow at temperatures of 5ºC or below. Cooling milk immediately to or below this temperature will prevent or reduce bacterial growth and any bacterial toxin production. However, cooling to 5˚C may not be necessary if the dairy product is to be fermented such as occurs with yoghurt. Provided the process of heat treatment, cooling and processing ensures the growth of microbiological hazards in the product is prevented or reduced, the requirements have been met.

(5) To avoid doubt, subclause 15(3) does not apply to the processing of dairy products that have been made using milk already processed in accordance with subclause 15(1).

Subclause 15(5) is included to clarify that dairy products manufactured using milk that has already undergone a heat treatment (or equivalent) process in accordance with subclause 15(1), do not have to be processed in accordance with subclause 15(3). Only one pasteurisation step or equivalent treatment is required to be undertaken during manufacture.

16 Processing of dairy products to make cheese and cheese products

Pasteurisation or equivalent processes, including microbiological hurdles during manufacture, can ensure the safety of cheese and cheese products by reducing to safety levels any pathogenic micro-organisms that may be present in the raw milk.

Clause 16 specifies that the processing of milk or dairy products (such as cream) to make cheese must include a pasteurisation step or equivalent processes to eliminate pathogenic micro-organisms. These processing options are specified under separate subclauses.

Milk or dairy products used to make cheese or cheese products must be processed –

(a) in accordance with subclause 15(1); or

Subclause 15(1) is discussed on pages 31-33. Other dairy products used to make cheese such as skim milk or the addition of cream during milk standardisation, may be processed in accordance with subclause 15(1). This subclause allows for pasteurisation, a heat process at least equivalent to pasteurisation or any other process at least equivalent to pasteurisation.

(b) 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 processing; or

Subclause 16(b) specifies alternative processing conditions to 16(a) that can be used for cheese manufacture. The time and temperature time process of no less than 15 seconds at 62° C (generally referred to as thermisation) is a less rigorous heat treatment than pasteurisation at 72°C for 15 seconds. A minimum storage time and temperature is specified for cheeses manufactured using thermised milk as a further safeguard. During storage the interplay of physical and chemical characteristic of the cheese, such as pH, water activity and salt content, should result in the die off of any pathogenic bacteria that may have been present.

Under subclause 16(b), the cheeses produced using thermised milk must be stored for at least 90 days from the date of processing. The date of processing means the date the curd was set.

(c) 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 processing; or

Subclause 16(c) in effect allows for the processing of extra hard grating cheeses[15] using raw milk (milk that has not been processed in accordance with subclause 16(a) or 16(b)). Extra hard grating cheeses are defined by the processing parameters and product characteristic specified under paragraphs 16(b)(i) and 16(b)(ii). These include:

- using a curd cooking step in production where the curd is heated to temperatures of 48°C and above
- a minimum storage time of 6 months from the date of processing (the date the curd was set) at a storage temperature of no less than 10°C
- a maximum moisture content of less than 36%.

Extra hard grating cheese varieties include Parmesan, Romano, Asiago, Montasio and Sbrinz. The low moisture content of these cheeses (<36%), the temperatures used during cooking of the curd and the long maturation/ripening periods involved have been assessed as achieving a level of bacterial reduction which provides for a microbiologically safe product.

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

Subclause 16(d) allows for the production of specific cheeses listed in Standard 4.2.4A *Primary Production and Processing Standard for Specific Cheeses*, using raw milk (milk that has not been processed in accordance with subclause 16(a) and 16(b)). Standard 4.2.4A sets out primary production and processing requirements for Gruyere, Sbrinz, Emmental and Roquefort cheese, including the legislation or documentation and production conditions that must be complied with. A copy of Standard 4.2.4A is provided at Appendix 3.

15 **The Codex International Standard for Extra Hard Grating Cheese (Codex Stan 278-1978) describes principle characteristics of this cheese category including a maximum moisture content of 36% and a minimum maturation period of 6 months. These parameters have been incorporated into the processing requirements.**

Appendix 1

Dairy food safety program resources developed by Australian governments

Australian Government Department of Agriculture, Fisheries and Forestry

For guidance on HACCP-based food safety programs for the dairy production sector, see the website link below

www.daff.gov.au/aqis/export/dairy/guidelines

Australia New Zealand Dairy Authorities' Committee

ANZDAC is a government committee with representatives from AQIS, FSANZ, the New Zealand Food Safety Authority and the state government authorities with responsibility for dairy. It was previously known as the Australian Dairy Authorities' Standards Committee (ADASC).

ANZDAC (June 2007), *Guidelines for Food Safety, Validation and Verification of Heat Treatment Equipment and Processes*.

ADASC (Nov 2000), *Minimum Sampling Guidelines for Dairy Products*.

ADASC (July, 1999), *Australian Manual for Control of Salmonella in the Dairy Industry*.

ADASC (July 1999), *Australian Manual for Control of Listeria in the Dairy Industry*.

Available from www.daff.gov.au/aqis/export/dairy/pubs-guidelines

Dairy Food Safety Victoria

DFSA, *Guidelines for Food Safety, Dairy Food Manufacturers*.

Available from www.dairysafe.vic.gov.au

Appendix 2 – Heat Treatment Equivalents to Pasteurisation for Common Types of Dairy Produce [16]

	All dairy produce (excluding ice cream) with						
	Milks with <10% fat and no added sweeteners and particles			Dairy produce with ≥ 10% fat and/or added sweeteners and concentrated dairy produce with > 15% total solids and particles			Ice Cream mixes with particles <1000 µm
Particle Diameter	<200 µm Ø	200 to <500 µm Ø	500 to <1000 µm Ø	<200 µm Ø	200 to <500 µm Ø	500 to <1000 µm Ø	
Minimum holding time (seconds)	Minimum Temperature (°C)						
1.0	81.6	-	-	84.4	-	-	-
2.0	79.0	81.6	-	81.8	84.4	-	-
3.0	77.6	79.0	-	80.4	81.8	-	-
4.0	76.5	77.6	81.6	79.3	80.4	84.4	-
5.0	75.7	76.5	79.0	78.5	79.3	81.8	-
6.0	75.1	75.7	77.6	77.9	78.5	80.4	-
7.0	74.6	75.1	76.5	77.4	77.9	79.3	-
8.0	74.1	74.6	75.7	76.9	77.4	78.5	-
9.0	73.7	74.1	75.1	76.5	76.9	77.9	-
10.0	73.3	73.7	74.6	76.1	76.5	77.4	85.5
11.0	73.0	73.3	74.1	75.8	76.1	76.9	-
12.0	72.7	73.0	73.7	75.5	75.8	76.5	-
13.0	72.4	72.7	73.3	75.2	75.5	76.1	-
14.0	72.1	72.4	73.0	74.9	75.2	75.8	-
15.0	72.0	72.1	72.7	74.8	74.9	75.5	79.5
30.0	70.7	70.8	70.9	73.5	73.6	73.7	-
60.0	69.4	69.4	69.5	72.2	72.2	72.3	-
Minimum holding time (minutes)	Minimum Temperature (°C)						
1	69.4	69.4	69.5	72.2	72.2	72.3	-
2	68.1	68.1	68.1	70.9	70.9	70.9	-
5	66.4	66.4	66.4	69.2	69.2	69.2	-
10	65.1	65.1	65.1	67.9	67.9	67.9	74.0
15	64.3	64.3	64.3	67.1	67.1	67.1	-
20	63.8	64.8	64.8	66.6	66.6	66.6	69.0
25	63.3	63.3	63.3	66.1	66.1	66.1	-
30	63.0	63.0	63.0	65.8	65.8	65.8	-

Notes:

1. Ø signifies particle diameter
2. Minimum holding time - The minimum holding time is set at 1 second to give an adequate safety margin. Shorter holding times w ill require validation to demonstrate the effectiveness of the time temperature combination in controlling the hazard(s).
3. Lowest allowable temperature - The pasteurising temperature given for a 30 minute holding time is lowest allowable temperature for pasteurising the specified product types.

16 Table reproduced from the Australia New Zealand Dairy Authorities Committee (ANZDAC) Guideline Validation and Verification of Heat Treatment Equipment and Processes (November 2006). The information in the table was sourced from the New Zealand Food Safety Authority, D121.1.Dairy Treatments Standard 2003.

Appendix 3

Standard 4.2.4A

Primary Production and Processing Standard for Specific Cheeses (Australia only)

Purpose and commentary

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

Table of Provisions

1 Requirements for certain cheese and cheese products

Clauses

1 Requirements for certain cheese and cheese products

Cheese and cheese products specified in Column 1 of the Table to this clause may be manufactured from milk and milk products that have been produced and processed using a method that –

(a) ensures that the cheese produced achieves an equivalent level of safety protection as cheese prepared from milk or milk products that have been heat treated in accordance with paragraph 2(1)(a) of Standard 1.6.2; and

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

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

Table to clause 1

Column 1	Column 2	Column 3
Cheese and cheese products	Legislation or documentation	Conditions
Gruyere, Sbrinz or Emmental cheese	The *Ordinance on Quality Assurance in the Dairy Industry* of the Swiss Federal Council of 18 October 1995	
Roquefort	The *Ministerial Order of 30 December 1993 on requirements relating to the premises, equipment and operation of milk collection or standardization centres and of establishments involved in the treatment or processing of milk or milk-based products* 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) salt concentration; and (c) moisture content. (2) Unpasteurised milk for cheese production must be tested and demonstrated to have no detected levels of *Listeria monocytogenes* in 25 ml of milk per tanker. (3) The cheese must be stored at an appropriate temperature for a period of no less than 90 days from the date of manufacture.

Editorial note:

Legislation or documentation will only be listed in the Table to clause 1 if it incorporates or provides for methods which provide a level of safety protection equivalent to that provided by a process that includes treatment of the milk or milk product in accordance with paragraph paragraph 2(1)(a) of Standard 1.6.2 before 5 October 2008 and then with paragraphs 16(a) and (b) of Standard 4.2.4 after 5 October 2008, 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 are not specifically covered in clause 3 of this Standard, and any applicable State and Territory requirements in relation to cheese production, including any specific requirements in relation to the safety of raw milk and raw milk cheese production.

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

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

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