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9 August 2006

FINAL ASSESSMENT REPORT

PROPOSAL P296

PRIMARY PRODUCTION AND PROCESSING STANDARD FOR DAIRY

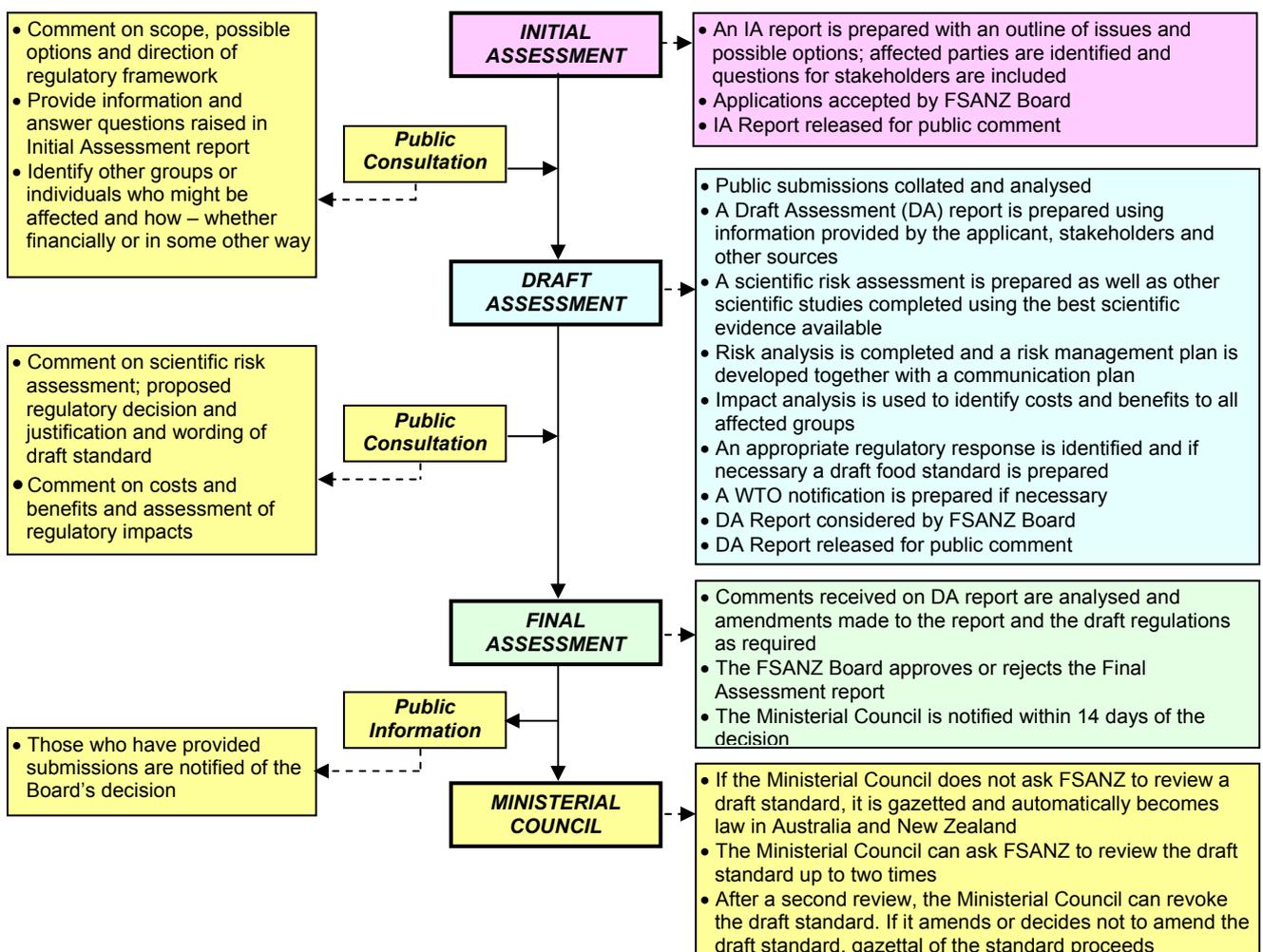
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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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.

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



Final Assessment Stage

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

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

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

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Executive Summary and Statement of Reasons

Government in Australia has endorsed a 'paddock-to-plate' approach to food safety. Food Standards Australia New Zealand's standard development process now addresses food safety across all parts of the food supply chain. Proposal P296 has been raised to assess the food safety issues across the dairy sector, from on-farm milk production to dairy product distribution, in order to propose appropriate risk management measures for a national standard.

Background

The dairy industry in Australia is a highly regulated sector and practices a high level of food safety management. Currently, these arrangements are implemented through six different sets of State based regulatory requirements as well as industry codes of practice and guidelines. Additionally, those dairy businesses wishing to export must comply with the requirements of the AQIS *Export Control (Milk and Milk Product) Orders 2005*. Industry and Government has recognised a benefit in the development of a single set of national requirements within a single standard.

The objective of the Primary Production and Processing Standard for Dairy Products is to provide nationally consistent regulatory requirements that protect public health and safety and are cost effective.

Initial Assessment

The Initial Assessment Report for P296 was released for public comment on the 15 December 2004 until the 7 March 2005. The Initial Assessment Report identified and discussed the key issues relevant to the development of a primary production and processing standard for the dairy sector. Submissions were received from industry, State regulators and industry associations and provided information that helped guide development of the scientific assessment work and Draft Assessment Report.

The Initial Assessment Report raised the issue of developing a management framework for raw milk (e.g. unpasteurised) and raw milk products. The development of a single national standard for dairy based on existing processing requirements has progressed ahead of the work required for raw milk products. A separate report will be developed in 2007 to specifically address raw milk and raw milk product issues.

Draft Assessment

The Draft Assessment Report for Proposal P296 was released for public consultation from 22 March 2006 until 10 May 2006. The Draft Assessment Report outlined the scientific assessment process and proposed risk management options for addressing food safety issues across the dairy supply chain. The comments received on the draft dairy Standard provided at Draft Assessment have helped inform the final drafting of the Primary Production and Processing Standard for Dairy Products, presented in this Final Assessment Report.

Scientific assessment

As part of the FSANZ standard development framework, a scientific assessment, *A Risk Profile of Dairy Products in Australia* (Risk Profile), was undertaken within the context of the current regulatory framework and practices. The Risk Profile determined that the current management practices in place within the Australian dairy industry support the production of dairy products with a high standard of public health and safety. The outputs from the Risk Profile have been used in development of the Primary Production and Processing Standard for Dairy Products. In particular it has been used to identify:

- the food safety risks along the dairy food supply chain;
- where these risks are best managed, and
- any gaps with the existing management strategies in place.

The Risk Profile examined both microbiological and chemical risks for the dairy sector. With regard to microbiological hazards, the Risk Profile considered the:

- identification and description of micro-organisms that may be associated with dairy products including key attributes of each organism and its public health impact;
- examination of epidemiological data (domestic and international) related to the consumption of dairy products;
- examination of prevalence and concentration data on potential hazards from products along the entire dairy food chain; and
- description of the dairy production, processing, distribution and consumption chain and current knowledge of the impact of each of these on public health and safety risks.

The examination of chemical hazards considered:

- agricultural and veterinary chemicals used in primary production;
- environmental contaminants, including heavy metals, organic contaminants and micronutrients;
- natural chemicals found in plants, fungi or bacteria associated with plants;
- food processing by-products;
- food additives, processing aids and those chemicals that may migrate from packaging.

Key findings

The key findings of the Risk Profile include:

- Consumption of dairy products is rarely linked to food-borne illness in Australia.
- A wide range of microbiological hazards may be associated with raw milk and dairy products, but these do not represent a problem under current management practices which:
 - control animal health;
 - ensure adherence to good milking practices;
 - require effective heat treatment e.g. pasteurisation; and
 - have controls to prevent post-pasteurisation contamination in the dairy processing environment.

- There are minimal public health and safety concerns regarding the use or presence of chemicals in dairy products due to the extensive regulatory and non-regulatory measures in place along the dairy industry primary production chain.
- Extensive monitoring of chemical residues in milk over many years has demonstrated a high level of compliance with the regulations.

Risk management

The outcomes of the Risk Profile demonstrate that the existing regulatory arrangements and industry initiatives that have been implemented are effective in protecting the public health and safety of consumers. The difficulty faced by the dairy industry, however, is in dealing with a number of different State based schemes. Proposal P296 has sought to develop a single national standard for milk production and processing based on the measures that are common across the State-based requirements and that support the high level of food safety evident in this industry.

Appropriate risk management options for the dairy supply chain were considered separately for on-farm primary production activities, bulk transport of milk and milk products, and processing. These options apply to the production of milk and milk products from all commercial milking animals.

On-farm primary production

An analysis of the hazards and controls at each of the steps identified for on-farm milk production was undertaken to identify the possible requirements needed to support the safe production of milk. A comparison of these controls with current regulatory requirements showed they were covered by existing measures and that no new requirements would be necessary.

Four regulatory options were considered for on-farm primary production:

- Option 1. The *status quo* (maintaining the current State-based systems);
- Option 2. Develop a national dairy Standard that specifies food safety requirements that the primary production business must comply with;
- Option 3. Develop a national dairy Standard that specifies food safety requirements that the primary production business must comply with plus the requirement to demonstrate compliance through appropriate documentation; and
- Option 4. Develop a national dairy Standard that requires the primary production business to have a documented food safety program plus specific controls that must be included.

An impact analysis of these options helped determine that the fourth option provided greatest cost benefit and is the preferred option.

Bulk transport of milk and milk products

As for on-farm primary production, an analysis of hazards and controls was undertaken for the collection and bulk transport of milk and milk products to identify the possible requirements needed at this step to support the safe production of milk.

The four regulatory options considered for on-farm primary milk production were also analysed for the milk transport stage. The preferred option was to develop a national Standard for dairy products that will require dairy transport businesses to have a documented food safety program and to specify controls that must be included to address food safety.

Processing

A hazard analysis for processing activities was undertaken in light of existing requirements in the Code that apply to processors, particularly the Chapter 3 – Food Safety Standards. Taking into account existing measures in place for the processing sector, three options were identified:

- Option 1. The *status quo* (maintaining the State-based system);
- Option 2. Develop a national dairy Standard that requires processing business to demonstrate their compliance with Standards 3.2.2 and 3.2.3 of the Code through record keeping/documentation; or
- Option 3. Develop a national dairy Standard that requires processing business to have a documented food safety program.

An impact analysis of these options helped determine that the third option would provide the greatest cost benefit and is the preferred option.

Decision

The Australian dairy industry produces dairy products of a high level of safety. This has been supported by industry initiatives and a State-based regulatory system that has implemented comprehensive regulatory requirements from on-farm through to processing and distribution. This State-based framework has, however, resulted in some variation in requirements across jurisdictions and impacted on industry's ability to streamline arrangements across the States in which they trade. Another level of compliance is added to those businesses registered for export that must also meet the requirements specified in the AQIS Export Control Orders.

The impact analysis of risk management options found that, while the existing system supports the safe production of dairy products, the lack of uniform national requirements for the dairy sector limits the rationalisation of industry operational and compliance costs. Additionally, a single national standard improves transparency in demonstrating regulatory requirements to importing countries and trading partners.

Based on the preferred options for on-farm primary production, bulk transport of milk and milk products and dairy processing, Standard 4.2.4 - Primary Production and Processing Standard for Dairy Products, has been developed (provided at Attachment 1 of this Final Assessment Report). Standard 4.2.4 specifies 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 processing activities up to retail). These requirements essentially consolidate existing regulatory measures into a single set of outcome-based national requirements that support the safe production of dairy products.

On-farm milk production requirements

Standard 4.2.4 requires dairy primary production businesses to:

- implement a documented food safety program (defined in Standard 3.2.1 – Food Safety Programs);
- include controls that manage hazards arising from:
 - inputs (feed, water, chemicals [including veterinary and agricultural chemicals] or other substances used in connection with the primary production of milk);
 - the design, construction, maintenance and operation of premises and equipment;
 - milking animals;
 - persons involved in milking; and
 - milking practices;
- ensure milk is only sourced from healthy animals;
- cool and store milk to prevent or reduce the growth of microbiological hazards;
- have pest control and cleaning and sanitising programs;
- ensure that persons undertaking primary production activities have appropriate skills and knowledge (competencies); and
- have a system to enable the tracing of inputs, milking animals and the milk produced.

Dairy collection and transport requirements

Standard 4.2.4 requires a milk transport business to:

- implement a documented food safety program;
- include controls that manage hazards arising from –
 - transport vehicles, equipment and containers used in the collection and transport of the milk; and
 - persons engaged in the milk transport business;
- have a cleaning and sanitising program;
- transport milk at a temperature and within a time that prevents or reduces the growth of microbiological hazards;
- ensure persons undertaking milk collection and transport activities have appropriate skills and knowledge (competencies);
- have a system in place to trace the dairy product.

Dairy processing requirements

Standard 4.2.4 requires dairy processing businesses to:

- implement a documented food safety program;
- have a system to enable tracing of dairy products and ingredients.

The processing requirements for milk and milk products and for cheese that were contained in Standard 1.6.2 of the Code have been relocated into Standard 4.2.4 under the dairy processing section.

These requirements have been revised to allow for the use of alternative technologies (any other approved process) to time-temperature treatments in the future, as they are developed and validated.

Statement of Reasons

At Final Assessment, FSANZ recommends that the Code be amended to include Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products into Chapter 4 for the following reasons. The proposed Standard:

- is consistent with the section 10 objectives of the FSANZ Act to protect public health and safety;
- provides a nationally consistent legislative framework for a whole-of-chain approach to dairy food safety;
- takes into account existing State-based and export requirements, providing a consolidated set of requirements based on scientific assessment;
- has been developed with regard to the measures specified in the Codex Code of Hygienic Practice for Milk and Milk Products, promoting consistency between domestic and international food standards;
- provides measures that are outcome based and do not impose any additional costs to industry over existing requirements;
- supports the recommendations of the COAG Senior Officials Working Group on Food Regulation and the National Competition Policy (NCP) Review of the Export Control Act 1982, for the implementation of an integrated national food regulatory system that systematically addresses food safety across the chain, and progresses the harmonisation of domestic and export standards.

1. Introduction

A whole-of-Government approach to the management of food safety is now being taken in Australia. Governments have agreed that Food Standards Australia New Zealand (FSANZ) addresses food safety throughout all parts of the food supply chain – a ‘paddock-to-plate’ approach. To this effect, FSANZ has developed a Primary Production and Processing Standard for Dairy Products (Proposal P296). To assist and advise in this process, FSANZ established a Standard Development Committee consisting of representatives from industry, consumers and jurisdictions. Additionally, a Dairy Scientific Advisory Panel was established to provide ongoing advice and guidance during the preparation of the scientific assessment work.

The dairy industry in Australia is comprehensively regulated on a State-by-State basis, with exporters additionally covered by Australian Quarantine and Inspection Service (AQIS) export arrangements. Proposal P296 supports the development of a uniform national regulation, consistent with the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) *Overarching Policy Guideline on Primary Production and Processing Standards*.¹ There is strong industry support for the development of a single national standard for the dairy sector.

FSANZ made an Initial Assessment of Proposal P296 in December 2004. The Initial Assessment Report was released for public comment on the 15 December 2004, inviting comment on the scope² of the standard and outlining the risk analysis approach underpinning the standard development process.

The second step in the standard development process comprised the development of a Draft Assessment Report for Proposal P296. This involved input from the Standards Development Committee, consideration of the submissions received on the Initial Assessment Report and consultations with industry members and government agencies. The Draft Assessment Report was released for public consultation from 22 March 2006 until 10 May 2006 and outlined the scientific assessment and proposed risk management options for addressing food safety issues across the dairy supply chain.

This Final Assessment Report has considered the comments provided in submissions and by the Standards Development Committee on the draft Standard presented at Draft Assessment. The recommendations of this report have been approved by the FSANZ Board and notified to the Ministerial Council

¹ These documents may be obtained from the FSANZ website <http://www.foodstandards.gov.au/>

² The Initial Assessment report for Proposal P296 raised the issue of developing a management framework for raw milk² and raw milk products, such as cheese. The work in this area is still ongoing and will be considered in a separate report in 2007. This Final Assessment Report proposes a national dairy Standard based on existing processing requirements.

2. Background

Overview of the dairy industry in Australia

The dairy industry is a major rural industry in Australia. The majority of milk and milk products are derived from bovine milk with only a small proportion from other species, such as goat, sheep and buffalo.

The farm gate value of production is \$2.8 billion (2003/04), ranking the dairy industry third behind the beef and wheat industries³. While the bulk of milk production occurs in Victoria (64% of total Australian production in 2003/04), all states, except the NT and the ACT, have a productive dairy industry⁴.

2.1.1 Bovine milk production

Bovine milk production in Australia is mainly concentrated near coastal areas where pasture growth generally depends on natural rainfall. Milk production is strongly seasonal, reflecting the pasture-based nature of the industry, with production peaks in October/November, tapering off in the cooler months of May/June.

Milk production in Australia peaked at over 11 billion litres in 2003/04. Most of this milk is further processed into a diverse range of milk products. The four major Australian consumer dairy products are drinking milk (fresh and UHT[white and flavoured]), cheese, butter and dairy blends, and yoghurt. There is also considerable production of milk powders (skim and whole milk), primarily for the export market. Table 1 below shows the percentage utilisation of Australian milk in 2003/04 in terms of dairy products produced.

Table 1: Utilisation of Australian Milk, 2003 - 04⁵

Dairy product	Percentage utilisation from milk (%)
Cheese	37
Skim milk powder/butter milk powder	21
Drinking milk	19
Whole milk powder	15
Butter/casein	5
Other	3

2.1.2 Goat milk production

The dairy-goat industry in Australia has expanded in recent years, building on market interest in specialty cheese production. In 2003/04 around 4.8 million litres of goat milk were produced in Australia, over half of this (~2.6 million litres) going into cheese production with a retail value of over \$20 million dollars⁶. About 2.1 million litres of goat milk went into the whole milk sector in 2003-04, as well as some yoghurt production. The main goat milk producing States are Victoria, Queensland and Tasmania.

³ Information sourced from Dairy Australia, 2004

⁴ Further details on the dairy industry can be found in the Initial Assessment Report for Proposal P296, available on the FSANZ website <http://www.foodstandards.gov.au/>

⁵ *ibid*

⁶ Victorian Farmers Federation Livestock Goat Committee, 2005

2.1.3 *Sheep milk production*

While there is an established sheep milk industry in Australia, it is still largely cottage based with most products made on farm in licensed factories. Sheep milk is primarily processed into yoghurt and cheeses with a retail value of around \$4 million per annum⁷.

There are around 8 sheep milking operations currently producing on a regular basis in Australia, one each in Victoria and Queensland and two each in South Australia, Western Australia and Tasmania.

2.1.4 *Buffalo milk*

Australia has two water buffalo dairy farms located in Victoria and Queensland. The main products made from water buffalo milk are cheese and yoghurts.

2.2 **Current regulatory framework for dairy in Australia**

The dairy industry in Australia is currently regulated under six different sets of State regulations, with exporters additionally covered by the AQIS Export Control (Orders) Regulations. The ACT and Northern Territory do not have specific dairy regulations as there is no established dairy industry within those jurisdictions. Although there are similar food safety requirements within the State based regulations, there is no uniform 'national' dairy scheme.

2.2.1 *State-based requirements*

Australia has comprehensive State-based regulations that support food safety in the dairy sector. An overview of this legislative framework is provided in Table 2. In general, these dairy regulations specify the implementation of food safety programs for on-farm production, for milk/dairy transport and for dairy processing (including storage and distribution of dairy products). A summary of the regulatory requirements of each jurisdiction is provided at Attachment 4.

The dairy authorities have different regulatory structures for dairy food safety. Tasmania and South Australia have implemented a Memorandum of Understanding with Victoria to adopt the *Code of Practice for Dairy Food Safety* as part of their legislative requirements. The *Code of Practice for Dairy Food Safety*, developed by Victoria, provides the minimum mandatory standards for the production, manufacture, storage and transport of milk and dairy foods and specifies the requirements for food safety programs. Western Australia has also been working towards implementing a Code of Practice based on the *Code of Practice for Dairy Food Safety*.

In New South Wales, the *NSW Dairy Manual* has been developed to support the implementation of the *Food Production (Dairy Food Safety Scheme) Regulation 1999*. The Dairy Manual specifies matters that, as a minimum, must be addressed by the Food Safety Program and provides guidance on how to develop a HACCP⁸ system. The Queensland *Food Production (Safety) Regulation 2002* applies food safety schemes to the dairy sector.

⁷ *ibid*

⁸ HACCP – Hazard Analysis Critical Control Point

It specifies that a Food Safety Program must be prepared, the information to be contained in the program, and specific food safety requirements of the dairy scheme.

Milk processing activities undertaken within the ACT and the Northern Territory are covered by their respective Food Acts.

Table 2: Summary of State legislative framework for dairy

State/Responsible Authority	Legislation	Requirements for food safety program
NSW (NSW Food Safety Authority)	<i>Food Production (Dairy Food Safety Scheme) Regulation 1999</i> <i>Food Act 2003</i>	<i>NSW Dairy Manual</i>
QLD (Safe Food Qld)	<i>Food Production (Safety) Act 2000</i> <i>Food Production (Safety) Regulations 2002</i> <i>Food Act 1981</i>	<i>Food Production (Safety) Regulations 2002</i>
SA (Dairy Authority of SA)	<i>Primary Product (Food Safety Schemes) Act 2004</i> <i>Primary Produce (Food Safety Schemes) (Dairy Industry) Regulations, 2005</i> <i>Food Act, 2001</i>	<i>Code of Practice for Dairy Food Safety, 2005</i>
TAS (Tasmanian Dairy Industry Authority)	<i>Dairy Industry Act 1994</i> <i>Food Act, 2003</i>	<i>Tasmanian Code of Practice for Dairy Food Safety</i>
VIC (Dairy Food Safety Victoria)	<i>Dairy Act 2000</i> <i>Food Act, 1984</i>	<i>Code of Practice for Dairy Food Safety, 2002</i>
WA (Health Department of WA)	<i>Health Act 1911</i> <i>Health (Food Hygiene) Regulations 1993</i>	Code of Practice for Dairy Food Safety (Under development)
Northern Territory (Health and Community Services/Environmental Health)	<i>Food Act, 1986</i>	(not required under Food Act)
ACT Department of Health/Environmental Health)	<i>Food Act, 2001</i>	(not required under Food Act)

The content of the regulatory documents also vary in terms of their level of prescription. For example, the code of practice developed in Victoria and adopted in South Australia and Tasmania is largely outcome based, while the NSW Dairy Manual requirements are more prescriptive, particularly in relation to sampling and testing. Supporting guidance documents have been developed to assist with implementation of State regulatory requirements.

The Australia New Zealand Dairy Authorities Committee (ANZDAC)⁹ in particular has produced many guidance documents for the dairy industry.

2.2.2 *Export requirements*

AQIS of the Department of Agriculture, Fisheries and Forestry is responsible for inspection and certification of Australian export food products. The AQIS export program operates within the statutory powers of the *Export Control Act 1982*.

The *Export Control Act 1982* was reviewed in 1999 as part of the comprehensive examination of legislation by the Australian Government to ensure compliance with the National Competition Policy (NCP). The review focused on those parts of the *Export Control Act 1982* which restrict competition or which result in costs or benefits for business. The review recommended the adoption of an integrated export assurance system based on 3 tiers:

- Tier 1: Australian Standards harmonised with International Standards/ Agreements (Codex, OIE, IPPC).
- Tier 2: Importing country conditions not covered by Australian Standards
- Tier 3: Emergency or special requirements by industry or government.

The *Export Control (Processed Food) Orders* were reviewed in line with recommendations of the NCP review of the *Export Control Act*. The new *Export Control (Dairy, Eggs & Fish) Orders* were gazetted in 2005. Subsequently these Orders were split in October 2005 to three commodity specific Orders, including the *Export Control (Milk and Milk Products) Orders* (Export Control Orders).

The Export Control Orders include a requirement for establishments to have a HACCP plan, documentation of the controls used and demonstration of compliance with importing country requirements. Specific requirements in the Export Control Orders cover:

- structural requirements (construction requirements for the factory, walls, floors, equipment);
- operational hygiene (hygiene controls for premises and equipment, pest control, processing requirements, health and hygiene requirements);
- sourcing of raw milk and ingredients
- product standards (microbiological limits, contaminants, residues, food additives),
- tracing systems;
- Codex HACCP
- Adequate records to demonstrate compliance
- audit arrangements.

An outline of the requirements of the Export Control Orders is provided at Attachment 5.

In order to streamline inspection/auditing services between AQIS and the State dairy Authorities, AQIS has introduced competition (contestability) into these services. When accredited by AQIS, a State Dairy Authority may conduct audits of export dairy establishments on behalf of AQIS.

⁹ Formally known as the Australian Dairy Authorities' Standards Committee (ADASC)

These audits cover requirements of the *Export Control (Milk and Milk Products) Orders*. Currently State Dairy Authorities in Victoria, Tasmania, New South Wales, Queensland, South Australia and Western Australia participate in this arrangement. AQIS remains ultimately responsible for managing the export inspection and certification system in accordance with importing country requirements and regularly reviews the arrangement.

2.2.3 *Australia New Zealand Food Standards Code*

The requirements of the *Australia New Zealand Food Standards Code* (the Code)¹⁰ are implemented through the State and Territory Food Acts and supporting legislation. There are a number of Standards within the Code that support the safe production of dairy foods, as outlined below.

In general, chemical use for milk production and processing activities is covered by:

- Standard 1.3.1 – Food Additives
- Standard 1.3.3 – Processing Aids
- Standard 1.3.4 – Identity and Purity
- Standard 1.4.1 – Contaminants and Natural Toxicants
- Standard 1.4.2 – Maximum Residue Limits
- Standard 1.4.3 – Articles and Materials in Contact with Food.

Dairy manufacturing businesses in Australia must also comply with the hygiene requirements of Standard 3.2.2 – Food Safety Practices and General Requirements and Standard 3.2.3 – Food Premises and Equipment. Standard 1.6.1 – Microbiological Limits for Food specifies microbiological standards for cheeses and powdered infant formula.

Processing requirements for milk and milk products and for cheese are specified in Standard 1.6.2 – Processing Requirements.

2.2.3.4 Processing requirements

Standard 1.6.2 specifies the following processing requirements for milk and liquid milk products:

<p>1</p> <p>(1)</p> <p style="padding-left: 20px;">(a)</p> <p style="padding-left: 20px;">(b)</p> <p>unless an applicable law of a State or Territory otherwise expressly provides.</p> <p>(2)</p>	<p>Processing of milk and liquid milk products</p> <p>Milk must be pasteurised by –</p> <p style="padding-left: 20px;">heating to a temperature of no less than 72°C and retaining at such temperature for no less than 15 seconds and immediately shock cooling to a temperature of 4.5°C; or</p> <p style="padding-left: 20px;">heating using any other time and temperature combination of equal or greater lethal effect on bacteria;</p> <p>Liquid milk products must be heated using a combination of time and temperature of equal or greater lethal effect on the bacteria in liquid milk that would be achieved by pasteurisation or otherwise produced and processed in accordance with any applicable law of a State or Territory.</p>
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¹⁰ The Food Standards Code is available on the FSANZ website <http://www.foodstandards.gov.au/>

Processing requirements for cheese and cheese products are specified separately to accommodate alternative production practices:

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 1 of Standard 4.2.4A.

Standard 4.2.4A – Primary Production and Processing Standard for Specific Cheeses sets out the primary production and processing requirements for Gruyere, Sbrinz, Emmental and Roquefort cheese made from raw milk.

2.1 Relevant international standards

2.3.1 Codex

The *Recommended International Code of Practice - General Principles of Food Hygiene*, (Code of Hygienic Practice) identifies control measures internationally recognised as essential to ensuring the safety and suitability of food. The principles outlined in the Code of Hygienic Practice largely informed the development of the Chapter 3 - Food Safety Standards. The Codex *Code of Hygienic Practice for Milk and Milk Products*¹¹ extends these principles to dairy primary production and processing through additional control measures for dairy hygiene.

The Codex *Code of Hygienic Practice for Milk and Milk Products* provides control measures 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 products.

Codex provides a number of overarching principles that should apply to the production, processing and handling of all milk and milk products as follows:

¹¹ Codex document (CAC/RCP 57, 2004)

- From raw material production to the point of consumption, dairy products should be subject to a combination of control measures, and these control measures should be shown to achieve the appropriate level of public health protection.
- Good hygienic practices should be applied throughout the food chain so that milk and milk products are safe and suitable for their intended use.
- Wherever appropriate, hygienic practices for milk and milk products should be implemented within the context of HACCP as described in the Annex to the Recommended International Code of Practice – General Principles of Food Hygiene. (Codex notes that there are limitations to the full application of HACCP principles at the primary production level.)
- Control measures should be validated as effective.

In relation to the primary production of milk, Codex identifies the application of control measures for the following areas:

- Environmental Hygiene
 - the management of water and other environmental factors to minimise contamination of the milk
- Hygienic Production of Milk
 - areas and premises for milk production
 - animal health
 - general hygienic practice (feeds, pest control, veterinary drugs)
 - hygienic milking
- Handling, Storage and Transport of Milk
 - milking equipment
 - storage equipment
 - premises for, and storage of, milk and milk related equipment
 - collection, transport and delivery procedures and equipment
- Documentation and Record Keeping

In addition to the principles outlined in the Codex Code of Hygienic Practice, the Codex *Code of Hygienic Practice for Milk and Milk Products* describes the following as key aspects of hygiene control systems for milk processing:

- Temperature and time controls
- Specific process steps (e.g. pasteurisation)
- Microbiological and other specifications
- Microbiological cross contamination
- Physical and chemical contamination

Annex II provides guidelines for the management of control measures during and after processing.

2.3.1 New Zealand

Consistent with the Ministerial Council Overarching Policy Guideline, Primary Production and Processing Standards apply in Australia only. In New Zealand the New Zealand Food Safety Authority (NZFSA), Dairy and Plant Products Group administers the requirements of the:

- *Animal Products Act 1999*
- *Animal Products (Dairy) regulations 2005*
- *Animal Products (Dairy Risk Management Programme Specifications) Notice 2005*
- *Animal Products (Export Requirements – Dairy Products) Notice 2005.*

These regulations can be viewed on the NZFSA website at: www.nzfsa.govt.nz

The Animal Products Act 1999 requires primary processors¹² and secondary processors¹³ of animal products to have a ‘Risk Management Program’.

A risk management programme is an assurance programme designed to manage known biological, chemical and physical hazards. The programme must include the application of Hazard Analysis and Critical Control Point (HACCP) principles, identifying the systems of control, and demonstrating that they are effective.

A risk management programme requires:

- systematic identification and analysis of the hazards inherent in animal material, animal product and processes;
- detail of how those hazards will be managed;
- documentation and record keeping; and
- provision for verification by recognised agencies independent from the business.

With regard to processing requirements for dairy products, these are specified within the *New Zealand (Milk and Milk Products Processing) Food Standards 2000*. These regulations cover the pasteurisation requirements for milk and milk products and other treatments permitted for cheese and ice cream.

3. Objective

The objective of a Primary Production and Processing Standard for Dairy Products is to provide nationally consistent regulatory requirements that protect public health and safety and are cost effective for industry. In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;

¹² **Primary processor** means a person who is a dairy processor, dairy processor means a person who for reward, is a dairy farm operator, transporters of dairy material from dairy farm to a place of processing manufacture or from processing to another processor, operator of any premises where dairy material is processed or stored

¹³ **Secondary processor** means any person who for reward processes animal product at any stage beyond its primary processing

- 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 addition, the dairy Standard will aim to:

- establish a nationally consistent legislative framework for a whole of chain approach to dairy food safety;
- be based on a comprehensive scientific risk analysis, using the best available scientific evidence;
- be outcome-based and minimal effective regulation;
- promote consumer confidence in an industry that is already highly regarded;
- be consistent with internationally recognised dairy standards and internationally recognised principles of food safety; and
- take into account existing State based requirements and industry schemes that have already been successfully implemented and support production for both the domestic and export markets;
- have regard to the relevant policy guidelines formulated by the Ministerial Council and notified to FSANZ, regarding primary production and processing Standards.

A national Standard will form a key part of an effective food safety system with responsibility being taken at all points across the food supply chain to manage food safety hazards. The Standard should be an integral part of the ‘food safety package’ that does not duplicate, but replaces current regulatory schemes and complements non-regulatory schemes to manage food safety risks. The Standard should recognise the industry’s ability to provide additional support – through, for example, codes of practice, industry preferred standards and industry guidelines and supporting material.

4 Scientific assessment

FSANZ uses various types of tools to assess risks to public health and safety, including risk profiling, quantitative and qualitative risk assessments and scientific evaluations. The outcomes of these assessments are used to identify and assess food safety hazards in order to develop efficient and cost-effective risk management measures. As discussed in section 2.2, the dairy industry in Australia already has comprehensive state-based regulatory requirements applying at farm and manufacturing level as well as industry codes of practice and guidelines that support the safe production of dairy products. The scientific assessment work for dairy, *A Risk Profile of Dairy Products in Australia* (Risk Profile), has been undertaken within this existing regulatory framework. The Risk Profile identified:

- food safety risks along the dairy food supply chain;
- where these risks are best managed, and
- gaps with current management strategies. Such gaps are referred to as residual risk.

4.1 Scope of the risk profile

The Risk Profile, provided at Attachment 2, examined risks along the dairy supply chain from milk production through to consumption of dairy products. The Risk Profile is divided into two parts:

- Part A the Microbiological Risk Profile; and
- Part B the Chemical Risk Profile.

The Risk Profile provides an objective analysis of relevant scientific data and information to identify the public health and safety risks associated with potential microbiological and chemical hazards associated with dairy products.

The **Microbiological Risk Profile (Part A)** was undertaken to gather the following information:

1. What microbiological hazards are associated with the Australian dairy supply chain and what is the likelihood that these hazards pose a risk to public health and safety under the current regulatory system?
2. What factors along the Australian dairy supply chain have the most significant impact on public health and safety risks?

The microbiological risk profile identified and examined potential hazards along the dairy supply chain from milk production through to consumption of dairy products and has considered the relevant inputs (e.g. feed, water, etc) into the dairy primary production and processing chain.

The microbiological risk profile encompassed the following elements:

- identification and description of microorganisms that may be associated with dairy products including key attributes of each organism and its public health impact (hazard identification/hazard characterisation);
- examination of epidemiological data (domestic and international) related to the consumption of dairy products;
- examination of prevalence and concentration data on potential hazards from products along the entire dairy food chain; and
- description of the dairy production, processing, distribution and consumption chain and current knowledge of the impact of each of these on public health and safety risks.

The **Chemical Risk Profile (Part B)** was undertaken to gather the following information:

1. To identify the chemicals associated with the Australian dairy supply chain which may potentially impact on public health and safety.
2. To assess the potential public health and safety risks associated with these chemicals, in the context of the current regulatory system.

3. To identify any areas in the current regulatory system which require further attention in relation to addressing potential public health and safety risks associated with chemicals in dairy products.

The chemical risk profile identified and examined where chemicals may enter the dairy supply chain from milk production through to retail of dairy produce. It also considered the relevant inputs (e.g. feed, water, etc) into the dairy primary production and processing chain. The chemical risk profile considered the following:

- agricultural and veterinary chemicals used in primary production;
- environmental contaminants, including heavy metals, organic contaminants and micronutrients;
- natural chemicals found in plants, fungi or bacteria associated with plants;
- food processing by-products; and
- food additives, processing aids and those chemicals that may migrate from packaging.

4.2 Key findings of the risk profile

Overall, the scientific assessment of the microbiological and chemical hazards across the dairy chain concluded that the current management practices in place within the Australian dairy industry support the production of dairy products with a high standard of public health and safety. The key findings are outlined below.

4.2.1 Microbiological hazards

The key findings from the Risk Profile in respect to microbiological hazards are:

- Australian dairy products have an excellent reputation for food safety, and this is supported by the lack of evidence attributing food-borne illness to dairy products;
- a wide range of microbiological hazards may be associated with raw milk and dairy products, but these do not represent a problem under current management practices which:
 - control animal health;
 - ensure adherence to good milking practices;
 - require effective heat treatment e.g. pasteurisation; and
 - have controls to prevent post-pasteurisation contamination in the dairy processing environment.

4.2.2 Chemical hazards

The key findings from the Risk Profile in respect to chemical hazards are:

- There are extensive regulatory and non-regulatory measures in place along the dairy industry primary production chain resulting in minimal public health and safety concerns regarding the use or presence of chemicals in dairy products.
- Extensive monitoring of chemical residues in milk over many years has demonstrated a high level of compliance with the regulations.

- Continuation of the current management practices, particularly monitoring programs for chemicals along the primary production chain, will ensure that the dairy industry continues to maintain a high standard of public health and safety.
- There are a number of areas where further research or monitoring of potential chemical hazards would assist in providing further reassurance that the public health and safety risk is low.

4.3 Findings of Part A – The Microbiological Risk Profile

The safety of dairy products relies on the quality of raw materials, correct formulation, effective processing, the prevention of recontamination of product, and maintenance of temperature control during distribution, retail sale and storage of the product in the home.

4.3.1 On-farm milk production and transport

Raw milk has a mixed microflora, which is derived from several sources including the interior of the udder, exterior surfaces of the animals, environment, milk-handling equipment, and personnel. In general, there are two means by which pathogens contaminate raw milk. Contamination may occur when micro-organisms are shed directly into raw milk from the udder as a result of illness or disease, or through contamination from the external surface of the cow and the milking environment. Primary production factors that impact on these routes of contamination and the microbiological quality of the raw milk include:

- animal-related factors e.g. animal health, herd size, age and production status;
- environment-related factors e.g. housing, faeces, feed, soil, and water; or
- milking and operation of milking equipment factors e.g. cleanliness of equipment and lines.

Some of these primary production factors can be managed to reduce the risk of contamination of raw milk by pathogens, while management of others will have limited impact on the final microbiological status of raw milk.

There is relatively little data on the prevalence of pathogens in raw milk in Australia although it is well established that raw milk may be contaminated with pathogenic micro-organisms. The quality of raw milk is dependent on animal health, exposure to faecal contamination, environmental contamination and temperature control.

The key risk factors that may affect the quality of raw milk on-farm are summarised in Table 3.

Table 3: Key risk factors that affect the quality of raw milk

Risk factor	Effect
Animal health	Disease in, sickness of, and carriers in milking animals can increase shedding of pathogens directly into raw milk, or in animal faeces.
Herd size	Herd size may have some effect on the prevalence of some pathogens.
Age/production status	Calves have an increased susceptibility to infection.
Housing	Intensive housing practices may increase risk of contamination of udders.

Risk factor	Effect
Faeces	Faeces may contaminate the udder and may introduce pathogens into raw milk.
Effluent	Effluent can contaminate pasture and the animal.
Feed	Contaminated feed can lead to shedding of pathogens into faeces.
Water-stock drinking	Water sources may be contaminated with cud and/or faecal material
Milking	Poor milking practices <i>i.e.</i> dirty teats; inadequate maintenance, sanitation and cleaning of equipment; and poor personal hygiene can lead to contamination of raw milk.
Water use during milking	Potential source of contamination during washing of teats and cleaning of milking equipment.
Storage	Poor temperature control of milk after milking can lead to growth of pathogens.
Transport	Poor temperature control of milk during transport can lead to growth of pathogens. Poor maintenance, sanitation and cleaning of tankers can lead to contamination of milk.

4.3.2 Milk processing and handling

Following milking, milk is transferred to the dairy processing facility where it subsequently undergoes a series of processes that transform liquid milk into a wide range of dairy products, many of which may be classified as ready-to-eat. The majority of these processes involve a heat-processing stage, typically pasteurisation or an equivalent process. Further steps involve physical processes such as separation, aeration, and homogenisation and product transformation by drying, churning, acidification, etc.

Pasteurisation represents the principal process for rendering dairy products safe for consumption. However, the effectiveness of pasteurisation is dependent upon the microbiological status of the incoming raw milk. Control of risk factors on-farm will minimise the opportunity for microbiological hazards to contaminate raw milk and reduce the likelihood and concentration of these hazards.

A survey of Australian dairy manufacturers determined that all respondents met the minimum time and temperature standards prescribed in the Code for the HTST (high temperature short time) pasteurisation of milk and cream. In many cases, milk was heated to a temperature and/or a time in excess of the prescribed minima. For the majority of dairy products, pasteurisation also represents an initial treatment before specific processes are used to transform raw milk into various manufactured products.

For dairy products containing elevated levels of fat or solids such as ice-cream mixes, cream and yoghurt, a higher time/temperature combination than that currently specified in the Code may be warranted to compensate for the protective effect of fat and solids on the micro-organisms present.

Post-pasteurisation contamination however, is an ongoing management issue for manufacturers in the provision of safe dairy products. Contamination may result from the environment, including equipment, personnel or contamination of finished product with raw materials. Rigorous control over hygiene, cleaning and sanitation, ingredients added subsequent to pasteurisation, product handling and packaging is therefore necessary to ensure safety of the final product post-heat treatment.

As many dairy products do not undergo a further pathogen reduction step prior to consumption, prevention of contamination and control over bacterial growth, storage time and temperature is of particular importance in minimising potential exposure to pathogens. Most liquid milk and cream products have a relatively short shelf-life, especially milk (10-16 days under optimum storage conditions) thus storing dairy products according to manufacturer instructions and following good hygiene and handling practices in the home is also important.

4.3.3 *Safety of dairy products*

In Australia, illness from dairy products is rare. Between 1995 – 2004 there were only eleven reported outbreaks directly attributed to dairy products and eight of these were associated with consumption of unpasteurised milk. In other Australian outbreaks, dairy products were an ingredient of the responsible food vehicle identified as the source of infection. However dairy products are a component of many foods and it is often difficult to attribute the cause of an outbreak to a particular food ingredient. Microbiological survey data for pasteurised dairy products in Australia show a very low prevalence of hazards of public health significance.

While commercial dairy products have rarely been identified as a source of food-borne illness in Australia, there have been a number of reports of outbreaks associated with consumption of dairy products internationally. Overseas data demonstrates that pathogens are frequently isolated from raw milk and raw milk products and unpasteurised dairy products have been the most common cause of these dairy-associated outbreaks of illness. Pathogens are found infrequently in pasteurised milk and pasteurised milk products.

The microbiological risk profile has identified a range of microbiological hazards potentially associated with the Australian dairy supply chain. The majority of these hazards pose little or no threat to public health because under current risk management conditions they are unlikely to be present in high numbers in raw milk, and the pasteurisation step effectively eliminates all but the spore-forming bacteria. This is supported by the lack of food-borne illness attributed to dairy products in Australia.

The factors along the Australian dairy supply chain that have the most significant impact on the safety of processed dairy products are:

- the quality of raw materials;
- correct formulation;
- effective processing (pasteurisation in particular);
- the prevention of recontamination of a product; and
- maintenance of temperature control during distribution, retail sale and storage of the product in the home.

The formulation of dairy products, effective processing, and prevention of recontamination of product all contribute to the level of risk a dairy product poses. Those dairy products which are prone to contamination after final heat treatment and provide a favourable environment for microbial growth, may be categorised as being of higher relative risk to public health and safety than products that do not. The intrinsic properties of the product *i.e.* the impact of water activity, pH, salt concentration, etc., influence pathogen survival and growth as does the storage environment. The relative risk from dairy products, based on intrinsic properties of the product, has been expressed graphically as a continuum in Figure 1.

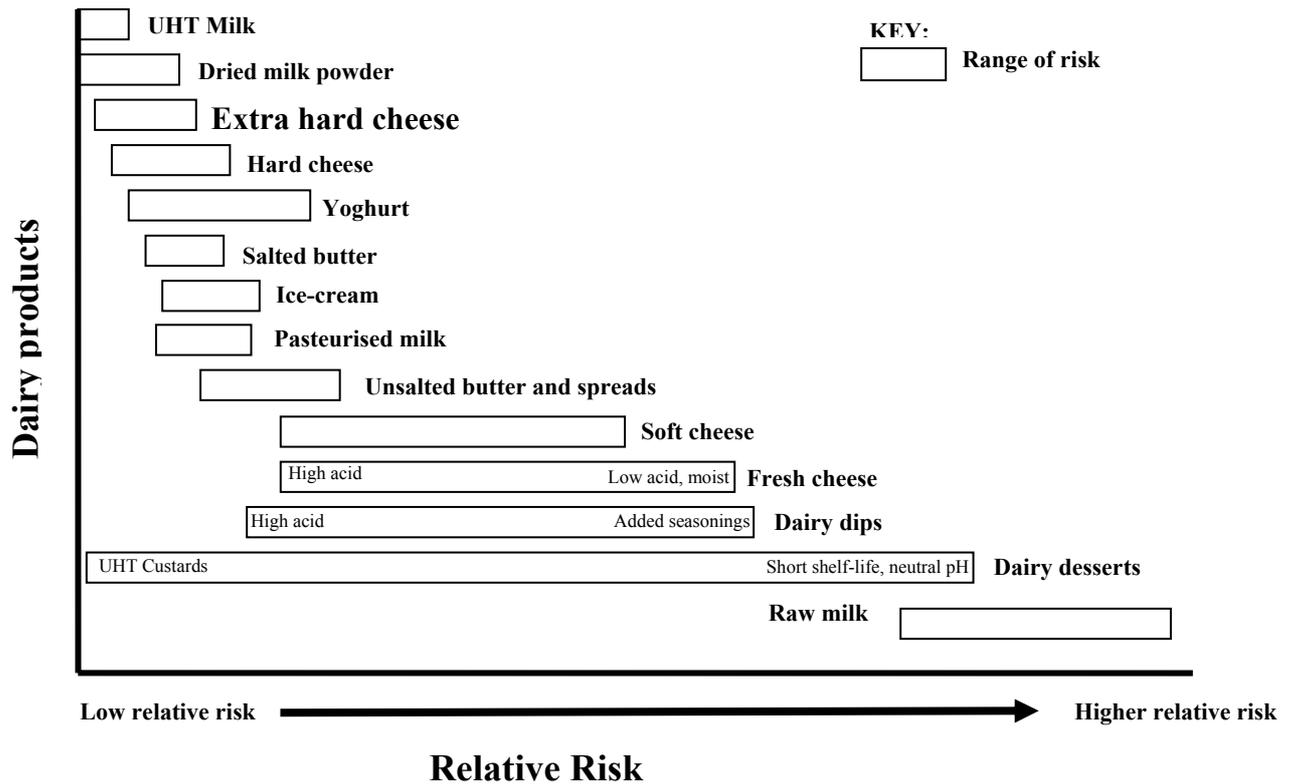


Figure 1: Relative risk of dairy products based on intrinsic properties of the product

4.4 Conclusions from the microbiological risk profile

A wide range of microbiological hazards may be introduced into milk during primary production and processing. Raw milk has a mixed microflora, which is derived from the udder, exterior surfaces of the animals, the environment (including faeces), milk-handling equipment, and personnel. In addition, the milking procedure, subsequent collection, storage of milk and processing milk into various dairy products carry the risks of further contamination or growth of intrinsic pathogens. Importantly, the composition of many milk products makes them good media for the growth of pathogenic microorganisms.

The safety of dairy products is due to the use of heat treatment and a combination of management and control measures along the entire dairy supply chain.

Control of animal health, adherence to good milking practices, and control over milking parlour hygiene have been important in reducing the microbial load in raw milk entering Australian dairy processing facilities.

There have been few reported failures i.e. food-borne illness attributed to dairy products in recent years. While dairy products have been the vehicles in some outbreaks, the cause is often multifactorial involving contaminated non-dairy ingredients, post-process (post-pasteurisation) contamination, and poor hygiene practices.

The almost universal use of pasteurisation in milk processing in Australia has resulted in the marketing of dairy products with an excellent reputation for safety and product quality.

The dairy industry has introduced significant measures to ensure product safety, including the adoption of codes of practice, adherence to *Listeria* and *Salmonella* control protocols, and the extensive use of HACCP-based food safety programs supported by laboratory verification.

Notwithstanding the above, there is need for ongoing vigilance and further development of safety control measures. Over the past twenty years we have seen the emergence of new pathogens and the re-emergence of traditional pathogens in various foods. These organisms often occupy specific environmental niches and may arise through changing technologies, methods of food handling and preparation, dietary habits and population. Post-processing contamination in-plant and the maintenance of control over contamination and storage conditions during transport, retail display and home use remain major factors impacting on the safety of dairy products.

4.5 Findings of Part B – The Chemical Risk Profile

4.5.1 Chemicals used in primary production

Chemicals are used at the primary production stage for a number of purposes, including pest and weed control, animal health and equipment sanitisation. The agricultural chemicals which cattle are exposed to may potentially leave residues. However, of the tests for agricultural chemicals (organophosphates, organochlorines and synthetic pyrethroids) in milk conducted over seven years in the Australian Milk Residue Analysis (AMRA) survey, there were no detections of these chemical residues above the maximum residue limits (MRLs). Additionally, there were no residues found in milk and milk products in the Australian Total Diet Survey (ATDS). The very low incidence of agricultural chemical residues in cattle is supported by the results of the National Residue Surveys.

Veterinary chemicals administered to dairy cattle are mainly antimicrobials and endo- and ectoparasiticides. Other veterinary chemical uses include reproductive therapy use and use of anti-inflammatory drugs or anaesthetics. During the 1998-2005 period of the AMRA surveys, more than 89,000 analyses were carried out for antimicrobials with 99.997% compliance with the MRL.

In order to comply with hygienic production and manufacturing practices, cleaning and sanitising agents are utilised throughout the whole production process to ensure that the products remain free from microbial or physical contamination. Sanitisers have the potential to contaminate milk and dairy products if quality assurance programs fail and residues are left in equipment. The water used on-farm for both agricultural and for cleaning purposes was found to be of high quality and free from chemical contamination.

While there are current regulatory and non-regulatory measures in place for chemicals used in primary production, areas of uncertainty have been identified where further compliance data may be necessary. These include residue data relating to the collection of colostrum for therapeutics manufacture and the off-label usage of veterinary therapeutics for minor species such as goats (discussed in Attachment 2).

4.5.2 Environmental contaminants

Environmental contaminants such as heavy metals and organic chemicals may enter the dairy production chain through stock feed or through the direct consumption of soil. Stock feed is an integral factor in dairy production, which may impinge on the quality of milk produced.

Stock feed contamination may also result from the presence of endogenous plant toxicants or mycotoxins, or environmental chemicals.

Milk is a very small contributor to the overall dietary intake of arsenic, cadmium, mercury and lead and, at the current levels found in milk, there are no public health and safety concerns. Overall, the data suggests that stock feed and soil do not significantly contribute to heavy metal contamination of milk.

The levels of the micronutrients iodine, selenium and zinc in milk have been examined and do not raise any public health and safety concerns. Although in the past (1960s – 1970s), the use of iodophor cleansers increased the levels of iodine in milk, revised use practices for iodophores has reduced the risk of iodine residues in milk. Selenium and zinc supplementation does not significantly change the micronutrient content of milk. Milk is considered to be an important source of these three micronutrients and has a role in preventing deficiencies for these micronutrients in the community.

Dioxins can occur naturally in the environment although the major source is from industrial practices. The major source of dioxin exposure is through the diet. Because of the lipid solubility of dioxins, dairy products can be a significant source of dietary exposure. Although the results of the recent National Dioxin Program indicated that the dietary contribution from dairy products compared to other products was significant, the overall dietary exposure to dioxins was low and did not raise any public health and safety concerns. PCBs are not naturally occurring but are found at low levels in the environment as a result of industrial activity. PCBs have not been detected in milk in the AMRA survey or in the ATDS.

Plant, fungal or bacterial toxins are potential contaminants in stock feed. These include aflatoxin, ochratoxin, trichothecene toxins, zearalenone, fumonisin, cyclopiazonic acid, corynetoxins, pyrrolizidine alkaloids, lupin alkaloids, phomopsins and ergot alkaloids. Of these, only aflatoxin M1 is regularly monitored in milk. While earlier data from the Australian Mycotoxin Data Centre survey showed some milk samples with aflatoxin residues, the more recent surveys have not detected any aflatoxin residues in milk. Further monitoring of stock feed for plant, fungal and bacterial toxins may be necessary to further characterise any potential public health and safety risks.

4.5.3 Chemicals used in processing

At the processing end of the dairy production chain, food additives and processing aids are used in the manufacture of a wide range of dairy products.

Food additives may be added to achieve a technological function, such as preservation or colouring, and are present in the final food, whereas processing aids fulfil a technological function during processing, but are not present in the final food.

The use of food additives and processing aids is regulated by the maximum permitted use levels in the Code. While there have been no recorded violations of the Code regarding the use of food additives or processing aids in dairy products, there is anecdotal evidence of the use of hydrogen peroxide as a preservative to prolong the shelf-life of cream.

4.5.4 Chemicals in dairy produce formed during or as a result of processing

Chemicals can be formed within dairy products due to processing or microbiological activity. Biogenic amines can be produced in cheese under circumstances which encourage decarboxylating activity (a function of the type of bacteria present and storage conditions). There is some data from case studies that indicates that biogenic amines present a potential public health and safety concern for some individuals.

Polycyclic aromatic hydrocarbons (PAH) are by-products of cooking processes and have been found in small quantities in smoked cheeses, although exposure to PAHs through dairy products is considered to be low.

At the end of the production chain, packaging may also lead to the unintentional migration of chemicals from the packaging material into dairy produce. There is a paucity of data on the levels of migration of chemicals from packaging materials into foods in general, although in most cases, the levels are expected to be very low. Because of the high lipid content of dairy products, migration of some plasticizers may be of concern.

4.6 Conclusions from the chemical risk profile

There are extensive regulatory and non-regulatory measures in place to ensure that chemicals used or present in dairy products present a very low public health and safety risk.

The Chemical Risk Profile has identified two major findings. Firstly, the extensive monitoring of chemical residues in milk over many years has demonstrated a high level of compliance with the regulations. Secondly, the regulations and control measures currently in place along the dairy industry primary production chain have resulted in minimal public health and safety concerns regarding the use or presence of chemicals in dairy products.

The Chemical Risk Profile has also identified a number of areas where further research or monitoring would assist in providing further reassurance that the public health and safety risk is low.

Continuation of the current management practices, particularly monitoring programs for chemicals along the primary production chain, will ensure that the dairy industry continues to maintain a high standard of public health and safety.

5. Risk Management

Following the scientific assessment process, FSANZ identifies and analyses the various options available to manage the risks associated with particular primary production and processing activities. This requires a detailed assessment of the level to which food safety risks require some form of regulatory (or other) intervention and of the potential impacts (costs and benefits) on the sector affected. The decision as to what risk management option is proposed takes into account the outcomes of the risk assessment process (*i.e.* the hazards and risks/ where are they most effectively managed) and factors such as economic, social and technical feasibility.

The dairy industry in Australia, through a system of State-based regulation and industry initiatives, practices a high level of food safety. Industry and regulators, however, have recognised a benefit in the development of a single set of national requirements within a single standard. The focus of risk management in this case is on the development of a single set of measures that are common across the jurisdictions and that support the high level of food safety evident in this industry.

5.1 The decision process

The technical feasibility, practicality and cost of any risk management option should be considered against its effectiveness in minimising food-borne risks to the extent required. The risk management decision process as to what regulatory measures should be included in the dairy Standard involves the following stages:

- clearly identifying the steps along the production chain;
- identifying, for those steps, what are the hazards associated with the activities undertaken;
- identifying the controls required to manage those hazards (including whether the hazard requires a control);
- identifying the possible risk management measure that support those controls;
- analysing the costs and benefits, and
- choosing the most appropriate option.

The decision process also involves identifying the extent to which the proposed risk management measures are met by current regulatory (or non-regulatory) requirements for the dairy industry – a gap analysis. This is important in the context of the conclusions of the Risk Profile that found dairy products in Australia have a very high level of safety due primarily to the existing risk management practices in place. In addition, to measure consistency with international standards, a comparison of the proposed risk management measures with measures outlined in the Codex *Code of Hygienic Practice for Milk and Milk Products* has been undertaken.

For the purpose of identifying appropriate risk management options, FSANZ has considered on-farm primary production activities, bulk transport of milk and milk products and processing activities separately.

5.2 Primary production

5.2.1 Steps identified for the on-farm primary production of milk

The on-farm steps identified for the production of milk include:

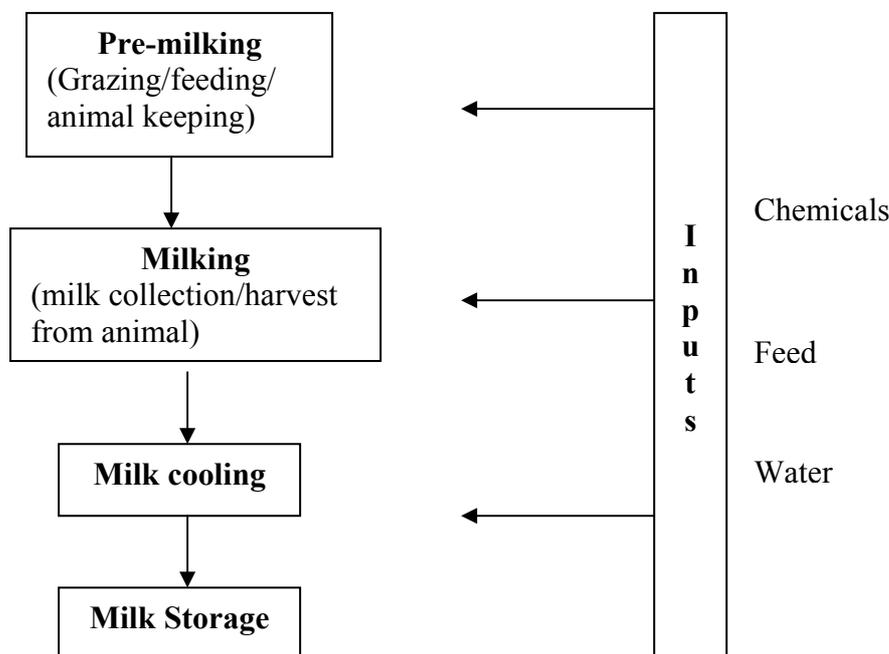


Figure 2: Steps identified for the primary production of milk

As outlined in Figure 2, the inputs identified across the primary production chain that may impact on milk safety and quality include animal feeds (e.g. pasture, grains and concentrates), chemicals (including environmental contaminants, agricultural and veterinary chemicals, cleaners and sanitisers) and water (for drinking and cleaning).

5.2.2 On-farm hazard analysis

The Risk Profile identified the potential hazards, and controls for them, at each of the steps identified in Figure 2. An analysis of these hazards and controls has been undertaken to identify possible requirements that would support the safe production of milk and is provided below in Table 4. In addition to chemicals, feed and water, other inputs to the production process considered in this hazard analysis include the milking animals, personnel, premises and equipment.

5.2.3 Identified controls

The requirements identified in Table 4 to support the safe production of milk on farm include:

- the management of hazards arising from the environment;
- the management of inputs on-farm (feed, water, chemicals) in order to prevent/minimise the contamination of milk;
- the management of animal health to prevent introduction of hazards into the milk, including the requirement to only source milk from animals of an appropriate health status;

- the adequate design, construction, maintenance and operation of premises and equipment to avoid/minimise contamination;
- implementation of appropriate health and hygienic practices of personnel involved in milking activities to avoid/minimise contamination of milk;
- implementation of cleaning and sanitising programs as appropriate;
- control of pests.

In addition, specific temperature control requirements relating to the milk cooling and storage steps have been identified:

Milk cooling: milk should be cooled to 5°C or below in a timely manner to minimise the growth of microorganisms (or in a manner that does not adversely affect the microbiological safety of the milk).

Milk storage: milk should be stored at 5°C or below to prevent the growth of microorganisms (or in a manner that does not adversely affect the microbiological safety of the milk).

Additional measures may be required that do not directly control hazards but may be considered as tools or supporting requirements to enable the food business to control hazards effectively. These measures include:

- having appropriate skills and knowledge (competencies);
- having a product tracing system; and
- having a system for animal identification.

Table 4: Identification of hazards and controls, including possible requirements, for the primary production of milk

Step	INPUTS	Hazards	CONTROL(S)	Requirement(s)
Pre-milking	Feed (including pasture, grains, concentrates, silage)	<p>Contamination of pasture with enteric pathogens from poorly treated effluent</p> <p>Contamination resulting from use of agricultural chemicals on pasture.</p> <p>Annual ryegrass toxicity</p> <p>Aerobic spoilage of silage resulting in increased <i>Bacillus</i> spp, growth of <i>Listeria monocytogenes</i></p> <p>Chemical contamination during manufacture (e.g. polycyclic aromatic hydrocarbons)</p> <p>Contamination of grains and concentrates during storage and transport (<i>Salmonella</i>, <i>E. coli</i>, <i>Campylobacter</i> & <i>B. cereus</i>)</p> <p>Mycotoxin residues</p> <p>Chemical contamination within storage facilities and transport vehicles</p>	<ul style="list-style-type: none"> • Effluent management • Good Agricultural Practice (GAP) – use of registered chemicals according to use instructions, observe withholding periods, store chemicals to prevent any environmental contamination. • Pasture management • Maintain anaerobic environment in silos (proper storage) • vendor declarations • Appropriate storage - construction and maintenance of storage facilities and transport vehicles to minimise contamination • Effective pest control (to minimise contamination of stored feed) • GAP with use of chemicals (including appropriate storage) • Use of fungicides (GAP) • Appropriate storage (keep feeds dry) 	<p>That animal feeds (including pasture) are managed such that they do not result in the contamination of milk.</p> <p>Compliance with Standards 1.4.2 and 1.4.1</p>
Pre-milking	Water (drinking)	<p>Water from wells, bores, dams a potential reservoir for pathogens (including enteropathogenic <i>E. coli</i>, <i>Campylobacter</i>, <i>Salmonella</i>)</p> <p>Chemical contamination from environment / use of agricultural chemicals.</p>	<ul style="list-style-type: none"> • Effluent and environmental management to minimise contamination • Maintaining appropriate water source (e.g. adequate supply and location) • Water treatment as appropriate • GAP with the use of agricultural chemicals. 	<p>That the use of water for milk production activities (including drinking water) should not result in the contamination of milk (water should be suitable for purpose)</p>

Step	INPUTS	Hazards	CONTROL(S)	Requirement(s)
Pre-milking	Agricultural, Veterinary and other chemicals	Contamination of pasture and water sources Treatment of animals resulting in residues in milk	<ul style="list-style-type: none"> • Appropriate storage (to prevent environmental contamination) • Good agricultural and veterinary practices (use of chemicals according to registered use/observance of withholding periods) 	Use of agricultural and veterinary chemicals does not result in the contamination of milk. (Compliance with Standard 1.4.2.)
	The animal	Contamination of milk from zoonoses (<i>Mycobacterium bovis</i> , <i>Brucella spp</i> , <i>Coxiella burnettii</i>) Bacterial contamination of milk resulting from mastitis (particularly infections with <i>Streptococcus agalactiae</i> , <i>S. aureus</i> & <i>Corynebacterium</i>) - spread of mastic infection between animals	<ul style="list-style-type: none"> • Disease elimination and control • Quarantine restrictions (Australia currently free from <i>Mycobacterium bovis</i>, and <i>Brucella abortus</i>). • Milk from animals with mastitis not used for human consumption • Appropriate antibiotic treatment • Culling of chronically infected cows • Good animal husbandry practices (including appropriate stock purchase/contract rearing) 	To implement measures to ensure that milk (for human consumption) is only sourced from animals of appropriate health status.
Milking	The animal	Bacterial contamination of milk resulting from mastitis (particularly infections with <i>Streptococcus agalactiae</i> , <i>Staph. aureus</i> & <i>Corynebacterium</i>) - spread of mastic infection between animals Bacterial contamination of milk as a result of teats/udders being contaminated with soil and faecal material.	<ul style="list-style-type: none"> • Good udder hygiene and treatment, including pre & post milking teat disinfection • Correct use of milking equipment • Monitoring of somatic cell count¹⁴ • washing and drying of teats, (only if visibly dirty). 	To take appropriate measures during the milking operation to prevent contamination from the animal (hygienic milking practice).

¹⁴ An industry program 'Countdown Downunder' has been initiated to help farmers achieve mastitis control and reduce cell counts. Inclusion of maxima cell counts in the buying standards and payment schemes has become widespread in Australia. Cell counts should be below 400 000 cells/ml. Counts below 250 000 cells/ml result in premium milk payments. The core of the Countdown Downunder program is a consistent set of 'best practice' mastitis control and milk quality guidelines.

Step	INPUTS	Hazards	CONTROL(S)	Requirement(s)
Milking	Milking premises	Milking parlour can be a source of contamination (from environment/pests/effluent)	<ul style="list-style-type: none"> • Premises should be situated and designed to minimise contamination <ul style="list-style-type: none"> - layout should minimise opportunities for food contamination - should be designed and constructed to enable appropriate cleaning - should provide for appropriate wastewater disposal/effluent management • Premises should be cleaned to remove soil, faecal material, milk residues etc 	<p>To ensure premises are sited, designed, constructed and maintained to minimise contamination of milk¹⁵.</p> <p>To ensure premises are cleaned to eliminate potential sources of contamination.</p>
	Milking Equipment	<p>Equipment can be a source of bacterial contamination of milk and can cause the spread of mastitis infection¹⁶ from animal to animal.</p> <p>Improper use of equipment can cause teat damage, increasing disease transfer between animals.</p>	<ul style="list-style-type: none"> • Equipment should be suitable for purpose. • Equipment should be well maintained and operated appropriately. • Equipment should be cleaned and sanitised. 	<p>To ensure that milking equipment is designed, maintained and operated to minimise contamination of milk.</p> <p>To ensure equipment is cleaned and sanitised for use.</p>
	Water	Use of contaminated water may result in contamination of equipment and facilities (resulting in contamination of milk)	<ul style="list-style-type: none"> • Maintain adequate and appropriate supply of water • Water treatment (as appropriate) 	That the use of water for milking activities should not result in the contamination of milk (water suitable for purpose)
Milking	Chemicals	Use of chemicals (cleaning/sanitising/agricultural) may result in contamination of milk (through residues left on equipment and facilities or through direct contact)	<ul style="list-style-type: none"> • Appropriate storage • GAP/GMP (use of chemicals according to registered use/observance of withholding periods etc.) 	<p>That the use of chemicals does not result in the contamination of milk.</p> <p>(Compliance with Standard 1.4.2)</p>

¹⁵ There are currently Codes of Practice for dairy premises such as the NSW Code of Practice for Dairy Buildings.

¹⁶ It is estimated that 20-25% of mastitis infection in Australia results from the spread of bacteria through milking equipment.

Step	INPUTS	Hazards	CONTROL(S)	Requirement(s)
	Milking personnel	<p>Infected workers (e.g. suffering from Norovirus, hepatitis, Salmonellosis) can contaminate milk through handling activities.</p> <p>Poor hygiene can lead to contamination of milk through handling activities (particularly with Micrococci and Staphylococci).</p>	<ul style="list-style-type: none"> Workers suffering from food-borne disease should not be allowed to undertake milking activities. Workers should employ good hygienic practices <ul style="list-style-type: none"> - wash and dry hands before milking activities/after going to the toilet etc. 	<p>To implement measures to ensure that milking personnel exercise good hygienic practices.</p> <p>To take measures to prevent persons suffering (or suspected) from food borne illness from undertaking milking activities.</p>
Milk Cooling	Milk cooling equipment/facilities	<p>Use of contaminated equipment may result in contamination of milk.</p> <p>Slow cooling of milk may allow for the growth of bacteria present.</p>	<ul style="list-style-type: none"> Equipment used should be suitable for purpose Equipment should be well maintained and operated appropriately. Equipment should be cleaned and sanitised. Milk should be cooled from 37 °C to 5 °C as quickly as possible (the use of a plate heat exchanger prior to refrigerated storage commonly used). 	<p>To ensure that milking cooling equipment is designed, maintained and operated to minimise contamination of milk.</p> <p>To ensure equipment is cleaned and sanitised for use.</p> <p>That milk is cooled as quickly as possible from the commencement of milking. Current requirement in State legislation is that milk should be cooled within 3.5 hours of the commencement of milking to 5 °C or below (4°C or below in NSW).</p>
	Water	As above for milking	As above for milking	That the use of water for milk cooling activities should not result in the contamination of milk.
Milk cooling	Chemicals	As above for milking	As above for milking	That the use of chemicals does not result in the contamination of milk.
	Personnel	As above for milking	As above for milking	Health and hygiene requirements as above for milking

Step	INPUTS	Hazards	CONTROL(S)	Requirement(s)
Milk storage	Milk storage equipment and facilities	Contamination from milk storage equipment and environment Growth of microorganisms if milk not kept under temperature control (e.g. <i>S. aureus</i>)	<ul style="list-style-type: none"> Storage equipment/facilities should be suitable for purpose (e.g. able to keep milk under refrigeration), sited and maintained to minimise contamination. Equipment/facilities should be cleaned and sanitised. Storage equipment should maintain milk at refrigeration temperatures (5°C or below) 	<p>To ensure that storage equipment/facilities are designed, maintained and operated to minimise contamination of milk.</p> <p>To ensure storage equipment/facilities are cleaned and sanitised for use.</p> <p>That milk is stored under temperature control (5°C or below).</p>
	water	As above for milking	As above for milking	That the use of water for milk storage activities should not result in the contamination of milk.
Milk storage	chemicals	As above for milking	As above for milking	That the use of chemicals does not result in the contamination of milk.
	personnel	As above for milking	As above for milking	Health and hygiene requirements as above for milking

5.3 Collection and transport

Collection and transport refers to the collection and bulk transport of milk from the farm to the processing facility as well as the bulk transport of dairy products between processing facilities (before final processing). A hazard analysis of the collection and transport step is provided in Table 5.

5.3.1 Identified controls

The requirements identified in Table 5 to support the safe collection and transport of bulk dairy products include:

- the adequate design, construction, maintenance of vehicles and equipment to avoid/minimise contamination;
- implementation of cleaning and sanitising programs;
- implementation of appropriate health and hygienic practices for personnel undertaking milk collection and transport activities; and
- the transport of milk at 5 °C or below (or in such a manner) to minimise the growth of micro-organisms.

Additional measures may be required that don't directly control hazards but may be considered as tools or supporting requirements to enable the food business to control hazards effectively. These measures include:

- having appropriate skills and knowledge (competencies);
- having a system for product tracing.

Table 5: Identification of hazards and controls, including possible requirements, for the bulk transport of milk/milk products

Step	INPUTS	Hazards	CONTROL(S)	Requirement(s)
Milk (& milk product) collection and transport	Milk tanker/vessel and collection equipment	Milk tanker/vessel and collection equipment may be a source of contamination. Time-temperature abuse during transport may allow for the growth of micro-organisms.	Equipment and vessel must be suitable for purpose <ul style="list-style-type: none"> - design and construction must enable appropriate cleaning/sanitising - transport vessel should be able to keep milk under temperature control (5°C or below) - transport vessel should not carry other substances that could result in the contamination of milk 	That milk transport/ collection vessels and equipment are designed, constructed and maintained to avoid the introduction of contaminants. That milk transport/ collection equipment is cleaned and sanitised. That milk is transported under temperature control (5°C or below).
	Water	Use of contaminated water may result in contamination of equipment and facilities (resulting in contamination of milk)	<ul style="list-style-type: none"> • Maintain adequate and appropriate supply of water 	That the use of water for milk collection and transport activities should not result in the contamination of milk (water suitable for purpose).
	Chemicals	Use of chemicals (cleaning/sanitising) may result in contamination of milk (through residues left on equipment and facilities or through direct contact)	<ul style="list-style-type: none"> • Appropriate storage • GMP (use of chemicals according to registered use) 	That the use of chemicals for milk collection and transport activities should not result in the contamination of milk.
	Personnel	Poor hygienic practices could result in the contamination of milk. Infected workers (e.g. suffering from a food-borne illness) undertaking activities where they could directly contact milk or equipment.	Transport personnel should employ good hygienic practices. Workers suffering from food-borne disease should not be allowed to undertake activities where they could contaminate milk or equipment.	To implement measures to ensure that personnel exercise good hygienic practices. To take measures to prevent persons suffering (or suspected) from food borne illness from undertaking activities where they may contaminate the milk.

5.4 Dairy processing

5.4.1 Scope

Dairy processing includes the production of:

- packaged milk (including flavoured and modified milks);
- cream;
- cheese;
- cultured and fermented milk products;
- butter/dairy blends;
- dried milk powders;
- concentrated milk products (e.g. evaporated/condensed milks);
- ice cream;
- dairy based deserts;
- dairy based dips;
- casein, whey and other functional derivatives; and
- colostrum

A number of different processing activities may be involved in the production of these products, impacting on product safety.

5.4.2 Hazard analysis

The steps involved in the processing of dairy products depend on the product being manufactured. These steps are described diagrammatically in the Microbiological Risk Profile (Appendix 1 of Attachment 2) for the range of dairy products considered. In general, however, the Microbiological Risk Profile identified pasteurisation as the main control for ensuring the microbiological safety of dairy products with post-pasteurisation contamination being the main concern (the Chemical Risk Profile addressing hazards more generally for processed products).

An analysis of the hazards and controls for processed milk products is provided in Table 6. Dairy processing businesses are already required to comply with the food safety requirements in Standards 3.2.2. and Standard 3.2.3 in Chapter 3 of the Code; specific processing requirements for milk and milk products and cheese in Standard 1.6.2, and general requirements of other standards (e.g. food additives, processing aids, maximum residue limits). Table 6, therefore, also provides a comparison of the controls identified for dairy processing with the measures already specified in the Code.

Table 6: Identification of hazards and controls associated with milk processing, including a comparison with the requirements of the Code

Product	Hazard	Controls	Requirements of the Code
Chilled – liquid milk and cream products	<p>Microbiological , chemical & physical contamination resulting from raw milk (+ ingredients added prior to pasteurisation)</p> <p>Growth of microorganisms (e.g. <i>S. aureus</i>) in raw milk</p>	<ul style="list-style-type: none"> • assurance that milk and ingredients supplied are of appropriate safety and suitability (may include testing) • appropriate storage <ul style="list-style-type: none"> - protected from contamination (storage equipment design/ construction and maintenance) - storage vessels cleaned and sanitised (no residues) - cold storage at 5°C or less • minimise contamination from pre-pasteurisation activities (e.g. separation) 	<p>Controls addressed by:</p> <ul style="list-style-type: none"> • Standard 3.2.2 – Food receipt • Standard 3.2.2 – Food Storage • Standard 3.2.2 – Cleaning, sanitising and maintenance • Standard 3.2.2 – Health and Hygiene requirements • Standard 3.2.3 – Food Premises and Equipment • Standard 3.2.2 – Food processing <p>• Standard 1.4.2 – Maximum Residue Limits</p>
	Survival/re-contamination with microorganisms	<ul style="list-style-type: none"> • pasteurisation <ul style="list-style-type: none"> - design/ construction/ maintenance of equipment - equipment cleaned and sanitised (no residues) - equipment operated effectively 	<p>Controls addressed by:</p> <ul style="list-style-type: none"> • Standard 3.2.2 – Food Processing (includes the requirement to use a ‘known’ process step to achieve the microbiological safety of the food) • Standard 1.6.2 – Processing Requirements • Standard 3.2.2 – Cleaning, sanitising and maintenance • Standard 3.2.3 – Food Premises and Equipment

Product	Hazard	Controls	Requirements of the Code
Chilled – liquid milk and cream products cont.	<p>Post-pasteurisation contamination (equipment and environment)</p> <p>Food handlers</p> <p>Addition of ingredients</p> <p>Packaging</p>	<ul style="list-style-type: none"> • Minimise contamination from the processing environment <ul style="list-style-type: none"> - design /construction /maintenance of establishment - cleaning and sanitising of processing environment (no residues) - pest control - GMP with regard to chemical use • Minimise contamination from equipment <ul style="list-style-type: none"> - design/ construction/ and maintenance of equipment - cleaning and sanitising of equipment • Systems in place to ensure hygiene and health of food handlers does not result in the contamination of food. • Assurances that ingredients supplied are of appropriate safety and suitability (may include testing) • Processing/treatment of ingredients to appropriate safety standard • Minimise contamination from packaging equipment and materials (use appropriate materials) 	<p>Controls addressed by:</p> <p>Standard 3.2.3 – Food Premises and Equipment</p> <p>Standard 3.2.2 – Cleaning, sanitising and maintenance</p> <p>Standard 1.3.3 – Processing Aids</p> <p>Standard 3.2.2 – Health and Hygiene requirements</p> <p>Standard 1.3.1 – Food Additives</p> <p>Standard 3.2.2 – Food receipt</p> <p>Standard 3.2.2 – Food processing</p> <p>Standard 3.2.3 – Food Premises and Equipment</p> <p>Standard 3.2.2 – Cleaning, sanitising and maintenance</p> <p>Standard 3.2.2 – Food packaging</p> <p>Standard 1.3.3 – Processing Aids</p> <p>Standard 1.4.3 – Articles and materials in contact with food.</p>

Product	Hazard	Controls	Requirements of the Code
Chilled – liquid milk and cream products cont.	Growth of microorganisms present	<ul style="list-style-type: none"> • Cooling post-pasteurisation and storage under temperature control (5°C or below) • Transport under temperature control (5°C or below) 	Controls addressed by: <ul style="list-style-type: none"> • Standard 3.2.2 – Food processing • Standard 1.6.2 – Processing Requirements (specifies the shock cooling of milk to 4.5°C) • Standard 3.2.2 – Food Storage • Standard 3.2.2 – Food Transportation
UHT – liquid milk and cream products	Microbiological and chemical contamination resulting from raw milk (+ingredients added)	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
	Growth of microorganisms in raw milk		
	Survival of microorganisms	<ul style="list-style-type: none"> • UHT processing - design/ construction/ maintenance of equipment - equipment cleaned and sanitised (no residues) - equipment operated effectively 	<ul style="list-style-type: none"> • Standard 3.2.2 – Food Processing (use of a ‘known process) • Standard 3.2.2 – Cleaning, sanitising and maintenance • Standard 3.2.3 – Food Premises and Equipment • Standard 1.3.3 – Processing Aids
	Post-process contamination	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
Cheese	Microbiological , chemical & physical contamination resulting from raw milk	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
	Growth of micro-organisms in raw milk		
	Survival of pathogens/re-contamination	<ul style="list-style-type: none"> • Heat treatment As above for chilled milk and cream products	<ul style="list-style-type: none"> • As above (for chilled liquid milk and cream products)
Cheese cont.	Growth of microorganisms during processing	Processing controls (e.g. appropriate starter cultures/monitoring of pH/appropriate time-temperature controls)	Standard 3.2.2 – Food Processing Standard 1.6.1 – Microbiological limits for Food (micro standards for cheeses)
	Post-heat treatment contamination	As above (for chilled liquid milk and cream products)	As above

Product	Hazard	Controls	Requirements of the Code
Cultured and fermented milk products	microbiological , chemical & physical contamination resulting from raw milk growth of micro-organisms in raw milk	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
	(Survival of pathogens/re-contamination)	<ul style="list-style-type: none"> Heat treatment As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
	Growth of microorganisms during processing Post-heat treatment contamination	Processing controls (e.g. appropriate starter cultures/monitoring of pH/appropriate time-temperature controls) As above (for chilled liquid milk and cream products)	Standard 3.2.2 – Food Processing Standard 2.5.3 – Fermented Milk Products specifies that microorganisms used in the fermentation must remain viable (minimum 1×10^6 cfu/g) and a maximum pH of 4.5. As above
Frozen milk products (ice cream)	Microbiological and chemical contamination resulting from raw milk (+ingredients added) Growth of microorganisms in raw milk	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
	Survival/recontamination during pasteurisation post-pasteurisation contamination (equipment and environment)	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
Milk powders	Microbiological and chemical contamination resulting from raw milk (+ingredients added) Growth of microorganisms in raw milk	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)

Product	Hazard	Controls	Requirements of the Code
	Survival of microorganisms /contamination during heating	<ul style="list-style-type: none"> Heat treatments The temperatures used during pre-heating and drying sufficient to destroy vegetative cells. water activity of final product	Standard 3.2.2 – Food Processing Standard 1.6.1 – Processing requirements
	Post- processing contamination	As above for liquid milk products	As above 9 for chilled liquid milk and cream products) Standard 1.6.1 – Microbiological limits for food specifies a micro standard for dried milk
Chilled mixed dairy foods (dairy deserts, dairy based dips)	Microbiological and chemical contamination resulting from raw milk (+ingredients added) Growth of microorganisms in raw milk	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
	Survival/recontamination during pasteurisation Post-pasteurisation contamination (equipment and environment/food handlers/addition of ingredients/packaging)	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)
	Growth of micro-organisms present	As above (for chilled liquid milk and cream products)	As above (for chilled liquid milk and cream products)

5.4.3 *Identified controls*

The comparison undertaken in Table 6 indicates that the requirements of the Code would provide, in general, controls to address all of the hazards identified for milk processing.

The Microbiological Risk Profile found that those dairy products which are prone to contamination after final heat treatment and provide a favourable environment for the growth of pathogens may be categorised as being of higher relative risk to public health and safety than products that do not. Optimum management of this ‘continuum’ of risk is for dairy processing businesses to understand and assess the characteristics of their own products and particular processing conditions. This supports a requirement for dairy processing businesses to systematically examine their operations to identify food safety hazards and implement controls commensurate with the food safety risk (e.g. food safety program). In addition, food businesses would have to comply with the existing regulatory requirements of the Code, in particular those in Chapter 3 – Food Safety Standards. This approach is commensurate with the current State based regulations which require food safety programs for dairy processors.

6. Risk Management Options

There are a number of options available to FSANZ in developing risk management measures for Primary Production and Processing standards. Risk management measures within a standard can range from the ‘prescribe and inspect’ approach of specifying where and how a business must control hazards (and inspecting the business to judge at one-point-in-time whether the business is complying), to ‘self regulate and audit’ where a business determines and implements its own internal control measures in order to fulfil the required food safety outcomes (e.g. through a food safety program). Establishing compliance in this case is through auditing.

The requirements of a Primary Production and Processing standard is not confined to only one of the above approaches but can contain control measures that are a combination of measures. This approach can accommodate measures to control specific activities or products that pose greater risk than others within the industry sector being managed. As discussed previously, additional measures (or tools) that help support control measures can also be included.

In developing Primary Production and Processing standards, the range of options must be consistent with the higher order principles in the Ministerial Guidelines. The measures should:

- be preventative;
- be non prescriptive (the business should have flexibility as to how to comply to achieve the stated outcome); and
- address safety and suitability (not quality).

In the course of developing food regulatory measures, FSANZ is also required to consider the impact of all identified options on all sectors of the community, including consumers, primary producers, the food industry and governments. The parties affected by this Proposal are:

- the Australian dairy industry (dairy farmers, transporters and processors);
- Government (State and Commonwealth); and
- consumers.

In relation to Proposal P296, it has been possible to draw on existing State-based regulations and Codex requirements, in the context of the findings of the Risk Profile, to develop regulatory options.

6.1 Primary production – on-farm

6.1.1 Options

FSANZ must consider different regulatory options including the *status quo*. Based on the controls identified in Section 5.2.3, four options have been identified:

- Option 1. Maintain the *status quo*;
- Option 2. Require the primary production business to implement specific measures to address the identified hazards;
- Option 3. Require the primary production business to implement specific measures to address the identified hazards plus the obligation to verify their compliance and demonstrate this through documentation; or
- Option 4. Require the primary production business to have a documented food safety program. Additionally, this option may include specifying particular measures that the food safety program or business must address.

6.1.2 Impact analysis

As discussed previously, the Australian dairy industry currently has comprehensive State-based regulatory requirements applying at farm level. The impact analysis of risk management options therefore includes a comparison of the identified risk management measures (from Section 5.2.3) with existing regulatory requirements. This analysis, presented in Table 7 also includes a comparison with the measures outlined in the Codex *Code of Hygienic Practice for Milk and Milk Products* (Code of Practice).

The comparison provided in Table 7 shows that the identified risk management measures are consistent with the principles provided in the Codex Code of Practice. Additionally, the gap analysis indicates that no new requirements are needed for the primary production of milk in Australia (there are no residual risks that need to be managed). That is, the risk management measures identified are largely covered by existing State dairy requirements¹⁷ though there are differences in how these are currently mandated (either generically through a provision to have a food safety program or specifically stated). There is, additionally, some variation in the level of prescription contained in State legislation.

This impact analysis qualitatively examines how the identified risk management measures can be applied through the four options listed above and the possible impacts on industry, government and consumers. This process will help identify the option that provides the greatest benefit over existing regulatory arrangements and which would support a regulatory amendment to the Code.

¹⁷ Western Australia has not been included in this analysis - as outlined in Section 2.2.1, WA has been reviewing its legislation to require comprehensive measures on-farm in line with the Code of Practice for Dairy Food Safety. Currently, requirements for milk and dairy produce are specified within the *Health Act 1911* (Division 4 - Milk and dairy produce) which make it an offence to sell contaminated milk (e.g. source from a diseased animal) or to allow persons suffering from an infectious disease to be involved in milking activities.

Table 7: Comparison of Risk Management Measures Identified for the Primary Production of Milk with Control Measures specified by Codex and State Regulations

Risk Management Measure/control	Codex Code of Hygienic Practice for Milk & Milk products	SA/TAS/VIC Code of Practice for Dairy Food Safety	NSW Dairy Food Safety Scheme	QLD Dairy Food Safety Scheme (Food Production Regulation 2002)
That animal feeds (including pasture) are managed such that they do not result in the contamination of milk.	✓ Section 3.2.3.1 Feeding	✓ Section 3.2.2.4 Animal feeds	Not specifically covered though should be addressed through requirement for a Food Safety Program	✓ Clause 61 – Stock food for consumption by animals to be milked
That the use of water for milk production activities (including drinking water) should not result in the contamination of milk (suitable for purpose)	✓ Section 3.1 Environmental hygiene	✓ Section 3.2.2.3 & 3.2.3.2 Environmental Contaminants and Sections 3.2.6	✓ Compliance with the NSW Code of Practice for Dairy buildings, covers having a supply of unpolluted water sufficient for operating needs.	✓ Clause 34 – Water supply
That the use of agricultural/veterinary and other chemicals does not result in the contamination of milk.	✓ Section 3.1 Environmental Hygiene Section 3.2.3.2 Pest Control Section 3.2.3.3 Veterinary Drugs	✓ Section 3.2.2 Chemical Contaminants Section 3.2.1 Cleaning and Sanitising	✓ Clause 8 - Protection of milk and dairy products on premises Clause 9 – protection of milk and dairy products being transported	✓ Clause 62 – Milk supplied must be free of chemical contaminants
To implement measures to ensure that milk (for human consumption) is only sourced from animals of appropriate health status	✓ Section 3.2.2 Animal Health	✓ Section 3.2.3.1 Animal Health	✓ Requirement for HACCP Food Safety Program (Dairy Manual specifies infectious disease/animal treatments must be covered within the FSP/covers EBL)	✓ Clause 60 – Animals to be milked must be free of disease
To take appropriate measures during the milking operation to prevent contamination from the animal.	✓ Section 3.2.4 Hygienic Milking	✓ 3.2.5 Hygienic Milking	Clause 8 – Protection of milk and dairy products on premises (good hygienic practices not explicitly stated)	Clause 63 – prevention of contamination

Risk Management Measure/control	Codex Code of Hygienic Practice for Milk & Milk products	SA/TAS/VIC Code of Practice for Dairy Food Safety	NSW Dairy Food Safety Scheme	QLD Dairy Food Safety Scheme (Food Production Regulation 2002)
To ensure premises are designed, constructed and maintained to minimise contamination of milk.	✓ Section 3.2.1 Areas and Premises for Milk Production Section 3.3.3 Premises for, and Storage of, Milk and Milking-Related Equipment.	✓ Section 3.2.4 Dairy Milking Premises, Storage and Equipment	✓ Clause 12 - Building not to be used as dairy building without licence Clause 14 - Maintenance Compliance with <i>Code of Practice for Dairy Buildings</i>	✓ Clause 66 – Design, construction and maintenance of dairy equipment. Compulsory Standard 3.2.2, Division 5 of the Code.
To ensure that equipment is designed, maintained and operated to minimise contamination of milk.	✓ Section 3.3.1 Milking Equipment Section 3.3.2 Storage Equipment	✓ Section 3.2.4 Dairy Milking Premises, Storage and Equipment	✓ Clause 13 - Equipment in dairy buildings Clause 14 - Maintenance Compliance with <i>Code of Practice for Dairy Buildings</i>	✓ Clause 66 – Design, Construction and maintenance of dairy and equipment Compulsory Standard 3.2.2, Division 5
To ensure premises are cleaned to eliminate potential sources of contamination.	✓ Section 3.2.1 Areas and Premises for Milk Production (covered by ‘maintained’)	✓ Section 3.2.7 Cleaning and Sanitising	✓ Clause 14 - Maintenance Compliance with <i>Code of Practice for Dairy Buildings</i>	✓ Clause 66 – Design, Construction and Maintenance of dairy equipment
To ensure equipment is cleaned and sanitised for use.	✓ Section 3.3.1 Milking Equipment (covered by ‘maintained’)	✓ Section 3.2.7 Cleaning and Sanitising	✓ Clause 14 - Maintenance Compliance with <i>Code of Practice for Dairy Buildings</i>	✓ Clause 66 – Design, Construction and Maintenance of dairy equipment (Compulsory Standard 3.2.2, Division 5, Cleaning, Sanitising & Maintenance)
To implement measures to ensure that milking personnel exercise good hygienic practices.	✓ Section 3.2.4 Hygienic Milking	✓ Section 3.2.5 Hygienic Milking	Clause 8 - Protection of milk and dairy products on premises (does not specifically refer to hygienic practices)	✓ Clause 65 – Health and hygiene requirements

Risk Management Measure/control	Codex Code of Hygienic Practice for Milk & Milk products	SA/TAS/VIC Code of Practice for Dairy Food Safety	NSW Dairy Food Safety Scheme	QLD Dairy Food Safety Scheme (Food Production Regulation 2002)
To take measures to prevent persons suffering (or suspected) from food borne illness from undertaking milking activities.	not specifically covered (hygiene covered generally under Section 3.2. 4 Hygienic milking) Annex 1 provides additional guidance for production of milk for raw milk products)	✓ Section 3.2.5 Hygienic Milking	✓ Dairy Manual specifies that milkers on farm must not milk cows whilst affected by an infectious disease (to be addressed in Food Safety Program)	✓ Clause 65 – Health and hygiene requirements (Compulsory Standard 3.2.2 Food Safety Practices and General Requirements, Divisions 3 and 4).
That milk is cooled as quickly as possible from the commencement of milking.	not specifically stated. Section 3.3 Handling, Storage and Transport of Milk notes that temperature abuse increases the microbiological load.	✓ Section 3.3 Standards – specifically states that milk must be cooled to 5°C within 3.5 hours of the commencement of milking.	✓ Dairy Food Safety Scheme– Clause 15 Cooling or packaging of milk. Specifically states that milk must be cooled to 4°C within 3.5 hours of the commencement of milking (or processed or packaged).	not specifically covered – reference to Australian Standard 1187 – Farm Milk Cooling and Storage
That milk is stored under temperature control at 5°C or below.	✓ Section 3.3 Handling, Storage and Transport of Milk Section 3.3.2 Storage Equipment (should minimise the growth of microorganisms)	✓ Section 3.3 Standards – states that milk should be kept at or below 5°C.	✓ Clause 15 – Cooling or packaging of milk (milk must be kept at 4 °C or less)	✓ Clause 64 – temperature control for stored milk (Advisory Standard, AS 1187- Farm Milk Cooling and Storage)

6.1.2.1 Option 1 – *status quo*

Maintaining the *status quo* means that existing State-based regulations (outlined under Section 2.2.1) and industry incentives would continue to be the primary risk management measures to address food safety issues on-farm. That is, there would be no nationally consistent regulatory framework (e.g. a Primary Production and Processing Standard) for dairy primary production.

Regulatory impact - industry

Dairy farmers in South Australia, Tasmania, Victoria, New South Wales and Queensland are currently required by State legislation to have food safety programs. The particular measures that these food safety programs must address, as well as the inclusion of specific prescriptive requirements, though similar, do differ across jurisdictions. While individual farmers do not have to operate across States, many dairy processors do. The arrangements they have with their milk suppliers must take into account and reflect regulatory requirements. This means that an industry operating across States may need to develop various arrangements according to the jurisdiction in which they trade. This may include a duplication of audit costs for those export businesses complying with both domestic and export requirements.

Maintaining the *status quo* provides no benefit to industry. Having inconsistent regulatory requirements across jurisdictions prevents the reduction of existing costs (e.g. being able to streamline arrangements across States) and potentially provides for an un-level playing field (e.g. dairy farmers in one jurisdiction having to comply with different requirements to a farmer operating in another State). In effect, maintaining the status quo may be viewed as supporting a cost to industry (an opportunity cost).

Regulatory impact – government

Option 1 poses no cost or benefit to State dairy regulators – enforcement agencies would continue to operate according to existing requirements.

Regulatory impact – consumers

Dairy products in Australia have a high level of safety. Maintaining the status quo and the existing regulatory arrangements would continue to support this level of safety. In terms of public health and safety, there would be no cost to consumers in maintaining the status quo. Equally, no benefits would be provided. The impact of option 1 on consumers is neutral.

Conclusion

Option 1 – maintaining the status quo is largely cost/ benefit neutral. None of the identified parties would benefit from Option 1, nor would it impose any costs. However, maintaining the current State-based regulatory framework may prevent any reduction in industry operating costs that could be achieved through having nationally consistent requirements.

6.1.2.2 Option 2 – require the primary production business to implement specific measures to address the identified hazards

Option 2 means the development of a national standard that requires primary production businesses (dairy farms) to comply with specific measures that have been identified as addressing the food safety hazards associated with the production of milk. Option 2 may be considered an outcome-based ‘prescribe and inspect’ regulatory approach. For example a specific control may be prescribed for the storage of milk such that ‘a dairy primary production business must store milk under temperature control’. Checking compliance with this requirement would be through inspection of premises and operations.

In summary, option 2 means:

- Measures at particular steps are specified such that the business does not have to decide where to implement controls. Industry guides and codes of practice can play an essential role in advising ways businesses can meet the measures, for example, alternative control measures that meet the outcomes (the requirements in the Standard).
- Compliance is checked by inspection of premises and operations taking place at the time of the enforcement agency visit - a snapshot at that particular point in time. Compliance cannot be checked through an audit process because there is no requirement for the business to record its actions or have a ‘system’ for managing food safety which identifies hazards, implements controls and has measures to deal with non conforming product (i.e. a documented food safety program).
- The onus of proof in demonstrating non-compliance with a requirement is on the enforcement agency i.e. the enforcement agency must demonstrate that a business is not complying for it to be an offence. The business does not have to prove or demonstrate that it is complying.

Regulatory impact – industry

The current State-based requirements for dairy farms to have food safety programs means that the primary production business must be familiar with its own production practices and how these may impact on milk safety and suitability. Option 2 takes away this requirement by simply prescribing the controls that need to be met without requiring the business to understand why (i.e. to analyse their own operations). This may assist businesses with limited resources, however it takes away the measures that have been implemented in recent years (e.g. requirement for food safety programs) that have supported an ongoing improvement in milk quality in Australia. Industry developed HACCP- based quality assurance programs for dairy farms and payment incentive schemes, whereby premium prices are provided for milk of higher quality (measured by cell count), provide further support for current measures (food safety programs). Option 2 provides no benefit to industry.

Regulatory impact – government

Option 2 would require dairy regulators to move from an audit to an inspection based compliance system. While audits are a more costly exercise in terms of resources required to go through the business operations and the records required to be maintained, they provide greater assurance that the primary production business is meeting its food safety requirements over time.

This increased level of assurance that the business is complying with food safety measures decreases the risk of product failure, and any resulting food safety incident, and provides a greater benefit to government than the inspection model. Option 2 therefore, provides no benefits to government and may impose a cost in terms of decreasing the level of safety assurance provided by existing audit requirements.

Regulatory impact – consumers

Option 2 would probably provide no costs or benefit to consumers (the dairy industry would ensure the continued supply of safe dairy products).

Conclusion

Option 2 may provide decreased compliance and enforcement costs (no audit required), however any savings could be offset by the potential reduction in the assurance of dairy safety and quality that is currently achieved through existing measures. Option 2 provides no overall benefit to any parties.

6.1.2.3 Option 3 – require the primary production business to implement specific measures to address the identified hazards plus the obligation to verify their compliance and demonstrate this through documentation

Option 3, like Option 2, means the development of a national standard that requires primary production businesses (dairy farms) to comply with specific controls that have been identified as addressing the food safety hazards associated with the production of milk. In addition, however, it would require the business to monitor those measures (or controls) to verify that were achieving the outcome required, and keep a record of the results of the monitoring. For example in addition to prescribing a requirement for the storage of milk such that ‘a dairy primary production business must store milk under temperature control’, the business may also be required to monitor the temperature of stored milk and maintain a record of the temperatures and the corrective action taken in the event that the product is found not to be under temperature control. In summary Option 3 means:

- Measures at specific steps are specified such that businesses do not have to decide which control measures are so important that they must be monitored and records kept. However, this does not require businesses to be involved in identifying the hazards in their business and deciding controls themselves.
- The business is obliged to have an on-going interest in food safety because records have to be maintained. This promotes a more proactive approach to food safety than Option 2, however may not provide a better understanding of food safety by the business.
- Industry guides and codes of practice may play a more important role than for Option 2 as they should advise on types/frequency of monitoring, records to be kept and appropriate corrective actions in addition to providing advice on control measures.
- Monitoring and corrective action records can be used to demonstrate compliance in the past (not just at the time of inspection) and provide greater assurance that the business is operating in accordance with the standard.

Regulatory impact – industry

As for Option 2, Option 3 takes away the existing requirement (achieved through food safety programs) for dairy farm businesses to analyse their own production practices and systems by simply prescribing the controls that need to be met without requiring the business to understand why. The requirement for record keeping, to verify their compliance with these controls, means that the business would need to document how corrective actions were implemented when controls were not met and would promote a greater interest and awareness of food safety issues. While this provides greater benefit than Option 2, it is still a reduction in the requirements that currently exist and which have supported an increase in milk quality in recent years. Option 3 would support the safe production of milk but would provide no real benefit over existing measures.

Regulatory impact – government

Option 3 should provide a greater level of assurance to enforcement agencies that the business is complying with food safety measures than Option 2 because of the record keeping requirements. Option 3 is a move away from the inspection model towards audit but still doesn't require an analysis of the businesses own operations and the addressing of hazards specific to it. While Option 3 provides greater benefit than Option 2, it does not provide a benefit to government over existing measures.

Regulatory impact – consumers

Option 2 provides no costs or benefits to consumers.

Conclusion

Option 3 provides greater assurance over milk quality and safety than Option 2, but not over existing measures. Option 3 provides no overall benefit.

6.1.2.4 Option 4 – require the primary production business to have a documented food safety program

Option 4 means the development of a national standard that requires a dairy primary production business to develop and implement a food safety program. In addition, specific control measures (identified in Section 5.2.3) that must be addressed by the food safety program could be specified in the standard. Option 4 means:

- Businesses are obliged to consider food safety as a day-to-day part of their business rather than a reaction to an inspection. This proactive approach to safety should result in a consistently safer product through a better understanding of managing food safety hazards.
- Compliance is based on verifying through an audit that the business is complying with the food safety program. There may be an initial assessment of the program to ensure it is adequate including an on site assessment, by the regulator, prior to the system being implemented by the business. Assurance through audit that a business is complying with its food safety program provides greater confidence that safe food is being produced compared with one point in time inspection and end point testing.

- The general (non prescriptive) nature of the requirement makes it essential that there is nationally applicable guidance to ensure consistent interpretation and application. This may include guidance on documentation required. It could also be supported by a nationally recognised system of validation.

Regulatory impact – industry

Existing State-based requirements already require dairy primary producers to have documented food safety programs that must address specified controls. Option 4, therefore would not impose increased requirements (therefore costs) over existing requirements. The identified controls that additionally could be included in a Standard are also comparable with existing State requirements (as outlined in Table 7), noting that there is variation across jurisdictions in how these are expressed in regulation, including the level of prescription.

Providing consistent regulatory requirements across jurisdictions provides a more level playing field for primary producers and allows industry to rationalise arrangements across the States in which they trade. Option 4 represents a consolidation of existing regulatory requirements into a single national standard, based on scientific assessment and with a minimum of prescription. The controls that would be specifically identified in the standard are also consistent with the Codex Code of Practice and, therefore, internationally recognised. Option 4 would provide a greater benefit to industry over existing State-based requirements.

Regulatory impact – government

Option 4 presents no new enforcement costs to government over existing measures. Food safety programs on farm are not currently mandated in Western Australia, however this jurisdiction has been moving towards implementing this measure and therefore any additional enforcement costs posed by audit requirements should already be planned for. The development of a single set of national requirements is consistent with the principles of the Council of Australian Governments (COAG) and supports the recommendations of the COAG Senior Officials Working Group on Food Regulation (SOWG). To this effect, Option 4 provides a benefit to government.

Regulatory impact – consumers

Option 4 provides no costs or benefits to consumers over existing requirements (the high quality and safety of dairy products in Australia would be maintained).

Conclusion

Option 4 reflects industry practices, consolidates existing State-based regulatory requirements and does not impose additional costs for implementation. This option provides an overall benefit to both industry and government compared to existing State-based measures. It is cost neutral for consumers.

6.1.3 Preferred option

Option 4 is the preferred option as it provides the greatest benefit to industry and government compared to the other options (the impact on consumers of all options deemed to be cost neutral).

This option means that the standard for the dairy sector will require dairy farmers (i.e. milk primary production businesses) to have food safety programs and will specify the controls that must be included to address food safety. In summary the regulatory requirements would be:

- the implementation of a food safety program;
- the management of inputs on-farm (feed, water, chemicals) in order to prevent/minimise the contamination of milk.
- the adequate design, construction, maintenance and operation of premises and equipment to avoid/minimise contamination.
- the implementation of appropriate health and hygienic practices of personnel involved in milking activities to avoid/minimise contamination of milk.
- the management of animal health to prevent introduction of hazards into the milk, including the requirement to only source milk from animals of an appropriate health status.
- the implementation of cleaning and sanitising programs as appropriate.
- the control of pests.
- the cooling of milk in a manner to minimise the growth of micro-organisms.
- the storage of milk in a manner to prevent the growth of micro-organisms.
- having appropriate skills and knowledge (competencies) for the tasks undertaken.
- having a product tracing system.
- having a system for animal identification.

These requirements essentially consolidate existing regulatory measures into a single set of preventative, outcome-based national requirements that support the safe production of milk.

6.2 Primary production – bulk transport of milk and dairy products

6.2.1 Options

As for on-farm primary production, four options have been identified for businesses involved in the bulk transport of milk and dairy products:

- Option 1. maintain the *status quo*
- Option 2. require the transport business to implement specific measures to address the identified hazards;
- Option 3. require the transport business to implement specific measures to address the identified hazards plus the obligation to verify their compliance and demonstrate this through documentation;
- Option 4. require the transport business to have a documented food safety program. Additionally, this option may include specifying particular measures that the food safety program must address.

6.2.2 Impact analysis

Existing regulatory requirements applying to the primary production of milk also cover the bulk transport of milk from farm to processor and bulk transport of dairy products between processing facilities. As for dairy farms, these transport businesses are also required, under State legislation, to have food safety programs.

A comparison of the identified risk management measures (from Section 5.3.1) with existing regulatory requirements and the control measures recommended in the Codex Code of Practice is provided below in Table 8. This comparison shows that the identified measures are largely covered by existing State-based dairy requirements and are consistent with Codex (no new requirements have been identified).

This impact analysis qualitatively examines how the identified risk management measures could be applied through the four options listed above and the possible impacts on industry, government and consumers. This process will help identify the option that provides the greatest benefit over existing regulatory arrangements and which would support a regulatory amendment to the Code.

6.2.2.1 Option 1 – *status quo*

Maintaining the *status quo* means that existing State-based regulations and industry requirements would continue to be the primary risk management measures to address food safety issues applying to milk collection and bulk transport. There would be no nationally consistent regulatory framework (e.g. a Primary Production and Processing Standard) to cover this step.

Regulatory impact – industry

As discussed for on-farm primary production, maintaining the *status quo* provides no cost or benefit to industry. Having inconsistent regulatory requirements across jurisdictions, however, possibly prevents the reduction of existing costs (e.g. being able to rationalise arrangements across States) particularly relevant to bulk transporters who operate across State borders. In effect, maintaining the *status quo* may be viewed as supporting a cost to industry (an opportunity cost).

Regulatory impact – government

Option 1 poses no cost or benefit to State dairy regulators – enforcement agencies would continue to operate according to existing requirements. The *status quo* could be considered cost neutral.

Regulatory impact – consumers

Option 1 would provide no cost or benefit to consumers.

Conclusion

Option 1 – maintaining the *status quo* is largely cost/ benefit neutral. However, maintaining the current State-based regulatory framework may prevent any reduction in industry operating costs that could be achieved through having nationally consistent requirements.

Table 8: Comparison of Risk Management Measures Identified for the Bulk Transport of Milk and Dairy Products with Control Measures specified by Codex and State Regulations

Risk Management Measure/Control	Codex Code of Hygienic Practice for Milk & Milk products	SA/TAS/VIC Code of Practice for Dairy Food Safety	NSW Dairy Food Safety Scheme	QLD Dairy Food Safety Scheme (Food Production Regulation 2002)
That milk transport/ collection vessels and equipment are designed, constructed and maintained to avoid the introduction of contaminants.	✓ Section 3.3.4 Collection, Transport and Delivery Procedures and Equipment	✓ Section 4.2.1 Delivery and Collection Section 4.2.2 Transport vehicles, Equipment and Vessels	✓ Clause 17 – Milk collection Clause 9 – protection of milk and dairy products being transported Division 4 – Requirements for milk transport	✓ Clause 33 – Transporting primary produce
That milk transport/ collection equipment is cleaned and sanitised	✓ Section 3.3.4 Collection, Transport and Delivery Procedures and Equipment	✓ Section 4.2.4 Cleaning and Sanitising	✓ Clause 17 – Milk collection Compliance with <i>Code of Practice for Collection of milk from Dairy Farms</i> . Division 4 – Requirements for milk transport	✓ Clause 33 – Transporting primary produce (Compulsory Standard 3.2.2, Division 5, Cleaning, Sanitising and Maintenance).
That milk is transported under temperature control.	✓ though not explicitly stated. Section 3.3.4 states milk should be collected, transported and delivered without undue delay (minimising the growth of microorganisms).	✓ Section 4.2.1 Delivery and Collection Section 4.3 Standards – milk must be collected at a temperature not exceeding 5°C and kept at or below this temperature.	✓ Clause 17 – Milk collection Compliance with <i>Code of Practice for Collection of milk from Dairy Farms</i> (milk should not be collected if temperature > 4°C).	✓ Clause 33 – Transporting primary produce (no temperature specified) - produce must be maintained under conditions that ensure the produce is acceptable (must include time & temperature controls to prevent, reduce or control pathogenic growth)

6.2.2.2 Option 2 – require the transport business to implement specific measures to address the identified hazards

Option 2 means the development of a national standard that requires bulk dairy transport businesses to comply with specific controls that have been identified as addressing the food safety hazards associated with this step. As discussed above under Section 6.1.2.2, checking compliance with these requirements would be through inspection of the vehicle and operations (a snap-shot in time).

Regulatory impact – industry

The current State-based requirements for dairy transport businesses to have food safety programs means that the business must be familiar with its own practices and how these may impact on milk safety and suitability. Option 2 takes away this requirement by simply prescribing the controls that need to be met without requiring the business to understand why (i.e. to analyse their own operations). As the bulk transport of milk and milk products only has to address a limited number of hazards (relating to contamination from the vehicle and equipment and temperature control) this may not be a significant concern. Industry, however, would still require HACCP based quality assurance programs to be in place. Option 2, therefore, does not provide any benefits over existing measures.

Regulatory impact – government

Option 2 would require dairy regulators to move from an audit to an inspection based compliance system. As discussed above for on-farm primary production, this decreases the level of assurance that the transport business is complying with food safety measures over time. Option 2 therefore, provides no benefits to government and may impose a cost in terms of decreasing the level of safety assurance provided by existing audit requirements.

Regulatory impact – consumers

Option 2 provides no costs or benefits to consumers.

Conclusion

Option 2 provides no overall benefit to any parties.

6.2.2.3 Option 3 – require the transport business to implement specific measures to address the identified hazards plus the obligation to verify their compliance and demonstrate this through documentation

Option 3, like Option 2, means the development of a national standard that requires transport businesses to comply with specific controls that have been identified as addressing the food safety hazards associated with the collection and transport of milk and milk products. In addition, however, it would require the business to monitor those measures (or controls) to verify that were achieving the outcome required, and keep a record of the results of the monitoring. Further discussion on Option 3 is provided above under Section 6.1.2.3.

Regulatory impact – industry

As for Option 2, Option 3 takes away the existing requirement (achieved through food safety programs) for transport businesses to analyse their own practices and systems by simply prescribing the controls that need to be met without requiring the business to understand why. The requirement for record keeping, to verify their compliance with these controls, means that the business would need to document how corrective actions were implemented when controls were not met and would promote a greater interest and awareness of food safety issues. While this provides greater benefit than Option 2, it is still a reduction in the requirements that currently exist and which have supported an increase in milk quality in recent years. Option 3 would support the safe collection and transport of bulk milk but would provide no real benefit over existing measures.

Regulatory impact – government

Option 3 should provide a greater level of assurance to enforcement agencies that the transport business is complying with food safety measures than Option 2 because of the record keeping requirements. Option 3 is a move away from the inspection model towards audit but still doesn't require an analysis of the businesses own operations. While Option 3 provides greater benefit than Option 2, it does not provide a benefit to government over existing measures.

Regulatory impact – consumers

Option 3 provides no costs or benefits to consumers.

Conclusion

Option 3 provides greater assurance over milk quality and safety than Option 2, but not over existing measures.

6.2.2.4 Option 4 – require the transport business to have a documented food safety program

Option 4 means the development of a national standard that requires a milk transport business to develop and implement a food safety program. In addition, specific control measures (identified in Section 5.3.1) that must be addressed by the food safety program could be specified in the standard. Further discussion on Option 4 is provided above in Section 6.1.2.4.

Regulatory impact – industry

Existing State-based requirements already require bulk dairy transport businesses to have documented food safety programs that must address specified controls. Option 4, therefore would not impose increased requirements (therefore costs) over existing regulations. The identified controls that additionally could be included in a Standard are also comparable with existing State requirements (as outlined in Table 7). Providing consistent regulatory requirements across jurisdictions allows industry to rationalise arrangements across the States in which they trade. Option 4 represents a consolidation of existing regulatory requirements into a single national standard, based on scientific assessment and with a minimum of prescription. This would provide a greater benefit to industry over existing State-based requirements.

Regulatory impact – government

Option 4 presents the same enforcement costs to government as existing measures. The development of a single set of national requirements is consistent with the principles of the Council of Australian Governments (COAG) and supports the recommendations of the COAG Senior Officials Working Group on Food Regulation (SOWG). To this effect, Option 4 provides a benefit to government.

Regulatory impact – consumers

Option 4 provides no costs or benefits to consumers over existing requirements (the high quality and safety of dairy products in Australia would be maintained).

Conclusion

Option 4 potentially provides a benefit to both industry and government compared to existing State-based measures. It is cost neutral for consumers.

6.2.3 Preferred option

Option 4 is the preferred option as it provides the greatest benefit to industry and government compared to the other options (the impact on consumers of all options deemed to be cost neutral). This option means that the PPP standard for the dairy sector will require transport businesses (milk collection and bulk transport to processors and between processing facilities) to have food safety programs and will specify the controls that must be included to address food safety. In summary the regulatory requirements would be:

- the implementation of a food safety program;
- the adequate design, construction, maintenance of vehicles and equipment to avoid/minimise contamination.
- the implementation of appropriate health and hygienic practices of personnel involved in collection and transport activities where there is potential to contaminate the dairy product.
- the implementation of cleaning and sanitising programs.
- the transport of milk at 5°C or below (or in such a manner) to minimise the growth of micro-organisms.
- having appropriate skills and knowledge (competencies) for the tasks undertaken.
- having a system for product tracing.

These requirements essentially consolidate existing regulatory measures into a single set of preventative, outcome-based national requirements that support the safe production of milk and milk products.

6.3 Dairy processing

6.3.1 Options

Based on the risk management measures identified in Section 5.4.3, three options have been identified for dairy processing businesses, including the *status quo*:

- Option 1: maintain the *status quo*;
- Option 2: require the processing business to demonstrate their compliance with existing regulatory requirements through record keeping/documentation; or
- Option 3: require the processing business to have a documented food safety program.

6.3.2 *Impact analysis*

This impact analysis qualitatively examines the possible impacts on industry, government and consumers of the three options listed above. This process will help identify the option that provides the greatest benefit over existing regulatory arrangements and which would support a regulatory amendment to the Code.

6.3.2.1 Option 1 – *status quo*

Dairy processing businesses are already required to comply with the food safety requirements in Standards 3.2.2 and Standard 3.2.3 in Chapter 3 of the Code, specific processing requirements for milk and milk products and cheese in Standard 1.6.2, and general requirements of other standards (e.g. food additives, processing aids, maximum residue limits). In addition State-based regulations require processing business to have food safety programs, including specific controls that must be addressed. In the case of establishments registered for export, they must comply with the *AQIS Export Control (Milk and Milk Products) Orders 2005* which require a HACCP plan and compliance with country export requirements. The *status quo* means that the current framework of State-based regulations and export standards would continue.

Regulatory impact – industry

While State-based regulations specify similar requirements, there are variations in how these are expressed in regulation, including the level of prescription. For processing businesses operating in more than one State, maintaining inconsistent regulatory requirements across jurisdictions may prevent the reduction of existing costs (e.g. being able to streamline arrangements across States) and potentially imposes an opportunity cost. This is further exacerbated for processing establishments that are registered for export in that they may need to maintain systems for both the export and domestic markets, including the varying requirements of the State in which their plant operates. The status quo maintains a cost to industry.

Regulatory impact – government

Option 1 does not pose any costs to regulators as enforcement agencies would continue to operate according to existing requirements. Nor would it provide any benefits. This is particularly the case in light of recent reviews such as the Food Regulation Review (1998) and the National Competition Policy (NCP) Review of the *Export Control Act 1982*, which support the implementation of an integrated national food regulatory system, including the harmonisation of domestic and export standards, to minimise costs.

Regulatory impact – consumers

There are no perceived costs or benefits to consumers in maintaining Option 1.

Conclusion

Option 1 – maintaining the status quo may present an overall cost to industry and does not support government policy. Maintaining the current State-based regulatory framework may prevent any reduction in industry operating and compliance costs that could be achieved through having nationally consistent requirements.

6.3.2.2 Option 2 – require the processing business to demonstrate their compliance with existing regulatory requirements through record keeping/documentation

As discussed previously, dairy processing businesses are already required to comply with the food safety requirements in Standard 3.2.2. and Standard 3.2.3 in Chapter 3 of the Code. Option 2 means the development of a national standard that requires dairy processing business to demonstrate this compliance through maintaining appropriate documentation/record keeping. It does not require the business to demonstrate it has systematically identified the hazards specific to their operations (as required for the development of a food safety program) and presents a less pro-active approach to achieving food safety as the process control requirements needed to be addressed are already provided.

Regulatory impact – industry

Option 2 takes away the existing requirement (achieved through food safety programs or HACCP plans) for processing businesses to demonstrate they have systematically analysed their own processing practices and systems to identify specific hazards and controls of the food business. This provides no benefit to processing establishments wishing to export as they are required to have a HACCP plan (not met by Option 2) and could support a duplication of compliance costs (one system required for domestic production, another for export). There is no benefit in removing the requirement for businesses to demonstrate they have systematically examined their processing operations and, therefore proactively managed their food safety issues.

Apart from providing nationally consistent regulatory requirements, Option 2 provides no benefit over the requirement for food safety programs/HACCP plans that currently support the production of safe, high quality dairy products in Australia.

Regulatory impact – government

Option 2 does provide consistent national requirements for dairy processing, though these would be different to those required under the Export Control Orders. In this regard, Option 2 may prevent the harmonisation of any audit or inspection arrangements for domestic and export standards. Option 2 provides no benefit over existing requirements.

Regulatory impact – consumers

Option 2 would support the continued safe production of dairy products in Australia. There would be no costs or benefits of this option to consumers.

Conclusion

Option 2 provides no overall benefit to any party and possibly imposes additional compliance costs for industry.

6.3.2.3 Option 3 – require the processing business to have a documented food safety program

Option 3 means the development of a national standard that requires a dairy processing business to develop and implement a documented food safety program. This reflects current State-based requirements and supports export requirements for a HACCP system. Other measures relevant to the processing of dairy products, such as the processing requirements currently specified in Standard 1.6.2 of the Code or traceability requirements, could also be specified within the PPP standard.

Regulatory impact – industry

As discussed, existing State-based requirements already require dairy processing businesses to have documented food safety programs. Option 3 would provide a nationally consistent requirement for a documented food safety program and compliments the requirements of exporting businesses for a HACCP plan under the Export Control Orders. This should allow for industry to rationalise operations and systems across jurisdictions and between domestic and export requirements. This could reduce operational and compliance costs and facilitate trade, providing a considerable benefit to industry.

Regulatory impact – government

Option 3 poses no new costs to government. The development of a nationally consistent regulation for dairy processing businesses potentially provides for the increased harmonisation of any enforcement/compliance arrangements for domestic and export requirements. Additionally, Option 3 is in line with the Food Regulation Review (1998) and the NCP Review of the *Export Control Act 1982*, which support the implementation of an integrated national food regulatory system, including the harmonisation of domestic and export standards. Option 3 could be seen as providing an overall benefit to government.

Regulatory impact – consumers

Option 3 provides no costs or benefits to consumers over existing requirements (the high quality and safety of dairy products in Australia would be maintained).

Conclusion

Option 3 potentially provides a benefit to both industry and government compared to existing measures. It is cost-neutral for consumers.

6.3.3 Preferred option

Option 3 is the preferred option as it provides the greatest benefit to industry and government compared to the other options (the impact on consumers of all options deemed to be cost-neutral).

This option means that the standard for the dairy sector will require processing businesses to have a documented food safety program (as defined by Standard 3.2.1). Existing processing requirements for milk and milk products in the Code would also be moved into the standard to complete the package of requirements.

Option 3 essentially consolidates existing regulatory measures into a single set of preventative, outcome-based national requirements that support the safe production of milk.

6.4 Primary Production and Processing Standard for Dairy Products

Based on the preferred options for on-farm primary production, bulk transport of milk and dairy products and dairy processing, Standard 4.2.4 Primary Production and Processing Standard for Dairy Products has been developed and is provided at Attachment 1. Standard 4.2.4 specifies 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.

6.4.1 Dairy primary production requirements

Standard 4.2.4 requires dairy primary production businesses to implement a documented food safety program. A food safety program is defined in Standard 3.2.1 – Food Safety Programs and must:

- systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business;
- identify where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control;
- provide for the systematic monitoring of those controls;
- provide for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control;
- provide for the regular review of the program by the food business to ensure its adequacy; and
- 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.

To reflect the controls identified under section 5.2.3, Standard 4.2.4 also specifies that the food safety program must:

- include controls that manage hazards arising from :
 - inputs (feed, water, chemicals [including veterinary and agricultural chemicals] or other substances used in connection with the primary production of milk);
 - the design, construction, maintenance and operation of premises and equipment;
 - milking animals;
 - persons involved in milking; and
 - milking practices.
- ensure milk is only sourced from healthy animals;
- ensure that milk is cooled and stored to prevent or reduce the growth of microbiological hazards; and
- include pest control and cleaning and sanitising programs.

Two supporting requirements are specified for milk primary production businesses:

- that persons undertaking primary production activities have appropriate skills and knowledge (competencies) for the task to be undertaken;
- that the business has a system to enable the tracing of inputs, milking animals and the milk produced

The requirements of Standard 4.2.4 apply to the production of colostrum as well as to milk.

6.4.2 Dairy collection and transport requirements

As for dairy primary production businesses, Standard 4.2.4 requires a dairy collection and transportation business to have a documented food safety program. To reflect the controls identified under Section 5.3.1, Standard 4.2.4 also specifies that the food safety program must:

- include controls that manage hazards arising from –
 - transport vehicles, equipment and containers used in the collection and transport of the milk; and
 - persons engaged in the milk transport business;
- have a cleaning and sanitising program; and
- transport milk at a time and temperature that prevents or reduces the growth of microbiological hazards.

Two supporting requirements are specified for dairy collection and transportation businesses:

- that persons undertaking dairy collection and transport activities have appropriate skills and knowledge (competencies) for the task to be undertaken;
- that the business has a system in place to trace the immediate supplier and immediate recipient of the dairy product.

6.4.3 Dairy processing requirements

Dairy processing businesses are defined in Standard 4.2.4 by the dairy products they manufacture. The list of products included reflects the products currently regulated under State dairy regulations.

Standard 4.2.4 requires dairy processing businesses to:

- implement a documented food safety program; and
- to have a system to trace dairy products and ingredients.

The processing requirements for milk and milk products and for cheese that were contained in Standard 1.6.2 of the Code have been relocated into Standard 4.2.4. These requirements have been revised to allow for the use of alternative technologies (any other process) to time-temperature treatments in the future, as they are developed and validated:

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

There has also been the addition of another clause to clarify that the processing requirements do not require a double heat treatment of milk products (e.g. if products are made using milk that has already been pasteurised, there is no requirement that the product be pasteurised again):

- (5) To avoid doubt, subclause 14(3) does not apply to the processing of dairy products that have been made using milk already processed in accordance with subclause 14(1).

These processing requirements may be reviewed further following the assessment of raw milk and raw milk products (discussed below under Section 7.2.2).

6.4.3.1 Dairy product storage and distribution

Dairy product storage and distribution is not specifically covered by the standard. The food safety system requirement of Standard 4.2.4 would cover all activities of the dairy processing business from receipt to distribution (up to retail) as appropriate. Businesses that do not process dairy products but are involved with their storage and distribution are covered by the food safety requirements of Chapter 3 of the Code:

6 Food storage

- (1) A food business must, when storing food, store the food in such a way that
 - (a) it is protected from the likelihood of contamination; and
 - (b) the environmental conditions under which it is stored will not adversely affect the safety and suitability of the food.
- (2) A food business must, when storing potentially hazardous food –
 - (a) store it under temperature control; and
 - (b) if it is food that is intended to be stored frozen, ensure the food remains frozen during storage.

10 Food transportation

A food business must, when transporting food –

- (a) protect all food from the likelihood of contamination;
- (b) transport potentially hazardous food under temperature control; and
- (c) ensure that potentially hazardous food which is intended to be transported frozen remains frozen during transportation.

6.4 Drafting changes following Draft Assessment

Many of the comments received at Draft Assessment on the draft dairy Standard (outlined below in Section 7.2) were concerned with the wording used in the drafting rather than the requirements specified by the Standard.

These comments have largely been taken into account in the final drafting, where appropriate, to further clarify the intent of the provisions specified. The main changes made to the draft Standard following Draft Assessment are discussed below.

6.4.1 *Title of Standard*

The title of the Standard has been changed from ‘Primary Production and Processing Standard for Milk’ to ‘Primary Production and Processing Standard for Dairy Products’. This was in response to submissions received and discussion by the Standards Development Committee which highlighted that the industry is more familiar and has greater understanding of the term ‘dairy’ and that it was important that producers and processors understood that the requirements were applicable to them. The change to the title has, consequently, resulted in a number of other changes to the drafting such that the standard consistently refers to ‘dairy products’ rather than ‘milk and milk products’, as appropriate.

6.4.2 *Definition of dairy processing businesses*

At Draft Assessment, Standard 4.2.4 defined processing businesses by the activities they undertook (e.g. pasteurisation, concentration, separation etc. of milk). It was raised in the submission process that this approach was potentially problematic in terms of future innovation (e.g. development of new processing technologies that have not been specifically included) and uncertainty around the scope of the standard (e.g. there is ambiguity as to which businesses are clearly captured in terms of activities). State regulations currently apply dairy regulations to businesses based on the products manufactured. FSANZ therefore has adopted this approach and a list of dairy products has been included in the Standard in order to define dairy processing businesses:

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.

6.4.3 *Controlling food safety hazards*

Standard 4.2.4 at Draft Assessment required dairy businesses to control potential food safety hazards by implementing a documented food safety system. Compliance with Standard 3.2.1 – Food Safety Programs was specified as meeting this requirement.

A definition of ‘food safety system’, however, has not been included in Chapter 3 or Chapter 4 of the Code. As such, this provision could be open to interpretation. The elements of a food safety program are, however, clearly defined and outlined in Standard 3.2.1. Additionally, many existing State-based dairy regulations require businesses to have a ‘food safety program’. At Final Assessment, therefore, Standard 4.2.4 has been changed so that a dairy business ‘must control its potential food safety hazards by implementing a documented food safety program’.

6.4.4 *Specific requirements for primary production*

At Draft Assessment, the draft Standard specified that primary production businesses must include controls to manage hazards arising from the environment. It was questioned in the submission process whether primary producers really could control environmental contaminants directly. Environmental contamination is a necessary consideration in that contamination of milk may result via environmental contamination of water, feed, equipment and premises. These environmental hazards, however, would be considered in relation to ‘inputs’, ‘the design, construction...of premises and equipment’ etc. The business should have control measures in place for these, but may not be able to directly ‘control’ environmental contaminants. The ‘environment’ has therefore been deleted from the Standard.

In addition, the wording relating to the ‘health of milking animals’ and ‘health and hygienic’ practices of milking personnel has been modified to clarify the requirement. Sourcing milk from healthy animals and having appropriate hygienic and health practices is the outcome required. This is achieved by having controls that manage hazards arising from the milking animal and the practices of the personnel involved with milking:

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.

This clause also now clarifies that milk should only be sourced from healthy animals:

- (2) For clause 3, the control measures must also—
 - (c) ensure that milk for human consumption is only sourced from healthy animals.

6.4.5 *Milk cooling and storage*

It was raised at Draft Assessment that the milk cooling and storage requirement was too prescriptive and not outcome based (e.g. milk must be cooled to 5°C or below within 3.5 hours from the commencement of milking). The food safety outcome required here is to prevent/minimise the growth of micro-organisms in milk by appropriate cooling and storage. An outcome based approach rather than prescribing a cooling regime is preferred and so the drafting has been amended at Final Assessment to reflect this. The guide to the standard can include examples of appropriate cooling and storage of milk, including the cooling to 5°C or below within 3.5 hours. In addition, the milk cooling requirement has been included under Clause (4) Specific requirements:

4 Specific requirements

- (2) For clause 3, the control measures must also—
 - (b) ensure that milk is cooled and stored at a temperature that prevents or reduces the growth of microbiological hazards in the milk;

6.4.6 *Animal identification and milk tracing*

Clause 4 requires that primary production businesses manage hazards arising from milking animals and that milk for human consumption is only sourced from healthy animals. Having an animal identification system supports this. Rather than covering this as a separate clause, the tracing of animals has been included under a more general tracing provision that also covers inputs and milk:

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.

6.4.7 *Dairy collection and transportation*

As for primary production, the wording of the specific requirements for dairy collection and transportation businesses has been clarified by removing ‘health and hygienic practices’ from persons engaged in the transport business and changing ‘vessels’ to containers:

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; and
- (b) persons engaged in the milk transport business.

Additionally, the requirement for a cleaning and sanitising program has been clarified such that it is the ‘food contact surfaces’ of transport vehicles that need to be cleaned and sanitised.

The time and temperature controls specified in the Standard at Draft Assessment have also been re-drafted into a more outcome based requirement:

10 Time and temperature controls

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

6.4.8 Dairy processing

At Draft Assessment, alternative systems were listed for dairy processing businesses in relation to complying with the requirement for a documented food safety system (changed to food safety program at Final Assessment). These alternatives have been removed from the Standard at Final Assessment because it was considered that this approach could result in inconsistent implementation of the requirement. Businesses may have in place different HACCP systems that meet the requirements of the Standard. These should be recognised by the Authority responsible for enforcement but the specific systems do not need to be specified within the Standard.

The processing requirements for milk and dairy products have been slightly modified since Draft Assessment in relation to cooling of milk or dairy products following heat treatment. Rather than specifying cooling to 5°C or below, a more outcome based approach has been taken¹⁸:

- (2) Milk processed under paragraph 14(1)(a) must be cooled immediately in a way that ensures that the growth of microbiological hazards in the milk is prevented or reduced.
- (4) Dairy products processed under paragraph 14(3)(a) must be cooled immediately in a way that ensures that the growth of microbiological hazards in the product is prevented or reduced.

Additionally, for processes other than heat treatment, it has been clarified that this would need to be validated and verified:

¹⁸ Note that Standard 3.2.2- Food Safety Practices and General Requirements of the Code also specifies cooling and storage requirements for potentially hazardous food.

Editorial note:

For paragraph 14(1)(c), any other process used would need to be validated by the business and verified by the Authority.

The product tracing requirement for dairy processing businesses has also been clarified to refer to dairy products and ingredients (rather than processing ingredients):

16 Product tracing

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.

7. Consultation

In addition to the FSANZ statutory public consultation requirement, further consultative mechanisms have been built into the development process for the primary production and processing standards. The development of the Primary Production and Processing Standard for Dairy Products has been undertaken in close consultation with the Standard Development Committee, which has representation from all the major stakeholder groups.

The Standard Development Committee has met routinely during the period from Initial to Draft Assessment (May 2005, October 2005 and December 2005) to provide input into this process, and again in May 2006 following the public submission period on the Draft Assessment Report.

7.1 Initial Assessment

As part of the FSANZ statutory consultation requirements, the Initial Assessment Report for Proposal P296 was released for an eight week consultation period from 15 December 2004 until 9 February 2005. This period was extended until 7 March 2005. Twenty two submissions were received in response to the Initial Assessment Report, primarily from industry, State regulators and industry associations. Many of these submissions provided information that helped guide development of the Risk Profile and the Draft Assessment Report. The major issues raised at Initial Assessment which have not been covered within the relevant sections of this report are discussed below.

Additionally, expert panels (Dairy Scientific Advisory Panels) were established by FSANZ to provide ongoing advice and guidance during the preparation of the Microbiological and Chemical Risk Profiles. Panel members for each risk profile were selected for their expertise and experience in the following areas: food processing/manufacturing; dairy farming; animal health; risk assessment; microbiology; toxicology/chemistry and public health (epidemiology). The Australian Pesticides and Veterinary Medicines Authority (APVMA) also provided ongoing advice and input into the development of the Chemical Risk Profile.

7.1.1 Definitions of dairy

The Initial Assessment Report for Proposal P296 raised that definitions for dairy products may need to be included in the Standard and that those contained in the *Codex General Standard for the Use of Dairy Terms* may be acceptable.

A number of submissions provided comment on the suitability of Codex terms.

Milk is already defined in Standard 2.5.1 of the Code, which also includes compositional requirements. Similarly other dairy products (e.g. cream, cheese, fermented milk products etc.) are defined within Part 2.5 – Dairy Products of the Code. The proposed dairy Standard has only needed to include definitions for the purpose of applying the provisions of the standard to the appropriate food business and to clarify the use of terms such as ‘control measures’ and ‘inputs’. The use of Codex dairy terms has therefore not been necessary. When the assessment of raw milk and raw milk products is undertaken (discussed below), additional definitions may need to be considered (e.g. ‘raw’ milk for consumption versus milk for further processing).

7.1.2 Raw milk and raw milk products

The Initial Assessment Report for Proposal P296 raised the issue of developing a management framework for raw milk and raw milk products, such as cheese, where the safety of such products can be assured. The first step to elaborating such a framework will be to undertake a rigorous safety assessment to identify and understand the hazards and risks associated with these products. However, this safety assessment isn’t expected to be finalised until the latter half of 2006. In order to progress the development of a single national standard for dairy, as well as incorporating a framework for managing raw milk products, it has been decided that a two-stage process meeting FSANZ statutory requirements is undertaken.

FSANZ has initially developed options for a dairy standard based on existing processing requirements in this Draft Assessment Report. The requirements for raw-milk products will be addressed in a separate Draft Assessment Report to be released in 2007. This will allow for the national dairy Standard to be gazetted in 2006 while the provisions for raw milk and raw milk products may be gazetted later in 2007. The outcome will be a single national standard for dairy.

The issues relating to raw milk and raw milk products raised in the submissions to the Initial Assessment Report for Proposal P296 will be considered in the subsequent Draft Assessment Report dealing explicitly with the assessment and management of raw milk/raw milk products.

7.1.3 Microbiological limits

A number of submissions raised issues in relation to the existing microbiological limits in Standard 1.6.1 of the Code. These include:

- There is a lack of clarity to how the existing limits should be used and what they mean e.g. should the presence of a pathogen in a dairy product, when there is no limit set for it, mean the product is unsafe.
- Existing limits are inadequate – industry and regulators need greater guidance
- Limits should only relate to safety (not quality) and include pathogens. Limits for indicator organisms and quality related requirements are better placed in the guideline document to the Standard.
- A significant number of dairy foods are not addressed by Standard 1.6.1.

The microbiological standards in the Code are essentially end-point specifications that do not, in themselves, require any safety measures to be implemented during processing. Microbiological standards simply prescribe a level of microbiological safety to be met at the end of processing.

It was raised during the review of the Australian *Food Standards Code* (1998 – 2000) that the role of microbiological standards may change as food safety programs are implemented across industry sectors and an outcome based rather than a prescriptive approach is taken towards ensuring food safety.

Rather than requiring mandatory end-point testing (microbiological standards), microbiological criteria could be used as performance measures or guideline levels.

A review of existing microbiological standards for dairy products has not been undertaken as part of the dairy Standard development process. Currently only a limited number of microbiological limits for dairy foods are specified in Standard 1.6.1. These include limits for cheese and dried milk, and unpasteurised (raw) milk and milk products (cheese and butter). There are, however, a number of guideline criteria for butter, cheese, cream, milk, powdered milk, ice cream and yoghurt currently contained within the User Guide for Standard 1.6.1.

As part of FSANZ's risk management processes, there is a need to examine the role of microbiological standards in light of the implementation of outcome based, preventative requirements for ensuring food safety across commodity sectors. Further consultation on this matter will be required. The limits for unpasteurised (raw) milk and milk products will be considered as part of the risk management measures that may be required for these products.

FSANZ will also examine the inclusion of microbiological guideline limits in the guidance document to Standard 4.2.4. This may involve reviewing those limits currently specified in the User Guide for Standard 1.6.1, particularly in light of any ANZDAC guideline limits.

7.1.4 Alternative technologies

Submissions supported the recognition of processes, other than pasteurisation, for dairy processing. The Microbiological Risk Profile examined the use of alternative technologies and found that, currently, there is insufficient data to provide support for the use of any one alternative technology as an alternative to thermal processing. Microfiltration is one technology currently used by the dairy industry (mainly for the reduction of spores), but is used in combination with pasteurisation.

Heat treatment (time/temperature specifications) will continue to be the core processing requirement for milk and milk products, and for cheese. The current processing requirements have been reworded however to recognise alternative, non-thermal processes that have been validated to ensure that they 'provide an equivalent or greater lethal effect on any pathogenic micro-organisms'.

7.1.5 Enforcement of outcome-based standards at the border

It was raised in submissions that imported foods are largely subject to end-point testing which is considered inefficient, unreliable and discriminatory to local industry that have to demonstrate compliance with a food safety management system to ensure food safety.

Ensuring that imported food complies with food legislation in Australia is a shared responsibility between Australian, State and Territory and Local Governments. The Australian Government, through the AQIS Imported Food Program (IFP), monitors imported food at the border for compliance with the requirements of the Code. IFP is jointly managed by FSANZ and AQIS, with FSANZ advising on food risk assessment policy for the program and AQIS having operational responsibility for inspection and sampling.

AQIS implements the testing of food in accordance with the *Imported Food Control Act 1992* and its associated regulations. To date most compliance is based on end-point inspection.

AQIS is still examining the issue of enforcing outcome-based standards at the border.

This includes examining options such as government to government certification arrangements, food safety programs implemented by importers, sampling and analysis, and mixes of these strategies. Whatever enforcement option is implemented, the following principles would apply:

- Australia cannot enforce its standards in other countries;
- equivalent health objectives between primary produce that is imported and domestic primary production may be achieved by a variety of options;
- the most appropriate options to ensure equivalence will include:
 - the current risk categorisation of product;
 - the assessment of the food safety record of imported primary produce; and
 - international trade obligations.

7.1.6 *Quarantine requirements*

The issue of biosecurity risks and the potential impact a national dairy standard may have on herd management and animal health issues with respect to imports (particularly for raw milk products) was raised in submissions.

AQIS and Biosecurity Australia maintain import requirements for dairy products entering Australia. A quarantine permit must be obtained in order to import dairy products. Conditions for import depend on the disease status of the exporting country (e.g. whether it has Foot and Mouth disease), and consignments must be accompanied by an import permit and a specific sanitary certificate signed by an Official Government Veterinarian of the exporting country. Regardless of the permissions of the Code, food entering Australia must comply with Australia's quarantine requirements. This issue will be discussed further in the assessment of raw milk and raw milk products.

7.2 **Draft Assessment Report**

The Draft Assessment Report for Proposal P296 was released for a six week consultation period from 22 March 2006 until 3 May 2006. This period was extended until 10 May 2005. Eighteen submissions were received from:

- Food Technology Association of Victoria
- Milk Vendors Association (South Australia)
- Dairy Authority of South Australia

- Private (Wilson, Kevin)
- Tasmanian Dairy industry Authority
- Parmalat Australia Ltd.
- Western Australia Department of Health
- Department of Primary Industries Victoria
- Safe Food Queensland
- New Zealand Food Safety Authority
- Fonterra Co-operative Group Ltd.
- NSW Food Authority
- NSW Farmers' Association
- National Foods Ltd.
- Department of Agriculture, Fisheries and Forestry
- Dairy Australia
- Queensland Health
- United States Government

A summary of these submissions is provided at Attachment 3. Many of the submissions provided comment on the definitions or terminology used within the standard and the need for further clarification of some clauses. These comments have been taken into account in finalising the drafting of Standard 4.2.4 and have been discussed above under section 6.4. The main issues raised are outlined below.

7.2.1 Title of Standard

The draft Standard attached to the Draft Assessment Report was named **Primary Production and Processing Standard for Milk**. A couple of submissions raised a preference for re-naming the standard to Primary Production and Processing Standard for **Dairy**, noting that the term 'dairy' encompasses regulation of the total dairy sector, whereas 'milk' may imply a more restricted application.

7.2.2 Definitions and Application

A number of issues were raised in relation to the definitions included in Division 1 of the draft Standard and its application:

- The draft Standard only refers to definitions in Chapter 3 of the Code. Definitions in other parts of the Code also need to be included, not just Chapter 3 (the definition of milk being in Standard 2.5.1).
- For consistency with Codex definitions, the definition for control should be changed to control measure (control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level).
- The definition of milk processing needs further clarification as it is unclear whether the current approach adequately covers those businesses currently captured by dairy regulations (i.e. the scope is unclear). Providing a list of activities here may also be problematic in terms of future innovations. A more general definition of milk processing could be provided and further information provided in the guide document.

- The definition of milk transport business includes the term ‘bulk’ – this may need defining/clarification (e.g. in large quantities or not packaged).
- The definition for milk (milk includes colostrum) contradicts the definition in Standard 2.5.1 and may need further clarification.
- Clarification around the standard applying to retail sale activities may be required (e.g. the manufacture of ice cream or gelati at retail premises).

7.2.3 Documented Food Safety System

Primary production, milk collection and transport and processing businesses are required by the draft Standard to implement a documented food safety system. A number of issues were raised in relation to this requirement:

- Clauses 3 and 9 (primary production and milk collection and transport requirements) only make reference to Standard 3.2.1 in relation to food safety systems. As for primary processing, alternatives should be provided (e.g. any other HACCP based system recognised by the Authority).
- Compliance with Standard 3.2.1 should be based on risk. There is no evidence to support that milk collection and transport is a high risk area. The requirement to implement Standard 3.2.1 here is too onerous.
- Specifying the Codex HACCP system may not be necessary – it raises whether another system other than Standard 3.2.1, Codex and one ‘recognised by the Authority’ is acceptable.
- For export markets the implementation of a full HACCP system at processing premises, in line with Codex principles, is required. This includes validation and verification systems. It is noted that the draft Standard does not mandate a full HACCP system.
- The term **Authority** is not defined in the Code. Clarification of this term should be provided.
- There should be criteria established for the acceptance of HACCP systems and these systems identified.

7.2.4 Primary Production Requirements

A number of comments were received on how the requirements for primary production businesses were worded in the standard and the need for greater clarity in how these are expressed:

- The wording used in the clause may be too vague e.g. the requirement is for the hazards to be managed which, for zoonotic disease agents could be achieved with pasteurisation, rather than sourcing milk only from animals of appropriate health status.

- It was questioned whether dairy farming business would really be able to control all of the hazards arising from the list specified. In particular, ‘the environment’ and the ‘health’ of persons involved in milking.
- The requirement to address hazards arising from ‘the health of milking animals’ does not seem to adequately address that milk is only sourced from animals of appropriate health status.
- The requirement for milk cooling and storage is too prescriptive and not outcome based. The requirement should be drafted as an outcome (businesses need to cool and store milk such that the microbiological safety of the milk is not adversely affected) with specific time temperature combinations included in the guide.
- The ‘microbiological safety’ of milk is not meaningful for milk cooling and storage as the milk is not for direct human consumption – it is to be processed. Allowing an alternative to the specified time and temperature for cooling should be removed.
- To allow for special circumstances ‘unless otherwise approved by the relevant Authority’ could be included.
- The requirement for an animal identification system is a specific action, not an outcome. Having an animal identification system may be the means of ensuring milk is only sourced from healthy animals (covered under clause 4), making this specific requirement unnecessary.
- The milk tracing requirement should also cover the traceability of inputs.

7.2.5 Collection and Transportation Requirements

The comments relating to the requirements in the draft standard for milk collection and transportation businesses included:

- A definition of ‘vessel’ should be included in the standard (other wise the interpretation may be very broad).
- The risk associated with the ‘health’ of persons engaged in milk transport activities is negligible and should not be included in the Standard.
- The wording used could be clearer, particularly in relation to keeping transport vehicles clean and sanitary (this wouldn’t apply to the whole vehicle).

7.2.6 Processing

Apart from the requirement for a documented food safety system, Division 4 of the draft standard included processing and traceability requirements for milk and milk products. The comments submitted on this section also sought further clarity on these provisions:

- Clause 16 is worded such that all milk must be cooled to 5°C or below which isn't appropriate for UHT milk. Specific provision should be made for UHT milk by amending the clause or providing a definition and processing conditions for UHT products. Additionally, the cooling requirement applying to milk should also apply to milk products.
- The meaning of the clause relating to the processing of milk products is not clear because it refers to micro-organisms that may be present in 'the milk' rather than 'the milk product'.
- The exemption from the processing requirement ('unless an applicable law of a State or Territory otherwise expressly provides') should be included to allow for the sale of unpasteurised goat milk in those States that currently permit it.
- The product tracing provision refers to milk processing ingredients. The term 'milk processing ingredients' should be clarified/defined.
- It was raised that another division was required in the standard to specifically cover the storage and transport of dairy products. While requirements for food storage and transportation are covered in Standard 3.2.2, product traceability and competencies are not.

7.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade. This notification enables other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

The proposed Primary Production and Processing Standard for Dairy Products in Chapter 4 of the Code will have implications for imported product. Notification was therefore made to the WTO on the 21 March 2006 in accordance with Australia's obligations under the Sanitary and Phytosanitary Measure (SPS) Agreement. One comment was received, from the United States Government, and has been addressed with other submissions received at Draft Assessment.

8. Conclusions and Recommendation

The Australian dairy industry produces dairy products of a high level of safety. This has been supported by industry initiatives and a State-based regulatory system that has implemented comprehensive regulatory requirements from on-farm through to processing and distribution. This State-based framework has, however, resulted in some variation in requirements across jurisdictions and impacted on industry's ability to streamline arrangements across the States in which they trade. Another level of compliance is added to those businesses registered for export that must also meet the requirements specified in the AQIS Export Control Orders.

The impact analysis of risk management options undertaken in Section 6 found that, while the existing system supports the safe production of dairy products, the lack of uniform national requirements for the dairy sector limits the rationalisation of industry operational and compliance costs, impacting on competition.

This Final Assessment Report for Proposal P296 recommends that a national standard for the dairy sector be included in Chapter 4 of the Code. This standard, Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products will be a new through-chain standard, specifying requirements from milk production on farm through to processing and distribution of dairy products.

8.1 Statement of Reasons

At Final Assessment, FSANZ recommends that the Code be amended to include Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products into Chapter 4 for the following reasons. The proposed Standard:

- is consistent with the section 10 objectives of the FSANZ Act to protect public health and safety;
- provides a nationally consistent legislative framework for a whole-of-chain approach to dairy food safety;
- takes into account existing State-based and export requirements, providing a consolidated set of requirements based on scientific assessment;
- has been developed with regard to the measures specified in the Codex Code of Hygienic Practice for Milk and Milk Products, promoting consistency between domestic and international food standards;
- provides measures that are outcome based and would not impose any additional costs to industry over existing requirements;
- supports the recommendations of the COAG Senior Officials Working Group on Food Regulation and the National Competition Policy (NCP) Review of the Export Control Act 1982, for the implementation of an integrated national food regulatory system that systematically addresses food safety across the chain, and progresses the harmonisation of domestic and export standards.

9. Implementation and review

Because of the non-prescriptive nature of the new Primary Production and Processing Standards, interpretive documents are essential for enforcement officials to assist with consistent implementation and for industry to understand the requirements of the standard. FSANZ will develop a guide to the Primary Production and Processing Standard for Dairy Products to provide consistent interpretation of the standard for enforcement agencies as well as to provide other guidance material that will assist industry to understand and meet the requirements. It is noted that there are already a number of guideline documents that have been developed for industry in relation to food safety requirements, particularly by ANZDAC, and these will be taken into account in this process. The guide will be developed in consultation with the Standard Development Committee and in conjunction with jurisdictions, industry and the Implementation Sub-Committee¹⁹.

¹⁹ The Implementation Sub-Committee comprises representatives from the Commonwealth, each state and territory jurisdiction and New Zealand, including representation from AQIS, FSANZ and Australian local

Implementation is the responsibility of the States and Territories. Jurisdictions already have comprehensive legislative requirements for the dairy sector that are consistent with the proposed dairy Standard. The process/mechanism by which State and Territory requirements are amended/updated to reflect the national dairy Standard is a matter for jurisdictions.

The Implementation Sub-Committee will facilitate the consistent national implementation of the Standard. It is charged with the responsibility for overseeing cross-jurisdictional agreement on consistent approaches to implementing and ensuring compliance with food standards. The Implementation Sub-Committee also has a major role in encouraging cost-effective approaches to compliance and enforcement.

A two-year implementation timeframe will be provided from the date the Primary Production and Processing Standard for Dairy Products is gazetted in the Code.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Risk Profile of Dairy Products in Australia
3. Summary of issues raised in public submissions to the Draft Assessment Report
4. Summary of State regulations applying to the dairy sector
5. Summary of Export Control (Milk and Milk Products) Orders, 2005

government. The Implementation Sub-Committee develops guidelines on food regulations and standards implementation and enforcement activities in order to achieve a consistent approach to the way regulations and standards are interpreted and enforced across jurisdictions.

Draft Variation to the *Australia New Zealand Food Standards Code*

To commence: 24 months from gazettal

[1] *Standard 1.6.2 of the Australia New Zealand Food Standards Code is varied by–*

[1.1] *omitting clause 1, substituting –*

1 Deleted

[1.2] *omitting clause 2, substituting –*

2 Deleted

[2] *Standard 2.5.1 of the Australia New Zealand Food Standards Code is varied by –*

[2.1] *omitting from the Purpose text the reference to Standard 1.6.2, substituting –*

Standard 4.2.4

[2.2] *omitting subclause 4(2), substituting -*

(2) Milk must be processed according to Standard 4.2.4 of this Code.

[3] *Standard 2.5.2 of the Australia New Zealand Food Standards Code is varied by omitting from the Purpose text the reference to Standard 1.6.2, substituting –*

Standard 4.2.4

[4] *Standard 2.5.3 of the Australia New Zealand Food Standards Code is varied by omitting from the Purpose text the reference to Standard 1.6.2, substituting –*

Standard 4.2.4

[5] *Standard 2.5.4 of the Australia New Zealand Food Standards Code is varied by omitting from the Purpose text the reference to Standard 1.6.2, substituting –*

Standard 4.2.4

[6] *Standard 2.5.5 of the Australia New Zealand Food Standards Code is varied by omitting from the Purpose text the reference to Standard 1.6.2, substituting –*

Standard 4.2.4

[7] *Standard 2.5.6 of the Australia New Zealand Food Standards Code is varied by omitting from the Purpose text the reference to Standard 1.6.2, substituting –*

Standard 4.2.4

[8] *Standard 2.5.7 of the Australia New Zealand Food Standards Code is varied by omitting from the Purpose text the reference to Standard 1.6.2, substituting –*

Standard 4.2.4

[9] *The Australia New Zealand Food Standards Code is varied by inserting -*

STANDARD 4.2.4

PRIMARY PRODUCTION AND PROCESSING STANDARD FOR DAIRY PRODUCTS

(Australia Only)

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.

Table of Provisions

Division 1 – Preliminary

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- 3 Controlling food safety hazards
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Division 4 – Dairy processing

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- 15 Processing of milk and dairy products
- 16 Processing of dairy products to make cheese and cheese products

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.

Risk Profile of Dairy Products in Australia

The Risk Profile is attached separately.

Attachment 3

Summary of Submissions Received on the Draft Assessment Report

Submitter	Comments
Food Technology Association of Victoria Inc.	<ul style="list-style-type: none"> • Submission supports a Primary Production & Processing Standard for Dairy and accepted Option 4 for on-farm and the bulk transport of milk and milk products, and Option 3 for milk processing as recommended by the Draft Assessment Report.
Milk Vendors Association (SA) Inc.	<ul style="list-style-type: none"> • Submission supports the Draft Assessment Report. However the Milk Vendors Association notes that the approach is to apply a consistent approach to food safety along the entire milk supply chain and to achieve uniform food safety requirements across Australia yet accredited dairy distributors have not been included in the proposed new draft. • Milk Vendors Association would support a standard which included dairy distributors.
Dairy Authority of South Australia	<ul style="list-style-type: none"> • Submission agrees with the general findings of the DAR and in general supports the draft variation to the Code. • Comments that Clause 2 of the draft Standards does not apply to retail sale activities and expressed concerns over the production of ice cream, gelati and yogurt etc at retail premises. • Raises some concerns relating to Clause 5: Milk cooling and storing in that it may be difficult for primary production businesses to demonstrate the efficiency of an alternative system. It is more likely that milk processing business will need to demonstrate that their milk collection process will not impact on food safety. • Notes that with the repeal of Standard 1.6.2, the ability for a state or territory to approve unpasteurised milk sales will be removed. Raises that the exemption should stand until the new Standard is developed unless it is covered by the 2 years from gazettal note on commencement. • Supports the standard including dairy distributors and requiring them to have control of food safety hazards as for other industry sectors. • Comments that Clause 11 (Time and temperature control) is left open for a milk transport business to demonstrate that transport above 5°C will not adversely affect the microbiological safety of the milk. As for Clause 5, this may need to be demonstrated by a milk processing business who decides to collect milk for processing soon after a farmer completes milking. • Notes that processor must have the ability to retain product for a period of time at incubation temperatures above 5°C after processing (cheese yoghurt). A separate clause or alteration to Clause 16(2) should be considered to cover this.
Kevin Wilson	<ul style="list-style-type: none"> • Raises concerns with raw milk and the importation of dairy products and the 'proposal to loosen import regulations'. In particular, that there are still concerns with Brucellosis and Bovine Tuberculosis in overseas countries and Australia should not be lowering its standard for imported product.

Submitter	Comments
Tasmania Dairy Industry Authority	<ul style="list-style-type: none"> • Supports the aims and objectives for the development of a National Standard for Dairy, as this approach will acknowledge existing programs and will consolidate internationally recognised Best Practice dairy food safety schemes; • Notes that the risk profile has determined that existing dairy food safety schemes have contributed to a high level of public health and safety; • Raises that the requirement in Division 2: Milk cooling and Storing Requirements may be problematic and may not be met because some large herds may take longer than 3.5 hours to milk. • Supports aligning definitions with Codex, or other recognised internationally recognised dairy standards.
Parmalat Australia Ltd	<ul style="list-style-type: none"> • Submission supports the development of the Dairy primary Production and processing Standard; • Comments that the correct title of the Standard may be required clarification: PPP Standard for Dairy or PPP Standard for milk. Parmalat suggest the term Dairy be the terminology used as it appropriately encompasses all activities associated with dairy products processing. <p><u>On-farm production</u></p> <ul style="list-style-type: none"> • Supports Option 4 that requires the primary production business to have food safety programs plus specific controls that must be included. • The proposed Standard 4.2.4 however does not adequately address all the regulatory requirements identified in the DAR: <ul style="list-style-type: none"> ⇒ Clause 4 does not specifically include that milk is only sourced from animals of an appropriate health status (Clause 4(d) only refers to control of hazards arising from the health of milking animals); ⇒ Clause 8 only allows for forward tracing – there is no requirement to be able to identify the animals from which the milk was derived <p><u>Bulk transport of milk and milk products</u></p> <ul style="list-style-type: none"> • Supports the option that requires a dairy transport business to have food safety programs plus specific controls that must be included • Raises that the wording of Clause 10 is very clumsy. It could be interpreted as requiring the whole vehicle used in the transportation of milk to be cleaned and sanitised, although this is clearly not the intention. Wording in the Victorian Code of Practice for Dairy Food Safety would be more precise ie. <i>‘Dairy food transport vehicles, equipment and vessels must be designed, constructed and maintained in a manner that will prevent the introduction of contaminants to milk or milk products and temperature increase’</i>. <p><u>Processing</u></p> <ul style="list-style-type: none"> • Supports Option 3 that requires a processing business to have a documented food safety management system (food safety program or Codex HACCP system) • Notes that the standard was to provide a ‘whole of chain’ approach to food safety yet has omitted any specific regulatory requirements for transport/storage of dairy products post processing. Current state regulations incorporate these requirements. It is assumed that any food safety requirements for food handling post processing will be covered by Standard 3.2.2; however the requirements in 3.2.2 are deficient in specifying requirements for <u>traceability</u> and <u>personal competency</u>. Recommends that the requirements for Dairy Distributors be incorporated as Division 5 into Standard 4.2.4. • Comments that Clause 15(2) (c) is not suitable defined – there needs to be criteria established for the acceptance of HACCP systems and these systems identified.

Submitter	Comments
	<ul style="list-style-type: none"> • Clause 16 is now worded such that all milk must be cooled to 5°C or below. This is not appropriate for all products – e.g. UHT milk is generally cooled to 25°C-30°C and aseptically packed. Provision should therefore be made for UHT milk by either applying a definition together with appropriate processing for UHT milk/milk products or amend clause 2 to allow cooling of milk above 5°C. • Supports that the Standard be accompanied by a User Guide.
Department of Health, Western Australia	<ul style="list-style-type: none"> • Raises that the existing processing requirements of Standard 1.6.2 provides for a State or Territory to regulate the sale of unpasteurised milk. Clause 16(1) of Standard 4.2.1 has not carried across this provision, therefore States would be contravening the Food Regulation Agreement, 2000 if they continued to regulate for raw goat milk. Submission recommends that this clause is amended to include ‘unless an applicable law of a State or Territory otherwise expressly provides’ and can then be reviewed through the second phase (dealing with raw milk issues). • The definition provided for milk (milk includes colostrum) appears to conflict with the definition for milk in Standard 2.5.1 of the Code, noting it is for a different purpose. Recommend that the proposed standard is amended to : <ul style="list-style-type: none"> 1 Interpretation milk includes other food products containing colostrum • Raises that the milk cooling and storing provision (Clause 5) is too prescriptive and not outcome-based (in line with the <i>Overarching Policy Guideline for Primary Production Standards</i>). Notes that this requirement has evolved from the Australian Standard N46 – 1963, Refrigerated Bulk Milk Tanks, which has not changed over time. Many herds take more than 3.5 hours to complete and there is no provision for the addition of subsequent milkings to an already cooled batch. Recommend that Clause 5 is amended to: <ul style="list-style-type: none"> 5 Milk cooling and storage A milk primary production business must demonstrate that the milk cooling and storage process undertaken will not adversely affect the microbiological safety of the milk. Or (if prescription is retained) 5 Milk cooling and storage A milk primary production business must cool milk to 5 °C or below within 3.5 hours from the commencement of filling a milk storage vessel and, apart from the addition of milk from subsequent milkings, store it at 5 °C or below until collection, unless the milk primary production business can demonstrate that the milk cooling and storage process undertaken will not adversely affect the microbiological safety of the milk. • Raises that, in relation to the milk tracing requirement (Clause 8), it is probably more important to be able to identify the sources of inputs. Recommends Clause 8 is amended: <ul style="list-style-type: none"> 8 Tracing A milk primary production business must have a system to identify the source of inputs and the immediate recipient of the milk. • Raises that Clause 11 (temperature control requirement) is incomplete because the microbiological safety statement does not include ‘milk products’. Recommend that Clause 11 is amended:

Submitter	Comments
	<p>A milk transport business must transport milk or milk products at 5 °C or below unless the milk transport business can demonstrate that the time and temperature controls used in the transport of milk or milk products will not adversely affect the microbiological safety of the milk or milk products.</p>
<p>Department of Health, Western Australia (cont.)</p>	<ul style="list-style-type: none"> • Raises the use of the term ‘Authority’ in Clauses 15 & 16 (‘approved by the Authority’ and ‘recognised by the Authority’). This submission notes that the term Authority is not defined in the Code and that the Model food Act defines ‘enforcement agency’²⁰ and ‘food safety auditor’. Pasteurisation aspects should be considered by a high level authority, however the food safety system could be considered by a system audit by a food safety auditor. Clarification for the use of the term ‘Authority’ should be provided. • Raises that Standards 2.5 make reference to Standard 1.6.2 and that this should be amended. • Raises that, with the decision not to specifically include the storage and distribution sector in the standard, there is no reference to the storage of milk and milk products. Notes that both Divisions 1 & 2 have reference to storage conditions, and this provision should be included in Division 4. recommend the addition of a new clause: Milk and milk products must be stored under conditions that will not adversely affect the safety of the milk or milk products. • Raises that Clause 18 is incomplete as it only refers to tracing for milk products and not milk. Recommend an amendment: A milk processing business must have a system to identify the immediate supplier of milk and milk processing ingredients and the immediate recipient of the milk or milk products.
<p>Victorian Department of Primary Industries (DPI) and Dairy Food Safety Victoria (DFSV)</p>	<p><u>General comments</u></p> <ul style="list-style-type: none"> • Support the objectives of the development of a PPP Standard for Milk and the need to have a nationally consistent Standard. • Supports the full adoption of Standard 4.2.4 by AQIS as the minimum food safety requirements for an export registered dairy processing business. • Notes the importance to both industry and government of interpretive material to support the standard. <p><u>Specific comments</u></p> <ul style="list-style-type: none"> • The definition of ‘control’ should be consistent with international standards (Codex) and should be amended to ‘Control measure’ – any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. • The definition of ‘milk processing’ in the draft Standard is based on a list of activities. Submission raises that this restricts the application of the standard to those activities and could potentially hinder innovation by the industry. Support defining ‘milk processing’ in a generic sense, with further explanation in an interpretive guide. • The draft standard states the definitions of Chapter 3 apply – Chapter 3 doesn’t define the source of milk (needs to be clarified) • The definition of ‘milk transport business’ uses the term ‘bulk’ which isn’t defined – needs to be clarified e.g. is the intention to refer to milk and milk products not in a retail package. • Clause (4) Specific Requirements. Submission raises that dairy farming businesses may not be able to control all of the hazards arising from the list in the standard. Specifically, the ‘environment’ and the ‘health’ of persons involved in milking – these should be removed.

²⁰ Under the Model Food Provisions Annex B, *enforcement agency* means:

(a) the relevant authority, or

(b) any person or body, or a person or body within a class of persons or bodies, prescribed by the regulations for the purposes of this definition.

Submitter	Comments
	<ul style="list-style-type: none"> The Clause (5) Milk cooling and storing requirement is a specific action rather than objective based – specific time temperature combinations could be included in a support document.
DPI & DFSV (cont.)	<ul style="list-style-type: none"> Clause (7) Animal Identification requirement is an action rather than an outcome – should be rewritten in terms of the outcome to be achieved. If the outcome is in respect to the health of milking animals, then it is already captured under Section 4(d). Clause (10) Specific Requirements refers to the ‘health’ of a person engaged in milk transport activities – this risk is negligible and shouldn’t be included in the standard. Clause (9) controlling food safety hazards requires milk transport business to implement Standard 3.2.1. This submission raises that there isn’t enough evidence provided that this is a high risk area and that compliance with Standard 3.2.1 is warranted (this should be based on risk)- the food safety system required doesn’t need to be so onerous. The standard needs to define what a ‘vessel’ is – term is very broad. The term ‘milk processing ingredients’ needs to be further defined for clarity.
Safe Food QLD	<ul style="list-style-type: none"> Submission seeks clarification as to whether the definitions in Standard 4.2.4, particularly in relation to milk primary production and milk processing businesses, is broad enough to reflect the scope of the Queensland Dairy Food Safety Scheme (noting that no definition of milk products is provided). Raises that consequential amendments to Standards 2.5 Dairy Products would be required with respect to Standard 1.6.2 when these provision are moved to Standard 4.2.4. Raises that the Preliminary Division makes reference to definitions in Chapter 3 of the Code – should it also make reference to Chapters 1 and 2. Raises that, for Division 2 Milk primary production and Division 3 Milk collection and transport that, in relation to food safety systems, only reference to Standard 3.2.1 is made. Alternatives should be provided, as is the case in Clause 15(2) – e.g. ‘any other Hazard Analysis and Critical Control point (HACCP) based system recognised by the Authority’.
New Zealand Food Safety Authority (NZFSA)	<ul style="list-style-type: none"> Suggests that the definition of milk processing include the addition of ‘and associated activities of milk and <i>milk products</i>’. Questions whether storage is included within this definition. Submission queries whether the definition of milk transport business is intended to include the processor to retail/export interface? Notes that, in relation to Clause 3, that the food safety system requirements focuses on hazards with no mention of wholesomeness (New Zealand Food Safety Program does). Raises whether the concept of fit for purpose should be included. Questions whether, in relation to Clause 4, it is clear that ‘inputs’ covers animal feed, vet drugs, water etc. Notes the different milk cooling requirement, to 5°, is different to the New Zealand standard (to 7°). In relation to clause 11, questions what information will be needed to demonstrate no adverse effect and who makes the assessment. Questions whether Clause 13 need to include traceability to the transport vehicle. In relation to clause 16 (3), raises whether product going into a further heating process is adequately covered. Is UHT allowed? Do Clauses 16 and 17 fit with the concept of a Food Safety Program where the food business is responsible for identifying the hazards and the means of control. Raises whether sugar content has been considered (in relation to the editorial note with clause 16). Notes that the thermisation times and temperatures in clause 17 are different to New Zealand Food Standards. Questions whether Clause 18 (product tracing) includes product streams such as whey or permeate.

Submitter	Comments
Fonterra	<ul style="list-style-type: none"> Supports the variation of the Food Standard Code with the insertion of Standard 4.2.4 – primary Production and Processing Standard for Milk.
NSW Food Authority	<p><u>Specific comment on the draft Standard</u></p> <ul style="list-style-type: none"> In relation to the definition for milk processing, the term ‘milk products’ needs a definition to enable clear interpretation. For the definition of milk transport business the term ‘milk processor’ should be replaced with ‘milk processing business’ for consistency. The requirements of clauses 3(2) and 4 appear broader than is requires. This may be due to the vagueness in the wording of the standard. For the requirement is to ‘manage the hazards arising from’ (you could demonstrate that the hazard would be managed later by pasteurisation). In clause 5, ‘Microbiological safety of the milk’ is not a meaningful term since the subject is raw milk (not legal for human consumption). It is submitted that this escape provision is removed. To cater for circumstances such as milk being picked up before cooled to 5°C, an alternative provision ‘unless otherwise approved by the relevant authority could be included. The outcome of clause 7 should be made clearer – eg. Not the identification of the animals per se, but that milk included in the milk supply is from animals of appropriate health status). Comments for Clause 9(2) and 10 as above for Clause 3. The requirement in 10(b) is not specific enough. Clause 11 (time and temperature controls) – comments as for Clause 5. Clause 15(2)(b) –may not be necessary to specify Codex system. This puts in question whether another system between Standard 3.2.1 and Codex is acceptable if not expressly recognised by the Authority. It is noted that no equivalent sub-clause is found in clause 3(2) and Clause 9(2). The use of ‘any pathogenic micro-organism’ in Clause 16(1)(b) could suggest the wrong meaning. Suggest this is replaced with ‘all pathogenic micro-organisms likely to be found in milk’. Suggests that the use of Clause 16(1)(b) and 9c effectively mean ‘approved by the Authority or otherwise’, making sub-clause (c) redundant. The meaning of Clause 16(3)(a) is not clear. Suggests: ⇒ ‘a heat treatment that uses a combination of time and temperature of equal or greater effect on all pathogenic micro – organisms likely to be present in the milk product, compared to that achievable by paragraphs 19(1)(a) or 16(1)9b) for milk; or’ Raises that pasteurisation of milk products should also have a shock cooling requirement equivalent to 16(2). For Clause 17(a), insert ‘and 16(2), or 16(3)’ after ‘16(1)’.
National Foods	<ul style="list-style-type: none"> Supports the development and adoption of a Dairy Primary production and processing Standard, leading to consistency in regulations throughout the jurisdictions and across the supply chain. Notes the broad ranging consultative process undertaken by FSANZ, the use of the standards development Committee and the use of Scientific Expert panels in the development of the microbiological and chemical risk assessment reports. Notes the inconsistency between the title of the proposal and the title of the Standard (Dairy/milk) and raises whether the use of ‘milk’ in the Standards title may be considered more restrictive than with Codex and the Export control Orders, Submission supports the term ‘Primary Production and Processing Standard for Dairy. Comments that the draft Standard meets COAG principles for minimum effective regulation and is underpinned by good science.

Submitter	Comments
	<p><u>Specific comments</u></p> <ul style="list-style-type: none"> • Raises that the definition for milk transport businesses only covers collection and transport of milk from farm to factory or inter-factory transfers of milk and milk products. Dairy distributors are not specifically addressed by the Standards, though they are within the Dairy Act (Victoria) 2000. • The description of ‘milk’ provided is not a true definition (noting the definition in Standard 2.5.2) and needs clarification. • Raises that there is frequent reference to ‘milk products’ though this is not defined. • Supports the requirements for primary production, milk collection and transport, and processing business to have a documented food safety program. • Questions the wording of Clauses 16(1) and 16(2) to require milk to be cooled to below 5°C following pasteurisation. This is not applicable to UHT processing (where filling may occur at 25°C and storage at ambient temperature). Inclusion of a specific definition for UHT (including processing and packaging conditions) is recommended. • Raises that Clause 16(4) may need revision as it implies that milk products’ may be made using pre-pasteurised milk.
NSW Farmers Association	<ul style="list-style-type: none"> • Supports the development of nationally consistent food safety requirements for the production and processing of milk. • Supports the use of outcomes based systems with minimal prescription to provide flexibility – noting that farming operations are undertaken in different regions and have different associated risk profiles. • Raises that the lack of specific detail in outcome based standards can lead to confusion and as such, the development of non-enforceable guidelines to interpret the requirements is supported. Notes that the ‘Guidelines for Food Safety on Dairy Farms’ (ANZDAC) have been developed. • Notes that the DAR refers to the <i>Food Production (Dairy Food Safety Scheme) Regulation 1999</i> which was repealed in May 2005. These requirements are now included in the <i>Food Regulation 2004</i>. • Notes that the risk management measures identified cover some that are not specifically identified in the NSW Scheme, however believes that the general principles of the NSW Scheme cover them and additional requirements wouldn’t be imposed. • In relation to skills and knowledge, submission notes that there is currently no specific competency in the NSW Vocational Education and Training curriculum for dairy food safety. It may be difficult to assess whether individuals possess the necessary skills and knowledge. Suggest an amendment to the drafting to ‘...ensure that persons undertaking primary production activities are aware of the food safety and hygiene matters commensurate with their work activities.’ • Submission raises, in relation to enforcement, the outcomes based approach allows for openness of interpretation by auditors and possible discrepancies between auditors. Development of the national audit criteria to address consistency is raised. Additionally, there is inequalities across jurisdictions in terms of the penalties imposed (e.g. \$2 750 in NSW for a penalty not exceeding 25 penalty units and \$2 096 in Victoria where a penalty not exceeds 20 penalty units).
Queensland Health	<ul style="list-style-type: none"> • Submission seeks clarification as to whether the definitions in Standard 4.2.4, particularly in relation to milk primary production and milk processing businesses, is broad enough to reflect the scope of the Queensland Dairy Food Safety Scheme (noting that no definition of milk products is provided). • Raises that consequential amendments to Standards 2.5 Dairy Products would be required with respect to Standard 1.6.2 when these provision are moved to Standard 4.2.4.

Submitter	Comments
US Government	<ul style="list-style-type: none"> • Submission questioned the scientific basis for the current processing requirements for cheese that allow for thermisation plus storage of product for 90 days. • Raised questions in relation to survey data on the detection/presence of pathogens in raw milk and raw milk cheeses. • Raised questions in relation to the definition of processing aids in the Food Standards Code • Sought more information on what Standard 3.2.1 – Food Safety Programs required. • Sought clarification on the wording used in relation to the production of biogenic amines. • Noted that the cooling requirement for milk is more onerous than the US. Questioned how ‘alternative cooling and storage practices’ would be evaluated and by whom. • Raised that the inclusion of the production of colostrum with milk processing requirements is confusing as colostrum is not milk or a milk product. • Raised the question as to whether the FSANZ regulations would require exporting countries to have risk-based food safety systems in place (via certification).

Summary of State Regulations Applying to the Dairy Sector

1. New South Wales

The NSW Food Authority was established in 2004 and operates under the *Food Act 2003*. The *Food Production (Dairy Food Safety Scheme) Regulation 1999* ('The Dairy Scheme') provides requirements for the dairy chain from milk harvest to distribution of finished products.

The Dairy Scheme is a regulatory package that includes:

- Operational requirements on food businesses, including food safety program (HACCP program) requirements where appropriate and relevant standards or other specific requirements
- A compliance regime, including licensing and audit arrangements
- Funding arrangements which include licence, audit, inspection and other fees
- A mechanism for consultation with the relevant industries or sectors on the scheme's operation.

The Dairy Scheme also makes reference to the NSW Dairy Manual, which contains technical interpretation and details of the Dairy Scheme. It also prescribes minimum sampling guidelines and provides guidance for the development of a HACCP program.

On-farm requirements

It is a condition of a dairy farmers licence that they:

- develop a HACCP food safety program;
- have the program certified by the Food Authority;
- comply with the program;
- provide evidence the program is reviewed at least every year.

The Dairy Manual specifies matters that, as a minimum, must be addressed. These include:

- keeping milk cold (cooling to and keeping at 4°C);
- selling unpasteurised milk or cream to factories;
- keeping milk away from contamination (cleaning and sanitising of vats, equipment, premises; proper use of antibiotics, pesticides and other chemicals);
- sourcing milk from cows not affected by an infectious disease (keep records of cows affected and any treatment records);
- management of effluent;
- preventing Enzootic Bovine Leucosis (EBL)
- keeping records of compliance.

The Food Authority audits the food safety program at least every twelve months.

Milk collectors

To be able to collect and transport milk from a dairy farm, a Milk Collector must be licensed by the NSW Food Authority. To be licensed, the Milk Collector must

- have an approved milk collection vehicle;
- develop a HACCP food safety program;

- have the program certified by the Food Authority;
- comply with the program;
- review the program at least every year.

The Dairy Manual specifies matters that, as a minimum, must be addressed. These include:

- keeping milk cold (milk pick up temperatures should not exceed 10 °C. The transport vehicle must be capable of maintaining milk at the pick up temperature);
- only collect milk that is suitable;
- keeping equipment clean and in good order;
- training of persons involved (must be competent).

Dairy processing

Dairy Factories within NSW are required to be licensed with NSWFA. As a condition of license they must have a HACCP food safety program in place.

The Dairy Manual specifies matters that, as a minimum, must be addressed by the Food Safety Program:

- keeping milk and cream cold (at a temperature no greater than 5°C);
- only using milk from licensed operators;
- pasteurisation of products (including testing against Australian Standard AS 2300 for phosphatase activity);
- minimising contamination from premises and equipment by complying with building and equipment requirements of the *Food Production Regulation 1999* (which requires compliance with the *Code of Practice for Dairy buildings*) and appropriate cleaning and sanitising programs;
- control of Listeria and Salmonella in accordance with the ANZDAC manuals;

Finished products must undergo microbiological testing , at a testing frequency, according to the Authority's minimum testing requirements.

Milk and Dairy Produce stores and vehicle vendors (a business that delivers and sells milk by vehicle) are also covered by NSW regulations. They are also required to have a food safety program that essentially ensures keeping dairy products at the correct temperature (below 5°C) and away from contamination (through requirements for premises and equipment).

2. Queensland

Safe Food Queensland (SFQ) is a statutory authority set up under the *Food Production (Safety) Act 2000*. SFQ addresses the safety of primary production and processing in Queensland by developing and implementing food safety schemes for primary production and processing sectors.

The Food Safety Scheme for Dairy Produce (the Dairy Scheme) commenced on 1 January 2003 with the introduction of the *Food Production (Safety) Regulation 2002*. The Dairy Scheme calls up the *Food Standards Code* and mandates a requirement for food safety programs for the following activities:

- Dairy farmers (cows, goats, sheep, buffalo, camel);
- Manufacturing and processing of dairy products;
- Transporting dairy produce;
- Production of unpasteurised goat milk;
- Dairy products for pet food.

The Food Production (safety) Regulation 2002 specifies food safety requirements for each food safety scheme. The food safety requirements applying to the Dairy Scheme specify for milk production:

- animals to be milked must be free of disease;
- stock food for consumption by animals to be milked should not contaminate milk;
- milk supplied to be free of chemical contaminants;
- the production and storage of milk in a way that prevents contamination;
- temperature control for stored milk that restricts the development of microbiological hazards in the milk;
- health and hygiene requirements for persons undertaking milking activities;
- the design, construction and maintenance of dairy and equipment to minimise contamination

Transport requirements are covered under general provisions for primary produce. These require the transporter to maintain the produce under conditions that ensure it is acceptable and to have a vehicle that is designed and constructed such that it can easily be cleaned and does not allow for the contamination of produce.

Dairy processors must comply with the food safety requirements of the Food Standards Code. Specific requirements applying to dairy processes covered by the *Food Production (Safety) Regulation* cover:

- receipt of dairy produce;
- processing requirements;
- storage of dairy produce;
- minimal standards for microbiological and chemical hazards and testing.

3. South Australia

The Dairy Authority of SA was established in 1993 under the *Dairy Industry Act 1992*. Its primary function is to ensure the safety and quality of the production and processing of dairy products in SA by monitoring standards and providing guidance to the dairy industry.

The Primary Produce (Food Safety Schemes) Act 2004 (replacing the *Dairy Industry Act 1992*) and *Primary Produce (Food Safety Schemes) (Dairy Industry) Regulations 2005* came into effect on 1 August 2005. These regulations established food safety schemes for dairy farmers, dairy manufacturers, dairy distributors and dairy produce carriers and requires them to be accredited. All dairy businesses must have an approved food safety program in place.

The *Primary Produce (Food Safety Schemes) (Dairy Industry) Regulations 2005* requires businesses to comply with the revised Code of Practice for Dairy Food Safety. The requirements of the Code of Practice cover dairy farms; dairy produce carriers (transport of liquid dairy produce in bulk); dairy manufacturing premises and dairy distributors.

Requirements for dairy farms

The Code of Practice requires a dairy farm Food Safety Program to provide for:

- Physical contaminants
- Chemical contaminants
 - veterinary and agricultural chemicals
 - pest control
 - environmental contaminants
 - animal feeds
- Microbiological contaminants
 - animal health
 - environmental contaminants
- Dairy milking premises, storage and equipment
- Hygienic milking
- Water supply and quality
- Cleaning and sanitizing
- Traceability
- Records (to demonstrate compliance)
- Personnel competency.

Specific provisions are also included for farms selling raw/unpasteurised goat milk.

Requirements for dairy produce carriers

The Food Safety Program for dairy produce carriers must be based on Codex HACCP principles and provide for:

- Delivery and collection (such that the tanker or vessel does not contaminate or taint milk and that milk is transported such that the growth of pathogenic microorganisms is prevented.)
- The design, construction and maintenance of transport vehicles, equipment and vessels.
- Water supply and quality
- Cleaning and sanitizing
- Identification and traceability (of milk and milk ingredients from suppliers to manufacturers, and of vehicles, equipment and vessels)
- Record keeping (to demonstrate compliance)

- Personnel competency.

Dairy produce carriers must collect dairy produce at 5 °C or below unless alternative temperature control procedures have been validated to ensure minimisation of pathogen growth.

Requirements for dairy manufacturers

The Food Safety Program for dairy manufacturers must be based on Codex HACCP principles and provide for the following:

- Physical contaminants
- Chemical contaminants
 - Veterinary and agricultural chemicals
 - Pest control
 - Environmental contaminants
 - Processing chemicals
 - Allergens
- Microbiological contaminants
 - Pathogen control
 - Storage and temperature control
- Design, construction and maintenance of dairy manufacturing premises and equipment
- Water supply and quality
- Cleaning and sanitizing
- Rework controls
- Product disposal
- Testing programs (to verify effective operation of the FSP)
- Identification and traceability (to allow trace back and trace forward of all dairy products and ingredients)
- Record keeping (maintained for a minimum of 3 years to demonstrate compliance)
- Personnel competency

In addition to compliance with the Food Standards Code, the Code of Practice requires manufacturers to comply with the ADASC manuals *Australian Manual for Control of Listeria in the Dairy Industry* and *Australian Manual for Control of Salmonella in the Dairy Industry*.

Requirements for dairy distributors

The Food Safety Program for dairy distributors must be based on Codex HACCP principles and provide for the following:

- Contaminants
- Pest control
- Temperature and storage control (such that produce is protected from the likelihood of contamination and under temperature control)
- Cleaning and sanitizing
- Identification and traceability (ensuring traceability of product from receipt to delivery)
- Record keeping (to demonstrate compliance)
- Personnel competency.

4. Tasmania

The Tasmanian Dairy Industry Authority (TDIA) is the authority responsible for developing, implementing and maintaining food safety and quality assurance programs in relation to the production, transport and manufacture of dairy produce in Tasmania. The TDIA is established under the *Tasmanian Dairy Industry Act 1994*.

The *Tasmanian Dairy Industry Act 1994* requires dairy business in Tasmania to be licensed by the TDIA. A condition of licence is to develop and implement a Food Safety Program according to the Tasmanian Code of Practice for Dairy Food Safety. As for South Australia, this Code of Practice is based on the Victorian Code of Practice for Dairy Food Safety, with requirements covering dairy farms; dairy produce carriers (transport of liquid dairy produce in bulk); dairy manufacturing premises and dairy distributors. The requirements of the Food Safety Program are as above for South Australia.

In addition to adopting the *Australian Manual for Control of Listeria in the Dairy Industry* and *Australian Manual for Control of Salmonella in the Dairy Industry* for dairy manufacturers, the Tasmanian Code of Practice also requires dairy manufacturing premises to comply with the relevant provisions of the Export Control (Processed Food) Orders.

5. Victoria

Dairy Food Safety Victoria (DFSV), established on 1 October 2000 under the *Dairy Act 2000*, is the authority responsible for the safety of all dairy foods produced in Victoria for domestic and export markets.

The *Dairy Act 2000* requires all dairy businesses operating in Victoria to be licensed with DFSV. This includes dairy farmers, dairy food carriers, dairy manufacturers and dairy distributors. As a condition of licence, dairy businesses must have a Food Safety Program that complies with the (Victorian) Code of Practice for Dairy Food Safety (DFSV, 2002). This Code of Practice sets the minimum mandatory standards for the production, manufacture, storage and transport of milk and dairy foods to safeguard public health.

The requirements of the (Victorian) Code of Practice for Dairy Food Safety have been outlined above under South Australia dairy regulations. A copy of the Code of Practice is available on the DFSV website at www.dairysafe.vic.gov.au

6. Western Australia

Dairy food safety is managed in Western Australia within the Dairy Safety Branch of the Department of Health. The Dairy Safety Program operates under the *Health Act 1911* and the *Health (Food Hygiene) Regulations 1993*.

The requirements for milk and dairy produce specified within the *Health Act 1911* (Division 4 – Milk and dairy produce) make it an offence to:

- sell contaminated milk (including using it for butter or cheesemaking), particularly in relation to milk from animals affected with any disease of livestock;
- allow persons suffering from an infectious disease to milk any animal or be involved in milk handling activities.

The legislation requires dairy premises to be properly constructed (it is up to local government to register dairy premises in accordance with local laws). It allows for local laws to be made to cover matters that may affect the safety and suitability of milk including the following:

- situation, construction, cleansing, water supply etc. of dairies, milk stores and milk shops;
- sterilisation and delivery of milk;
- cleansing and disinfecting dairies, milk stores, milk shops and removing diseased animals or persons.

Western Australia is currently reviewing its legislation to implement a Code of Practice for Dairy Food Safety. The majority of dairy farmers in Western Australia do already have an industry developed HACCP based quality assurance program. While there is not a regulated requirement for these programs, they are required by most milk processors.

Summary of Export Control (Milk and Milk Products) Orders 2005

The *Export Control (Milk and Milk Products) Orders 2005* together with the *Export Control (Prescribed Goods – General) Orders 2005* provide conditions and restrictions on the export of dairy, eggs and fish. These Orders can be obtained from the Department of Agriculture Fisheries and Forestry website at: www.daff.gov.au

Provided below is an outline of the requirements of the Export Control Orders that apply to the management of food safety and suitability, structural requirements, operational hygiene, preparation and transport, product standards and tracing systems.

Management of food safety and suitability (Schedule 2)

A registered establishment must have a Hazard Analysis Critical Control Point (HACCP) plan that:

- identifies each of the steps in food preparation;
- identify the potential hazards that may be occur for each step;
- identifies the methods of control of each potential hazard (unless met by the operational hygiene requirements);
- identifies the critical control points, the critical limits and the procedure to be used to monitor the potential hazards and the corrective actions to be taken if a critical limit is exceeded (for each significant hazard);
- identifies procedures used to verify compliance with the HACCP plan;
- provides for record keeping and documentation to demonstrate compliance with the HACCP plan.

Schedule 2 also covers management practices to be in place within the establishment and approved arrangements.

Structural requirements (Schedule 3)

Requirements in Schedule 3 for processed food establishments cover:

- construction of premises, equipment and vehicles (covering the immediate surrounds; floors; walls and ceilings; fixtures, fittings and equipment; food carrying compartments, containers sytem units and vehicles; measuring devices and storage facilities);
- cleaning and sanitising of premises and equipment;
- handwashing facilities;
- amenities;
- effluent and waste;
- lighting;
- ventilation;
- water supply (premises must have a supply of potable water available for use at a volume, pressure and temperature that is adequate for purpose).

Operational Hygiene (Schedule 4)

Operational hygiene requirements cover:

- Hygiene controls for premises and equipment (there must be a documented program of operational controls for the hygienic preparation of processed food) covering -
 - standard of cleanliness
 - requirement to clean and maintain;
 - vehicles etc. for the transport of processed food;
 - environmental contamination;
 - pests;
 - hazardous substances.
- Hygiene requirements for processing covering -
 - measures to prevent contamination
 - calibration of measuring instruments
 - refrigeration chambers
 - ingredients
 - potable water
 - microbial limits.
- Personal hygiene and health requirements covering –
 - food borne diseases
 - conditions and injuries
 - personal cleanliness
 - personal effects and clothing/protective clothing

Preparation and transport (Schedule 5)

Part 1 of these requirements, Division VII covers the sourcing of milk. It requires that milk is only sourced from an establishment where there is disease management in place and there are effective measures in place to prevent the contamination of milk.

Part 2 of the preparation and transport requirements Division IV covers the processing requirements for milk and milk products (pasteurisation). These reflect the requirements of the Food Standards Code and allow for any other heat treatment specified in an approved arrangement.

Other matters covered include:

- packaging
- storage, handling and loading;
- transport.

Product standards (Schedule 6)

This schedule specifies that processed food for export must meet the requirements of the Food Standards Code with respect to –

- metal or non-metal contaminants
- agricultural and veterinary chemicals
- microbiological limits

Identification, tracing systems, integrity and transfer (Schedule 8)

This schedule requires that all processed food prepared at the establishment can be:

- identified;
- traced; and
- if necessary, recalled.

It requires trace-back records for processed food and ingredients, as well as information on the outer container of processed food leaving the establishment to allow for identification.