

9-04

15 December 2004

INITIAL ASSESSMENT REPORT

PROPOSAL P296

PRIMARY PRODUCTION & PROCESSING STANDARD FOR DAIRY

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED**

(See 'Invitation for Public Submissions' for details)

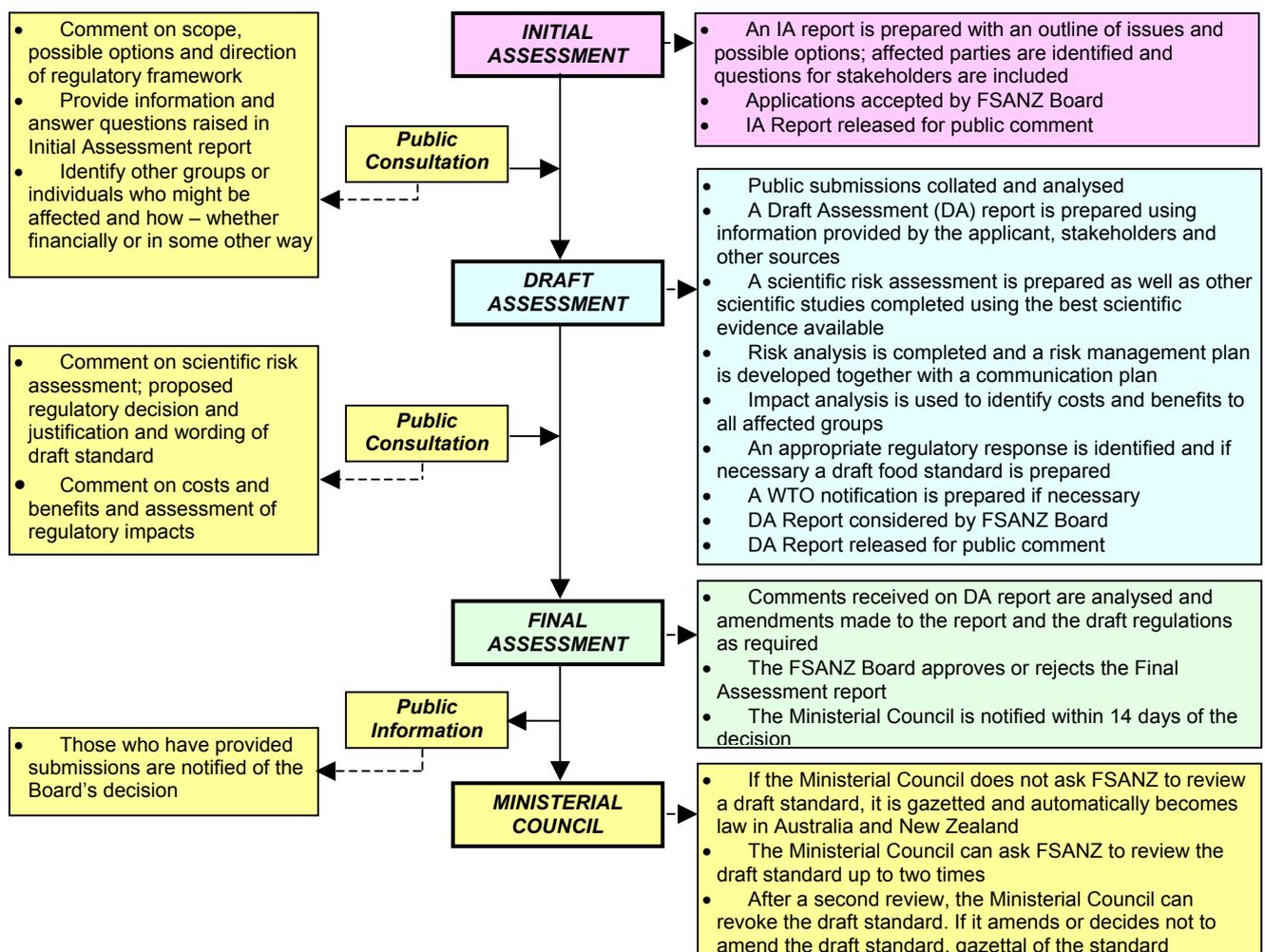
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report for Proposal P296, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing developing a Primary Production and Processing Standard for the dairy industry for approval by the FSANZ Board.

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

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

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

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

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

Submissions need to be received by FSANZ **by 6pm (Canberra time) 9 February 2005.**

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

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

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

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Executive Summary

Australia enjoys a high level of food safety and like other nations we face the challenge of continually improving food safety and reducing food-borne illness. Globally, food-borne illness is a growing public health problem because of changes in the way food is produced and manufactured, changes in consumer requirements and increasing global trade in food.

A whole of Government approach to the management of food safety is now being taken in Australia. Governments have agreed that food safety should be addressed throughout all parts of the food supply chain (*i.e.* from *paddock-to-plate*) to maximise food safety. This approach aims to maintain or improve public health and safety and ensure that consumers continue to have the highest confidence in the safety of the food they consume, without imposing undue costs on industry

Dairy products form a significant component of the diet of most Australians. Food Standards Australia New Zealand (FSANZ) has commenced development of the Primary Production and Processing (PPP) Standard for Dairy (Proposal P296). A Standard Development Committee (SDC) has been established to advise and assist FSANZ throughout this process and comprises representatives of the dairy industry, State and Territory governments, Australian Commonwealth Government agencies, New Zealand and the Consumers' Association.

The dairy industry in Australia is a highly regulated sector and practices high levels of food safety management. At the moment, these arrangements are implemented through State based dairy regulation and industry codes of practice and guidelines. The dairy industry is very keen to develop a single set of national dairy regulations – through a single Dairy PPP Standard.

FSANZ is therefore collaborating with dairy regulators, industry groups and consumers around the country to develop a single national standard encompassing a whole of food supply chain process. Although this standard will not apply in New Zealand we are also consulting with New Zealand Government and industry because of the increasing integration of the two industries.

Any new standard developed in this process will form part of Chapter 4 and may amend Chapter 3 of the *Australia New Zealand Food Standards Code* (the Code) and will be nationally consistent and conform to the principle of minimum effective regulation *i.e.* requirements will only be put in place to the extent necessary to protect the public health and safety.

The standard development process requires assessment of public health and safety risks associated with the consumption of dairy products, the food safety management controls that are in place at the moment and also an understanding of the practical issues associated with the production and processing of dairy. This Initial Assessment Report discusses these issues and raises a number of questions in relation to the:

- current operation of the dairy industry;
- hazards potentially present in dairy products that could result in food-borne illness and how these are controlled;
- evaluating the risk to public health from dairy products;

- existing regulatory requirements; and
- potential scope of the new national Dairy PPP Standard.

FSANZ seeks submissions from stakeholders to ensure that any new standard is effective, relevant, provides benefits to consumers, is cost-effective for industry and can be enforced in a nationally consistent manner.

The data and information gathered from stakeholders at this initial stage will be evaluated in the risk assessment process covering the science, the economics and any social impacts . The outcomes of the risk assessment will be considered and inform a proposed food safety management strategy for the dairy industry, and this will be described in the Draft Assessment Report. FSANZ will be seeking comment on the Draft Assessment Report during 2005.

1. Introduction

FSANZ's primary responsibility is to protect the health and safety of consumers through the development of food standards. FSANZ intends to ensure that Australia's dairy industry is able to continue to provide consumers with some of the safest products in the world - now and into the future.

Before FSANZ recommends a new PPP Standard, FSANZ will examine the entire dairy supply chain to understand the nature and impact of potential hazards. FSANZ will then evaluate the effectiveness of current management practices in controlling those hazards and identify any areas in need of enhanced or different control.

FSANZ seeks initial comment from stakeholders in relation to the development of a dairy PPP Standard. This includes advice on the dairy industry and existing food safety management strategies, potential public health hazards present in dairy products, and the stage of the dairy supply chain where these hazards could be introduced and how these are presently managed. The Standard developed as part of this process will be part of Chapters 4 and possibly 3 of the Code, which are only applicable in Australia.

This section details the regulatory framework for the development of PPP Standards, knowledge of the Australian dairy industry and existing food safety management strategies.

1.1 Regulatory framework for development of Primary Production and Processing Standards

In 1997 the Commonwealth, State and Territory Governments agreed to a comprehensive review that examined the regulatory burden on businesses and the clarity and efficiency of food regulatory arrangements. The resultant Blair Report recommended a national 'paddock-to-plate' approach to food regulation to protect public health and safety.

The Council of Australian Governments (COAG) Senior Officials Working Group on Food Regulation (SOWG), formed in 1999, recommended that all existing domestic food standards, including standards that cover primary production and processing, be combined to produce a single set of national standards consistent with internationally recognised Codex Alimentarius Commission¹ ('Codex') standards. The development of the national 'paddock-to-plate' standards is the responsibility of FSANZ and aims to:

- ensure that food safety is addressed systematically across the entire food chain;
- provide nationally consistent standards that will set a benchmark for industry obligations to produce safe food;
- provide minimum impost on industry to achieve the most effective food safety outcomes;
- harmonise with international standards; and
- increase public confidence in the safety of food products.

¹ Codex Alimentarius Commission (Codex) is the international body whose purpose is protecting the health of consumers, ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. Codex develops food standards, guidelines and codes of practice under the Joint FAO/WHO Food Standards Programme.

In developing PPP Standards, FSANZ works within the framework of the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) *Overarching Policy Guideline on Primary Production and Processing Standards* and *FSANZ's Protocol for the Development of Primary Production and Processing Standards*.² These guidelines emphasise the food safety nature of the standards. The different stages in the Standard development process are detailed in Figure 1.

When developing national standards FSANZ has statutory obligations with respect to section 10 of the FSANZ Act, which establishes the following objectives in descending order of priority:

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

FSANZ also has a statutory requirement to consider the impact of any proposed standard on the food industry and have regard to the:

- need for standards to be based on risk analysis, using available scientific evidence;
- the promotion of international consistency in setting food standards;
- the promotion of an internationally competitive and sustainable food industry;
- the promotion of fair-trading in food; and
- any written policy guidelines formulated by the Ministerial Council and notified to FSANZ e.g. the Ministerial Council *Overarching Policy Guideline on Primary Production and Processing Standards*.

Under the Inter-Governmental Agreement between the Australian, State and Territory Governments, once any new standard has been approved and gazetted, it will be implemented under State and Territory legislation. Development and subsequent application of the standards to industry sectors will be dependent on an analysis of the public health and safety risks, economic, social and political risks and current risk management practices. The primary consideration will be protection of public health and safety. This will be discussed further in Section 4.

Quality attributes or specific production methodologies that do not relate to food safety will, in general, need to be handled through industry mechanisms and not a mandated food Standard. A Primary Production and Processing Standard for dairy would not include labelling, compositional or additive/contaminant/ residue standards. These requirements are largely in place already in Chapters 1 and 2 of the Code. However, there may be a need to consider these elements of the Code further, as a result of this work.

² These documents may be obtained from the FSANZ website <http://www.foodstandards.gov.au/>

There are also standards in Chapter 3 of the Code that address general food safety requirements and the construction and operation of food premises and equipment. These apply to the secondary (further) processing of dairy products and, where possible, FSANZ would not be seeking to duplicate these requirements in a Dairy PPP Standard.

To assist in the development of PPP Standards, FSANZ establishes a Standard Development Committee (SDC) for each primary production and processing sector considered. The Dairy SDC consists of representatives from the dairy industry, the Consumer's Association, research organisations, jurisdictions and relevant FSANZ staff.

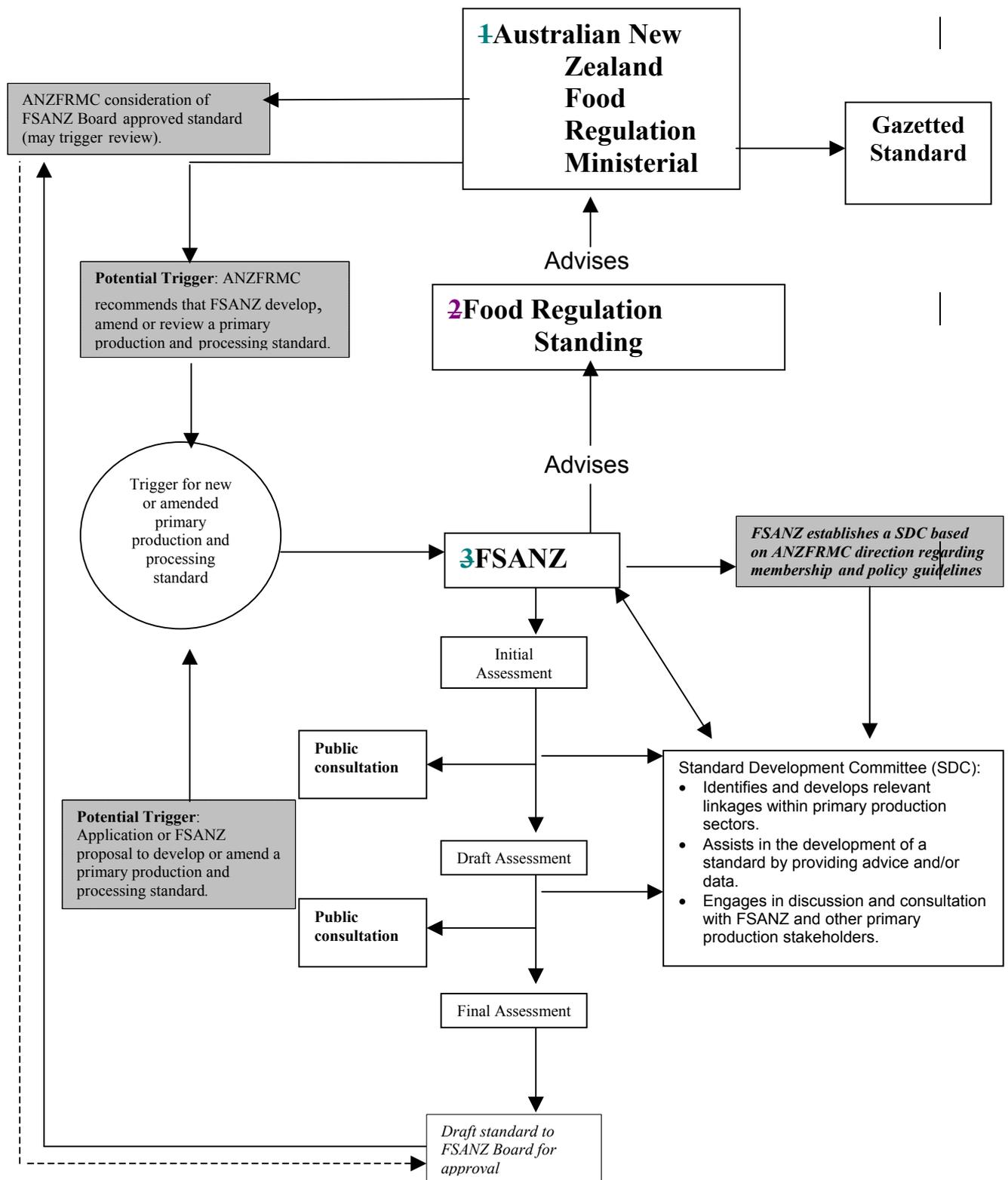


Figure 1: FSANZ’s standard development process for primary production and processing standards

The Dairy SDC has provided FSANZ with an insight into the current operations of the industry and the role of existing regulations in food safety matters. The SDC has also assisted FSANZ to prepare this Initial Assessment Report. However, the SDC may not necessarily have representation from all stakeholders, such as small producers, importers and other groups. In recognition of this, it is proposed to actively involve other stakeholders through development of broader networks, state and territory public consultations and possibly the establishment of specific satellite groups to consider specific issues. Any issues arising from these broader consultations will be discussed with the SDC.

FSANZ's intention is that all relevant stakeholders are actively involved in the development of recommendations on PPP Standards and that transparency is maintained throughout the process. This Initial Assessment Report seeks comment, information and data from all relevant stakeholders regarding the issues and questions raised and/or any other relevant issues. The comments, information and data provided during this consultation will be considered during the development of the Draft Assessment Report, which will be released for consultation in 2005.

Regulatory impact analysis is a critical part of the standards development process and must take into account the impacts on, and views of all affected stakeholder groups - including industry, consumers, and governments of proposed regulatory options. FSANZ must also ensure that the cost of the overall system is commensurate with the assessed level of risks and benefits. These issues are raised in this Initial Assessment Report (see Section 4) and will also be considered in the Draft Assessment and Final Assessment Reports to meet the requirement of the Office of Regulation Review. FSANZ must also ensure that PPP Standards do not unnecessarily restrict trade and that they fulfil Australia's obligations to World Trade Organization (WTO) agreements.

1.2 Dairy Industry in Australia

The dairy industry is a major rural industry in Australia. The majority of the milk and milk products are derived from bovine milk and 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 industries.

Australian bovine milk production costs are well below those in most major dairy producing countries around the world. Most dairy production is located in coastal areas where pasture growth generally depends on natural rainfall. Dairy is one of Australia's leading rural industries in terms of adding value through further or downstream processing. Much of this processing occurs close to farming areas, thereby generating significant economic activity and employment in country regions. A detailed overview of the bovine milk industry (prepared by Dairy Australia) is provided in Attachment 2.

Table 1: Australian Dairy Outlook (Source: ABARE)

| | | 2002-04 | 2003-04 | 2004-05 | % change |
|-------------------------|---------|----------------|----------------|----------------|-----------------|
| Cow numbers | 000 | 2050 | 2028 | 2042 | 0.7 |
| Milk yields | L/cow | 5037 | 4963 | 5010 | 0.9 |
| Production | | | | | |
| Total milk | ML | 10326 | 10065 | 10231 | 1.6 |
| - Market sales | ML | 1924 | 1951 | 1953 | 0.1 |
| - Manufacturing | ML | 8402 | 8114 | 8278 | 2 |
| Butter | kt | 149 | 130 | 130 | 0 |
| Cheese | kt | 368 | 364 | 380 | 4.4 |
| WMP | kt | 170 | 158 | 160 | 1.3 |
| SMP | kt | 215 | 206 | 204 | -1 |
| Milk price | cents/L | 27.1 | 26.7 | 27.9 | 4.5 |
| Value of exports | A\$m | 2378 | 2178 | 2269 | 4.2 |

The small dairy-goat industry in Australia supplies milk and milk products valued at \$1 million/year to a niche market. Seasonality of milk supply, small farm numbers and industry experience limit the supply of goat milk for processing and hence the potential for the processing industry to grow. There are a number of vertically integrated producers and manufacturers. The main products are drinking milk, speciality cheese and yoghurt. The Australian Goat Milk Association (AGMA) was formed in 2000 to represent the industry.

There is an established market in Australia for the sheep milk products such as cheese and yoghurt. There are sheep dairy farms in Victoria, NSW, South Australia and Western Australia. Although the majority of sheep milk is produced in the Mediterranean basin, Australia has the potential to be a major producer of sheep milk.

Water buffaloes are also used for milk production. Australia's only water buffalo dairy farm is located in Victoria. The herd was started in 1995 with importation of Riverine Buffalo from Italy and Murrah buffalo from Bulgaria in 1996. The main products made from water buffalo milk are cheese and yoghurts.

Due to lack of readily available data and information for the non-bovine dairy industry, it is difficult to estimate the size and scale of the operations. The bovine dairy industry data is available from Dairy Australia and other industry organisations.

FSANZ is seeking data and information on the non-bovine dairy sectors.

2. CURRENT REGULATORY ISSUES

The dairy industry in Australia has approached FSANZ seeking development of a single national dairy standard. Dairy in Australia is currently regulated under six³ different sets of State regulations, and exporters are also covered by AQIS export arrangements. In addition, food hygiene requirements for the dairy is also regulated under Chapter 3 – Food Safety Standards of the Code. For a description of the various dairy regulatory arrangements in Australia see Attachment 1 and Table 2.

While a number of States have adopted similar food safety requirements for dairy, there is no uniform ‘national’ dairy scheme. The dairy industry in Australia recognises benefit in consolidating current arrangements within one food standard. This approach is consistent with the ‘paddock to plate approach’ endorsed by the Ministerial Council in July 2002, and being progressed through FSANZ’s food standards processes. Any standard developed will be applied to domestic and imported products. Issues regarding the implementation of any dairy standard at the border will be considered.

Before considering options for regulatory changes to the Code, it is necessary to determine if the benefits of any amendment may be justified, or whether existing arrangements are adequate. To do this it is necessary to estimate the impact of the lack of a single national standard. If no nationally consistent standard is of minor consequence, justification for amendment of the Code may be difficult. If considerable benefits can be identified, action to develop a national standard would be a positive course of action.

Protection of public health and safety is the primary consideration in the development of any standard in the Code. Given the very low level of food-borne illness associated with dairy products in Australia, it is likely that existing State-based regulations adequately address the public health and safety risks arising from consumption of dairy products.

However, with increasing growth and mergers of dairy companies within Australia and greater global trade in dairy commodities, it is expected that the dairy industry would benefit from a consolidation of arrangements with a single national scheme. Were this scheme to maximise harmonisation between domestic and export arrangements, the benefits would presumably be greater. Taking this further, should these requirements be based around the Codex dairy standard⁴ (Codex Code of Hygienic Practice for Milk and Milk Products, finalised in 2004), Australian legislative requirements would be further harmonised with international requirements.

These benefits to the dairy industry would likely be in the form of lower implementation costs through similar or consistent compliance arrangements for companies operating across borders.

³ Only the six States, and not the ACT or the NT, have dairy industries and hence dairy regulations, albeit that the territories each have a milk processing establishment.

⁴ Codex General Standard for the Use of Dairy Terms, www.codexalimentarius.net/download/standards/332/CXS_206e.pdf

Comment is sought on the impact (major, moderate, minor or insignificant) of the lack of a single national dairy standard, and whether this would warrant development of a mandatory national standard.

Comment is sought on perceived outcomes if a ‘do nothing’ approach was taken.

Comment is also sought on the benefits that would result should a national standard be adopted.

3. OBJECTIVE

The specific objective of any agreed Primary Production and Processing Standard for Dairy will be to develop a single national food safety management strategy that protects public health and safety whilst imposing no unjustified costs on industry.

Food standards dealing with consumer information and to prevent misleading and deceptive conduct are already in place within the Food Standards Code. However, additional or changed requirements may emerge through this process.

In addition, any Dairy standard would 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;
- provide assurance for overseas customers of a national approach to managing dairy food safety through a whole of chain approach including on-farm, transportation of milk and processing establishments, rather than a dependence on different State based legislation;
- 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

The Dairy Standard will be developed with regard to FSANZ’s statutory obligations and the following Ministerial policy guidelines:

- be a set of outcomes-based national standards for the relevant primary production and processing sectors/commodities and/or be of general relevance to primary production and processing activities;
- have a consistent regulatory approach across the Standards;
- be consistent with the s10 objectives of the FSANZ Act, recognising that the protection of public health and safety has priority;
- be consistent with the approach outlined in Chapter 3 of the Code;
- be consistent with internationally recognised Codex standards, save where, after consideration of a risk assessment, it is clear that the relevant standard does not sufficiently protect public health and safety in Australia;
- address food safety across the entire food chain where appropriate;
- facilitate trade;
- be not more trade restrictive and comply with Australia's obligations under World Trade Organization Agreements;
- ensure that the regulatory framework promotes consumer confidence;
- ensure the cost of the overall system should be commensurate with the assessed level of risks and benefits;
- provide a regulatory framework that applies only to the extent justified by market failure;
- provide for collaborative action among enforcement agencies to optimise the use of resources and effectiveness.

4. RELEVANT ISSUES

In order to progress the development of a standard, FSANZ is required to consider a number of possible regulatory options. Before formulating some regulatory options, FSANZ must consider the full range of issues likely to arise in developing a Dairy PPP Standard.

As an early step in the process, FSANZ has established a formal Standards Development Committee comprising industry, consumers and government. The issues set out in this section have been identified through early discussions of the SDC. FSANZ welcomes comments on these issues, and any others, from all interested parties.

4.1 Definition of Dairy

To determine what should be encompassed in a future Dairy PPP Standard, an agreed definition of dairy products would need to be determined. A set of definitions that may be acceptable is that defined by the Codex Alimentarius Commission⁵.

Briefly, these are:

- Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.

⁵ (Codex General Standard for the Use of Dairy Terms, www.codexalimentarius.net/download/standards/332/CXS_206e.pdf)

- Milk product is a product obtained by any processing of milk, which may contain food additives, and other ingredients functionally necessary for the processing.
- Composite milk product is a product of which the milk, milk products or milk constituents are an essential part in terms of quantity in the final product, as consumed provided that the constituents not derived from milk are not intended to take the place in part or in whole of any milk constituent.
- A reconstituted milk product is a product resulting from the addition of water to the dried or concentrated form of the product in the amount necessary to re-establish the appropriate water to solids ratio.
- A recombined milk product is a product resulting from the combining of milkfat and milk-solids-non-fat in their preserved forms with or without the addition of water to achieve the appropriate milk product composition.
- Dairy terms means names, designations, symbols, pictorial or other devices which refer to or are suggestive, directly or indirectly, of milk or milk products.

It is recognised that these definitions are intended to encompass the broader range of dairy products, and not just those resulting from PPP activities.

It is likely that State and export dairy regulations already in place in Australia use this or a similar definition to cover milk and milk products resulting from primary production activities. These will be considered.

4.1.1 Species

It will be necessary for any Dairy Standard to include consideration of what species of animal should be included. FSANZ is aware of dairy operations that utilise milk of bovine, camel, goat, sheep, and buffalo origin. Comment is sought on whether the Dairy PPP Standard should encompass products from the species listed and/or any other animal. Conversely, is there any reason not to include the milk of all mammalian species (other than human), to cover future developments in the dairy industry?

4.1.2 Boundary of the Standard

4.1.2.1 On-farm

The exact boundary of the Dairy PPP Standard will need to be determined. Consideration will be given to the extent of on-farm regulations currently in use by State Governments, the model provided by the Codex Code of Hygienic Practice for Milk and Milk Products (adopted in July 2004, ALINORM 04/27/13) and the on-farm requirements for dairy exports from Australia. The effectiveness and efficiency of these arrangements will be taken into account in the development of the Dairy Primary Production and Processing Standard.

4.1.2.2 Processing

Milk is processed into a variety of value added dairy products in Australia and overseas. Consideration will be given to how well these production processes are currently regulated in the Code and in State dairy regulations, and whether they should be covered in the Dairy PPP Standard.

4.1.2.3 Inputs

Inputs to dairy products can occur at on-farm and processing/manufacturing stages. Current on-farm systems require management of inputs to primary production (on-farm inputs). It is anticipated that in the development of the Dairy PPP Standard, FSANZ would only consider food safety aspects of on-farm inputs, such as animal feed or veterinary chemicals. It is recognised that these inputs are largely covered by legislation external to the Code. It is the responsibility of the farmer/industry to ensure that on-farm inputs comply with relevant legislation, and hence these aspects are outside the Code. FSANZ will consider all other inputs that occur post-farm.

Comment is sought on the adequacy of the Codex definition for milk and milk products, and whether this would capture all of the products likely to be addressed by a Dairy PPP Standard.

Comment is sought on any variations currently in use under State dairy regulations and the benefits or problems arising from those definitions.

Comment is sought on the list of species that should be covered by this standard. Is there any reason not to include the milk of all mammalian species (other than human), to cover future developments in the dairy industry?

Comment is sought on the boundary of the Dairy PPP Standard, and how far this might extend into processing requirements normally covered by Chapter 3 of the Code.

Comment is sought on the regulation of inputs (such as water, stock feed) to primary production and processing. These are currently outside the scope of the Code. What reference should be made to regulation of these inputs in the Dairy PPP Standard?

4.2 Food Safety Requirements

Duplication of any of the existing Code requirements under Chapter 3 – Food Safety Standards is not intended. However, it may be practical to move some requirements from Chapters 1-3 to the proposed Chapter 4 - Dairy Primary Production and Processing Standard (such as pasteurisation, for example), where they may be more appropriate to primary production and processing activities.

4.2.1 Food Hygiene in Processing Plants

General food safety requirements for processing, manufacturing, retail, and distribution of food are included in Chapter 3 of the Code. However, there are no ‘dairy-specific’ requirements. Although, theoretically, the Chapter 3 food safety standards should be applied in Australian dairy plants under current State arrangements, some States have indicated that they consider these Chapter 3 requirements to be insufficient to ensure food safety in dairy processing facilities. Consequently, some States have developed more extensive requirements. Codex also provides detailed examples of the types of requirements that may be appropriate for dairy processing plants, in its Code of Hygienic Practice for Milk and Milk Products.

Consideration will need to be given to the best mix of food safety requirements for the Chapter 4 – Dairy Primary Production and Processing Standard, and may be based on Codex and existing State requirements.

4.2.2 Microbiological Limits and Processing Requirements

Chapter 1 of the Code contains a set of microbial limits and processing requirements for some dairy products (Standard 1.6.1 – Microbiological Limits for Food, and Standard 1.6.2 – Processing Requirements).

FSANZ may need to consider whether the existing microbiological limits and processing requirements are appropriate and adequate in the light of any new regulatory measures for dairy.

4.2.3 Food Safety Risk Management Practices

4.2.3.1 Aspects of existing management practices

Management of hazards on-farm (as required by State/AQIS regulation) and pasteurisation are key food safety elements of Australia’s dairy industry. Standard 1.6.2 – Processing Requirements (Australia only) – requires pasteurisation or heating to any other time and temperature combination of equal or greater effect on bacteria for milk and liquid milk products, unless an applicable State or Territory law otherwise expressly provides. Editorial notes address the products captured by liquid milk products and processing requirements in New Zealand (which were recently amended).

The combination of process technologies (High Temperature Short Time, and Ultra High Temperature in particular), advances in refrigeration, and effective hazard management has resulted in a strong food safety record for Australian dairy products. Subsequently, this has allowed the creation of valuable export opportunities. Development of a Dairy PPP Standard will consolidate this food safety record by establishing nationally consistent standards framework.

4.2.3.2 Alternative Technologies

The Codex General Standard for the use of Dairy Terms allows for the adjustment of milk to compositional criteria contained in the various Codex standards for milk and milk products. This facilitates the introduction of other technologies.

Alternative technologies such as microfiltration, ultrafiltration, ultra high pressure, ultrasonication and electric pulse fields are being developed with potential application to dairy products. Emerging technologies can also be used in combination with heat treatment and sanitary packaging equipment. Hurdle technology involves the use of several different preservation techniques to prolong the shelf life of processed foods.

Considerable risk assessment work has already been done in Australia and around the world in association with emerging technologies and with regard to milk from non-bovine animals. FSANZ will be drawing on this information in its assessment of the human health risks that are relevant to the development of a Dairy PPP Standard.

Standard 1.6.2 also provides processing requirements for cheese and cheese products, permitting thermisation of milk for cheese making and referring to Standard 2.5.4 – Cheese, for processing requirements for three Swiss cheeses. An editorial note in Standard 2.5.4 refers to control measures, including for example pasteurisation, shown to achieve the appropriate level of health protection for milk and milk products.

4.2.3.3 Raw Milk Products

Many overseas countries allow the production and import of raw milk products. In Australia this is currently limited to specific imported raw milk cheese varieties, and the production of unpasteurised goat milk in some States.

FSANZ will need to consider the safety of raw milk products from all species not already in the Code, and whether these may be produced with appropriate management techniques (by use of, for example, extended ripening, thermisation, alternative technology) to ensure an appropriate level of safety. This safety determination will be based on a careful consideration of the food safety risks (building on, for example, NSW Food Authority sheep and goat milk risk assessment) and what, if any, process or end point controls would be effective and necessary to ensure these products are safe for human consumption. FSANZ will require access to a range of data sources, particularly regarding raw milk production and associated human epidemiology, in order to conduct a robust, science-based risk analysis.

FSANZ is currently progressing an Application (A499) from the French Government seeking regulatory approval for a specific type of French raw milk cheese (Roquefort, made from sheep milk) in Australia. Because this Application was received some time ago, it is being dealt with through FSANZ's statutory processes for dealing with applications, a process separate to the development of a Dairy PPP Standard. The due date for finalisation of this application is Sept 2005. However, FSANZ also has on hand a range of other Applications for raw milk cheeses, and it may be necessary for the Dairy PPP Standard to elaborate a framework to assess the safety of these products.

Comment is sought on the following issues:

- **What level of detail, prescription or principle is required for minimum effective food safety regulation of on-farm/processing facilities in the Dairy PPP Standard.**
- **What components of the Codex Code of Hygienic Practice for Milk and Milk Products are relevant for Australian conditions?**
- **Are the current microbiological limits and processing requirements adequate, too restrictive or too permissive?**
- **To what extent should ‘process’ controls and ‘end point’ controls be used?**
- **What level of review may be required for existing food safety management practices on-farm and during processing?**
- **To what extent do food safety regulatory requirements prevent or inhibit small or new businesses?**
- **Do the industry costs reflect the risks?**
- **What are the key risks to public health and safety for the consumption of unpasteurised milk?**
- **What are the key risks to public health and safety for the consumption of unpasteurised milk products?**
- **What sources of data (particularly quantitative microbial information) are available for assessing the safety of raw milk and milk products?**

4.3 Process for assessing the risk to public health

4.3.1 Introduction

A scientific assessment of risks⁶ to public health and safety from milk and milk products will be undertaken by FSANZ to inform risk management decisions.

A number of tools can be used to assess risks to public health and safety, including risk profiling, quantitative and qualitative risk assessments and scientific evaluations. The application of these tools to the assessment of the risk to public health and safety is dependent on the purpose of the assessment and on the availability, quality, and quantity of relevant data.

⁶ Codex defines the term risk as ‘*a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food*’

Once the scope of the assessment has been determined, it involves an evaluation of all available and relevant scientific data concerning the safety of the commodity under consideration and the properties of the hazards. This requires utilisation of appropriate and rigorous scientific data and includes procedures to address uncertainty and variability in the conclusions that are drawn from the data.

The process of undertaking a risk assessment⁷ has been established internationally by the Codex Alimentarius Commission, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The risk assessment process used by FSANZ is consistent with international protocols and consists of four distinct steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

In undertaking risk profiling and other scientific evaluations FSANZ follows established international guidelines where available, and incorporates elements of the Codex risk assessment framework where appropriate.

The outcome of the scientific assessment of risks to public health and safety may include a statement on the probability and severity of an adverse health effect due to the consumption of a food containing a particular biological, chemical or physical agent. The scientific assessment may also identify where in the production chain controls over hazards will have the greatest impact on minimising risk *i.e.* informing risk managers where intervention will be most effective.

4.3.2 Approach

FSANZ will initially evaluate risks to public health and safety through the dairy product supply chain. The approach will utilise available information including current scientific and epidemiological data, and published Australian and international risk assessments. This evaluation may be in the form of a Risk Profile⁸ describing the current situation in Australia. This may be followed by a quantitative risk assessment to specifically examine hazards associated with the production of raw milk and raw milk products and assess the risks they pose to public health and safety. The scientific assessment will also examine the safety provided by new alternative technologies in comparison to pasteurisation as described in the previous section (page 19).

The assessment of risks to public health and safety from milk and milk products will examine associated hazards, epidemiological and other data to determine whether these hazards have presented, or are likely to present a public health risk, and identify where in the food supply chain these hazards may be introduced.

Access to appropriate data is essential for the assessment of risks to public health and safety, as the risk assessor requires a good understanding of the entire production chain (paddock-to-plate) and knowledge of the various factors that may impact on the safety of milk and milk products. This includes data on:

⁷ Risk assessment is a scientific process undertaken to characterise the risk to public health and safety posed by food-borne hazards associated with a food commodity.

⁸ Risk profiling is defined by FAO/WHO as ‘*the process of describing a food safety problem and its context, in order to identify those elements of the hazard or risk relevant to various risk management decisions*’

- on-farm inputs (e.g. feed, water, veterinary interventions etc)
- whether there is any contamination of dairy products with specific hazards at all points along the production/supply chain, and if so the levels and extent of contamination;
- epidemiological data linking adverse health outcomes to those hazards; and
- information on dietary exposure to the hazards in milk and milk products.

The following sections seek comment, information and data on many of these issues, and responses will inform approaches employed during the risk assessment process. FSANZ will work closely with the dairy industry and relevant agencies to ensure that as much relevant, Australian data as possible can be incorporated into its assessment of risks to public health and safety.

4.3.3 *Milk and milk products and human disease in Australia*

As part of the Scientific Evaluation the incidence of food-borne disease arising from milk and milk products will be examined. Milk and milk products are commonly consumed foods in Australia, however they are rarely identified as sources of food-borne illness by health departments⁹.

Specific pathogens, and the food vehicles for illness are rarely identified and only a small proportion of cases that occur in the community are notified to health departments. Therefore the exact cause of illness is usually only determined when specific epidemiological studies are conducted or when an outbreak has occurred¹⁰. Investigators often identify the specific food that people had eaten before becoming ill, but often do not identify the original source of product contamination, such as infected humans, animals or flaws in handling the food.

In Australia, the Australian Government Department of Health and Ageing established OzFoodNet in 2000 as a collaborative project between the Commonwealth and States and Territories to enhance the surveillance of food-borne diseases and to provide a means for facilitating the national investigation of and determine the causes of food-borne illness. During 2002, OzFoodNet did not document any food-borne outbreak attributable to milk or milk products. Although there were 3 outbreaks attributed *Salmonella* contamination in cakes filled with cream and/or custard in bakeries, investigation of these outbreaks were attributed to food handling practices on the premises¹¹.

Australian epidemiological data on the extent and cases of human disease associated with the consumption of milk and milk products are being sought. Where there is an absence of Australian data, overseas data may be considered taking into account the difference in farming practices, production methods etc.

⁹ The OzFoodNet Working Group (2003) Food-borne disease in Australia: incidence, notifications and outbreaks. Annual report of the OzFoodNet network, 2002. *Commun Dis Intell* **27**;209–43.

¹⁰ Hall, G.V., D'Souza, R.M., Kirk, M.D. (2002). Food-borne disease in the new millennium: Out of the frying pan and into the fire? *Med J Aust* **177**;614–618.

¹¹ The OzFoodNet Working Group (2003) Food-borne disease in Australia: incidence, notifications and outbreaks. Annual report of the OzFoodNet network, 2002. *Commun Dis Intell* **27**;209–43.

Comment and data is sought on the extent and cases of human disease associated with the consumption of milk and milk products.

Comment and data is sought on the extent and cases of human disease associated with the consumption of raw milk and raw milk products.

4.3.4 Consumption of milk and milk products in Australia

There are two types of food consumption data that are frequently used in microbiological risk assessments: food production statistics and food consumption surveys. Food production statistics provide an estimate of the amount of food commodities available to the total population. This type of data may include national statistics on per-capita food production (Attachment 2) consumption surveys (such as national nutrition surveys) provide detailed information regarding the types and amounts of foods consumed by individuals or households and sometimes the frequency with which the foods are consumed. The pattern and quantity of food consumed can then be used in a risk assessment to assist in determining exposure to a particular hazard.

Dairy products are commonly consumed foods in Australia, with approximately 83 % of respondents from the 1995 Australian National Nutrition Survey¹² (13,858 respondents) consuming milk and other liquid milk products.

The average consumption of milk and liquid milk products by consumers is 347 grams/day. Approximately 9% of respondents consume cheese with an average daily consumption for consumers of 29.7 grams and approximately 15% of respondents consume ice cream with an average daily consumption for consumers of 112 grams.

Comment and data is sought on the consumption of milk and milk products in Australia.

Information is sought on the type of milk products available in the Australian food supply and the proportion of the market that they supply.

4.3.5 Possible hazards associated with milk and milk products

The development of a PPP Standard for Dairy products will need to focus on hazards that significantly contribute to a public health risk and include principally biological and chemical hazards.

¹² Australian Bureau of Statistics and Department of Health and Family Services (1997). *National Nutrition Survey 1995*. Australian Government Publishing Service, Canberra.

4.3.5.1 Hazards of a biological nature

Milking animals may carry a wide range of microorganisms, some of which are human pathogens. In addition, the milking procedure, and subsequent collection and storage of milk carry the risks of further contamination or growth of inherent pathogens. Importantly, the composition of many milk products makes them good media for the outgrowth of many pathogenic micro-organisms.

Micro-organisms likely to be considered in the scientific assessment include:

| | |
|---|--|
| <ul style="list-style-type: none">• <i>Campylobacter jejuni/coli</i>• <i>Staphylococcus aureus</i>• <i>Listeria monocytogenes</i>• <i>Salmonella</i> spp.• <i>Yersinia enterocolitica</i>• <i>Streptococcus</i> spp. | <ul style="list-style-type: none">• <i>Mycobacterium</i> spp.• <i>Brucella</i> spp.• Pathogenic <i>Escherichia coli</i> (EHEC)• <i>Bacillus</i> spp.• <i>Coxiella burnetii</i>• <i>Enterobacter sakazakii</i> |
|---|--|

Comment and information is invited on the list of biological hazards to be considered in the risk assessment.

Comment and information is invited on other hazards involved in human illness associated with milk and milk products that have not been identified in this Report.

4.3.5.2 Hazards of a chemical nature

Risks of a chemical nature associated with dairy may be endogenous to the product (milk-based allergens), a result of further processing (e.g. biogenic amines) or introduced throughout the primary production and processing chain (e.g. chemical contaminants, agricultural and veterinary chemicals and chemicals used in food processing). Where possible, the review will identify and characterise the hazard associated with specific chemicals, and utilise relevant chemical residue and exposure surveys to characterise the risks associated with dairy products.

The assessment of the risks associated with chemicals in dairy products will be undertaken from the perspective that most chemicals, which may present a risk in relation to dairy products, have been previously assessed and are regulated by specific Standards in the Code. In general, chemicals are regulated in specific foods where there is a potential public health and safety risk. The assessment of potential risks associated with chemicals in dairy products will consider both those chemicals currently regulated within the Standards as well as any other potential chemicals that may be a public health and safety risk.

Comment and information is invited on chemical hazards associated with dairy products.

4.3.5.3 Hazards of a physical nature

The physical hazards associated with dairy products are mostly extrinsic (e.g. metal inclusions, plastic, glass and other material that is foreign to the nature of the food).

Extrinsic physical hazards are potentially introduced at all stages along the dairy processing chain. Sources for such contaminants include facilities and equipment, improper production procedures, packaging materials and poor employee practices. Physical hazards associated with milk and milk products will not be specifically addressed in the scientific assessment as they are adequately addressed by requirements relating to safe and suitable food in state and territory legislation.

4.3.6 Consideration of hazards in species other than bovine

The predominant species from which milk may be obtained in Australia is bovine animals. However it is proposed that the scientific assessment consider where data is available, milk and milk products from the species listed in Section 4.1.1, as follows:

- cows (bovine species);
- buffalo (bubaline species);
- goats (caprine species);
- sheep (ovine species); and
- other species such as camel.

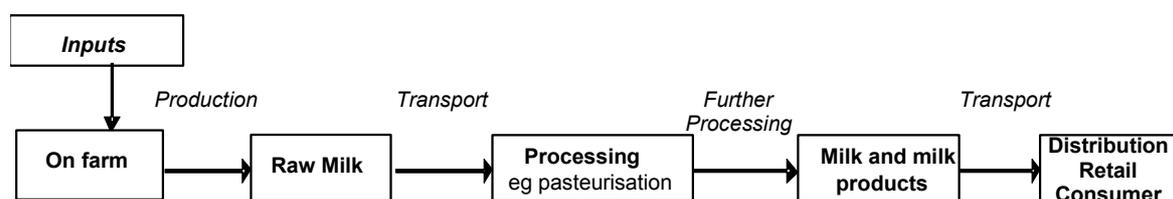
The scientific assessment will focus on the potential hazards associated with the above list of species. Information will be sought on the nature and extent of hazards associated with these other species.

Comment is sought on the inclusion of these and any other milking animal species for consideration in the risk assessment.

Quantitative data (including prevalence and concentration data) are sought on both biological and chemical hazards specific to both raw and pasteurised milk obtained from cows, sheep, goats, buffalo and camel.

4.3.7 The milk and milk products supply chain

The scientific assessment will consider hazards that can be introduced from milking animals, the farm environment, and the processing of milk into milk products. On-farm inputs considered will include feed, water, etc.



Taking into consideration the definitions of dairy products as outlined in Section 4.1, the milk products to be considered in the scientific assessment may include the following:

- Milk and liquid milk products and cream and cream products
- Cheese
- Dried milk powders
- Butter and butter products
- Ice cream
- Yoghurt and fermented milk products
- Dairy based dips and dairy desserts
- Colostrum
- Whey products and other functional milk derivatives (e.g. lactoferrin)

Comment is sought on the type and categorisation of milk products to be considered in the scientific evaluation.

Comment is sought on food safety issues resulting from on-farm practices.

Information, data (including prevalence and concentration/level data) and comment are sought on the potential hazards in the dairy product supply chain that may be introduced during on-farm production of milk, transport and during processing, for both domestic production and imports.

Information, data (including prevalence and concentration/level data) and comment are sought on the potential hazards that may be introduced during subsequent processing into milk products, both domestic production and imports.

Information is sought on how potential hazards are currently managed.

What sources of data (particularly quantitative microbial information) are available for assessing the safety of various processes, such as alternative technologies in comparison to pasteurisation?

5. REGULATORY OPTIONS

Using the scientific evaluation of the public health and safety risks associated with dairy products, an analysis of how these risks are currently being managed and an understanding of the costs and benefits of regulation FSANZ will develop and analyse some regulatory options for a Dairy standard.

In assessing regulatory options, FSANZ conforms to the guidelines set out by the Office of Regulation Review¹³. Briefly, these guidelines encompass:

¹³ Office of Regulation Review 1998, *A Guide to Regulation (second edition)*.

1. *Issue identification*
 - Specification of the issue involved (in this case, development of a nationally consistent Standard for Dairy PPP in the Code)
2. *Specification of the desired objective(s)*
 - Objective of the desired regulatory action (including information on existing legislation)
3. *Identification of options*
 - Lists the various regulatory and possible non-regulatory options identified
4. *Assessment of impacts (cost/benefit analysis)*
 - Consider impact of each identified option on government, industry, and consumers
5. *Consultation*
 - Outlines the consultation process, and includes a summary of the views elicited
6. *Recommended option*
 - A statement of the preferred option and why this is preferred over other alternatives

FSANZ seeks comments on possible regulatory arrangements for inclusion in the Dairy Standard. For instance, regulation could be based on:

- end point testing of products against set microbiological criteria;
- process controls through food safety management plans which may or may not require auditing;
- pasteurisation may be required in all circumstances;
- some raw milk products may be permitted, provided adequate food safety outcomes can be delivered in other specified ways.

Comment is sought on whether validation and verification controls in place are adequate?

Comment is sought on all of these regulatory possibilities or any other regulatory or non-regulatory measures for managing food safety.

Comment is sought on their likely effectiveness and their costs and benefits

6. IMPACT ANALYSIS

6.1 Impact Analysis

A regulatory impact analysis will be conducted during the development of the Dairy PPP Standard to identify the most appropriate regulatory measures to be included in a Standard. this will include a benefit-cost or cost effectiveness analysis.

6.2 What impacts will be considered

The following sections list questions for consumers, industry and Government regarding the impact of food safety management strategies. FSANZ must consider the impact of any food safety management strategies proposed in later stages of the standards development process on all sectors of the community, including the dairy industry, governments, and consumers. Comments, information and data supplied in response to the questions listed below and any other issues that are raised will be considered in the impact analysis.

6.3 Consumers

What are the potential public health risks attributable to the consumption of dairy products?

What impact does household food handling and food preparation practices have on the risk of food-borne illness from the consumption of dairy products? Which practices are the most important for preventing food-borne illness associated with dairy products?

What interest is there in access to new dairy products currently unavailable in Australia?

6.4 Dairy Farmers, Manufacturers and Distributors

What major public health and safety risks have been associated with milk and milk products? How could any new regulatory measures, if developed, help minimise these risks?

Which stages of the dairy supply chain have the food safety risks been associated with? How have you gone about minimising these risks? What are the regulatory measures in place to help minimise these risks? Are additional measures needed?

Have food safety incidents impacted on your operation? How?

How are food safety risks controlled in your operation?

What is the value of consistency of food safety management arrangements across the dairy industry in Australia? Can current regulations be consistently applied nationally? If not what new strategies would help achieve national consistency?

Are the current national and State/Territory food safety regulations:

- **too prescriptive?**
- **necessarily prescriptive?**
- **commensurate with the food safety risks they are addressing?**
- **easy to understand?**

- easy to implement?
- effective?

Why/why not?

Are the answers to the above questions likely to change depending on the size of the operation?

Are there issues associated with the cost of the current regulations to your business?

Are any of these costs due to duplication of the current regulations that may be addressed through development of a single, national food safety standard for dairy?

Are there any gaps in the current food safety regulations for dairy production, processing and retail?

Can you describe the safety of your dairy product(s) through the supply chain?

What are the impacts of differences in regulation of dairy products between Australia and New Zealand? Australia and overseas countries?

Do you wish to develop or import new dairy products that are currently not permitted in Australia? What are they?

Are smaller producers and manufacturers disadvantaged by the current arrangements, if at all?

6.5 Government

To what extent are current food safety regulations enforceable in the dairy supply chain including enforcements of the regulations for imported dairy products?

How could existing dairy regulations be changed to improve the efficiency of implementation and compliance activities?

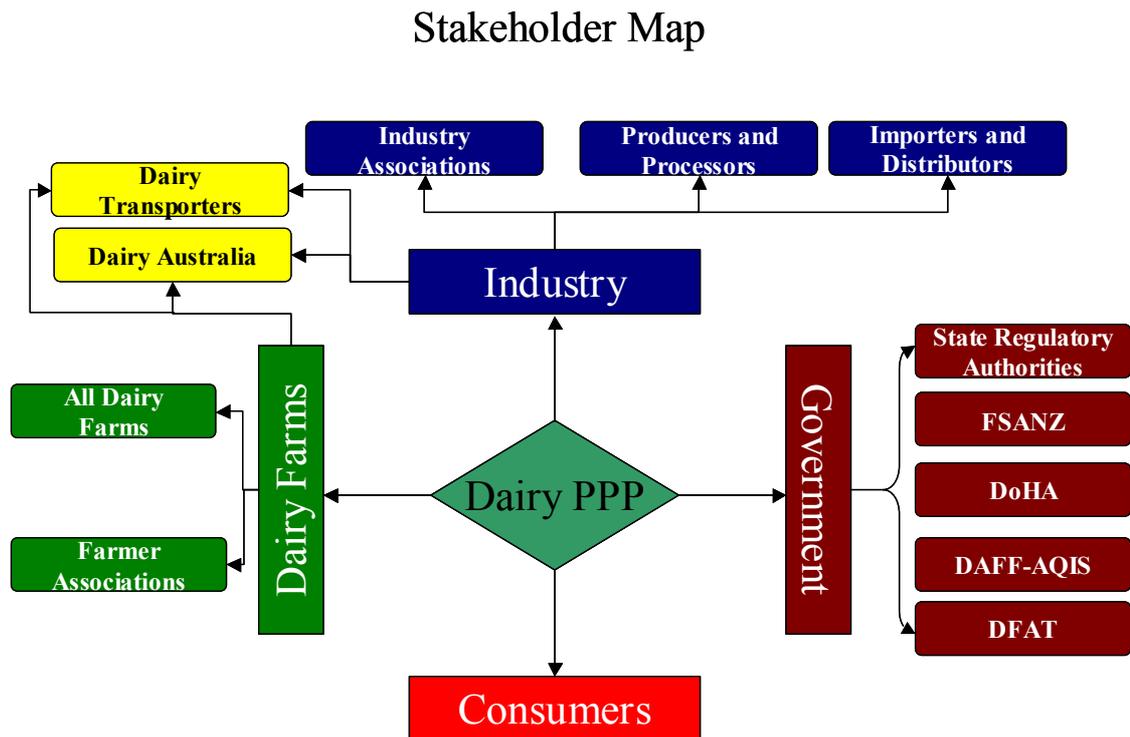
Are there areas of duplication and unnecessary cost associated with compliance activities that could be reduced through development of a single, national food safety standard for dairy?

To what extent are the current food safety regulations delivering the outcomes they were designed for? Could any other measures be used to help deliver the outcome?

Do existing arrangements have differential impacts on small and large producers or manufacturers? What improvements could be made?

7. CONSULTATION

The SDC, which has representation from all the major stakeholder groups, advises FSANZ on wide range of issues. Additional stakeholder consultations will be carried out as required by FSANZ. These stakeholders will be identified with the help of SDC members, direct contacts or other appropriate methods. The comments and issues will be recorded and addressed during compilation of Draft Assessment Report.



7.1 World Trade Organization (WTO)

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

8. CLOSING REMARKS

This Initial Assessment Report provides the first opportunity for stakeholders to comment on and supply information and data to FSANZ regarding a PPP Standard for Dairy.

FSANZ welcomes and encourages stakeholder input. The comments, information and data provided during this consultation will be considered during the development of the Draft Assessment Report, which will be the next formal opportunity for stakeholders to comment.

Attachments

1. State and Dairy Export Regulations
2. Overview of the Bovine Dairy Industry

State Regulations

NEW SOUTH WALES

Responsible Agency

The NSW Food Authority (NSWFA) is a State Government agency established in April 2004, and was formed by merging SafeFood NSW with the food regulatory activities of NSW Health. As Australia's first completely integrated or 'through-chain' food regulation agency, the NSWFA is responsible for food regulation across the entire food industry, from primary production to point-of-sale.

NSWFA provides the regulation framework for industry to produce safe and correctly labelled food by:

- contributing to national food policies and standards;
- establishing NSW regulations and food safety programs;
- developing food laws in consultation with stakeholders; and
- auditing, inspecting and enforcing food regulations.

The Authority also educates consumers on food safety by:

- cultivating good food handling practices;
- sharing information on food safety; and
- providing information on correct labelling.

Legislation

NSWFA was established 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 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.

It also makes reference to the NSW Dairy Manual ('the Manual') published by NSWFA, which contains technical interpretation and details of the Dairy Scheme. For example, the Manual prescribes minimum sampling guidelines for the verification of dairy product HACCP programs. and cross-references *Listeria* and *Salmonella* clearance programs developed by ADASC.

Food Safety Arrangements

NSWFA works with local government to enforce all aspects of the Australian and New Zealand Food Standards Code, the NSW Food Act 2003 and the State's food safety programs. Food safety programs target food safety risks throughout the food supply chain and are tailored to individual industries, sectors or businesses. The programs incorporate national standards and are introduced by regulation under the Food Act.

NSWFA ensures that industry complies with food safety programs by licensing or recording notification of food businesses in NSW, auditing and inspecting their operations regularly and where necessary, penalising non-compliance.

It is a condition of a dairy farmers licence that a certified HACCP system be in place on the farm to control both food safety and quality issues. A dairy farm HACCP system is certified by NSWFA through a certification audit. Following this NSWFA conducts a 6 monthly compliance audit. Once it is shown that the farm HACCP system is running effectively, NSWFA Food Safety Officers then audit the system on an annual basis.

Dairy Factories within NSW are required to be licensed with NSWFA. They are also required to have a fully operational HACCP system in place. New licensees are given a period of 3(three) months to establish this HACCP food safety program which is then certified and consequently audited by NSWFA Food Safety Officers.

Compliance and Enforcement Activities

NSWFA's Compliance Unit implements food safety schemes in accordance with the regulations. The Unit schedules and conducts routine audits and inspections in the dairy industry to ensure compliance with the standards specified in legislation.

On-farm compliance

The HACCP manuals cover both quality and safety issues and both areas are audited. The quality areas are audited on behalf of the farmers' respective factories of supply. Once a farm audit is completed, the Dairy Farm HACCP Audit Checklist and Dairy Building Inspection Report are completed.

Classification of non-conformities - with respect to the food safety systems that are operating on most dairy farms throughout NSW, the following are the rankings of defects that are commonly found at the farm level:

Critical Defects

- Identification of treated cows
- Contagious human diseases
- Observe WHP's and identify paddocks sprayed with chemicals

Serious Defects

- Correct quantities of sanitiser, test dip/spray and detergents
- Teat dip/spray to manufacturer's recommendation
- Purchased feed declaration

Major Defects (Records)

- Vat cooling time
- Wash up procedure
- Sanitiser residue
- Recording treated cows
- Test milk of doubtful cows
- Tested milk of agisted / purchased cows
- Identify sold stock
- Record treated cows
- Record drug and medicine purchases
- Record chemical and spray purchases
- Record feed purchases
- Internal Audit

Major defects (Procedures)

- Drain sanitiser from plant
- Use accredited detergent, sanitiser and teat dip/spray
- Consult with vet on type, dose rate, administration method of drugs
- Do not feed antibiotic treated milk to calves for slaughter
- Milk treated cows last or into test bucket
- Dairy buildings to be maintained at A or B rating
- Use veterinary drugs and medicines purchased from approved outlets
- Store drugs and medicines in a secure area or to manufacturers recommendations
- Restrict dairy animals from effluent sprayed paddocks for at least 14 days
- Mix sprays according to label of Agronomist advice
- Store and mix agricultural sprays away from the dairy premises

Minor Defects

- All other areas of non conformance are minor

Manufacturing/processing plant compliance

AQIS has delegated the audit of NSW exporting dairy establishments to NSWFA. Hence, audits for these establishments are for dual purposes, thereby minimising duplication of audit. This is facilitated by NSWFA's adoption of AQIS's audit regime as set out in the *Export Control (Food Processed) Orders* for all dairy plants.

Non conformities are classified and dairy factories in NSW are rated using the establishment rating table in Schedule 7 of the *Export Control (Food Processed) Orders*. This enables uniformity when issuing the factory with a rating at the end of the audit.

Enforcement

The Enforcement Unit complements the routine auditing and compliance inspections by conducting unannounced inspections of premises in industries covered by food safety schemes which have been identified as high risk areas and responds to risk areas such as recalls, complaints, product traceability and unlicensed activities.

QUEENSLAND

Responsible Agency

Safe Food Queensland (SFQ) is a statutory authority set up under the *Food Production (Safety) Act 2000*. SFQ is responsible for food safety in the primary production and processing sector and, with its regulatory partner Queensland Health, ensures food safety for the entire food chain starting with farm inputs.

SFQ addresses the safety of primary production and processing in this State by developing and implementing food safety schemes for each activity involved in the primary production and processing sector.

Legislation

The Food Safety Scheme for Dairy Produce commenced on 1 January 2003 with the introduction of the *Food Production (Safety) Regulation 2002* under the *Food Production (Safety) Act 2000*. The scheme involves 1,000 dairy farms and 44 dairy processing premises. This legislation dovetails seamlessly with the *Food Act 1981* for through chain coverage of the dairy industry.

Food Safety Arrangements

The regulatory arrangements that are now in place in Queensland are in line with national Food Safety Standards that require all food businesses to take responsibility for food safety using risk management principles. The Dairy Scheme calls up the 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
- Goat milk
- Dairy products for pet food

All dairy factories in Queensland have in place HACCP based food safety programs that meet the requirements of the *Export Control (Processed Food) Orders* and are accredited and audited by SFQ officers.

Manufacturers must test their products in line with the ADASC *Minimum Sampling Guidelines for Dairy Products* (Attachment 3) that includes regular testing of soft cheeses for *Listeria monocytogenes*.

In addition dairy processing factories must comply with *Listeria* and *Salmonella* Clearance Manuals. Other matters relating to food safety of dairy produce are covered by the *Food Act 1981*.

Compliance activities

For the domestic market dairy processing activities have been divided into high and low risk to determine auditing frequency (high – 3 and 6 months, low – 6 and 12 months).

On farm

SFQ accredits all dairy farms in Queensland and requires that the farm operates to a food safety program meeting the requirements of the Dairy Food Safety Scheme. Ninety percent (90 %) of farms have their food safety programs verified by external approved auditors.

SOUTH AUSTRALIA

Responsible Agency

The Minister of Agriculture, Food and Fisheries is responsible for the safe production and processing of dairy products in SA. The *Dairy industry Act 1992* establishes the Dairy Authority of SA and provides the powers for it to administer the Act. The Dairy Authority is an independent Statutory Authority reporting to the Minister.

The Dairy Authority of SA was established in 1993. Its primary function is to ensure the safety and quality of the production and processing dairy products in SA by monitoring standards and providing efficient, professional and reliable guidance to the dairy industry. The *Dairy industry Act 1992* requires licensing of dairy farmers (including goat and sheep dairy farmers), processors and vendors, who must have in place approved HACCP-based food safety programs. The Authority registers dairy food carriers on a voluntary basis.

The Dairy Authority conducts mandatory second party audits to verify compliance with relevant food safety and dairy industry standards as a condition of licence for dairy processors. The Authority conducts third party audits of dairy farms for some dairy processors, and other farms are audited by the processors themselves.

The Department of Health - Food Section undertakes surveillance to monitor compliance with food labelling and food composition standards of the Food Standards Code adopted under the Regulations under the Food Act. The Food Section also works with local government officers in the Investigation of food poisoning incidents. Where concerns about unsafe food involve serious food poisoning incidents or overlap council boundaries, the Food Section will generally play a major role in the investigation. Should a concern over the safety of a food be serious enough to warrant the recall of a food, the Food Section will work with the manufacturer to ensure the recall is effectively conducted and will coordinate the recall with other state authorities to prevent the food being distributed and sold.

Legislation

On the 9th August 2001 the South Australian Parliament passed the new *Food Act 2001*. The *Food Act 2001* and *Food Regulations 2002* came into operation on the 1 December 2002. The Australia New Zealand Food Standards Code is adopted under these Regulations. Administration of the South Australian *Food Act 2001* and Regulations is shared between the Department of Health and local council authorities (defined in the Regulations as Enforcement Agencies).

The *Dairy Industry Act 1992* establishes the Dairy Authority of SA and provides the powers for it to administer the Act. From 1 July 2003 a new Code of Practice modelled on the Victorian Code of Practice for Dairy Food Safety replaced existing standards and codes of practice.

Food Safety Arrangements

As in Victoria, all processors have in place approved HACCP-based food safety programs in compliance with the Code of Practice for Dairy Food Safety, and export premises comply with Schedules 2, 3 and 7 of the *Export Control (Processed Food) Orders*.

Manufacturers must test their products in line with the ADASC *Minimum Sampling Guidelines for Dairy Products* (Attachment 3) that includes regular testing of soft cheeses for *Listeria monocytogenes*. In addition, dairy processing factories must comply with the Listeria and Salmonella Clearance Manuals.

Compliance Activities

As in Victoria.

On farm

All dairy farms must have in place an approved dairy farm food safety program in accordance with the Code of Practice for Dairy Food Safety.

TASMANIA

Responsible Agency

Tasmanian Dairy Industry Authority (TDIA) is an independent statutory authority, its Board reports to the Tasmanian Minister for Primary Industries and Water. The TDIA is 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 and administers dairy food safety legislation at federal, state and local government level. Dairy premises are required by law to be licensed by the TDIA.

The Goals of the TDIA as contained in the Dairy Industry Act 1994 are to ensure:

- Production of consistently safe, reliable Tasmanian dairy products for all consumers.
- A strong Tasmanian dairy industry, with a sustainable reputation for world's best practice and dairy products.
- Develop and implement programs in relation to the manufacture of dairy produce designed to ensure the safeguard of public health and protection of consumers and ensure truth and accuracy in labelling.

Objectives:

- Provide a comprehensive dairy food safety service for Tasmania.
- Extend Tasmania's clean, green image to *clean, green and safe*.

The TDIA is sufficiently empowered under the Dairy Industry Act 1994 to enable it to perform its functions efficiently and effectively, including, but not limited to:

- setting and administering minimum standards for the production, testing, processing, distribution and handling of dairy produce;
- entering into any contract or arrangement;
- engaging consultants or other contractors;
- charging a fee for services provided by it under the Act; and,
- doing anything necessary or convenient to perform its functions.

An authorised officer may, amongst other things: –

- (a) enter, inspect and examine any dairy premises or any other premises on which –
- (i) dairy produce is manufactured, tested, graded, stored or packed; or
- (ii) there is conducted a business in respect of which a licence is required; and
- (b) enter, inspect and examine any dairy premises or other premises which the authorized officer reasonably suspects are being used for the purposes in paragraph (a); and
- (c) inspect and examine any records, product, material, equipment, plant or facility on any premises or vehicle relating to or used for receiving, collecting, processing, producing, manufacturing, transporting, storing, distributing, packaging, sealing, testing, grading, selling, purchasing or disposing of dairy produce; and

- **(d)** inspect and examine any records kept by a licensee for the purpose of verifying information given to the Authority by the licensee for the purposes of this Act; and
- **(e)** take copies of or extracts from any records referred to in paragraph (c) or (d); and
- **(f)** take samples, not exceeding 10% of the total volume, of any dairy produce or any material, chemical or other substance or thing used or suspected of being used in connection with the production, preparation, processing, manufacture, testing or grading of any dairy produce; and
- **(g)** conduct, or cause to be conducted, any examination, grading or analysis the authorized officer considers necessary to determine the composition, safety or quality of any dairy produce; and
- **(h)** stop and inspect any vehicle used, or constructed, for the transport of milk.

The TDIA will:

- consult with the Tasmanian dairy industry;
- ensure that quality systems meet nationally and internationally recognised HACCP principles and provide independent accreditation of quality and food safety systems to international standards;
- carry on the business as AQIS's authorised agent for Tasmania's dairy product exporters to facilitate export to overseas countries;
- participate in extrinsic audits by overseas delegations;
- maintain a dairy licence data base;
- monitor and control all legislative conditions of dairy licenses
- employ competent food safety auditors accredited by internationally recognised bodies:- JAS-ANZ, QSA.

TDIA staff are involved in providing a range of key services including:

- Management of pathogen control programs.
- Contributing to the development of Codes of Practice.
- Collaborating with national policy bodies.
- Contributing to development of operational standards.
- Participating in the Australian Milk Residue Analysis survey.
- Developing and approving Food Safety programs, FPA, AQA.
- Assisting with a standardised approach to On-Farm QA.
- Administering dairy farm Code of Practice program.
- Monitoring dairy farm effluent management practices.
- Assistance with problem solving.
- Monitoring of milk testing programs in dairy laboratories.
- Ensuring milk testing meets legislative requirements.
- Provision of training services in food hygiene, food handling, personnel hygiene, bulk milk grading.
- Provision of general, scientific and technical support to manufacturers.
- Ensuring truth and accuracy in labelling.

Legislation

Dairy Industry Act 1994 and the *Tasmanian Code of Practice for Food Safety*, based closely on the DFSV Code. Administers AQIS provisions for all dairy exporters and has adopted the Export Control (Processed Food) Orders for all licensed dairy manufacturers and processors.

Tasmania has adopted the Food Standards Australia New Zealand Food Standards Code and the Food Safety Standards

The *Food Act 2003* is Tasmania's principle food safety legislation, whose objectives are to ensure food for sale is both safe and suitable for human consumption and to prevent misleading conduct in connection with the sale of food.

The Food Act 2003 applies to:

- any equipment used or capable of being used in, or in connection with, the sale of food;
- food that is for sale;
- any premises kept or used in any manner or to any degree for the manufacture or sale of food; and
- any vehicle kept or used in any manner or to any degree for the manufacture or sale of food.

Food Safety Arrangements

All Tasmanian dairy licenses, including dairy farms, factories, depots and stores and distributors must comply with the Tasmanian Code of Practice for Dairy Food Safety and have their food safety programs approved by and registered with the TDIA. Bulk milk transporters will need to demonstrate their competency and have their food safety programs approved by and registered with the TDIA.

The following principles of through chain food safety have been adopted:

- Dairy food safety programs are a pre-requisite to industry participation
- The whole production chain needs to be part to the quality and safety continuum
- TDIA will be the auditor

Manufacturers must test their products in line with the *ADASC Minimum Sampling Guidelines for Dairy Products* (Attachment 3), that includes regular testing of soft cheeses for *Listeria monocytogenes*.

In addition, dairy processing factories must comply with *Listeria* and *Salmonella* Clearance Manuals.

Compliance activities

As outlined for Victoria. All auditing is carried out by the Tasmanian Dairy Industry Authority.

On farm

In November 2001 the TDIA resolved that on-farm food safety programs would become mandatory from 1 January 2003. Recognising that there would be a phase-in period the full implementation is expected from 31 December 2003. The TDIA has adopted, and amended for Tasmanian application, DFSV's Code of Practice for Dairy Food Safety.

VICTORIA

Responsible Agency

Under the *Dairy Act 2000*, Dairy Food Safety Victoria (DFSV), established on 1 October 2000 is the organisation responsible for the safety of all dairy foods produced in Victoria for domestic and export markets. It reports to the Minister for Agriculture.

The objectives of the Authority as stated in the *Dairy Act 2000* are to:

- Ensure that standards which safeguard public health are maintained in the Victorian dairy industry, and
- Ensure that it performs its functions and exercises its powers efficiently and effectively.

The functions of DFSV as stated in the *Dairy Act 2000* are to:

- establish, maintain and improve –
 - a) the food safety standards of dairy food
 - b) the construction and hygiene standards for plant and equipment in dairy manufacturing premises
 - c) the maintenance, cleanliness and hygiene standards of dairy transport vehicles
- monitor and review the above standards
- approve and monitor the implementation of food safety programs
- administer the DFSV licensing systems
- ensure appropriately qualified persons are appointed as authorised officers
- fix and charge fees for carrying out of its functions and exercising its powers
- protect public health in consultation with the Department of Human Services or a Municipal Council, and
- advise the Minister on matters relating to dairy food safety administration.

DFSV has all the powers needed to enable it to perform its functions under the *Dairy Act 2000*. Also, DFSV may:

- enter into agreements or arrangements with third parties for the provision of services to or by DFSV,
- fix and charge fees for its services, including the services of its authorised officers, and
- expend its funds in carrying out its functions or in paying salaries and allowances to its members.

Certain businesses and vehicles operating in the dairy industry sector need to be licensed. A current and valid dairy license must be held by:

- a dairy farmer
- a dairy manufacturer
- a dairy food carrier
- a dairy distributor

A person owning or using a dairy transport vehicle that is to be used for transporting dairy food in bulk must hold a dairy industry licence.

Legislation

The *Dairy Act 2000* (see above). All dairy premises operating in Victoria are required to be licensed with DFSV, under Part 3, Section 22 of the *Dairy Act 2000*.

All Victorian food businesses, including dairy premises, are required under the *Food Act 1984*, to comply with the Australia New Zealand Food Standards Code – Volume 2, including Chapter 3, Food Safety Standards.

Part 4, Section 31 of the *Dairy Act 2000* authorises DFSV to make Codes of Practice. The Minister must approve any Code of Practice made under this Part of the *Dairy Act 2000*.

This Code has been developed in consultation with the Victorian dairy industry using a risk-based approach and considering the international Codex requirements and the provisions of the *Dairy Act 2000*

In addition dairy processing factories must comply with Listeria and Salmonella Clearance Manuals (these can be provided on request).

The (Victorian) Code of Practice for Dairy Food Safety (DFSV, 2002) sets the minimum mandatory standards for the production, manufacture, storage and transport of milk and dairy foods to safeguard public health and must be used by all dairy premises in conjunction with the Australia New Zealand Food Standards Code - Volume 2 (ANZFA, 2000).

All dairy premises are required to have an approved Food Safety Program (FSP) in place. Food Safety Programs must be validated and audited (verified) on a regular basis.

The Code of Practice for Dairy Food Safety (DFSV, 2002) replaces the Code of Practice for the Quality Assurance of Milk and Dairy Produce (VDIA, 1995), which was made under the Dairy Industry Act (1992). This Code was approved by the Minister for Agriculture and Aboriginal Affairs on 3rd September 2002 and came into operation from 1st December 2002.

Verification activities

Dairy manufacturers in Victoria are audited by DFSV in line with requirements of Schedules 7 and 8 of the *Export Control (Processed Food) Orders*.

On-farm

See above - in Victoria dairy farms are licensed by DFSV under the provisions of the *Dairy Act 2000*.

Most of the Australian dairy companies have adopted a variation of an on-farm QA program recommended by the Australian Dairy Industry Council. The Australian dairy industry has endorsed the inclusion of the elements, which have been outlined in previous applications, as being essential for any dairy on-farm food safety program.

The (Victorian) Code of Practice for Dairy Food Safety mandates for the first time that the owner of every dairy farm must have an approved food safety program in place and sets out the requirements of the program. The latest version of the Code, is now available on the DFSV website at www.dairysafe.vic.gov.au under the heading 'Documents'.

- Dairy Food Safety Victoria licenses dairy farms and acts as an 'auditor of an auditor'; they audit manufacturers' own audits of the on-farm QA system of their farm suppliers.

The DFSV 'On-farm Food Safety Strategy' sets out the major principles for the implementation of the Code in relation to on-farm food safety programs. The strategy formalises, amongst other things, the approval of programs, qualifications of auditors, auditing of the programs and the monitoring by DFSV, which includes 'auditing the auditors'.

The DFSV auditing process for the on-farm programs, as described in the strategy, has been formally implemented at the beginning of 2003.

WESTERN AUSTRALIA

Responsible Agency

The Dairy Safety Branch operates within the Environmental Health Directorate of the Department of Health Population Health Division. The programs are complementary to those of the Meat Safety Branch, which audits all domestic meat abattoirs, processors and transport, and the Food Safety Branch, which co-ordinates local government enforcement of the Code.

The Dairy Safety Program provides a preventative public health measure in reducing the probability of food poisoning outbreaks and therefore protection of the integrity of Western Australian dairy products, through the following programs and services:

- Monitoring farm milk supply
- Auditing farm HACCP based quality systems
- Auditing/inspecting dairy export establishments
- Monitoring dairy product quality

Legislation

The Dairy Safety Program operates under the *Health Act 1911* and the *Health (Food Hygiene) Regulations 1993*. The Food Safety Standards of the FSANZ Code have been adopted. The legislation covers the entire dairy industry/chain.

Food Safety Arrangements

Export dairy premises are required to have food safety plans under export legislation. These premises are audited by the Department of Health under an MOU.

There is no regulated requirement for food safety plans in domestic only premises

Some non-export premises have developed food safety plans, which are audited by either the Department of Health or third party auditors.

The Department of Health operates a dairy food surveillance program of product lines from the non-export premises. The testing program includes pathogens listed in the Food Standards Code, Export Control (Processed Foods) Orders and the *ADASC Minimum Sampling Guidelines for Dairy Products*.

On farm

96% of dairy farmers have an industry developed HACCP based quality assurance program. While there is not a regulated requirement for these programs, they are required by the milk processors. There is a varying degree of enforcement of this requirement.

Table 2: Summary of Dairy industry regulations in different states in Australia

| | <u>New South Wales</u> | <u>Queensland</u> | <u>South Australia (SADA)</u> | <u>Tasmania (TDIA)</u> | <u>Victoria (DFSV)</u> | <u>Western Australia</u> |
|--|--|---|---|---|---|--|
| Legislation | Food Act 2003 (& Food Standards Code) Food Production (Dairy Food Safety Scheme) Regulation 1999 | a) Food Production (Safety) Act 2000 & Food Production (Safety) Regulations 2002 (SFQ) b) Food Act 1981 (QLD Health Dept) | Dairy Industry Act 1992 | Dairy Industry Act 1994 | Dairy Act 2000 | <ul style="list-style-type: none"> • Health Act 1911 • Health (Food Hygiene) Regulations 1993 • Food Safety Standards |
| Scope of legislation – up to? | Food Act: farm to retail Dairy Food Safety Scheme Reg.: Farm to distribution | a) Dairy - up to manufacturing (SFQ) b) Distribution from manufacturer & retail (QLD Health) | Farm to distributor | Farm to distributor | Farm to distributor | Entire food industry |
| Foods Safety Plans | Yes | a) Yes b) to be implemented under revisions to the Food Act | From 1 July 2003 | Yes | Yes | Yes |
| Legislated requirement | Yes - Condition of Licence | Yes | Yes – condition of licence | Yes | Yes | <ul style="list-style-type: none"> • Processor requirement. • Regulation proposal currently under development. |
| Location of FSP Outline - Basis of requirements | Dairy Manual | a) FPS Act b) to be implemented under revisions to the Food Act | Code of practice | Tasmanian Code of Practice for Dairy Food Safety | Code of practice | Not applicable |
| Who does the audits | 2 nd party for higher risk businesses; 3 rd party for low risk (e.g. milk vendors) <ul style="list-style-type: none"> • Export: MOU with AQIS | <ul style="list-style-type: none"> • Processor: 2nd Party • Farm: 2nd Party or SFQ approved private auditors • Export: MOU with AQIS | <ul style="list-style-type: none"> • Processors: SADA • Farms: 350 SADA with processor follow-ups, 150 processor auditor (approved by SADA) | <ul style="list-style-type: none"> • Export: MOU with AQIS • Domestic: 3rd party with TDIA as preferred auditor | <ul style="list-style-type: none"> • Manufacturers: DFSV • Farm, carrier, distributor: contractor with DFSV, but not payment. | Department of Health |
| Frequency of Audit | <ul style="list-style-type: none"> • Processor: as per AQIS • Others: 1/year | <ul style="list-style-type: none"> • Processor: as per AQIS • Farms: 1 per year but consider performance | <ul style="list-style-type: none"> • Processor: as per AQIS • Farms: 1/year | <ul style="list-style-type: none"> • Processor: as per AQIS • Farms: 1/year with follow-ups as required • Vendor: 1/year with follow-ups as required | <ul style="list-style-type: none"> • Processor: as per AQIS • Farm: 1 per 2 years but < 2.5 yrs | 1 / year |
| Classification of non conformities | Yes | Yes | Yes | Yes | Yes | Yes |
| Follow-up of non conformities by regulator | As auditor and by Enforcement Unit | Farms: Both major and critical non-conformances | Notify SADA | Yes | Notify DFSV if critical | No |
| Action for continued non-compliance | <ul style="list-style-type: none"> • Failure letter • Show cause letter • Cancellation of license • Prosecution | <ul style="list-style-type: none"> • Incidence report – show cause re suspension/cancellation | Cancel licence | Cancel licence | Advise DFSV – can suspend/cancel | No |
| Rating system | Yes | No | No | Yes | No | No |
| Appeal Process | <ul style="list-style-type: none"> • Audit: Regional Manager • Licence: Administrative Appeals Tribunal | Magistrates Court | No | <ul style="list-style-type: none"> • Audit: TDIA Board • Licence: Magistrate | Licence: Victorian Civil & Administrative Tribunal Act 1998 | Executive Director Public Health |
| Registration/Licence Requirement | Licence | Accreditation | Licence (Tanker driver voluntary) | Licence | Licence | No |
| Time span of Reg/Lic | 1 year | 1 Year | 1 year | 1 year | 1 year | Not applicable |
| Number of Processors | 107 | 44 | 34 | 27 | 143 manufacturers | 32 |
| Number of Dairy Farms | 1125 | 1000 | 447 | 540 | 6221 (incl sheep, goats & buffalo) | 298 |
| Dairy Beef module | On request | Farmer optional module | Considering | Considering - by request | No | Farmer option including requirements for MSA |

| | | | | | | |
|---|---|--|--|--|---|-------------------------------|
| <p>Scope of Regulations eg ice cream, fruit juice, quiche/dips</p> | <ul style="list-style-type: none"> • Manufacture and Wholesaling of dairy products – defined as >50% milk components. | <ul style="list-style-type: none"> • Ice cream if NOT predominantly a retail business. • Juice – if in dairy plant. • Quiche/dips – not at present. • Other aspects covered by Food Act 1981 | <ul style="list-style-type: none"> • >50% milk or milk solids • Wholesale ice cream | <ul style="list-style-type: none"> • No ice cream | <ul style="list-style-type: none"> • Ice cream if wholesale. • Includes non dairy & dairy derivatives inc salads & lasagne. | <p>Ice cream if wholesale</p> |
|---|---|--|--|--|---|-------------------------------|

Dairy Export Regulations

The Australian Quarantine and Inspection Service (AQIS) of the Department of Agriculture, Fisheries and Forestry is responsible for inspection and certification of Australian export food products. The AQIS export programs operate within the statutory powers of the *Export Control Act 1982*. The provisions include (a) power to prohibit the export of goods, unless prescribed conditions are met; (b) penalties where export takes place in breach of the prescribed conditions; penalties for contravention of official mark provisions, false trade descriptions and declarations; (c) powers for discretionary issue of certificates to meet importing country authority requirements; (d) the power to enter and inspect registered processing premises to determine whether food is produced and stored under required conditions; etc.

Subordinate legislation regulating the export dairy products includes the *Prescribed Goods (General) Orders* that provide for registration of establishments to prepare prescribed goods and the *Export Control (Processed Food) Orders* that include (a) structural requirements, standards of construction for the factory; walls, floors, equipment, (b) operational standards, standards of good manufacturing practice e.g. temperature controls, hygiene, (c) product standards (microbiological, physical and chemical), (d) systems of inspection, inspection frequency, documentation requirements; etc. Hazard Analysis Critical Control Point (HACCP) is mandatory when preparing/processing dairy products for export. Further details of the export legislation can be found at www.aqis.gov.au.

In order to streamline inspection/auditing services between AQIS and State Dairy Authorities, AQIS has introduced competition (contestability) into these services: when accredited by AQIS, State Dairy Authorities may conduct inspection/audits of export dairy establishments on behalf of AQIS. These audits cover requirements of the *Export Control (Processed Food) Orders* and currently State Dairy Authorities in Victoria, Tasmania, New South Wales, Queensland and Western Australia participate in the arrangement. AQIS remains ultimately responsible for managing the export inspection and certification system in accordance with importing country requirements and regularly reviews State Dairy Authorities. Attached is a diagram with an overview of the export dairy system.

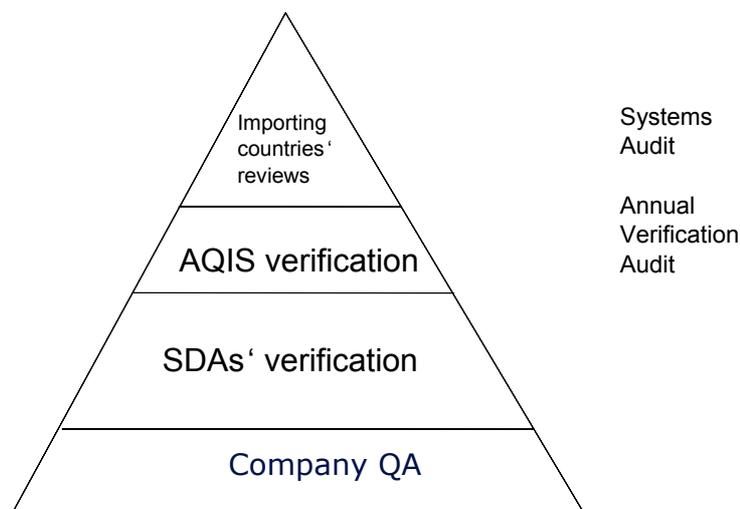


Figure 2: Overview of the Australian dairy export system

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, Fish & Egg) Orders* will be submitted to the Minister for Agriculture, Fisheries and Forestry for consideration before the end of 2004. Attached is a diagram with an overview of the three tier system.

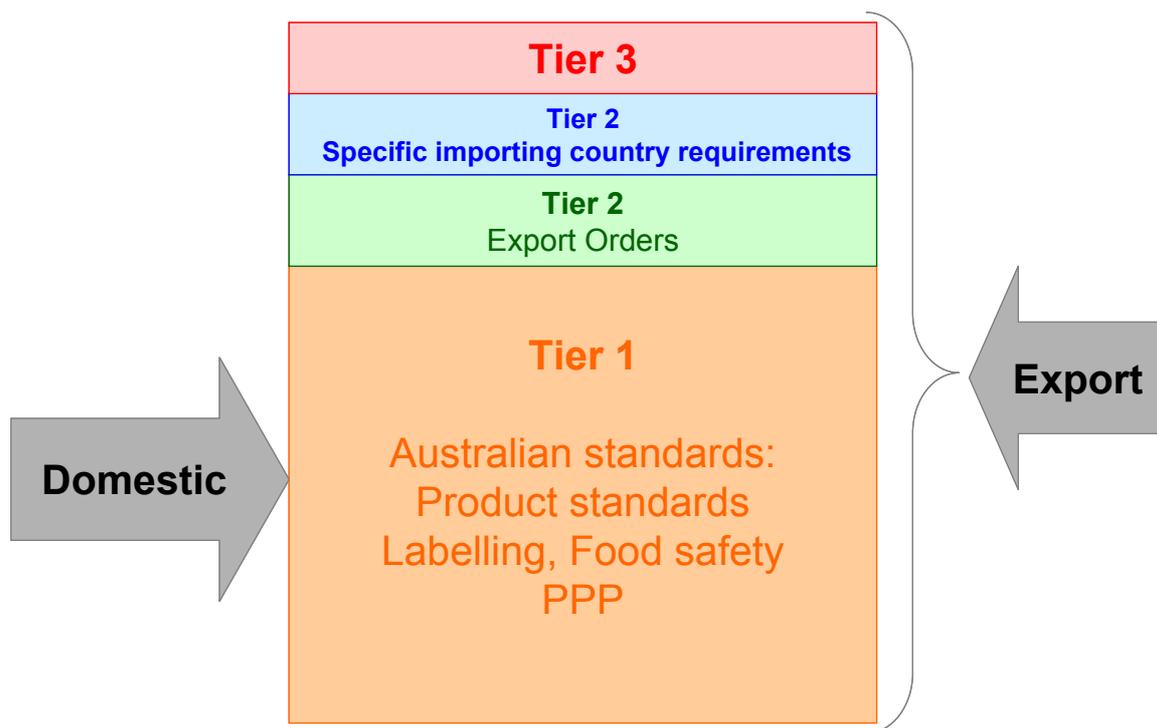


Figure 3: Overview of the three-tier system

Overview of the Bovine Dairy Industry

The following information has been provided by Dairy Australia with data and information taken from sources as referenced in the text. The report has been incorporated into the IAR with few modifications. The following section provides background to the Australian bovine dairy industry and its contribution to the economy.

An important rural industry

The dairy industry is a major rural industry in Australia. The farm gate value of production is \$2.8 billion (2003/04), ranking the dairy industry third behind the beef and wheat industries.

Table 3: Australian Dairy Industry – Key Measures

| At June 30 | 1980 | 1990 | CAGR 1980s | 2000 | CAGR 1990s | 2004P | CAGR since 1990 |
|---------------------------------------|---------|---------|---------------|---------|---------------|---------|-----------------------|
| Milk production (M. lts) | 5,432 | 6,262 | 1.4% | 10,847 | 5.6% | 10,075 | 3.5% |
| Dairy cows ('000) | 1,880 | 1,654 | -1.3% | 2,171 | 2.8% | 2,028 | 1.5% |
| Farm numbers | 21,994 | 15,396 | -3.5% | 12,896 | -1.8% | 9,611 | -3.3% |
| Value of Farm Production*(\$M.) | \$2,700 | \$2,517 | -0.7% | \$3,187 | 2.4% | \$2,922 | 1.1% |
| Value of ex-Factory Production*(\$M.) | \$6,915 | \$6,216 | -1.1% | \$9,578 | 4.4% | \$8,897 | 2.6% |
| Estimated value-added* (\$M.) | \$1,684 | \$1,857 | 1.0% | \$2,148 | 1.5% | \$2,007 | 0.6% |
| Per capita consumption (milk equiv) | 239 | 244 | 0.2% | 266 | 0.9% | 279 | 1.0% |
| Export Value*(\$M.) | \$815 | \$456 | -5.7% | \$2,906 | 20.4% | \$2,374 | 12.5% |
| Export Share of Production | 22% | 31% | | 59% | | 52% | |

Sources: ABS, Dairy Australia, state authorities

*Expressed in 2003/04 dollars.

CAGR: Compound Annual Growth Rate

Dairy is one of Australia's leading rural industries in terms of adding value through further or downstream processing. Much of this processing occurs close to farming areas, thereby generating significant economic activity and employment in country regions. ABARE estimates a regional economic multiplier in the order of 2.5 for the dairy industry.

Strong growth characterised the dairy industry through the 1990s, with growth slowing in recent years due to unfavourable seasons e.g. severe drought in 2002/03. Nevertheless, Australia's climate and natural resources are generally favourable for dairying and allow the industry to be predominantly pasture-based, with approximately 70-80% of cattle feed requirements coming from grazing. The result is efficient, low cost, high quality milk production.

Australian milk production costs are well below those in most other major dairy producing countries around the world. Most dairy production is located in coastal areas where pasture growth generally depends on natural rainfall. However, the inland irrigation schemes in northern Victoria and southern New South Wales have become quite significant and now account for around one quarter of total milk production. Feedlot-based dairying remains unusual in Australia, although the use of supplementary feed, with hay, silage and grains, is becoming more widespread. Australian dairy farmers continue to increase on-farm productivity through improved pasture, feed and herd management techniques.

Dairying is a well-established industry in many areas of Australia. While the bulk of milk production occurs in Victoria (64% in 2003/04), all states have a productive dairy industry, supplying fresh milk to nearby cities and towns. In addition, a wide range of high quality manufactured products - from fresh lines such as yogurt and a wide variety of cheese types, to bulk and specialized milk powders – are produced in most Australian states.

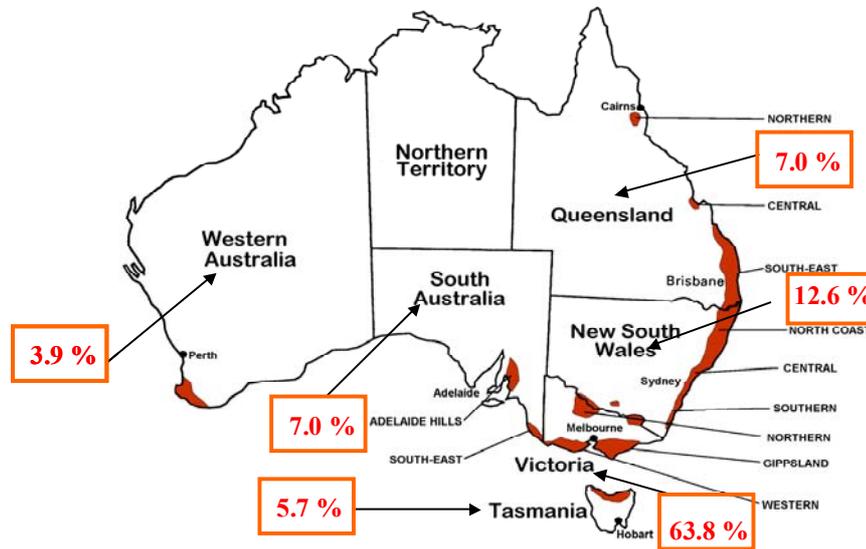


Figure 4: Milk production in different states of Australia.

Milk production

While farm numbers have decreased over the last two decades, milk output steadily increased due to increasing cow numbers and improved cow yields. Unfavourable seasonal conditions in 2000/01 led to the first drop in milk production, followed by the severe and widespread drought of 2002/03 and its subsequent impact last year.

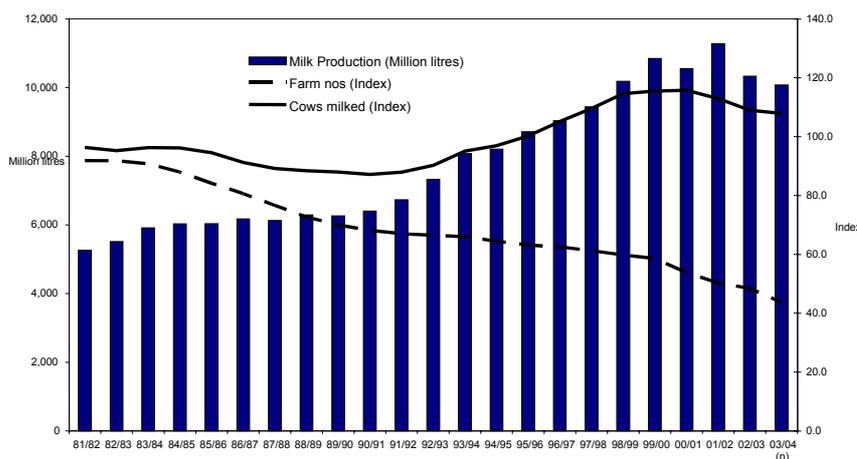


Figure 5: Australian Milk Production vs. Indices of Farms and Cows Milked

Nevertheless, the underlying trend towards fewer farms, larger herds and increasing levels of production continues. Farmers have made many changes to their general farm management practices and adopted a range of new technologies - including soil testing, fodder conservation, supplementary feeding, improved animal genetics, artificial insemination programs, the use of new milking technology, and the widespread use of computers to record and monitor herd performance.

Australian milk production remains strongly seasonal, reflecting the pasture-based nature of the industry. Milk production peaks in October / November, tapering off in the cooler months of May / June. The development of long shelf-life manufactured products, particularly in the south-east regions, has enabled maximum milk utilisation within the seasonal cycle.

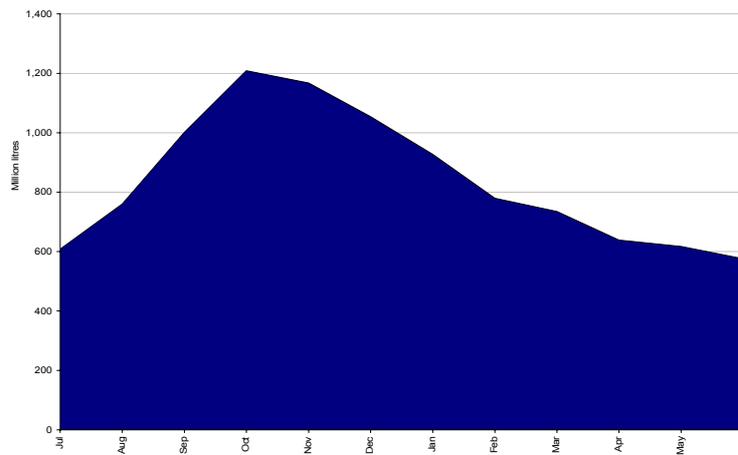


Figure 6: Seasonality of Milk Production in Australia 2003/04 (million litres)

The seasonality of milk output in the states of Queensland, New South Wales and Western Australia is less pronounced due to a greater focus on drinking milk and fresh products in the product mix. Farmers in these states manage calving and feed systems to ensure more even year-round production.

Australian milk production reached 10,075 million litres in 2003/04, a decrease of 2.5% on the previous year. This further decline on the ‘drought year’ reflects the slow nature of the recovery - particularly apparent in livestock industries, where herds take time to recover. Nevertheless, the 2003/04 season did finish with six consecutive months of positive growth in milk production.

Milk production is concentrated in the south-east corner of Australia, with the states of Victoria, Tasmania and South Australia accounting for 77% of total output.

Dairy manufacturing

As in the farm sector, the milk-processing sector is undergoing continued rationalisation. This has resulted in increasing milk processing per factory, as larger operations have allowed improved efficiency and economies of scale. The lack of growth in milk production over the last two years has relieved the pressure on Australian dairy companies to continue to invest in increasing processing capacity – at least in the short term.

Table 4: Milk Production (million litres)

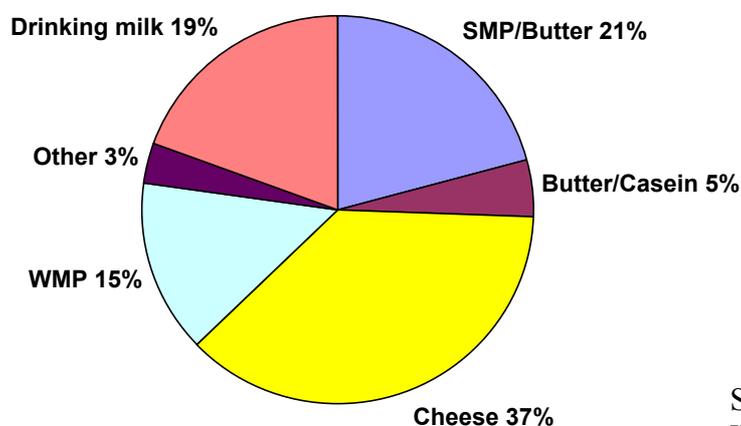
| | NSW | VIC | QLD | SA | WA | TAS | AUST |
|-------------|-------|-------|-----|-----|-----|-----|--------|
| 1979/80 | 907 | 3,151 | 508 | 329 | 222 | 315 | 5,432 |
| 1989/90 | 879 | 3,787 | 629 | 356 | 267 | 343 | 6,262 |
| 1994/95 | 1,087 | 5,114 | 740 | 485 | 343 | 437 | 8,206 |
| 1995/96 | 1,114 | 5,482 | 751 | 512 | 341 | 514 | 8,714 |
| 1996/97 | 1,192 | 5,634 | 797 | 535 | 349 | 529 | 9,036 |
| 1997/98 | 1,242 | 5,866 | 822 | 580 | 387 | 543 | 9,440 |
| 1998/99 | 1,286 | 6,414 | 827 | 646 | 403 | 603 | 10,179 |
| 1999/00 | 1,395 | 6,870 | 848 | 713 | 412 | 609 | 10,847 |
| 2000/01 | 1,326 | 6,784 | 760 | 699 | 388 | 590 | 10,546 |
| 2001/02 | 1,343 | 7,405 | 744 | 715 | 393 | 671 | 11,271 |
| 2002/03 (r) | 1,301 | 6,584 | 720 | 733 | 404 | 585 | 10,328 |
| 2003/04 (p) | 1,271 | 6,434 | 674 | 703 | 403 | 590 | 10,075 |

Source: Dairy manufacturers

Both farmer-owned co-operatives and public and private companies process milk in Australia. Co-operatives dominate the industry, accounting for approximately 70% of all milk output. The three largest co-operatives – Murray Goulburn Co-operative Limited, Bonlac Foods Limited and the Dairy Farmers Group account for over 60% of all milk production, and over 70% of all milk used for manufacturing. While the largest co-operative has a volume that accounts for over 30% of Australia’s milk production, there are also a number of medium sized co-operatives with milk intake between 100 and 600 million litres.

As well as farmer co-operatives, there are a number of multinational dairy companies operating within the Australian dairy industry, including Fonterra (Bonlac), Parmalat, Nestle, Kraft, Snow Brand and Bongrain (Lactos).

Other Australian dairy companies cover a diverse range of markets and products. The publicly listed National Foods Limited is heavily involved in the drinking milk and fresh dairy product markets, while there are also many highly specialized farmhouse cheese manufacturers.



SMP: Skim Milk Powder
WMP: Whole Milk Powder

Figure 7: Utilisation of Australian Milk 2003/04

In line with international trends, there has been a general movement in Australia's product mix toward increased cheese and whole milk powder production, and away from butter and skim milk powder lines.

Dairy markets

Over the last two decades the volume of Australian milk production has expanded at a faster rate than domestic consumption, with an increasing proportion destined for export markets. Australia now exports over 50% of its annual milk production.

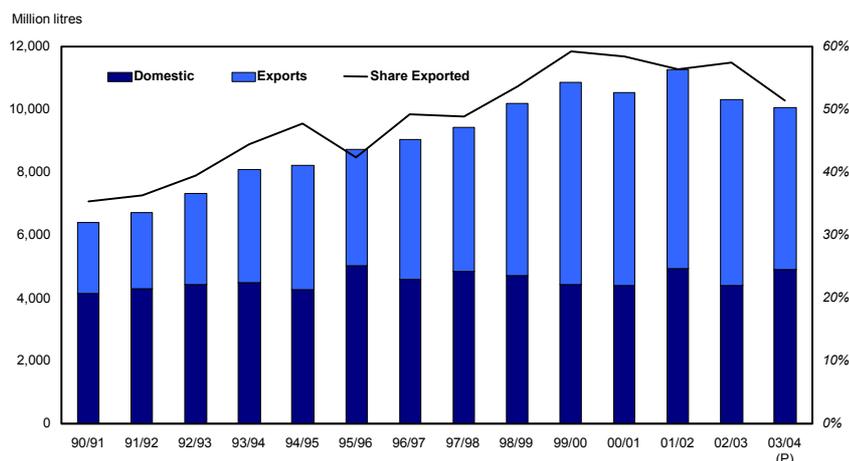


Figure 8: Australian Consumption and Exports (Milk Equivalents)

While Australia accounts for an estimated 2% of world milk production, it is an important exporter of dairy products. Australia ranks third in terms of world dairy trade with a 13% share of all dairy product exports, third behind New Zealand and the European Union.

Japan is the single most important export market for Australia, accounting for over 18% of Australia's exports by value. Australian exports are concentrated in Asia/East Asia, comprising 67% of the total value of \$A2.4 billion dollars.

Table 5: Australian Exports by Product by Region 2003/04 (\$A million)

| | Sth East Asia | Other Asia | Europe | Middle East | Africa | Americas | Other | Total |
|--------------|---------------|------------|------------|-------------|-----------|------------|------------|--------------|
| Butter/AMF | 53 | 42 | 24 | 27 | 11 | 24 | 1 | 182 |
| Cheese | 52 | 396 | 78 | 117 | 31 | 52 | 11 | 738 |
| Milk | 42 | 35 | 3 | 5 | 2 | 1 | 16 | 104 |
| SMP/BMP* | 249 | 118 | 4 | 27 | 12 | 31 | 21 | 463 |
| WMP** | 266 | 149 | 5 | 58 | 33 | 9 | 29 | 549 |
| Other | 61 | 125 | 13 | 2 | 2 | 111 | 25 | 339 |
| Total | 723 | 864 | 126 | 237 | 91 | 228 | 104 | 2,374 |

Source: Dairy manufacturers and ABS

*Also includes dairy component of mixed powders (mixtures)

**Also includes infant powder

BMP: Buttermilk Powder

AMF: Anhydrous Milk Fat

The Asian markets have considerable potential for growth as incomes rise and diets become more ‘Westernised’. Australian dairy companies have proven track records in supplying these markets over the past decade. The Middle East and the Americas are also important markets for many products.

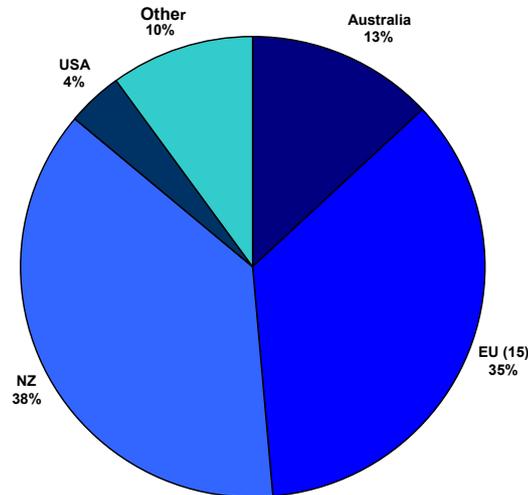


Figure 9: Exporters’ Share of World Trade – 2003 (Milk Equivalents)

Australia’s top five export markets by volume in 2003/04 were Japan, Philippines, Malaysia, Singapore and Indonesia; while the top five export markets by value were slightly different in Japan, Malaysia, Philippines, USA and Taiwan. There has been little change in the ranking of these markets over recent years.

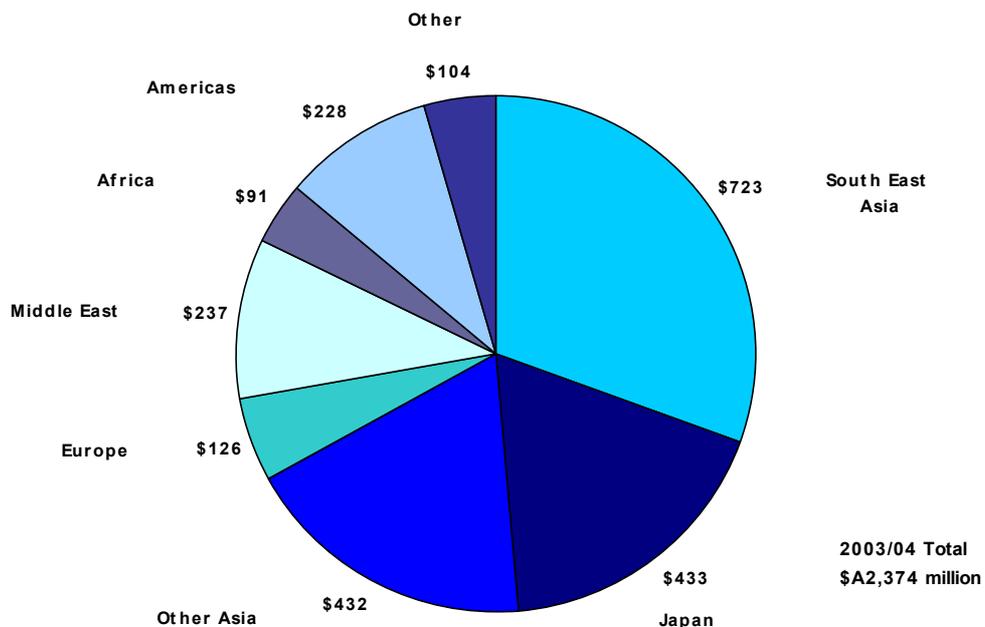


Figure 10: Value of Australian Exports by Region – 2003/04 (\$A million)

Australian consumption of dairy products

The four major Australian consumer dairy products are drinking milk (fresh and UHT, white and flavoured), cheese, butter and dairy blends, and yogurt.

Per capita consumption trends over the past two decades vary quite significantly by individual product. These reflect changes in consumer tastes and preferences in response to a multitude of variables such as multicultural and ethnic influences on food consumption; health perceptions of dairy products and manufacturers' responses to trends (such as low fat variants); new product development; flavour and packaging innovations; competitive category offerings; distribution and availability of product.

Per capita consumption of milk in Australia is estimated at just less than 100 litres per year. Cheese consumption has seen a consistently strong growth to around 12 kilograms per head per annum. Butter consumption slowed during the 1970's and 1980's as people began to limit their intake of saturated fats. However the trend has flattened out over the last decade. The consumption of Yogurt has been growing steadily for both convenience and health attributes.

Table 6: Per Capita Consumption of Major Dairy Products (litres/kgs)

| | MILK [lts] | CHEESE [kgs] | Butter/AMF [kgs] | YOGURT [kgs] |
|-------------|---------------|-----------------|---------------------|-----------------|
| 1998/99 | 102.5 | 10.7 | 2.9 | 5.1 |
| 1999/00 (r) | 101.5 | 11.1 | 3.9 | 5.4 |
| 2000/01 (r) | 99.6 | 11.3 | 3.3 | 5.3 |
| 2001/02 (r) | 97.7 | 11.6 | 3.2 | 5.6 |
| 2002/03 (r) | 97.4 | 12.0 | 3.2 | 5.8 |
| 2003/04 (p) | 98.0 | 11.7 | 3.8 | 5.9 |

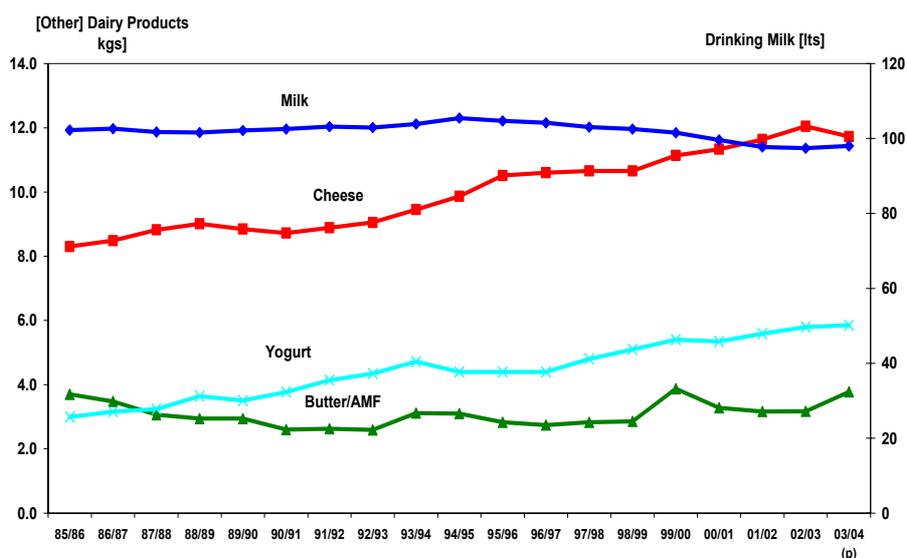


Figure 11: Per Capita Consumption (litres/kgs)