

ACCREDITATION HANDBOOK



DAIRYSAFE
Leaders in dairy food safety

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CONTENTS

Introduction	4
Dairysafe's Obligations	5
Your Obligations	5
Dairysafe's position in the Australian New Zealand food regulatory framework	6
Dairysafe's role	7
Legislative requirements	7
Primary Produce (Food Safety Schemes) Act 2004	7
Food Act 2001	7
Australia New Zealand Food Standards Code	8
Export requirements	8
Who needs to be accredited?	8
Obtaining accreditation	10
Regulatory requirements – dairy farms	12
Regulatory requirements – dairy processors	13
Regulatory requirements – dairy transporters	15
Verifying Compliance	16
Audits	16
Compliance activities	16
Product surveillance	16
Non-compliance	17
Roles and responsibilities	17
Application of regulatory tools	18
Factors to be considered in determining compliance and enforcement options	18
Factors to be ignored in determining compliance and enforcement options	19
Queries	19
Dairysafe assistance	19

PRE-AMBLE

This handbook outlines what is required to obtain accreditation and operate as an accredited dairy business, where to find additional resources to assist you, and clearly detail your legal obligations to produce safe dairy products.

INTRODUCTION

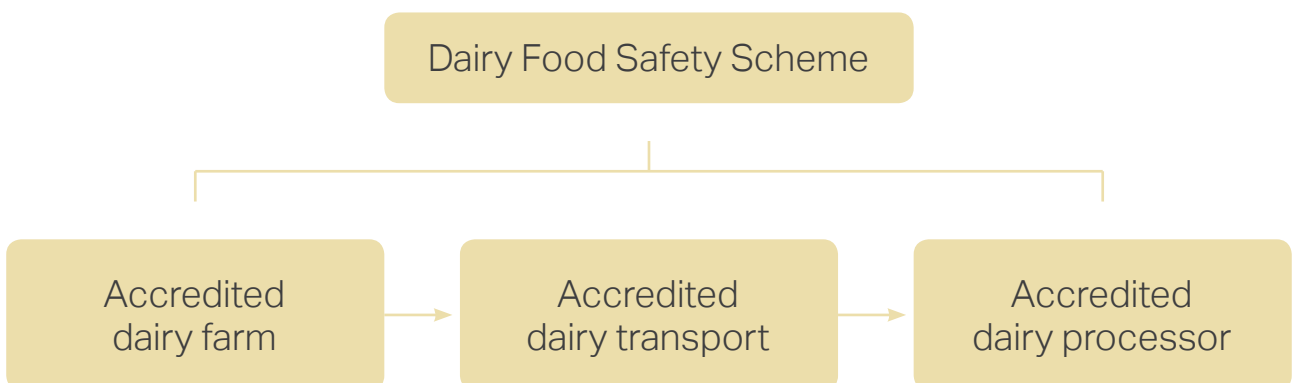
The Dairy Authority of South Australia, trading as Dairysafe, is a statutory authority reporting to South Australia’s Minister for Primary Industries and Regional Development.

Dairysafe is constituted under the *Primary Produce (Food Safety Schemes) (Dairy) Regulations 2017* as an accreditation body. Its functions include being responsible for the dairy food safety scheme, monitoring compliance by farmers, transporters and processors with Standard 4.2.4 of the Food Standards Grade, to enforce Standard 4.2.4, to approve food safety arrangements, to monitor implementation of food safety arrangements, and to carry out functions assigned under the regulations or by the Minister.

When businesses fail to meet their obligations under the legislation, Dairysafe’s authorised officers and/or approved auditors may employ a range of compliance options to ensure compliance with national food safety standards.

Dairysafe is responsible for ensuring the South Australian dairy industry complies with food safety standards to safeguard public health. It does this by administering South Australia’s dairy food safety scheme ensuring milk is sourced from an accredited dairy farm, milk is transported by an accredited transport business, and dairy products are produced by an accredited dairy processor operating in accordance with an approved food safety arrangement specifying compliance with Australia’s food safety standards at each point in the production process.

The *Primary Produce Food Safety Schemes Act 2004* and the *Primary Produce (Food Safety Schemes) (Dairy) Regulations 2017* provide the legislative foundation for Dairysafe’s responsibilities and functions.



Dairysafe's obligations

- › Administer the dairy industry food safety scheme
- › Approve food safety arrangements for accredited businesses
- › The accreditation of dairy farmers, dairy processors and dairy transporters
- › Ensure all accredited businesses have the capacity and capability to comply with Standard 4.2.4
- › Monitor compliance by accredited businesses through audit, assessment, inspection and testing
- › Advise or make recommendations to the Minister on matters relating to the dairy food safety scheme
- › Approve individuals to carry out audits to monitor compliance with food safety arrangements

Your obligations as a producer, transporter or processor

- › As an accredited dairy business operator, you are responsible for ensuring the food you produce is safe
- › You have a legal requirement to ensure your farm, transport, or food processing business complies with national regulatory food safety standards
- › To have or employ the skills and knowledge appropriate for the type of food production activities of your business - you need to understand your obligations as an accredited dairy business, in particular regulatory requirements for food safety and hygiene



Dairysafe's position in the Australian New Zealand food regulatory framework



Australia's food regulation policies are developed by the Australia and New Zealand Ministerial Forum on Food Regulation. Members include a Minister from New Zealand, Ministers from the Australian Government, health Ministers from the Australian states and territories, and Ministers from related portfolios where nominated by their jurisdictions.

National food safety standards to protect the health and safety of consumers are developed in line with these regulatory policies by Food Standards Australia New Zealand (FSANZ) and published in the Australia New Zealand Food Standards Code.

The states and territories are responsible for administering the requirements of the Food Standards Code.

Dairysafe's role

In South Australia, Dairysafe is responsible for accrediting dairy businesses, monitoring compliance and enforcing the food standards in the dairy industry through administration of the *Primary Produce (Food Safety Schemes) Act 2004* and the *Primary Produce (Food Safety Schemes) (Dairy) Regulations 2017*.

Dairysafe is responsible for ensuring that standards which safeguard public health are maintained in the South Australian dairy industry. This includes:

- › administering the accreditation system
- › verifying compliance with regulatory requirements
- › taking appropriate compliance action in the event of non-compliance

Legislative requirements

As a dairy business operator in the South Australian dairy industry you have an obligation to comply with legislative provisions that apply to your type of business.

Primary Produce (Food Safety Schemes) Act 2004

The Act consolidated previous primary industry food safety legislation into one Act and extends the legislative framework to all primary industries enabling the implementation of national primary production and processing standards within the Food Standards Code.

The aim is to manage significant food safety risks, establish administrative arrangements for food safety schemes, and for accrediting primary production and processing businesses.

The Act establishes the *Primary Produce (Food Safety Schemes) (Dairy) Regulations 2017*. The regulations establish the Dairy Authority of South Australia (trading as Dairysafe), and requires dairy farmers, milk transporters and dairy processors to:

- › obtain accreditation from Dairysafe,
- › have an approved food safety arrangements,
- › comply with the conditions of the accreditation, and
- › comply with Standard 4.2.4

Food Act 2001

In South Australia the *Food Act 2001* is the primary piece of food safety legislation and provides the framework within which all food safety and suitability issues are regulated. The Act requires that all parts of the food industry, including primary industries, produce safe and suitable food or face significant penalties. The Act provides for extensive powers to prevent or mitigate a serious threat to public health, and this includes the power to apply emergency orders to all parts of the food industry, including primary industries.

The Act requires that:

- › food produced must be safe and suitable
- › food handling must be hygienic
- › food businesses must comply with the Australia New Zealand Food Standards Code.

However, some parts of the Act have been limited in their application regarding primary food production. The *Primary Produce (Food Safety Schemes) Act 2004* completes South Australia's food safety legislative framework by covering food safety requirements for primary food production.

Australia New Zealand Food Standards Code

The Food Standards Code sets national requirements for the composition, safety, handling, labelling and primary production and processing of food in Australia and is applied and enforced in South Australia through the *Food Act 2001*.

The Food Standards Code is a collection of food standards, set out in four chapters, which all have relevance for dairy businesses, with specific requirements for dairy primary production and processing outlined in Standard 4.2.4, including the requirement for dairy businesses to implement a documented food safety program.

Export requirements

In addition to the legal requirement to be accredited with Dairysafe, if you are intending to export dairy food your business must be registered with the Commonwealth Department of Agriculture and Water Resources – read about the export registration requirements at <http://www.agriculture.gov.au/export/controlled-goods/dairy> or call 1800 900 090.

WHO NEEDS TO BE ACCREDITED?

It is a requirement under Part 3, Section 12 of the *Primary Produce (Food Safety Schemes) Act 2004* that a producer of primary produce must not engage in a class of activities to which a food safety scheme applies without an accreditation if accreditation is required by the food safety scheme.

Part 4, regulation 15 of the *Primary Produce (Food Safety Schemes) (Dairy) Regulations 2017* specifies a person must not engage in a class of activities to which the dairy industry food safety scheme applies without an accreditation.

Part 2, regulation 6 of the Regulations establishes the dairy industry food safety scheme as applying to the following classes of activities:

- › carrying on a dairy primary production business – dairy farmer – an activity carried on for a commercial purpose that involves the production of milk for human or animal consumption and includes the keeping, grazing, feeding and milking of animals and the storage of milk on the premises at which the animals were milked
- › carrying on a dairy processing business – dairy manufacturer – an activity carried on for a commercial purpose that involves the manufacture of dairy products
- › carrying on a dairy transport business – dairy transporter – an activity carried on for a commercial purpose involving the collection and transport of milk from a dairy primary production business to a dairy processing business or the transport of bulk milk or dairy products between dairy processors

Note: the Regulations define dairy products as being:

- › milk (as defined in these regulations) - milk (including colostrum) derived from a cow, camel, goat, sheep or buffalo
- › any other product included in the definition of dairy product in Standard 4.2.4 of the Food Standards Code

Standard 4.2.4 of the Food Standards Code defines dairy products as including:

- > milk
- > colostrum
- > liquid milk products
- > cream and thickened cream
- > butter, butter concentrate, buttermilk, concentrated buttermilk, dairy blend, ghee, and anhydrous milk fat (butter oil)
- > casein, caseinate, and cheese
- > whey, whey cream and concentrated whey cream
- > cultured milk and yoghurt
- > ice cream and ice cream mix
- > buttermilk powder, lactose powder, milk sugar, powdered milk, skim milk powder, whey powder, milk protein powder and other milk concentrates

The owner of any business producing these types of products, or transporting milk must have a current accreditation for the specific dairy business activities.



OBTAINING ACCREDITATION

To be issued an accreditation to operate as a dairy processor you need to develop a documented food safety program that complies with the requirements of the Food Standards Code. All dairy businesses must also ensure the premises used and/or vehicles comply with the Food Standards Code.

When Dairysafe is satisfied that your food safety program and premises are appropriate for operating your business, and the business has the requisite skills and competency, your accreditation will be issued.

The accreditation process involves the following steps:

1. Ensuring the applicant has the capability to comply with requirements of accreditation

The applicant must complete the Dairy Australia 'Are you trade ready' on-line assessment course – <https://tradeready.dairyaustralia.com.au/domestic-only/>

Premises meets the requirements for construction and equipment –

- > compliant with Food Standards Code, Standard 3.2.3
- > are fit for purpose
- > are in a good state of repair
- > are able to be cleaned and sanitised effectively
- > Note: Dairy Food Safety Victoria excellent reference document – 'Hygienic design: guidelines for dairy food manufacturing premises'

Develop a food safety program for the operation of the dairy business

- > Note: Dairy Food Safety Victoria's excellent reference document – 'Developing a food safety program: guideline for dairy food manufacturers'

Comply with microbiological testing criteria for producing dairy products

- > ensure an end product testing program is implemented as per Microbiological Testing Criteria located at www.dairy-safe.com.au

Staff have adequate skills & knowledge –

- > an accredited business must ensure that persons undertaking processing or transport activities have skills and knowledge of food safety and hygiene matters commensurate with their work activities

2. Application for accreditation submitted to Dairysafe

3. Application fee paid

4. Initial premises assessment by Dairysafe

5. Correction of any deficiencies identified by Dairysafe

6. Provide your draft food safety program to Dairysafe

- 7. Final premises approval by Dairysafe
- 8. Verification by Dairysafe of the suitability of your food safety program
- 9. Accreditation fee paid to Dairysafe
- 10. Accreditation application considered and granted subject to full compliance with conditions of accreditation
- 11. Product testing program in place with results provided to Dairysafe
- 12. First audit of business operations by Dairysafe auditors

Important Note: Dairysafe can refuse to issue an accreditation and can also cancel or suspend an accreditation where there is non-compliance with legislative requirements.



REGULATORY REQUIREMENTS – DAIRY FARMS

An accredited dairy farmer must comply with the following regulatory requirements:

1. Ensure that the accredited dairy is maintained, and the milk is produced, handled and stored, in accordance with requirements of Standard 4.2.4 of the Food Standards Code.
2. Comply with the conditions of accreditation.
3. Immediately notify Dairysafe of any changes to the ownership of the business or prior to making any changes to the dairy, equipment or processes carried out at the dairy.
4. Maintain a valid food safety program - Standard 4.2.4 of the Food Standards Code requires a dairy farm must control potential food safety hazards by implementing a documented food safety program which outlines control measures for managing hazards arising from inputs, such as veterinarian medicines and agricultural chemicals, premises and equipment, milking animals, and milking personnel and practices.

Food safety programs must also include support programs outlining measures for managing animal health, cleaning and sanitising, pest control, milk cooling and storage temperatures, and traceability of inputs, animals milked and milk produced.

Most large-scale dairy manufacturers with direct farm supply have developed a farm quality assurance (QA) program template within their company QA system which incorporates the regulatory food safety program requirements for dairy farms.

5. Ensure your food safety program passes the audit by the Dairysafe auditor, which will occur every 12 months. A new applicant will be audited within 3-6 months from commencement of the dairy operation.
6. Comply with any specific condition of accreditation, request for information or specified action from a Dairysafe officer in respect of a non-conformance identified at audit.

Supporting resources are available on the Dairysafe website - <http://dairy-safe.com.au/>

- > Legislation – Act and Regulations
- > Food Standards Code – Standard 4.2.4 Primary Production and Processing Standard for Dairy Products
- > Guide to Standard 4.2.4 – Part 1 Dairy Primary Production Requirements
- > ANZDAC Guidelines for Food Safety – Dairy Farms
- > Application for Accreditation
- > Bulletin #2 - Cooling of bulk raw milk



REGULATORY REQUIREMENTS

– DAIRY PROCESSORS

An accredited dairy processor must comply with the following regulatory requirements.

1. Comply with all requirements of the Food Standards Code and the *Primary Produce (Food Safety Schemes) (Dairy) Regulations 2017* with respect to the conduct of the dairy business and the processing, handling, packaging and storage of dairy food.
2. Comply with the conditions of accreditation.
3. Immediately notify Dairysafe of any changes to the ownership of the business or any proposed changes to the products or processes used to manufacture the products.
4. Maintain a valid food safety program - Standard 4.2.4 of the Food Standards Code requires a dairy processor to control potential food safety hazards by implementing a food safety program which includes documented control measures at each point in the manufacturing process.

Food safety programs must also include support (pre-requisite) programs outlining measures for managing arrangements for cleaning and sanitation, pest control, maintenance, and staff training as well as raw material control, calibration, and product traceability.

Dairy Australia's Manufacturing Resource Centre has training courses on:

- > Food Recall
 - > Micro Testing
 - > Developing a Food Safety Program
5. Ensure your food safety program passes the audit by the Dairysafe auditor, which will occur every 6-12 months.
 6. Comply with the microbiological testing requirements of product specified by Dairysafe.
 7. Comply with any written action request by an authorised officer or Dairysafe.

Supporting resources are available on the Dairysafe website - <http://dairy-safe.com.au/>

- > Legislation – the Act and Regulations
- > Food Standards Code – Standard 4.2.4 Primary Production and Processing Standard for Dairy Products
- > Food Standards Code – Standard 1.6.1 – Microbiological Limits in Food
- > Food Standards Code – Standard 3.2.2 – Food Safety Practices and General Requirements
- > Food Standards Code – Standard 3.2.3 – Food Premises and Equipment
- > Guide to Standard 4.2.4 – Part 3 Dairy Processing
- > Application for Accreditation
- > Bulletin #1 – micro testing protects you and your business
- > National Guidelines – Pathogen Management – Guidelines for Dairy industry response to pathogen detections in dairy product and the processing environment
- > Compendium of Microbiological Criteria for Food
- > Dairysafe Microbiological Testing Criteria
- > Safe Food Australia – A guide to the Food Safety Standards (November 2016)
- > ANZDAC Guideline for validation and verification of heat treatment equipment and processes
- > Hygienic design: guidelines for dairy food manufacturing premises (Dairy Food Safety Victoria)

- › Technical Information Note – *Listeria monocytogenes* – management in dairy factories (Dairy Food Safety Victoria)
- › Technical Information Note – High temperature-short time pasteurisation of milk (Dairy Food Safety Victoria)
- › FSANZ recall protocol
- › Managing recalls – ‘Recall Ready Reckoner’
- › Food Recalls – general information and support documents
- › Developing a recall training program
- › Recall preparedness self-assessment
- › ‘Are you trade ready’ – a self-assessment tool to identify if you’re ready to commence as a dairy processor
- › Food recall training – This course has been developed by Safe Food Queensland with federal funding from the Package Assisting Small Exporters (PASE) program and is available to all dairy processors throughout Australia, free of charge



REGULATORY REQUIREMENTS

– DAIRY TRANSPORTERS

An accredited dairy transporter must comply with the following regulatory requirements.

1. Comply with all requirements of the Food Standards Code and the *Primary Produce (Food Safety Schemes) (Dairy) Regulations 2017* with respect to the conduct of the transportation of milk.
2. Comply with the conditions of accreditation.
3. Immediately notify Dairysafe of any changes to the ownership of the business, or prior to making any changes to the equipment or processes.
4. Maintain a valid food safety program - Standard 4.2.4 of the Food Standards Code requires a dairy transporter to control potential food safety hazards by implementing a food safety program which includes documented control measures for managing hazards arising from transport vehicles, equipment and containers, and personnel involved in the collection and transport of milk products.

Food safety programs must also include support (pre-requisite) programs outlining measures for managing arrangements for cleaning and sanitation, product traceability, time and temperature controls to prevent or reduce the growth of microbiological hazards, and staff with suitable skills and knowledge to undertake their work activities.

5. Tankers or vessels used for the bulk transport of milk and milk products must only be used to collect milk from dairy farms; transport milk and milk products or transport potable water or food grade liquids that will not contaminate milk and milk products or leave residues.
6. Comply with any written action request by an authorised officer or Dairysafe.

Supporting resources are available on the Dairysafe website - <http://dairy-safe.com.au/>

- > Legislation – the Act and Regulations
- > Food Standards Code – Standard 4.2.4 Primary Production and Processing Standard for Dairy Products
- > Guide to Standard 4.2.4 – Part 2 Dairy Collection and Transport Requirements
- > Conditions of Accreditation
- > Application for Accreditation



VERIFYING COMPLIANCE

Dairysafe undertakes regular activities to verify compliance with conditions of accreditation, the *Primary Produce (Food Safety Schemes) (Dairy) Regulations 2017* and the Food Standards Code.

This is primarily undertaken via Dairysafe audits of dairy farms, dairy processors and dairy transporters to assess compliance with requirements in the food safety program and the approved arrangement.

Audits

Dairysafe auditors conduct the audits with the exception of export registered dairy processors which are audited by the Commonwealth Department of Agriculture and Water Resources.

The first Dairysafe audit occurs within the first within 3 months after accreditation is issued and commercial operation has begun. Once the initial audit is passed the frequency of audits will revert to:

- > 6-12 monthly for dairy processors
- > Annually for dairy farms and dairy transporters

The audit frequency can increase with additional audits being required at the expense of the business where significant non-compliance occurs.

Compliance activities

Dairysafe routinely undertakes compliance activities, mainly through an audit program, however compliance action may also result from:

- > planned monitoring, surveillance and compliance programs; and
- > investigations; and
- > response to notifications; and
- > advice received from other regulatory agencies.

Product surveillance

Dairy processors are required to implement a product testing program that meets the requirements outlined in the 'Dairysafe Microbiological Testing Criteria'.

The testing program forms an element of your Food Safety Program and approved food safety arrangement and provides another measure to verify safe production.

The program data generated by the test results can demonstrate that your food safety program is delivering a product which meets the parameters for safe food. The results also provide confidence in the capacity of the food safety program to consistently deliver the required result of safe food production.

Dairysafe also conducts product surveillance to independently monitor the microbiological status of South Australian dairy products.

This activity is in addition to in-house testing undertaken by dairy processors, and focuses mainly on high-risk dairy products such as soft cheeses, dairy desserts and dips.

The results, combined with dairy processors' in-house test results, allow Dairysafe to review trends in the microbiological status of products and benchmark processors. The combined data provides Dairysafe with ongoing verification of an effective regulatory system and can also act as an early indication of process control problems and compliance with the Food Standards Code.

NON-COMPLIANCE

Dairysafe works closely with other agencies, including State, interstate and federal regulatory agencies, to achieve national consistency in the application of food standards and regulation.

In terms of managing non-compliance Dairysafe applies the following principles:

- a) compliance with the provisions of the Act is essential for the effective management of food safety risks and the supply of safe food;
- b) the use of compliance tools to encourage industry to comply with the legislation is preferred, whereas the use enforcement tools, such as prosecution, is applied only in appropriate circumstances;
- c) compliance strategies should seek to maximise public health outcomes through appropriate regulatory tools that maintain the integrity of the regulatory system;
- d) the most effective compliance strategy is one where the collective expertise and experience available across Dairysafe and allied stakeholders is utilised;
- e) business has the obligation of ensuring the production of safe food and Dairysafe's role is to verify that accredited businesses comply with food safety arrangements.

In applying compliance and enforcement arrangements Dairysafe will:

- > apply a risk-based, graduated and proportionate approach with the emphasis placed on the regulatory objectives;
- > involve the application of strategies most likely to generate compliance;
- > involve the application of multiple strategies in certain circumstances;
- > be applied in a way that is fair, impartial and transparent;
- > be carried out by trained, designated personnel in a manner consistent with the powers set out in the legislation;
- > be carried out in a way that supports accredited businesses comply, including simple and straightforward ways for accredited businesses to engage; and
- > be timely and coordinated.

Roles and responsibilities

Dairysafe's role and responsibility is to:

- > administer the dairy industry food safety scheme; and
- > approve food safety arrangements to be adopted by accredited businesses; and
- > accredit dairy farmers, dairy processors and dairy transporters; and
- > ensure accredited businesses have the capacity and capability to comply with Standard 4.2.4 of the Food Standards Code; and
- > monitor compliance by accredited businesses through audit, assessment, inspection and testing; and
- > approve individuals to carry out audits to monitor compliance with food safety arrangements.

Accredited businesses are responsible for:

- > holding accreditation with Dairysafe; and
- > implementing and maintaining an approved food safety arrangement; and
- > within their food safety arrangement:
 - validate and monitor the process control measures, and
 - investigate and correct non-conformance with food safety standards to prevent recurrence.

Application of regulatory tools

The overriding consideration for Dairysafe to take compliance action will always be in the public interest.

It is in the public interest that the health of consumers be protected. A decision to employ a compliance strategy involves a principled consideration of factors including, but not limited to the following:

- > risk to public health and safety;
- > seriousness of the alleged offence;
- > maintenance of public confidence in the supply of safe and suitable food;
- > circumstances of the alleged offence;
- > prevalence of the offence;
- > alleged offender's circumstances including previous history;
- > effectiveness of legal action;
- > cost of proceeding with a prosecution;
- > effectiveness of enforcement measures;
- > punishment and deterrence.

A graduated and proportionate response to non-compliance is applied by Dairysafe using one or more of the following:

- > verbal warnings
- > Corrective Action Request (CAR)
- > increasing the audit frequency at the operator's expense,
- > Compliance Order,
- > expiation,
- > notices,
- > seizure of product,
- > suspension or revocation of accreditation, or
- > prosecution.

A graduated response applies mild sanctions in the first instance, followed by more severe sanctions should non-compliant activity continue.

A proportionate response is the application of a sanction proportionate to the identified non-compliance capable of providing incentive to the business to amend non-compliant behaviour.

Each matter will be assessed on its merits before determining the most suitable compliance or enforcement option.

Factors to be considered in determining compliance and enforcement options

Factors assessed before determining compliance and enforcement action include:

- > the risk of a 'food safety incident';
- > the extent of the food safety risk;
- > the potential impact of the incident on the consumer, potential impact on industry, and any potential profit earned through the offending action;

- > any prima-facie evidence that an offence is likely to have occurred;
- > the level of public interest and need for consumer protection;
- > the level of deterrence warranted (based on risk, prior knowledge and compliance history);
- > previous non-compliance, breaches or offences;
- > culpability;
- > mitigating or aggravating circumstances;
- > willingness to address the non-compliance;
- > prevalence of the breach/offence;
- > consistency of approach to similar breaches/offences;
- > length of time since the alleged non-conformance occurred;
- > possible impact on other proceedings;
- > level of personal or financial hardship;
- > cultural, linguistic or communication limitations;
- > impact of new or transitional legislative requirements.

Factors to be ignored in determining compliance and enforcement options

Dairysafe is very mindful that the following factors represent a conflict of interest and must be rigorously ignored when making compliance and enforcement decisions:

- > any element of discrimination or bias against the person such as ethnicity, nationality, political association, religion, gender, sexuality or beliefs
- > possible political advantage or disadvantage to a government or any political group or party
- > the possible effect of the decision on the personal or professional circumstance of those responsible for the decision
- > any personal feelings of decision-makers toward other parties involved.

Additionally, the Code of Ethics for the South Australian Public Sector requires all employees to uphold the values of the public sector at all times, particularly when determining compliance and enforcement action.

QUERIES

Dairysafe should be your first point of contact for queries, incident notifications, or to advise of changes in your business – (08) 8223 2277

DAIRYSAFE ASSISTANCE

Dairysafe has developed a range of support documents designed to help build the technical knowledge and expertise necessary for you to produce safe dairy food.

Visit the Dairysafe website to find out more - <http://dairy-safe.com.au/>



DAIRYSAFE

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