

Compliance and enforcement policy

Introduction

Victoria's dairy industry is the largest in Australia and the safe production of dairy food is critical to its reputation and continued growth. All those involved in the production of dairy food need to ensure that food is produced, manufactured and handled in a safe manner to prevent products becoming unsafe or unsuitable for consumption. It is also important that the consumers of dairy food are informed in a clear and accurate way about the content of dairy food so that they can make informed choices about its consumption.

Dairy Food Safety Victoria (DFSV) was established under the *Dairy Act 2000* (Vic) as the dairy regulator, with the core objective of ensuring that standards which safeguard public health are maintained in the Victorian dairy industry. DFSV licenses all dairy businesses operating in Victoria, monitors compliance with the regulatory framework and, where necessary, takes appropriate compliance and enforcement action when non-compliance occurs.

Licensees are responsible for meeting their regulatory obligations and the Victorian dairy food industry has consistently demonstrated high compliance rates. The DFSV Compliance Strategy 2018–2022 explains the regulatory framework, including the issuance of licences for all dairy businesses and compliance activities.

This Compliance and Enforcement Policy¹ (the Policy) sets out DFSV's expectations for dairy businesses, including a strong culture of voluntary compliance within the industry. DFSV's Licensing Policy describes the approach adopted for licensing Victorian dairy businesses.

Scope and application

This document sets out DFSV's policy and approach in administering and ensuring compliance with the regulatory framework, comprising the following regulatory instruments:

- Dairy Act 2000 (Dairy Act): established DFSV and the licensing system for the Victorian dairy industry. It requires dairy farmers, manufacturers, carriers and distributors to hold a valid and current licence and to comply with the licence conditions.
- Food Act 1984 (Food Act): is the key legislation that controls the sale of food in Victoria. Under the
 Act, food businesses, which includes dairy carriers, manufacturers and distributors (but not farms),
 are legally responsible for ensuring that food sold to customers is safe and suitable to eat. In
 summary, the Food Act requires that:
 - o food must be safe and suitable
 - o food handling must be hygienic
 - food businesses must comply with the Australia New Zealand Food Standard Code.
- Australia New Zealand Food Standards Code (the Code): sets national standards for the
 composition, safety, handling and labelling of food in Australia and is applied and enforced in
 Victoria under the Food Act. The Code is a collection of food standards, all of which have relevance
 for dairy businesses. However, there are specific requirements for dairy businesses outlined in
 Standard 4.2.4 (Primary Production and Processing Standard for Dairy Products).

¹ This Policy is consistent with the Australia and New Zealand Food Regulation Compliance, Monitoring and Enforcement Strategy 2017

Principles

In carrying out its regulatory function, DFSV applies the following principles:

- **Focus on outcomes** encourage behaviour which results in voluntary compliance and is focused on outcomes for consumers.
- **Supportive** provide relevant advice and assistance to achieve compliance and increase industry knowledge.
- Effectiveness and efficiency act in an effective and efficient way, to ensure the safety and quality of dairy products, and take adequate precautions, whilst not necessarily restricting innovation or economic viability for the dairy food sector.
- **Proportionate** ensure regulatory responses are proportionate to the problem that is being addressed and based on an assessment of risk.
- **Impartiality and integrity** act within its powers, with integrity and without any real or perceived conflicts of interest.
- Consistency and fairness ensure that the application of the regulatory framework across the dairy food industry is consistent and fair, including ensuring natural justice for licensees, and that the particularities of each licensee is considered, when appropriate.
- **Transparent** provide documentation and implement decision-making processes that are open, clear and understandable for sectoral participants.
- Responsive be responsive to industry and community developments in food production, safety and public health.

Regulatory approach

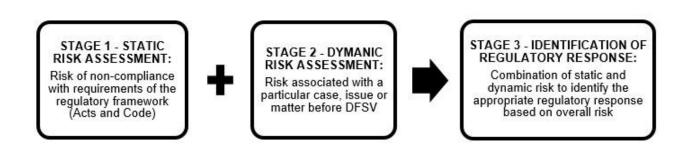
Compliance and enforcement decision-making framework

DFSV applies a risk-based approach, focusing regulatory activities and resources on licensees and compliance areas where possible or actual non-compliance or food safety risks are greatest.

This involves a comprehensive risk assessment and application of a regulatory response that is commensurate with the overall risk (Figure 1).

For each matter under consideration by DFSV, the combination of static and dynamic risk assessment leads to an overall risk assessment and identification of the relevant response.

DFSV implements a graduated response, using the range of powers available under the Dairy Act to address non-compliance, commensurate with the level of regulatory risk and risk to public health.



Regulatory activities

DFSV's core regulatory activities can be divided into three main categories:

- · application-based regulatory activity
- · proactive regulatory activity
- · reactive regulatory activity.

The risk-based approach is applied to all three of these categories of regulatory activity undertaken by DFSV.

DFSV is also accredited by the Commonwealth Department of Agriculture and Water Resources to undertake activities supporting streamlined export certification.

Application-based regulatory activity

Part 3, Section 22 of the Dairy Act requires all dairy businesses operating in Victoria to be licensed with DFSV, (please refer to <u>DFSV's Licensing Policy</u> for full details).

Proactive regulatory activity

Much of DFSV's approach to regulatory activity is proactive. Activities are directed at encouraging voluntary compliance, as well as effective monitoring of the industry, to ensure any breach is avoided altogether or identified quickly, before it may cause any adverse outcome. This category of regulatory activity is undertaken, as a matter of course, before actual or possible non-compliance is detected.

Compliance audits

DFSV monitors licensee compliance with regulatory requirements by auditing food safety programs as well as premises involved in the production, distribution, transportation and sale of dairy food products. Audits are conducted to determine whether or not licensees have complied with the requirements of their approved food safety program and whether the program is adequate for the business being conducted with consideration of the regulatory requirements.

DFSV authorised officers (food safety managers) are empowered to attend and enter premises which are used for dairy food production, with or without notice or consent for the purposes of monitoring compliance or investigation and they may issue orders, infringement notices and official warnings.

DFSV conducts audits, in accordance with the requirements of the National Food Safety Audit Policy.

Product testing

DFSV also conducts a Product Surveillance Program, which evaluates the microbiological and physicochemical status of dairy food products manufactured in Victoria. The data enables assessment of compliance with the requirements in the Code and provides verification of the effectiveness of the industry's food safety systems.

Advice and information

A key focus of DFSV's regulatory approach is to promote understanding of regulatory requirements and provide information to support industry compliance.

DFSV produces a range of technical information and guidance material that outlines the regulatory obligations and DFSV's expectations of licensees' premises, operations and management of food safety in their businesses.

Reactive regulatory activity

DFSV may become aware of non-compliance through:

- regular audits undertaken as part of its proactive regulatory activity
- · mandatory reporting of pathogen detections
- complaints received from licensees, other agencies and the general public about products manufactured by, or about the operational practices and standards of facilities of DFSV licensees.

Where DFSV becomes aware of an actual or possible instance of non-compliance or a risk to food safety, it has the power to undertake a wide range of actions in response. These actions can be broadly labelled as reactive regulatory activity.

In determining the appropriate response, DFSV authorised officers assess the static and dynamic risk in accordance with the compliance and enforcement decision-making framework, which includes consideration of:

- the impact of the non-compliance on public health
- the nature of the obligation that has not been complied with
- the profile of the regulated entity
- the conduct of the regulated entity resulting in and following non-compliance.

Non-conformance with food safety programs

A deficiency, or failure, of a licensee to comply with their approved food safety program is categorised as a non-conformance. A non-conformance is further classified as a minor, major or critical. Corrective action requests (CARs) are issued in accordance with the non-conformance classifications described.

The timeframes within which corrective actions must be completed and the level of oversight of completion are determined on the basis of assessment of the regulatory or food safety risk.

Minor non-conformance – poses no immediate risk or is deemed an overall low level of risk to public health and is not likely to lead to the production of unsafe food. Closure within 6 months or as agreed.

Major non-conformance – may lead to the production of unsafe food unless remedial action is taken to correct the non-conformance within a specified period. Action plan to mitigate risk formulated and implementation commenced within 28 days or as agreed.

Critical non-conformance – presents an imminent and serious risk to the safety of the food intended for sale, will cause significant unsuitability of food intended for sale. Action plan to mitigate risk formulated and implementation commenced within 7 days or as agreed.

Other enforcement action

If an authorised officer identifies a non-compliance that requires action but does not warrant the issuance of a formal enforcement order, they may direct that action is taken to address the non-compliance and/or warn that failure to take the necessary action may result in formal enforcement action. A licensee may be required to provide evidence to DFSV that the action has been taken within a specified timeframe.

An investigation of a non-compliance may also result in a request to recall a product, or referral to the Department of Health and Human Services to consider use of its power under the Food Act to recall a product. DFSV will escalate its enforcement response when requests to comply are not met.

Issuing orders

S46 of the Dairy Act provides for authorised officers to take immediate action if they are satisfied or suspect that premises or equipment are unclean or substandard or dairy food is unfit for human consumption. The authorised officer may order the premises or equipment to be cleaned, to stop use of part or all of a premises, or a specific piece of equipment, or order that dairy food not be removed from the premises or seize the food.

Under S19 of the Food Act, if an authorised officer advises DFSV that with respect to a dairy food business:

- · a food premises is in an unclean or unsanitary state or a state of disrepair
- food being prepared, handled or sold at a food premises is unsafe or unsuitable
- food is being prepared, sold or handled at a food premises in a manner which makes it likely that it is unsafe or unsuitable

DFSV may order in writing that the premises be put into a clean and sanitary condition or steps be taken to ensure that the food prepared, sold or handled is safe and suitable and that until the required actions have been completed, the premises must not be used to prepare, sell or handle food and the use of the premises limited as specified in the order.

Orders will be issued in conjunction with a CAR when the food safety risk related to the food safety program non-conformance warrants. Orders are regarded as an escalation from a CAR and it is an offence under Section 46 (4) of the Dairy Act to comply with an order issued under this section.

DFSV will escalate its compliance and enforcement response where an initial regulatory response is unsuccessful in securing compliance. Failure to cooperate with DFSV will be taken seriously as DFSV considers that this demonstrates a high level of culpability and undermines the integrity of the regulatory framework.

Enforcement programs

Where a licensee has an unsatisfactory compliance history or risk profile, an enforcement program may be imposed. These circumstances may include a critical CAR raised at a previous audit, the identification of serious food safety risks, continued poor performance related to compliance monitoring activities, or issues concerning the capability of the business to manage food safety.

An enforcement program will include, as a minimum, one enforcement audit of the food safety program in addition to regular compliance audits, unannounced inspections and/or additional sampling and testing of product ordered by an authorised officer for external analysis.

DFSV may also use powers under S26 (3) of the Dairy Act to impose additional licence conditions on either a temporary or ongoing basis.

Once the licensee has demonstrated satisfactory compliance with the requirements of the enforcement program the licensee will be advised that their program has been successfully completed or that the program has been revoked.

Licence status decisions

Under S26(1) of the Dairy Act, DFSV may decide to refuse to renew, cancel or suspend a dairy industry licence on the grounds that the licensee has not complied with, or the premises or vehicle does not comply with regulatory requirements or that the licensee has failed to comply with any condition specified in the licence.

Any decision to refuse to renew, cancel or suspend a licence, or to amend or vary a condition of licence may be appealed, within 28 days of notification of the decision, to the Victorian Civil and Administrative Tribunal.

Withdrawal or suspension of food safety program approval

S42(1) of the Dairy Act requires that DFSV withdraw or suspend approval for a food safety program if it considers there has been a failure to comply with the program and the failure is so serious that it cannot be dealt with by increased monitoring requirements under the program.

Whilst food safety program approval is withdrawn/suspended:

- no food produced by the business at the licensed premises is permitted to be sold
- should any products be manufactured during this time they are not permitted to be sold under any circumstances and must be disposed of by the licensee.

If the food safety program approval is withdrawn or suspended the licensee must apply to DFSV in writing for a new approval or revocation of the suspension of approval and the licensee will be required to demonstrate, to the satisfaction of DFSV, adequate commitment to compliance with the program.

Prosecution

DFSV will consider prosecution as an enforcement tool when legislative breaches have occurred. This may be after the use of less severe enforcement tools have been considered to ensure the business is compliant. DFSV will escalate its compliance and enforcement response where an initial regulatory response is unsuccessful in securing compliance. However, prosecution may be used in the first instance if DFSV considers the breach to be serious enough to warrant prosecution.

Further information

Victorian dairy licence handbook

Developing a food safety program: guidelines for dairy food manufacturers

Hygienic design: guidelines for dairy food manufacturing premises

Microbiological testing criteria

A guide to managing allergens in the dairy industry

Dairy pathogen manual

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