EXPLANATORY STATEMENT

<u>Issued by Authority of the Secretary, Department of Agriculture, Water and the Environment</u>

Export Control Act 2020

Export Control (Milk and Milk Products) Rules 2021

Authority

The Export Control Act 2020 (the Act) sets out the overarching legislative framework for the regulation of exported goods, including food and agricultural products, from Australian territory, and enables the Secretary of the Department of Agriculture, Water and the Environment (the Secretary) to make rules that detail the requirements and establish conditions relating to the export of certain goods.

The Act provides provisions for the application of the Act and how the Act interacts with State and Territory laws. The *Export Control (Milk and Milk Products) Rules 2021* (the Milk Rules) may prohibit the export of prescribed goods from Australian territory, or from a part of Australian territory unless prescribed export conditions are adhered to. These conditions ensure the importing country requirements are satisfied, reflect industry standards, and meet Australia's international obligations. Prescribed milk and milk products are regulated by the Milk Rules.

The Milk Rules are made by the Secretary under section 432 of the Act. Section 432 of the Act relevantly provides that the Secretary may, by legislative instrument, make rules prescribing matters required or permitted by the Act, or that are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

A number of provisions in the Act set the parameters of the Secretary's rule-making power and either:

- provide examples of the kinds of things for which the Secretary may make provision in the rules; or
- set out the default matters for the provision and allow the Secretary to give further detail, or set additional requirements, in the rules.

Under section 289 of the Act, the Minister may issue directions to the Secretary about the performance of the Secretary's functions or the exercise of the Secretary's powers in making rules under section 432 of the Act. Directions made by the Minister to the Secretary are legislative instruments but are not subject to disallowance or sunsetting. At the time of commencement, a Ministerial direction has not been made under section 289 of the Act for the purposes of rules relating to milk and milk products.

Purpose

The purpose of the Milk Rules is to ensure milk and milk products exported from Australian territory satisfy requirements to enable and maintain overseas market access. The Milk Rules include measures to ensure exported milk and milk products reflect relevant standards, are described accurately and are traceable. The Milk Rules also include measures to ensure the integrity of milk and milk products exported from Australia.

By setting out key requirements for the export of milk and milk products in the Milk Rules, and having those Rules made by the Secretary, the regulatory framework can be kept fit for purpose if importing country requirements change. Many changes are technical matters, concerning the way that goods are to be produced, prepared, or exported. Having the capacity to change the Milk Rules quickly is crucial to ensuring that Australian producers, processors and exporters do not experience disruption in market access and can continue to export goods that meet requirements. This is particularly important because one non-compliant export of goods can have significant consequences for other exports, including restrictions on, or the closure of, market access.

The Milk Rules, in conjunction with the Act, set out the requirements that are particular to the export of milk and milk products from Australian territory. Wherever possible, the Milk Rules have been made consistent with other commodity specific export rules that share the same requirements, to ensure consistency in the new framework for stakeholders and regulators that deal in multiple commodities. This will allow for a streamlined approach to regulating the different commodities that will be prescribed and make the framework more accessible to stakeholders.

Background

In 2015 the then Department of Agriculture (now the Department of Agriculture, Water and the Environment (the Department)) conducted a comprehensive review of the export of agricultural products through the *Agricultural Export Regulation Review* (the Review). The Review found most stakeholders accepted the current level of regulation and understood the need for it to be maintained to protect market access and Australia's reputation. However, it also recognised that there was scope for improvement, including increasing flexibility and opportunities for government-industry cooperation, reducing complexity and duplication, and strengthening compliance and enforcement arrangements.

Based on these findings, two regulatory options were considered:

- option one: maintain the existing regulatory arrangements;
- option two: consolidate and improve the legislative framework.

On considering the findings of the Review, the Australian Government agreed to improve the legislative framework to address the issues identified by the Review. As part of that process, existing export-related requirements were streamlined and consolidated into an improved legislative framework comprising of the Act and commodity specific rules, which will support the Act. These improvements reduce duplication as well as make it easier to understand and comply with export requirements.

The improvements to the legislative framework are not intended to make significant changes to export policy or the current baseline of regulation. It is intended to provide a more consistent and clearer framework that is flexible and responsive to emerging issues.

Impact and Effect

The Milk Rules impose regulatory controls on milk and milk products that are to be exported from Australia so that these products meet trade requirements. These controls maintain and strengthen the existing regulatory controls and oversight for the export of goods.

Chapter 1 deals with formal and preliminary matters and sets out the special meanings of words and phrases used in the Milk Rules.

Chapter 2 deals with matters relating to exporting goods. These include:

- defining prescribed goods;
- prohibiting the export of certain goods;
- applying for exemptions; and
- the issue of government certificates.

Chapter 4 deals with matters relating to registered establishments. These include:

- requirements relating to construction, equipment and facilities;
- conditions of registration;
- application for registration, renewal and suspension of registration; and
- matters relating to applications.

Chapter 5 deals with matters relating to approved arrangements. These include:

- requirements for approval;
- conditions of approval of an approved arrangement, including trade descriptions and official marks; and
- applications for the approval of a proposed arrangement and for the renewal, variation, suspension and revocation of an approved arrangement.

Chapter 7 deals with matters relating to export permits. These include:

- conditions for the issue of an export permit; and
- application for an export permit and, variation, suspension and revocation of an export permit.

Chapter 8 provides for other matters relating to export. These include:

- trade descriptions; and
- official marks.

Chapter 9 deals with matters relating to powers and officials. These include:

- provisions for the conduct of audits and carrying out of assessments; and
- powers and functions of authorised officers in relation to inspections.

Chapter 10 deals with compliance and enforcement in relation to samples taken:

- in exercising monitoring or investigation powers; and
- dealing with things seized in exercising investigation powers.

Chapter 11 deals with miscellaneous matters such as:

- review of decisions;
- record-keeping;
- taking and storage of samples;
- compensation for the damage or destruction of goods; and
- relevant Commonwealth liabilities

Chapter 12 provides a scheme of transitional and savings provisions that will preserve the rights and liabilities under the former Orders (the old *Export Control (Milk and Milk Products) Orders 2005* and the old *Export Control (Prescribed Goods—General) Order 2005*).

Consultation

In accordance with the requirement for consultation under section 17 of the *Legislation Act 2003*, the Milk Rules have been informed by consultation with stakeholder groups including industry representatives and state and territory regulatory agencies responsible for the administration and regulation of milk establishments. The level of regulatory oversight will not change under the new legislative framework, however the requirements are easier to understand, administer and use.

A public consultation draft of the Milk Rules was published on the Department's website from 28 February 2019 to 31 May 2019. During this time, the Department consulted with stakeholders through information sessions held between 12 March 2019 and 14 March 2019, and between 19 March 2019 and 22 March 2019 in Australian capital cities. Seven written submissions were received and considered in further developing these rules.

An exposure draft of the Milk Rules was released on 7 September 2020 as part of a package of revised commodity specific rules for 60 days of public consultation to ensure Australia's compliance with international obligations under the World Trade Organization's Sanitary and Phytosanitary Agreement. Two submissions were received during this time, and feedback obtained from all consultation rounds was considered in the development of the Milk Rules.

The Office of Best Practice Regulation within the Department of the Prime Minister and Cabinet (PMC) was consulted in the development of the Act and the subsequent Milk Rules. The Act established a new regulatory framework, which is supported by a number of subordinate legislative instruments, that aims to improve Australia's agriculture export legislation (which is a key initiative to support the export of Australian goods and products).

A Regulatory Impact Statement *Improvements to agriculture export legislation* [OBPR ID: 19535] was previously developed under this framework, with stakeholders included in the consideration of commodity specific rules, and the mandatory obligations on Australian businesses and the relevant industries. A copy of the Regulation Impact Statement was previously provided with the explanatory memorandum to the Export Control Bill 2019.

Details and Operation

Details of the Milk Rules are set out in Attachment A.

The Milk Rules is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Milk Rules commence at the same time as section 3 of the Act commences.

Other

The Milk Rules is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in <u>Attachment B</u>.

Details of the Export Control (Milk and Milk Products) Rules 2021

CHAPTER 1—PRELIMINARY

Part 1—Preliminary

1-1 Name

Section 1-1 provides that the name of the instrument is the *Export Control (Milk and Milk Products) Rules 2021* (the Milk Rules).

1-2 Commencement

Section 1-2 provides for the Milk Rules to commence at the same time as section 3 of the *Export Control Act 2020* (the Act).

Section 2 of the Act provides for section 3 of the Act to commence at a single time to be fixed by Proclamation. However, if section 3 of the Act does not commence before 3 am on 28 March 2021 (in the Australian Capital Territory), then it will commence at that time (item 2 of the table in section 2 of the Act).

1-3 Authority

Section 1-3 provides that the Milk Rules are made under the Act.

1-4 Simplified outline of this instrument

Section 1-4 provides a simplified outline of the matters covered in the Milk Rules and details the structure. The outline is not intended to be comprehensive and is included to assist readers. It is intended that readers will rely on the substantive provisions on the Milk Rules.

The Milk Rules prescribe matters and make other provisions in relation to milk and milk products for the purposes of the Act. Chapters in the Milk Rules have the same name and number as corresponding Chapters in the Act. Gaps in the Chapter numbering in the Milk Rules are because some Chapters of the Act are not relevant to the export of milk and milk products.

Part 2—Interpretation

1-5 Definitions

Section 1-5 contains definitions of key terms that are used in the Milk Rules. The note at the start of this section lists some of the terms used in the Milk Rules which are defined in section 12 of the Act. Such terms will have the same meaning in the Milk Rules as they have in the Act

Section 1-5 will also include some 'signpost' definitions that refer readers to the sections in which terms are substantively defined.

Some key concepts for the regulatory framework established by the Milk Rules are *milk* and *milk product*. These are key concepts because they broadly set the scope of what can be regulated by the Milk Rules; only *prescribed milk* and *prescribed milk products* are regulated by the Milk Rules and these terms are defined, respectively, as milk and milk products that are prescribed goods under Division 1 of Part 1 of Chapter 2.

Milk is defined as the lacteal secretion obtained from an animal. *Milk product* is defined as a product containing milk or containing an ingredient derived from milk. The example following the definition of *milk product* explains that a product containing milk power, whey powder, milk fat or milk protein is a milk product. The note following the definition of *milk product* explains that a milk product that does not have milk or milk products as a major component is not a prescribed milk product unless subsection 2-1(2) of the Milk Rules applies in relation to the milk product (see paragraph 2-1(3)(e)).

Section 1-5 also defines the term *exporter*, in the context of exporting prescribed milk or milk products, as the applicant for an export permit for the milk or milk products or, if an export permit has been issued for the milk or milk products – the holder of the permit. This is an important concept because it clarifies who is generally being regulated by the requirements of the Milk Rules.

Other key concepts that are defined in section 1-5 are *registered establishment*, which means an establishment that is registered (under Chapter 4 of the Act) for a kind of export operations in relation to prescribed milk or milk products, and *relevant importing country authority*, which means the authority or body that is responsible for regulating the importation of milk or milk products into that country from Australian territory.

The purpose of the definitions of *resources industry structure* and *installed* is to provide certainty around the kinds of structures (for example, oil rigs and similar off-shore structures) that are covered by the Milk Rules. Goods consigned to a *resource industry structure* that is *installed* in an area are not required to comply with prescribed export control conditions (see paragraph 2-2(f) of the Milk Rules). The definition of *resources industry structure* means a resources industry fixed structure (as defined in the *Sea Installations Act 1987*) and a resources industry mobile unit (as defined in the *Sea Installations Act 1987*) that is not a vessel. This definition of *resources industry structure* includes a fixed structure (including a pipeline) or a moveable or floatable structure (that is not a vessel) that is used off-shore wholly or principally for exploring or exploiting natural mineral resources.

1-6 Meaning of loaded for export

Section 1-6 provides a definition for when milk or milk products are *loaded for export*. This is when the milk or milk products are placed into a container system unit at a registered establishment for export; or are loaded into or onto an aircraft or a vessel for export without first being placed into a container system unit.

This stage in the export supply chain is important as it is a critical point of regulatory control before a consignment of milk or milk products leaves Australian territory. There are certain obligations that apply at this point in the supply chain and the definition ensures these persons know when these obligations apply.

These obligations under the Milk Rules include:

- that prescribed milk and milk products not be loaded for export where an export permit has been revoked, or the holder of an approved arrangement has been given a direction that the milk and milk products are not to be dealt with as export for food (subsection 5-25(4));
- that prescribed milk and milk products must not be loaded for export into or onto a conveyance, unless the conveyance, container system unit and equipment used for loading comply with the requirements of Part 2 of Chapter 5 of the Milk Rules (subsection 5-21(2)); and
- A trade description must be applied no later than the time the prescribed milk or milk products are packed in their immediate container before being loaded for export (subsection 5-27(2) of the Milk Rules).

CHAPTER 2—EXPORTING GOODS

Part 1—Goods

Division 1—Prescribed goods

Division 1 of Part 1 of Chapter 2 of the Milk Rules sets out which kinds of goods will be *prescribed goods* for the purposes of the Act. Prescribed goods are subject to the regulatory controls imposed by the Act, including the requirement to comply with the prescribed export conditions.

2-1 Milk and milk products that are prescribed goods

Subsection 28(1) of the Act allows the Secretary to prescribe kinds of goods for the purposes of the Act. A kind of good prescribed by rules made for the purposes of subsection 28(1) is a *prescribed good*. The Act regulates the export of *prescribed goods*.

Subsection 2-1(1) prescribes certain milk or milk products that are intended to be exported as food as *prescribed goods* for the purposes of subsection 28(1) of the Act. This means that goods that:

- are milk or milk products derived from a bovine animal; and
- are intended to be exported as food;

will be subject to the regulatory controls in the Act and the Milk Rules, including the requirement to comply with prescribed export conditions. This general rule is, however, subject to the express exceptions set out in subsection 2-1(3), which details the milk or milk products that are generally taken not to be prescribed goods, and the circumstances in which those products will be prescribed goods (set out in section 2-2 of the Mile Rules).

The first note following subsection 2-1(1) notifies the reader that the term *food* is defined in section 12 of the Act. This definition provides that *food* includes any substance or thing of a kind used, or capable of being used, for human consumption, or as an ingredient or additive in any substance or thing of a kind used or capable of being used for human consumption, whether or not the substance or thing is in a condition fit for human consumption.

The second note following subsection 2-1(1) explains that milk and milk products covered by subsection 2-1(1) are taken not to be *prescribed goods* for the purposes of the Act in the circumstances set out in subsection 2-2 of the Milk Rules.

Subsection 2-1(2) provides that goods listed under subsection 2-1(3) will be prescribed milk or milk products (*prescribed goods*) for the purpose of subsection 28(1) of the Act only where the goods are intended to be exported to a particular country (the *importing country*), and one or more requirements of the Act must be met in order to meet a requirement of the importing country.

In such circumstances the goods will be considered prescribed goods (and thus be subject to the requirements of the Act and the Milk Rules) for the purposes of importing to that country, but will not be prescribed goods when exported to another country that does not have the same importing requirements. This is explained in the note following subsection 2-1(2).

The example following subsection 2-1(2) explains that goods listed in 2-1(3) would be prescribed if a requirement of the Act would need to be complied with in order to meet an importing country requirement.

The note following subsection 2-1(2) explains that where subsection 2-1(2) applies to milk or milk products, the Act will apply in the same way as it applies to goods prescribed for the purposes of the Act under subsection 2-1(1).

Subsection 2-1(3) lists milk and milk products that are not prescribed for the purposes of subsection 28(1) of the Act, even if they would ordinarily fall within the definition of *milk* or *milk product* and are intended for export as food. Goods listed in subsection 2-1(3) will only be subject to the regulatory controls set out in the Act and the Milk Rules (including the requirement to comply with the prescribed export conditions) to the extent that they also fall within subsection 2-1(2). The goods listed in subsection 2-1(3) are:

- ice cream;
- cheesecakes, Bavarian desserts and similar desserts;
- colostrum;
- milk or milk products encased in pastry or a fruit or vegetable product;
- milk products where milk or milk products are not the major component;
- milk or milk products that are derived from the lacteal secretion obtained from an animal other than a bovine animal;
- milk or milk products that are animal food or pharmaceutical material;
- any other milk or milk products that are not covered by subsection 2-1(1);
- liquid milk and milk products exported in a consignment of not more than 10 litres;
- milk or milk products not covered in the above exported in a consignment of not more than 10 kilograms;
- milk or milk products in the form of a tablet or capsule;
- milk or milk products for export to New Zealand.

The terms *animal food* and *pharmaceutical material* are defined in section 1-5 of the Milk Rules.

The purpose of subsections 2-1(2) and (3) is to remove barriers to trade where there is minimal risk to food safety and human and animal health, while ensuring importing country requirements are met. This provides flexibility to increase or decrease the level of regulation for the export of milk or milk products where there are changes in importing country requirements. This also provides for the regulation of milk and milk products for export where there is a need to focus on exports that attract the most risk.

2-2 Milk and milk products that are taken not to be prescribed goods

Subsection 28(4) of the Act allows the rules to prescribe goods that are taken not to be prescribed goods for the purposes of the Act in specified circumstances.

Section 2-2 is made for the purposes of subsection 28(4) of the Act. It sets out the circumstances when milk and milk products that are prescribed under subsections 2-1(1) and (2) of the Milk Rules are taken not to be prescribed goods for the purposes of the Act.

It is not necessary for the milk or milk products to be subject to the regulatory controls in the Act in the circumstances listed in section 2-2, as these goods are:

- intended to be consumed in transit (paragraphs 2-2(a) and (b)) on a flight or voyage; or
- being transited through Australia (paragraphs 2-2(c) and (d)); or
- not being imported into another country (paragraphs 2-2(e) and (f)) but to an external Territory or a *resources industry structure*.

Requiring milk or milk products in these circumstances to meet the requirements of the Milk Rules would be redundant and excessively burdensome as the goods are intended to be consumed and not enter another country or to be re-exported in the same condition in which they entered Australia.

Subsection 2-2(d) provides an exception for milk and milk products that are imported into Australian territory and then exported in the same covering in which, and with the same trade description with which they were imported.

The first note following section 2-2 alerts the reader that milk or milk products are in the same covering in which they were imported if they are in the same immediate container in which they were packed when imported and refers the reader to the definition of *immediate container* in section 1-5 of the Milk Rules.

The second note following section 2-2 explains that a resource industry structure that is not installed is taken to be a vessel in accordance with the *Sea Installations Act 1987*.

Division 2—Prohibited export and prescribed export conditions

Division 2 of Part 1 of Chapter 2 of the Milk Rules sets out specific requirements that must be complied with when exporting prescribed milk or milk products (prescribed export conditions). The purpose of the prescribed export conditions is to ensure that prescribed goods are exported in accordance with the requirements in the Act and the Milk Rules.

2-3 Purpose and application of this Division

Subsections 2-3(1) and (2) provide that Division 2 of Part 1 of Chapter 2 of the Milk Rules is made for the purposes of section 29 of the Act and that it applies to prescribed milk or milk products.

The first note following subsection 2-3(1) refers the reader to Division 1 of Part 1 of Chapter 2 of the Milk Rules for what goods are prescribed milk or milk products.

The second note following subsection 2-3(2) notifies the reader that, under subsection 2-2 of the Milk Rules, milk and milk products are taken not to be prescribed goods in certain circumstances.

Subsection 2-3(3) provides that a provision of Division 2 does not apply to prescribed milk or milk products which is to be exported in a circumstance referred to in subsection 52(1) or (3) of the Act (for example, a commercial sample) and for which an exemption from that provision is in force in relation to the prescribed milk or milk products under Part 2 of Chapter 2 of the Act.

This acknowledges that Part 2 of Chapter 2 of the Act allows certain persons to apply for and be granted an exemption from one or more provisions of the Act in the circumstances listed in section 52. For instance, a person may be granted an exemption from having to comply with one or more of the prescribed export conditions in relation to the export of prescribed milk or milk products for experimental purposes.

2-4 Export of prescribed milk or milk products is prohibited unless prescribed conditions are complied with

Section 29(1)(a) of the Act allows the rules to prohibit the export of prescribed goods from Australian territory or from a part of Australian territory unless the conditions prescribed by the rules are complied with.

Subsection 2-4(1) lists the prescribed export conditions that must be complied with for the export of prescribed milk or prescribed milk products from Australian territory. The export of prescribed milk or milk products is prohibited unless these conditions are met. These conditions are necessary to enable and maintain market access for goods exported from Australian territory and to ensure compliance with importing country requirements. The prescribed export conditions maintain the integrity of our exports, Australia's positive relationships with trading partners and our reputation as a reliable exporter of safe and high-quality products.

The prescribed export conditions that apply to the export of prescribed milk or milk products are:

- that the operations (other than operations to which subsection 2-4(2) applies) to prepare the milk or milk products for export are carried out at an establishment that is registered for those operations in relation to the milk or milk products, and that the registration is not suspended in relation to those operations; and
- that an approved arrangement covering operations (other than operations to which subsection 2-4(2) applies) to prepare the milk or milk products for export at the registered establishment must be in force and not suspended at the time the operations are carried out; and
- that, at the time of the export, the exporter holds an export permit for the milk or milk product that is in force and not suspended.

For each export of prescribed milk or milk products, all prescribed export conditions must be complied with.

The first note following subsection 2-4(1) notifies the reader that additional conditions may also apply to the export of particular prescribed milk or milk products that also fit within other regimes, such as particular milk products covered by the *Export Control (Organic Goods) Rules 2021*.

The second note following subsection 2-4(1) alerts the reader that a person may commit an offence or be liable to a civil penalty if prescribed goods are exported in contravention of prescribed export conditions (see Division 4 of Part 1 of Chapter 2 of the Act).

The third note following subsection 2-4(1) alerts the reader that the occupier of a registered establishment may commit an offence or be liable to a civil penalty if export operations are carried out while the registration of the establishment is suspended (see section 136 of the Act).

The fourth note following subsection 2-4(1) alerts the reader that the holder of an approved arrangement may commit an offence or be liable to a civil penalty if export operations are carried out while the arrangement is suspended (see section 177 of the Act).

The fifth note following subsection 2-4(1) clarifies that while a suspended export permit remains in force, it does not authorise the export of goods while suspended (subsection 232(2) of the Act).

Subsection 2-4(2) provides for certain operations to store or chill unpasteurised milk that are carried out at an establishment where no other operations to prepare prescribed milk or milk products for export are carried out.

The first note following subsection 2-4(2) explains that all these operations must meet the requirements of items 1 and 2 of subsection 2-4(1), unless an exemption is in force in relation to the milk under Part 2 of Chapter 2 of the Act.

The second note following subsection 2-4(2) notifies the reader that requirements relating to pasteurisation and other treatments are outlined under section 5-19 of the Milk Rules.

Part 2—Exemptions

Part 2 of Chapter 2 of the Milk Rules sets out matters relating to exemptions from one or more provisions in the Act in relation to prescribed milk or milk products.

Under Part 2 of Chapter 2 of the Act, an exemption from one or more requirements of the Act (including prescribed export conditions) may be granted following an individual application in certain circumstances, rather than in relation to all milk or milk products of a particular kind or exported to a particular country. This is to enable a reduced level of regulatory oversight in circumstances where there is minimal risk posed by exporting the milk or milk products while ensuring importing country requirements are met.

2-5 Application of this Part

Section 2-5 provides that Part 2 of Chapter 2 of the Milk Rules applies only in relation to prescribed milk or milk products, which are called *relevant goods* in this Part.

The first note following section 2-5 draws the reader's attention to Division 1 of Part 1 of Chapter 2 of the Milk Rules, which sets out what are prescribed milk or milk products.

The second note following section 2-5 notifies the reader that, under section 2-2 of the Milk Rules, milk and milk products are taken not to be prescribed goods (see section 12 of the Act) in the specified circumstances.

2-6 Prescribed circumstance—testing the market

Subsection 52(1) of the Act provides that Part 2 of Chapter 2 of the Act applies in relation to a kind of goods that are to be exported:

- as a commercial sample; or
- for experimental purposes; or
- in exceptional circumstances; or
- in special commercial circumstances; or
- in other circumstances prescribed the rules.

Paragraph 52(1)(e) of the Act allows other circumstances in which an exemption can be sought to be prescribed by the rules. A person may apply for an exemption from one or more provisions of the Act in relation to an export of prescribed goods in the circumstances prescribed by rules made for the purposes of paragraph 52(1)(e).

Section 2-6 is made under paragraph 52(1)(e) of the Act, and prescribes that testing the market in relation to the relevant goods to be exported is a circumstance in which a person may apply for an exemption from one or more provisions of the Act in relation to the export of prescribed milk or milk products.

2-7 Prescribed meaning—commercial sample

Section 52(2) of the Act provides that the rules may prescribe the meaning of *commercial sample*, for the purposes of subsection 52(1) of the Act. Subsection 52(1) provides that Part 2 of Chapter 2 of the Act applies in relation to goods that are to be exported as a commercial sample.

Section 2-7 defines the meaning of *commercial sample* for the purposes of paragraph 52(2)(a) of the Act as a quantity of relevant goods, for use as a sample for commercial purposes, in the case of liquid, which does not exceed 50 litres, and, in any other case, which does not exceed 60 kilograms.

2-8 Period for making application for exemption

Subparagraph 53(3)(f)(i) of the Act allows the rules to prescribe the period within which an application for an exemption from one or more provisions of the Act may be made.

Section 2-8 is made for the purposes of subparagraph 53(3)(f)(ii) of the Act and prescribes the timeframe in which an application for an exemption from one or more provisions in the Act must be made in relation to relevant goods. This period is 120 days ending on the day that is 10 business days before the proposed date of export of the relevant goods (if operations to prepare the relevant goods for export have started), or the proposed date to start carrying out those operations (in any other case). The timeframe is to ensure the Secretary has a reasonable amount of time to assess applications for exemption prior to the export of the prescribed milk or milk products.

The first note following section 2-8 refers the reader to subparagraph 53(3)(f)(ii) of the Act, which allows the Secretary to allow a different period in which the application may be made in an individual case.

The second note following section 2-8 explains that an application for an exemption must comply with the requirements in subsection 53(3) of the Act.

2-9 Conditions of exemption—matters to which Secretary must have regard

Section 55 of the Act allows the Secretary to impose conditions on an exemption. When deciding whether to impose a condition on an exemption, the Secretary is required to have regard to the matters prescribed by the rules (subsection 55(2)).

Section 2-9 is made for the purposes of subsection 55(2) of the Act, and requires the Secretary, in deciding whether it is necessary to impose conditions on an exemption that relates to prescribed milk or milk products, to consider whether imposing the condition would ensure that one or more objects of the Act will be met in relation to the goods.

The note following section 2-9 notifies the reader that an exemption may be subject to any conditions that the Secretary considers necessary (see subsection 55(1) of the Act). For example, an exemption may be made subject to a limit on the number of consignments that may be exported, or to any condition relevant to the registration of an establishment or approval of an arrangement, to ensure the relevant goods are fit for human consumption.

2-10 Instrument of exemption

Subsection 56(1) of the Act requires the Secretary, if an exemption was granted under paragraph 54(1)(a) of the Act in relation to relevant goods, to give the applicant an instrument of exemption stating certain information. Paragraph 56(1)(h) requires the instrument to include any other information prescribed by the rules.

Section 2-10 prescribes, for the purposes of paragraph 56(1)(h) of the Act, that an instrument of exemption in relation to relevant goods that are to be exported in the circumstance prescribed by section 2-6 (testing the market) must state a unique identifier for the establishment where operations to prepare the relevant goods for export (other than storing, handling or loading) were last, or will be, carried out.

2-11 Period of effect of exemption

Paragraph 57(b) of the Act allows the rules to prescribe the period that an exemption remains in force unless it is revoked earlier.

Section 2-11 is made for the purposes of paragraph 57(b) of the Act and provides the period of effect of an exemption that relates to prescribed milk or milk products to be 12 months starting on the day the exemption takes effect, or another period specified in the instrument of exemption. The Secretary will have the discretion to determine the appropriate period in the instrument of exemption. It may be appropriate that some exemptions remain in force for different periods. This will provide the necessary flexibility to deal with changing circumstances for regulating prescribed goods.

The note following section 2-11 explains that, under paragraph 57(a) of the Act, an exemption takes effect on the date specified in the instrument of exemption under paragraph 56(1)(e) of the Act.

2-12 Variation of conditions of exemption—matters to which Secretary must have regard

Section 58 of the Act allows the Secretary to vary the conditions imposed on an exemption that is in force. When deciding whether it is necessary to vary a condition on an exemption, the Secretary is required to have regard to the matters prescribed by the rules (subsection 58(3)).

Section 2-12 is made for the purposes of subsection 58(3) of the Act and requires the Secretary, in deciding whether it is necessary to vary conditions on an exemption that relates to prescribed milk or milk products, to consider whether varying the condition would ensure that one or more objects of the Act are met in relation to the goods.

This requirement is intended to ensure that exemptions are approved in circumstances where the objectives of the Act are met and goods exported from Australia are of the highest standard, strengthening Australia's reputation as a trading partner.

Part 3—Government certificates

Part 3 of Chapter 2 of the Act provides for government certificates to be issued for goods that are to be exported or have been exported. Part 3 of Chapter 2 of the Milk Rules sets out specific requirements relating to the issue of government certificates for milk and milk products that are to be or have been exported.

A government certificate is an official document containing details about the product being exported. The purpose of the government certificate is to confirm to importing country authorities that the milk or milk products have met specified requirements of that country. Government certificates may be issued electronically, providing an efficient means of facilitating trade.

2-13 When government certificate may be issued in relation to milk or milk products

Section 62 of the Act allows the rules to make provision for and in relation to the issue of government certificates in relation to goods that are to be, or that have been, exported.

Section 2-13 is made for the purpose of subsections 62(1) and (2) of the Act and provides that a government certificate may be issued for milk and milk products that will be, or have been, exported. A certificate can be issued for any milk or milk products, whether they are prescribed or non-prescribed goods, so long as the goods are to be, or have been, exported.

The note following section 2-13 refers the reader to section 11-4 of the Milk Rules, which requires a government certificate (other than a certificate issued by electronic means) to be retained in a secure place when it is not being used.

2-14 Matters stated in government certificate—manufacturing grade milk or milk products

Subsection 62(1) of the Act allows the rules to make provision for and in relation to the issue of government certificates in relation to a kind of goods that are to be, or have been, exported.

Section 2-14 provides that, for the purposes of subparagraph 62(2)(b)(ii) of the Act, a government certificate issued in relation to manufacturing grade milk or milk products that are to be exported may not state certain matters. These matters are:

- that the conditions of the registration of an establishment for operations to prepare the milk or milk products for export have been complied with;
- the conditions of an approved arrangement for operations to prepare the milk or milk products for export have been complied with;
- that the milk or milk products are fit for human consumption.

Manufacturing grade, in relation to milk or milk products, is defined in section 1-5 of the Milk Rules to mean milk or milk products that are not fit for human consumption but are suitable for further processing to make them fit for human consumption.

2-15 Requirements before issue of government certificate—condition of milk or milk products

Section 62 of the Act allows the rules to make provision for and in relation to the issue of government certificates in relation to goods that are to be, or that have been, exported.

Subparagraph 62(2)(b)(iii) of the Act allows the rules to make provision for requirements that must be complied with in relation to a kind of goods before a government certificate in relation to goods of that kind may be issued.

Section 2-15 prescribes, for the purposes of subparagraph 62(2)(b)(iii) of the Act, that before a government certificate making a statement in relation to the condition of milk or milk products is issued, the analysis, assessment or examination of the milk or milk products required for the certificate must be carried out in:

- a laboratory accredited by NATA or IANZ to perform the analysis, assessment or examination; or
- in another laboratory accredited against international standards and approved by the Secretary.

Section 1-5 of the Milk Rules defines *NATA* as the National Association of Testing Authorities and *IANZ* as the accreditation scheme known as International Accreditation New Zealand.

2-16 Circumstances for refusing to issue government certificate

Section 67 of the Act requires the issuing body (currently the Secretary), on receiving an application for a government certificate in relation to a kind of goods, to decide to either issue the certificate or refuse to issue the certificate. The issuing body may refuse to issue the certificate if one or more of the grounds in subsection 67(3) are met. Paragraph 67(3)(g) allows the rules to prescribe additional circumstances to refuse to issue a government certificate.

Subsection 2-16(1) sets out, for the purposes of paragraph 67(3)(g) of the Act, additional circumstances for an issuing body to refuse to issue a government certificate in relation to all milk or milk products. These additional circumstances are necessary to protect Australia's trade reputation and ensure Australia complies with international obligations and sanitary matters relating to food safety, animal health or human health.

The additional circumstances for refusing to issue a certificate include:

• a condition or disease present in Australian territory that is likely to affect the acceptability of the milk or milk products to the importing country;

- the export of the milk or milk products could result in trade in the export of goods from Australia being adversely affected;
- the applicant for the certificate failed to return a government certificate as required, to retain a government certificate in a secure place or to provide facilities and assistance to an auditor as required.

These circumstances ensure that government certificates are not issued for milk or milk products that could cause harm to Australia's trade reputation.

The additional circumstances set out in subsection 2-16(2) only apply to applications for a government certificate in relation to prescribed milk or milk products. The additional circumstances are where:

- a prescribed export condition that applies in relation to the milk or milk products has not been complied with;
- an applicant has failed to comply with a direction under subsection 305(1) of the Act (dealing with non-compliance with the Act);
- an export permit is not in force for the prescribed milk or milk products.

The purpose of this subsection is to ensure that a government certificate may be refused if there has not been compliance with the regulatory controls in the Act for prescribed goods.

The note following subsection 2-16(2) explains that paragraphs 67(3)(a) to (f) of the Act set out other grounds for the refusal of a government certificate.

2-17 Changes that require holder of certificate to give additional or corrected information to the issuing body

Subsection 74(2) of the Act requires the holder of a government certificate to provide certain additional or corrected information to the issuing body if the holder becomes aware that information included in their application (or other document provided to the issuing body) was incorrect or incomplete (paragraph 74(1)(a)), or if a change prescribed by the rules occurs (paragraph 74(1)(b)).

Section 2-17 is made for the purposes of paragraph 74(1)(b) of the Act and has the effect that the holder of the government certificate must provide the issuing body with relevant additional or corrected information where there are reasonable grounds to suspect that:

- the integrity of the milk or milk products cannot be ensured;
- an importing country requirement relating to the milk or milk products will no longer be met or is not likely to be met prior to the import of the products into the importing country;
- for prescribed milk or milk products only a prescribed export condition relating to the milk or milk products has not been complied with in circumstances where the condition should have been complied with.

The purpose of this provision is to place an obligation on the holder of the government certificate to monitor the goods (to the extent it is reasonable to do so) to ensure the government certificate continues to accurately reflect the circumstances for issuing the certificate, and to inform the issuing body when the relevant circumstances change.

This will allow the issuing body to consider whether one or more of the grounds to revoke the government certificate (under section 75 of the Act) are met in light of the changed circumstances and ensures government certificates are only provided where the goods are supplied in compliance with the Act and the Milk Rules, enhancing Australia's reputation as a reliable trading partner.

2-18 Return of government certificate

Subsection 76(1) of the Act allows the rules to require a person who is in possession of a government certificate that was issued to the person to return the certificate to the issuing body in the circumstances (paragraph 76(1)(a)), and timeframe (paragraph 76(1)(b)), required by the rules.

Subsection 2-18(1) prescribes, for the purposes of paragraph 76(1)(a) of the Act, the circumstances in which a government certificate in relation to milk or milk products must be returned to an issuing body. These circumstances are if the milk or milk products are no longer intended for export to the country for which the government certificate was issued, or where the certificate has been revoked under section 75 of the Act. The purpose of this requirement is to ensure that government certificates are not misused, by placing an obligation on the holder to return the certificate where the milk or milk products are no longer intended for export or the certificate has been revoked.

Subsection 2-18(2) is made for the purposes of paragraph 76(1)(b) of the Act and provides that a government certificate must be returned within 10 business days starting on the day the circumstance listed in subsection 2-18(1) of the Milk Rules occurs. Ten days is a reasonable timeframe for the holder to return the certificate to the issuing body but is short enough to mitigate against the risk that the certificate would be misused.

Subsection 2-18(3) provides that the requirement in section 2-18 to return the government certificate does not apply to a government certificate that was issued electronically, as there will not necessarily be a physical certificate to return.

Failure to comply with the requirement to return a government certificate in the circumstances set out in section 2-18 will be a contravention of a civil penalty provision (subsection 76(2) of the Act).

CHAPTER 4—REGISTERED ESTABLISHMENTS

Chapter 4 sets out matters relating to registered establishments. The purpose of registering an establishment is to ensure that:

- the facilities and equipment at the establishment are fit for the purpose of preparing, handling, storing or inspecting products for export;
- appropriate hygiene and the necessary measures to produce the goods according to trade descriptions and other requirements applicable to a given commodity are maintained; and
- the goods comply with importing country requirements.

The Secretary may, on application by the occupier of an establishment, register the establishment for export operations in relation to prescribed milk or milk products. The registration of the establishment is subject to certain conditions.

It is a prescribed export condition that operations to prepare prescribed milk or milk products for export must be carried out at an establishment registered for those operations in relation to milk or milk products (section 2-4 of the Milk Rules).

Part 1—Requirements for registration

Division 1—Requirements relating to construction, equipment and facilities

4-1 Purpose of this Division

Subsection 112(1) of the Act provides that, on receiving an application under section 111 to register an establishment, the Secretary must decide to register the establishment, or to refuse to register the establishment. Subsection 112(2) sets out the requirements of which the Secretary must be satisfied before deciding to register an establishment, having regard to any matter the Secretary considers relevant. Paragraphs 112(2)(c) and (f) allow additional matters and requirements (respectively) to be prescribed by the rules.

Section 4-1 provides that Division 1 of Part 1 of Chapter 4 of the Milk Rules is made for the purposes of paragraphs 112(2)(c) and (f) of the Act, and prescribes additional requirements relating to the construction of an establishment and its equipment and facilities that must be met for an establishment to be registered for operations to prepare prescribed milk or milk products for export.

This means that the requirements prescribed in Division 1 of Part 1 of Chapter 4 (sections 4-2 to 4-8) are requirements that the Secretary must be satisfied of prior to registering an establishment for operations to prepare prescribed milk or milk products for export (for the purposes of paragraph 112(2)(f) of the Act) and matters that the Secretary must have regard to when deciding whether the construction of the establishment and its equipment and facilities are suitable for carrying out export operations to prepare prescribed milk or milk products for export (for the purposes of paragraph 112(2)(c) of the Act).

The first note following section 4-1 explains that the requirements in Division 1 of Part 1 of Chapter 4 of the Milk Rules also apply in relation to an application to renew the registration of an establishment under section 4-16 of the Milk Rules.

The second note following section 4-1 explains that other requirements that must be met are provided by paragraphs 112(2)(a), (b) and (e) of the Act, and Division 2 of Part 1 of Chapter 4 of the Milk Rules. Additionally, an approved arrangement must be in place for operations to prepare the milk or milk products for export (referring to paragraph 112(2)(d) of the Act and item 2 of the table in section 2-4 of the Milk Rules).

4-2 Equipment, facilities and essential services—general

Section 4-2 details the equipment, facilities and essential services required by establishments prior to registration for operations to prepare prescribed milk and milk products for export.

Section 4-2 requires an establishment to have the buildings, equipment, facilities and essential services to ensure that operations to prepare prescribed milk or milk products intended for export can be carried out at the establishment in accordance with the requirements of the Milk Rules.

This ensures only those establishments that operate safely and hygienically are eligible for registration. These requirements must continue to be met once the establishment is registered (see section 4-13 of the Milk Rules).

4-3 Measuring devices

Subsection 4-3(1) requires establishments to have accurate measuring devices, for example temperature measuring devices, to assess compliance with the Milk Rules prior to registration.

This ensures only establishments that operate safely and hygienically are eligible for registration. These requirements must continue to be met once the establishment is registered (see section 4-13 of the Milk Rules). It is important for businesses to continue to operate out of approved premises with appropriate facilities to ensure the health and safety of workers and the quality of the export goods.

The note following subsection 4-3(1) refers the reader to the *National Measurements Act* 1960 for guidance on Australian legal units of measurement. The note also refers the reader to section 13 of that Act for its application in relation to contracts, dealings or transactions made or entered into in connection with the export of goods.

Subsection 4-3(2) requires that temperature measuring devices at an establishment must be able to measure the temperature of milk and milk products with an accuracy of plus or minus (+/-) 1 degree Celsius, and be readily accessible in refrigeration chambers and other equipment used for controlling the temperature of milk and milk products.

4-4 Establishment (including construction)

Section 4-4 details the requirements, including those relating to plans and specifications, the immediate surrounds, and floors, walls and ceilings of an establishment, that must be met prior to registration for operations to prepare prescribed milk or milk products for export.

Subsection 4-4(1) requires that an establishment (including its construction) must:

- facilitate operations to prepare prescribed milk and milk products that are fit for human consumption; and
- be fit for the purpose for which it is used; and
- have sufficient capacity for the maximum quantity of milk and milk products prepared there at any one time; and
- be able to be effectively cleaned; and, if necessary, sanitised if there is a risk it may cause contamination of milk or milk products; and
- be able to be easily accessed, inspected and monitored.

Subsection 4-4(2) requires that an establishment (including its construction) and, in particular the floors, walls and ceilings in its food handling areas, areas used for cleaning and sanitising (other than for cleaning vehicles) and areas for personal hygiene must, to the extent practicable, not permit entry or harbourage of pests, exclude dirt, dust, fumes, smoke and other contaminants, and minimise the accumulation of contaminating substances.

The note following subsection 4-4(2) refers the reader to the definition of *establishment* in section 12 of the Act, which provides that an establishment includes a structure, building or conveyance and a place (whether or not enclosed or built on), including a place situated underground or under water.

Subsection 4-4(3) requires an establishment and its equipment to comply with any plans and specifications that accompany the application for registration.

Subsection 4-4(4) requires that places around buildings, roads and other areas that are part of an establishment or immediately around and serving the establishment must be treated in such a way (e.g paved, graded, landscaped or otherwise) to minimise the risk of dust, pests or contaminants entering food handling areas. It also requires such buildings, roads and other areas to have adequate drainage.

Subsection 4-4(5) requires that floors in an establishment must be constructed in an appropriate way for carrying out operations to prepare milk or milk products for export.

Subsection 4-4(6) requires that floors in food handling areas, areas used for cleaning and sanitising (other than for cleaning vehicles) and areas for personal hygiene must be able to be effectively cleaned (and if necessary, sanitised where there is a risk of contamination of milk or milk products), be smooth, impervious and have adequate drainage.

Subsection 4-4(7) provides that floors in areas used for cleaning vehicles must be able to be effectively cleaned, be impervious and have adequate drainage.

Subsection 4-4(8) provides that walls and ceilings in an establishment must be constructed wherever necessary to protect milk and milk products and their ingredients from contamination and in a way that is appropriate for carrying out operations to prepare milk and milk products for export.

Subsection 4-4(9) provides that walls and ceilings in food handling areas, areas used for cleaning and sanitising (other than for cleaning vehicles) and areas for personal hygiene must be able to be effectively cleaned (and, if necessary, sanitised if there is a risk of contamination of milk or milk products) and be smooth and impervious.

Subsection 4-4(10) provides that walls and ceilings in areas used for cleaning vehicles must be able to be effectively cleaned and be impervious.

4-5 Fixtures, fittings and equipment

Subsection 4-5(1) sets the general requirements relating to fixtures, fittings and equipment that are required in an establishment. These fixtures, fittings and equipment (including in refrigeration chambers and storage areas) must facilitate operations to prepare prescribed milk and milk products that are fit for human consumption, be fit for purpose, and have sufficient capacity for the maximum quantity of milk and milk products prepared using them at any one time.

Subsection 4-5(2) provides that the fixtures, fittings and equipment in an establishment must be constructed in a way that:

- ensures they do not cause contamination of milk or milk products; and
- allows them to be easily and effectively cleaned and, if necessary, sanitised if there is a risk they may cause contamination of milk or milk products; and
- allows adjacent floors, walls, ceilings and other surfaces to be easily and effectively cleaned and effectively accessed, inspected and monitored; and
- to the extent practicable, does not permit the entry or harbourage of pests, excludes dirt, dust, fumes, smoke and other contaminants and minimises the accumulation of contaminating substances.

Subsection 4-5(3) prescribes requirements for the food contact surfaces of fixtures, fittings and equipment. These must be able to be easily and effectively cleaned (and if necessary, sanitised if there is a risk they may cause contamination of milk and milk products), be smooth and impervious, and be made of materials that do not cause contamination of milk or milk products.

4-6 Storage facilities for items other than milk or milk products

Subsection 4-6(1) requires an establishment to have adequate facilities to store items that could contaminate milk or milk products (such as chemicals, clothing and personal belongings).

Subsection 4-6(2) provides that the facilities must be located where there is no risk of stored items contaminating milk or milk products.

The note following subsection 4-6(2) refers the reader to subsection 5-9(10) of the Milk Rules, which sets out requirements for the storage of hazardous substances.

4-7 Cleaning and sanitising facilities

Section 4-7 prescribes a number of requirements in relation to the cleaning and sanitising of buildings and equipment at an establishment, and in relation to hand washing facilities.

Subsection 4-7(1) prescribes that an establishment must have facilities appropriate to ensure the effective cleaning and sanitising of buildings, fixtures, fittings, and equipment at the establishment.

Subsection 4-7(2) requires that facilities for cleaning and sanitising equipment in contact with milk and milk products must be readily accessible by food handlers where the equipment is used.

Subsections 4-7(3) to (5) provide that an establishment must have hand washing facilities that must:

- be located in or adjacent to areas where food handlers work if there is a risk that their hands may cause contamination of milk or milk products; and
- have an adequate supply of warm, or hot and cold, potable water over a sink equipped with hands-free operated taps; and
- have an adequate supply of suitable hand sanitising preparation; and
- have suitable and sufficient hygienic means of drying hands; and
- be clearly identified as for use for washing hands, arms and face only.

Section 1-5 of the Milk Rules defines *potable*, in relation to water, as water that is acceptable for human consumption. The note following this definition also directs the reader to the *Australian Drinking Water Guidelines (2011)* for further guidance on potable water.

4-8 Amenities

Section 4-8 makes provision for amenities in an establishment for use by food handlers. *Amenities* is defined in section 1-5 of the Milk Rules as including toilets, showers, locker rooms, change rooms, canteens, kitchens and sleeping quarters on a vessel. *Food handler* is defined in section 1-5 of the Milk Rules as meaning a person who directly handles milk, milk products or their ingredients or who handles food contact surfaces.

Subsections 4-8(1) and (2) provide that these amenities must be adequate and conveniently located for use by food handlers, be separate from, and not open directly onto, food handling areas, be well lit and ventilated, and not be a source of contamination of milk or milk products.

Subsections 4-8(3) and (4) provide that hand washing facilities must be provided in or adjacent to toilets, and have an adequate supply of warm, or hot and cold, potable water over a sink equipped with hands-free operated taps, have an adequate supply of suitable hand sanitising preparation, and have suitable and sufficient hygienic means of drying hands. This ensures the safety and welfare of the food handlers and assists prospective occupiers to know what to look for prior to securing an establishment.

4-9 Essential services

Section 4-9 prescribes requirements in relation to essential services in an establishment.

Subsection 4-9(1) provides that there must be a sewerage and waste system that effectively disposes of and, if necessary, treats, all sewage and waste, prevents the sewage or waste contaminating milk or milk products or polluting the establishment's water supply, and ensures that discharge is contained and directed to the drainage system.

The example following subsection 4-9(1) describes a situation where discharge from refrigeration would be directed to the drainage system for the purposes of paragraph 4-9(1)(c).

Subsections 4-9(2) and (3) provide that there must be designated areas for the separation and storage of waste and inedible material before their removal from the establishment. The facilities and containers used to store waste and inedible material must adequately contain their contents, prevent access by pests, prevent pollution of the establishment's water supply or contamination of milk or milk products, and be clearly identified for use for storage of waste and inedible material only.

Subsections 4-9(4) and (5) provide that there must be sufficient natural or artificial light for carrying out operations to prepare milk or milk products for export, and the lighting system must not be a source of contamination of milk or milk products.

The note following subsection 4-9(4) refers the reader to the Australian/New Zealand Standards AS/NZS 1680.1:2006 *Interior and workplace lighting, Part 1: General principles and recommendations* and the Australian/New Zealand Standards AS/NZS 1680.2.4:1997 *Interior lighting, Part 2.4: Industrial tasks and processes,* for guidance on lighting.

Subsection 4-9(6) provides that ventilation (whether natural or mechanical) must be adequate to effectively minimise the risk of airborne contamination (including steam, smoke and condensation) of milk or milk products and, where appropriate, to control ambient temperature.

Subsections 4-9(7) to (9) provide that there must be a supply of potable water available for use at a volume, pressure and temperature that is adequate for the purposes it is used for. Potable and non-potable water must be supplied in separate lines (including outlets) that are clearly identified as being for use for potable or non-potable water, and any recirculated water must have a separate distribution system that is clearly identified.

Subsections 4-9(10) and (11) provide that the reticulation system must prevent the back siphonage of used or contaminated water, and non-potable water reticulation systems must not contaminate the potable water reticulation systems.

Division 2—Other requirements

4-10 Purpose of this Division

Subsection 112(1) of the Act provides that, on receiving an application under section 111 to register an establishment, the Secretary must decide to register the establishment, or to refuse to register the establishment.

Subsection 112(2) of the Act allows the Secretary to register an establishment for a kind of export operations in relation to a kind of prescribed goods, and, if applicable, a specified place to which the goods may be exported, if the Secretary is satisfied that the requirements in subsection 112(2) are met. Paragraph 112(2)(f) allows other requirements to be prescribed by the rules.

Section 4-10 provides that, for the purposes of paragraph 112(2)(f) of the Act, Division 2 of Part 1 of Chapter 4 of the Milk Rules prescribes other requirements that must be met for an establishment to be registered for operations to prepare prescribed milk or milk products for export.

This means that the requirements prescribed in sections 4-11 are requirements that the Secretary must be satisfied of prior to registering an establishment for operations to prepare prescribed milk or milk products for export (for the purposes of paragraph 112(2)(f) of the Act).

4-11 Operations must be carried out in a way that will ensure requirements of the Act are met

Subsection 4-11(1) provides that operations at an establishment to prepare prescribed milk or milk products for export must be carried out in a way that will ensure the requirements of the Act are complied with.

Subsection 4-11(2) provides that if operations other than export operations are carried out, those operations must not affect the hygienic preparation of prescribed milk or milk products for export.

Part 2—Conditions of registration

4-12 Purpose of this Part

Section 113 of the Act sets out the conditions that apply to the registration of an establishment. This includes the conditions prescribed by the rules made for the purposes of paragraph 113(1)(b) (other than any of those conditions that the Secretary decides are not to be conditions of the registration).

Section 4-12 provides that Part 2 of Chapter 4 of the Milk Rules (sections 4-12 to 4-14) prescribes, for the purposes of paragraph 113(1)(b) of the Act, conditions for the registration of an establishment for operations to prepare prescribed milk and milk products for export.

The first note following section 4-12 explains that the conditions in Part 2 of Chapter 4 (sections 4-12 to 4-14) also apply in relation to the registration of an establishment that has been renewed, as per paragraph 118(b) of the Act.

The second note following section 4-12 alerts the reader that section 144 of the Act provides for fault-based offence and civil penalty provisions for the contravention of conditions of registration. Failure to comply with the provisions of this Part may result in contravention of section 144 of the Act.

4-13 Requirements for registration continue to be met

Section 4-13 provides that the requirements for the registration of an establishment for operations to prepare prescribed milk and milk products for export prescribed by Part 1 of Chapter 4 of the Milk Rules must continue to be met after the establishment is registered.

This is to prevent registered establishments from meeting the requirements of Part 1 of Chapter 4 of the Milk Rules to gain registration and later altering their building facilities and amenities in a way that results in the requirements no longer being met. It is important for businesses to continue to operate out of approved premises with appropriate facilities to ensure the integrity and safety of the milk and milk products..

4-14 Other operational hygiene requirements

Section 4-14 prescribes additional operational hygiene requirements that must be met by an establishment, in relation to live animals and notifiable diseases.

Subsection 4-14(1) prohibits an occupier of a registered establishment from permitting the entry of live animals in food handling areas at an establishment.

Subsection 4-14(2) requires an occupier of a registered establishment to immediately notify an authorised officer if they are aware that milk or milk products at the establishment are derived from an animal that is affected by, or is suspected of being affected by, a notifiable disease.

Subsection 4-14(3) provides that if the occupier gives the notification under subsection 4-14(2) orally, the occupier must as soon as practicable after giving the notification, also give the notification in writing.

Part 3—Renewal of registration

4-15 Period within which application to renew registration must be made

Section 116 of the Act deals with applications to renew the registration of an establishment. Subsection 116(4) provides that an application for renewal must be made within the period prescribed by the rules (paragraph 116(4)(a)), or a longer period allowed by the Secretary (paragraph 116(4)(b)).

Section 4-15 prescribes, for the purposes of paragraph 116(4)(a) of the Act, the timeframe in which an application to renew the registration of an establishment for operations to prepare prescribed milk and milk products for export must be made. This timeframe is 60 days starting on the day that is 180 days before the expiry date for the registration. In other words, the application must be submitted when the registration is between 180 days and 120 days from expiring. This period allows the Secretary sufficient time to consider the application before a decision is made.

The first note following section 4-15 provides an example that, if the registration expires on 8 July in a year (other than a leap year), an application for renewal can be made in any time between 9 January and 10 March in that year.

The second note following section 4-15 explains that, under subsection 116(1) of the Act, an application for renewal of the registration of an establishment will only need to be made if there is an expiry date for the registration.

4-16 Requirements for renewal of registration

Subsection 117(1) of the Act provides that, on receiving an application under section 116 to renew the registration of an establishment, the Secretary must decide to renew the registration or to refuse to renew the registration. Subsection 117(2) of the Act provides that the Secretary may refuse to renew a registration of a registered establishment if the Secretary is not satisfied with one or more of the listed matters or requirements, having regard to any matter the Secretary considers relevant. Paragraphs 117(2)(e) and (g) respectively allow additional matters and requirements to be prescribed by the rules.

Section 4-16 prescribes, for the purposes of paragraphs 117(2)(e) and (g) of the Act, the requirements of Part 1 of Chapter 4 of the Milk Rules are prescribed in relation to an establishment that is registered to prepare prescribed milk or milk products. This means the Secretary must have regard to whether the additional requirements in sections 4-1 to 4-11 in relation to registration of an establishment have been met (such as those relating to the construction of equipment, facilities and fixtures, cleaning and sanitising facilities, provision of amenities and essential services such as water and waste) before deciding whether to renew or refuse to renew of the registration of an establishment for operations to prepare prescribed milk or milk products.

The requirements for renewing a registration are the same as those for registering an establishment. This ensures registered establishments continue to operate in the manner approved by the Secretary. This will prevent registered establishments from merely meeting the requirements at the initial application phase and later reverting to unsatisfactory practices.

The note following section 4-16 refers the reader to the other requirements for renewal of registration of an establishment in paragraphs 117(2)(a) to (d) of the Act, and also notes that an approved arrangement covering operations to prepare the prescribed milk or milk products for export must also be in force (paragraph 177(2)(f) of the Act and item 2 of the table in section 2-4 of the Milk Rules).

Part 4—Suspension of registration

4-17 Request by occupier for suspension

Subsection 125(1) of the Act provides that the occupier of a registered establishment may request that the Secretary suspend the registration of the establishment in relation to a kind of export operations and a kind of prescribed goods and if applicable, a place to which goods may be exported. Subsection 125(2) of the Act allows a request to be made under subsection 125(1) only in the circumstances prescribed by the rules.

Subsection 4-17(1) provides, for the purposes of subsection 125(2) of the Act, that an occupier of a registered establishment may make a request under subsection 125(1) of the Act to suspend the registration of the establishment in relation to operations (the *relevant operations*) to prepare prescribed milk or milk products for export if:

- the occupier of the establishment is undertaking, or proposes to undertake, renovations or maintenance of the establishment that prevent, or would prevent, the relevant operations being carried out; or
- the relevant operations cannot be carried out in circumstances outside the control of the occupier.

The examples following subsection 4-17(1) alert the reader that circumstances outside the control of the occupier, for the purposes of paragraph 4-17(1)(b), include flood, fire, disease, oil spill or other disaster, roadworks restricting access to the establishment and extended seasonal closures.

Subsection 4-17(2) provides that the requirement that the operations cannot be carried out in circumstances outside the occupier's control does not apply if the circumstances relate to a notifiable disease, or any other condition or disease that is likely to affect the fitness for human consumption of milk or milk products or the acceptability of milk or milk products to an importing country.

Subsection 4-17(3) provides that an occupier cannot request a suspension under subsection 4-17(1) if, before the request was made, the Secretary had given the occupier of the establishment a notice of suspension under subsection 127(2) of the Act in relation to the registration of the establishment, and had not decided whether to suspend the registration or not.

4-18 Other grounds for suspension

Section 127(1) of the Act provides that the Secretary may suspend the registration of an establishment in relation to one or more kinds of export operations and one or more kinds of prescribed goods and, if applicable, one or more places to which goods may be exported if the Secretary reasonably believes any of the grounds listed in paragraphs 127(1)(a) to (k) exist. Paragraph 127(1)(k) allows the rules to prescribe additional grounds for suspension of registration.

Section 4-18 prescribes, for the purposes of paragraph 127(1)(k) of the Act, additional grounds where the Secretary may suspend the registration of an establishment are where:

- prescribed milk or milk products are being prepared at the establishment under unhygienic conditions or in an unhygienic way; or
- an assessment of prescribed milk or milk products at the establishment is not possible.

Part 5—Matters relating to applications

4-19 Application of this Part

Section 4-19 provides that Part 5 of Chapter 4 of the Milk Rules applies in relation to applications made under the following:

- section 111 of the Act to register an establishment for operations to prepare prescribed milk or milk products for export;
- section 116 of the Act to renew the registration of an establishment for operations to prepare prescribed milk or milk products for export;
- section 120 of the Act to do the following in relation to a registered establishment for operations to prepare prescribed milk or milk products for export:
 - o vary the registration, or the particulars relating to the registration, of an establishment.;
 - o approve an alteration of an establishment; or
 - o vary the conditions of the registration of an establishment.

4-20 Initial consideration period

Section 379 of the Act details the requirements for dealing with applications made under the Act. Subsection 379(3) allows the rules to prescribe the period in which an application must be considered by the Secretary. If the Secretary does not make a decision on the application within the prescribed consideration period, the application is taken to have been refused.

Section 4-20 prescribes, for the purposes of subsection 379(3) of the Act, that the initial consideration period is 120 days. The initial consideration period may be extended in accordance with subsection 379(5) of the Act. The period of 120 days is appropriate, having regard to the matters the Secretary must consider in granting or refusing an application.

The note following section 4-20 explains that under subsection 379(4) of the Act, the consideration period starts on the day after the day the Secretary receives the application.

4-21 Period within which request relating to application must be complied with

Subsection 379(9) of the Act allows the Secretary to make a number of requests in relation to a relevant application, including requesting additional information or requesting consent to enter premises. Subsection 379(10)(b) allows the rules to prescribe a maximum period within which the request must by complied with.

Section 4-21 prescribes, for the purposes of paragraph 379(10)(b) of the Act, a period of 6 months within which a request from the Secretary in relation to an application to register an establishment must be complied with. The initial consideration period may be extended under section 379 of the Act. The period prescribed by this section is appropriate as it permits sufficient time to comply with matters provided in subsection 379(9) of the Act. The period provides certainty for industry.

CHAPTER 5—APPROVED ARRANGEMENTS

Part 1—Requirements for approval

The purpose of the approved arrangement is to clearly describe the processes and practices which, when correctly applied by the holder of an approved arrangement, underpin the Department certification of products for export.

The Secretary may, on application by a person, approve a proposed arrangement for a kind of export operations in relation to prescribed milk or milk products. An approved arrangement is subject to certain conditions.

5-1 Purpose of this Part

Subsection 151(1) of the Act provides that, on receiving an application under section 150 of the Act to approve a proposed arrangement, the Secretary must decide to approve the arrangement or refuse to approve the arrangement. Subsection 151(2) sets out the requirements of which the Secretary must be satisfied before approving a proposed arrangement. Paragraph 151(2)(d) allows the rules to prescribe additional requirements that must be satisfied.

Section 5-1 provides that, for the purposes of paragraph 151(2)(d) of the Act, Part 1 of Chapter 5 of the Milk Rules (sections 5-1 to 5-5) prescribes additional requirements of which the Secretary must be satisfied before approving a proposed arrangement for export operations in relation to prescribed milk or milk products. Approved arrangements provide the framework for the Secretary to have regulatory oversight of export operations and activities.

5-2 Proposed arrangement for operations to prepare prescribed milk or milk products

Subsection 5-2(1) provides that section 5-2 applies in relation to a proposed arrangement for operations to prepare prescribed milk or milk products for export at a registered establishment.

Section 5-2 sets out the requirements that must be met for the approval of a proposed arrangement for operations to prepare prescribed milk or milk products at a registered establishment. These are necessary to enable the Secretary to efficiently deal with an application for approval of an arrangement and decide if the proposed arrangement meets the requirements of the Act and importing country requirements.

Subsections 5-2(2) to 5-2(4) detail the general requirements for approval of a proposed arrangement, including:

- that the arrangement records that the applicant is committed to meeting the applicable objects of the Act, and complying with the requirements of the Act
- that the arrangement covers each stage of the export operations to be undertaken and

- that the arrangement records details of the matters set out in subsection 5-2(4), including:
 - o the management practices and organisational structure of the applicant;
 - o the resources to be provided and personnel to be used to carry out the operations (and their training);
 - the system of controls to be implemented to ensure that the conditions prescribed by Divisions 2 to 8 of Part 2 of Chapter 5 of the Milk Rules are met; and
 - o any other controls to be implemented to ensure that there will be reasonable grounds for issuing an export permit or government certificate for the prescribed milk or milk products covered by the arrangement.

Subsection 5-2(5) provides that details of matters required to be recorded in the proposed arrangements by subsection 5-2(4), other than the system of controls, must be appropriate to ensure compliance with the requirements of the Act and importing country requirements.

Subsection 5-2(6) requires the proposed arrangement to identify any importing country requirements relating to the operations and the prescribed milk or milk products covered by the arrangement that will not be met through ordinary compliance with the Act (other than section 5-7 of the Milk Rules), and the additional system of controls to be implemented to meet those importing country requirements will be met. This allows for flexibility where the requirements of the importing country are different from the requirements of the Act, while ensuring transparency about the control measures needed to meet importing country requirements.

The note following subsection 5-2(6) explains that section 5-7 of the Milk Rules makes it a condition of an approved arrangement for export operations that all applicable importing country requirements are met.

Subsection 5-2(7) requires the implementation of a Hazard Analysis and Critical Control Point (HACCP) plan for each stage of the operation to prepare the prescribed milk or milk products for export. The HACCP is a system that identifies, evaluates and controls hazards that are significant for food safety. This process control is designed to prevent the occurrence of problems by assuring that controls are applied at any point in the production of milk or milk products for export, where hazardous or critical situations could occur. A hazard could include physical, biological or chemical contamination of the product or the product packaging.

Subsection 5-2(8) sets out the requirements for the HACCP plan. The HACCP plan must identify the potential hazards that may be reasonably expected to occur for each stage of the operations, the means of control for each potential hazard, and for each significant hazard, the critical control points, critical limits, procedures to monitor the hazard, corrective action to be taken if critical limit exceeded, and procedures to be used to assess the effectiveness of this corrective action.

The HACCP plan must also identify procedures to be used to verify compliance with that plan, the frequency of such procedures, as well as provide for records to be made and documents kept to demonstrate compliance with the plan and its effectiveness.

The note following section 5-2(8) refers the reader that the Codex requirements for HACCP plans provide guidance, and sets out the following principles for HACCP plans: conduct a hazard analysis, identify critical control points, establish critical limits, establish monitoring procedures, establish corrective actions, establish verification procedures, and keep records.

Codex is defined in section 1-5 of the Milk Rules as the Codex Alimentarius issued by the Codex Alimentarius Commission of the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization. The Codex Alimentarius can be viewed on the FAO website.

Subsection 5-2(9) provides that subsection 5-2(8) (requirements for HACCP plan) does not apply to a potential hazard that is controlled by meeting the operational hygiene requirements under section 5-4 of the Milk Rules.

Subsection 5-2(10) defines a *significant hazard* for operation in relation to milk or milk products (alone or in combination with other hazards) as a hazard that (alone or in combination with other hazards) is of such a nature that its elimination, or control or reduction to an acceptable level, is essential for operations to prepare milk or milk products that are fit for human consumption.

5-3 Equipment

Section 5-3 provides that the proposed arrangement must provide for measures to ensure that measuring devices, used at the registered establishment to comply with the requirements of Part 2 of Chapter 5 of the Milk Rules, are accurately calibrated to assess compliance with those requirements.

5-4 Operational hygiene

Subsection 5-4(1) provides that section 5-4 applies in relation to a proposed arrangement for operations to prepare prescribed milk or milk products at a registered establishment.

Subsection 5-4(2) provides that the proposed arrangement must provide for measures in relation to the establishment and its equipment to ensure that milk and milk products at the establishment are not contaminated by environmental contamination (including airborne or water contamination).

Subsection 5-4(3) provides that the proposed arrangement must provide for measures to ensure adequate hygiene in relation to milk and milk products. These include measures to:

• protect the milk or milk products and their ingredients from contamination by any thing or activity; and

- minimise the growth of pathogens in the milk or milk products and their ingredients that could adversely affect the export of the milk or milk products as food fit for human consumption given the conditions under which they are to be stored, handled and transported; and
- ensure the fitness for human consumption of the milk and milk products and their ingredients is not otherwise adversely affected.

Subsections 5-4(4) and (5) provide that, without limiting subsection 5-4(3), the proposed arrangement must provide for measures to prevent milk or milk products that are not fit for human consumption from being a source of contamination for the prescribed milk or milk products or their ingredients, and provide for measures to validate the effectiveness of temperature controls required under Part 2 of Chapter 5 of the Milk Rules.

Section 5-4(6) requires that the proposed arrangement must provide for procedures to evaluate the fitness for human consumption of all milk and milk products (including returned products), all ingredients received at the establishment and all milk and milk products prepared at the establishment for export as food.

Subsections 5-4(7) to (9) detail the requirements of a proposed arrangement in relation to water usage. The proposed arrangement must provide for all water to be potable unless the water is used only in circumstances where there is no risk of it coming into contact with or contaminating milk or milk products.

The proposed arrangement must also record details of the system of controls (including in relation to treatment, testing and verification) to be implemented to ensure the water is potable, and provide for the analysis of potable water for the presence of *E. coli* to be performed by a laboratory accredited by NATA. *NATA* is defined in section 1-5 of the Milk Rules as the National Association of Testing Authorities.

5-5 Identification, traceability and integrity

Section 5-5 requires the proposed arrangement to provide for measures for the identification, traceability and integrity of the milk and milk products to ensure milk or milk products can be identified, traced and, if necessary, recalled. This requirement is important to ensure that milk and milk products are fit for human consumption and will meet the requirements of importing countries.

Part 2—Conditions of approved arrangement

Division 1—Purpose of this Part

5-6 Purpose of this Part

Section 152 of the Act deals with conditions imposed on an approved arrangement. Paragraph 152(1)(b) allows the rules to prescribe conditions that will apply to an approved arrangement (unless the Secretary decides the condition is not to be a condition of the approved arrangement).

Subsection 5-6(1) provides that Part 2 of Chapter 5 of the Milk Rules (sections 5-6 to 5-41) prescribes, for the purposes of paragraph 152(1)(b) of the Act, the conditions of an approved arrangement for a kind of export operations in relation to prescribed milk or milk products.

Subsection 5-6(2) has the effect that the conditions in Part 2 apply to an approved arrangement if the condition relates to a kind of export operations covered by the arrangement.

Applying conditions to the approved arrangements for export operations in relation to prescribed milk or milk products prevents approved arrangements from merely meeting the requirements in Part 1 of Chapter 5 of the Milk Rules in order to gain approval and then later altering procedures or processes in a manner detrimental to achieving the purpose of the approved arrangement. It is important that businesses continue to operate under an approved arrangement with appropriate processes and controls to ensure the goods are fit for human consumption and continue to meet importing country requirements.

The first note following section 5-6 refers the reader to paragraph 157(1)(b) of the Act, which provides that the conditions also apply to an approved arrangement that has been renewed.

The second note following section 5-6 alerts the reader that failure to comply with a condition of an approved arrangement is an offence and the contravention of a civil penalty provision under section 184 of the Act.

Division 2—General

Division 2 of Part 2 of Chapter 5 of the Milk Rules (section 5-7) imposes general requirements on approved arrangements for operations to prepare prescribed milk or milk products for export.

5-7 Importing country requirements must be met

Section 5-7 provides that an approved arrangement must ensure all importing country requirements relating to both the export operations carried out in relation to prescribed milk or milk products, and the prescribed milk or milk products themselves, are met. Ensuring all applicable importing country requirements are covered and met by the approved arrangement enables ongoing market access for prescribed milk or milk products that are exported from Australia

The note following section 5-7 refers the reader to the Manual of Importing Country Requirements (MICoR) for guidance on specific importing country requirements. This manual is available on the Department's website (http://www.awe.gov.au). Access to the document may require a password.

The definition of *MICoR* is set out in section 1-5 of the Milk Rules, which means the *Manual of Importing Country Requirements* published by the Department.

Division 3—Operational hygiene

Division 3 of Part 2 of Chapter 5 of the Milk Rules (sections 5-8 to 5-12) provides for a range of requirements for approved arrangements for export operations to prepare prescribed milk or milk products, in relation to the hygiene of an establishment and its equipment, and personal hygiene.

5-8 Purpose of this Division

Section 5-8 provides that Division 3 of Part 2 of Chapter 5 of the Milk Rules (sections 5-8 to 5-12) prescribes conditions of an approved arrangement for operations to prepare prescribed milk or milk products for export at a registered establishment.

It is important that an approved arrangement includes details of the controls in place at the establishment to ensure that the hygiene requirements set out in Division 3 are met. This is required to ensure:

- the facilities available and the equipment are fit for the purpose of preparing, handling, storing or inspecting products for export;
- appropriate hygiene and the necessary measures to produce the goods according to trade descriptions and other requirements applicable to a given commodity are maintained; and
- the goods comply with importing country requirements.

5-9 Hygiene control—establishment and its equipment

Section 5-9 prescribes a number of requirements for registered establishments and equipment in relation to cleanliness, maintenance, pests and hazardous substances.

Subsections 5-9(1) to (5) provide requirements that must be met in relation to cleanliness of the registered establishment.

Subsection 5-9(1) requires a registered establishment to be kept clean and free of garbage (other than in garbage containers), recycled matter (other than in recycling containers), food waste (other than in a designated area for the separation and storage of waste an inedible material before their removal from the establishment), dirt, grease and other visible matter that could contaminate prescribed milk or milk products.

Subsection 5-9(2) requires that floors, walls and ceilings in food handling areas, areas used for cleaning and sanitising equipment and protective clothing, and areas for personal hygiene must be cleaned and sanitised whenever it is necessary to prevent the contamination of prescribed milk or milk products.

Subsection 5-9(3) requires that fixtures, fittings and equipment and the food contact surfaces of such items must be cleaned and sanitised whenever it is necessary to prevent the contamination of prescribed milk or milk products.

Subsection 5-9(4) provides that equipment used for carrying out operations to prepare prescribed milk or milk products at the establishment must be kept clean and free of food waste, dirt, grease and other visible matter that could contaminate the milk or milk products.

Subsection 5-9(5) requires that places around buildings, roads and other areas that are part of the establishment, or immediately around and serving the establishment, must be cleaned to the extent necessary to ensure they are not a source of contamination of prescribed milk or milk products.

Subsections 5-9(6) and (7) prescribe requirements in relation to maintenance. An establishment's buildings, fixtures, fittings and equipment must be maintained in the state of repair necessary to facilitate operations to prepare prescribed milk and milk products that are fit for human consumption. Equipment at the establishment must be maintained in a state of repair and working order to facilitate operations to prepare prescribed milk or milk products that are fit for human consumption and having regard to its use.

Subsections 5-9(8) and (9) relate to pests, and require that the entry of pests into, and the harbourage of pests in, the establishment and its equipment must be prevented. In relation to the prevention of the entry of pests, this is to the extent practicable.

Subsections 5-9(10) and (11) relate to hazardous substances. Subsection 5-9(10) requires that hazardous substances at the establishment be stored in containers that are labelled with the name of the substance and a warning about its toxicity and use and that are not used for any purpose other than the storage of hazardous substances. Hazardous substances must also not be a source of contamination for prescribed milk or milk products.

Subsection 5-9(11) provides that any other substances that may be a source of contamination for prescribed milk or milk products must not be used or stored in food handling areas, other than as necessary for hygienic or preparation purposes.

5-10 Measuring devices

Section 5-10 requires that measuring devices used at a registered establishment for the purposes of meeting a requirement of Part 2 of Chapter 5 of the Milk Rules must be accurately calibrated.

5-11 Hygiene control—processing

Subsection 5-11(1) requires that refrigeration chambers at a registered establishment must achieve the temperatures required under Part 2 of Chapter 5 of the Milk Rules for chilling, freezing, maintaining, thawing and tempering prescribed milk and milk products, taking account of the maximum quantity of milk or milk products to be chilled, frozen, maintained, thawed or tempered at any one time using the refrigeration chambers.

The note following subsection 5-11(1) notifies the reader that the approved arrangement for operations to prepare the milk or milk products must provide for measures to validate the effectiveness of the temperature controls, and directs the reader to subsections 5-15(9) and 5-16(2) and (4) of the Milk Rules.

Subsection 5-11(2) provides that ingredients for prescribed milk or milk products must be fit for the purpose for which they are used and must be labelled, stored and handled in a way that ensures their identity can be ascertained.

Subsection 5-11(3) requires that water must be potable and must contain no detectable *E. coli* for every 100 millilitres of water tested.

Subsections 5-11(4) and (5) require steam and compressed air and other processing gases that are used or come into contact with prescribed milk or milk products or food contact surfaces to be free from substances that have the potential to cause harm to human health and that may be a source of contamination for the milk or milk products.

5-12 Personal hygiene and health

Subsections 5-12(1) to (6) set out the general requirements in relation to personal hygiene and health.

Subsections 5-12(1) and (2) make provisions in relation to a person known or suspected to be suffering from a medical condition, or to be a carrier of a medical condition (other than *Staphylococcus aureus*), likely to be transmitted through food. Such a person must:

- not be in any food handling area of a registered establishment in any capacity in which there is a risk of the person directly or indirectly contaminating prescribed milk or milk products with pathogens; and
- if they are at an establishment, or if they suspect that the medical condition may have resulted in contamination of prescribed milk or milk products at the establishment, they must immediately inform a person who manages or controls operations to prepare milk or milk products about the medical condition.

A *medical condition* is defined in section 1-5 of the Milk Rules and means a medical condition that could affect the fitness for human consumption of milk or milk products and includes an injury, an infected skin lesion or a discharge from the ear, nose or eye. Exempting *Staphylococcus aureus* from these requirements is consistent with the personal hygiene requirements in the Standard 3.2.2 Food Safety practices and General Requirements of Australia and New Zealand Food Standards Code (Food Standards Code) which provides that a carrier of a foodborne disease does not include a person who is a carrier of *Staphylococcus aureus*.

Subsections 5-12(3) to (5) provide that a person in a food handling area must also:

- take all practicable measures to ensure that the person's body, anything from the body, and anything the person is wearing, do not contaminate prescribed milk or milk products or food contact surfaces, and avoid unnecessary contact with prescribed milk or milk products (subsection 5-12(3));
- not do anything that could result in contamination of prescribed milk or milk products in the area or that is likely to adversely affect the fitness for human consumption of the milk or milk products. (subsection 5-12(4)); and

• at all times wear protective clothing (including a hair covering) and footwear that are suitable to prevent anything from the person's body contaminating prescribed milk or milk products in the area, and are clean, sanitary and in good repair (subsection 5-12(5)).

The note following subsection 5-12(3) notifies the reader that a visitor to a food handling area is a person in the food handling area.

The example following subsection 5-12(4) provides things a person in a food handling area could do which could result in contamination of prescribed milk or milk products or is likely to adversely affect the fitness for human consumption of the milk or milk products. The examples provided are eating, smoking, chewing, spitting, sneezing or coughing over unprotected milk or milk products or food contact surfaces.

Subsection 5-12(6) provides that personal belongings and clothing must not be stored in food handling areas.

Subsections 5-12(7) to (9) prescribe particular requirements in relation to food handlers. A food handler who has a medical condition must take all practical measures to prevent the condition resulting in contamination of prescribed milk or milk products or their ingredients. Coverings used for medical conditions must be effective in preventing contamination of prescribed milk or milk products, and must be waterproof, firmly secured and conspicuous in colour.

Food handlers must also wash (using a sanitising agent) and thoroughly dry their hands on entering a food handling area, immediately after using the toilet, after touching their nose or mouth, and whenever necessary to avoid contaminating prescribed milk or milk products at the establishment. Such hand washing requirements apply regardless of whether the food handler has been wearing, or is intending to wear, gloves.

Division 4—Preparation and transport

Division 4 of Part 2 of Chapter 5 of the Milk Rules (sections 5-13 to 5-26) imposes conditions that apply to approved arrangements concerning the preparation and transport of prescribed milk or milk products for export.

5-13 Sourcing milk and milk products

Subsection 5-13(1) provides that prescribed milk and milk products must not be sourced from areas where there are reasonable grounds to believe that potentially harmful pathogens or substances are present and could result in unacceptable levels in the milk or milk products.

Examples are provided following subsection 5-13(1) of potentially harmful pathogens and substances. These are pesticides, fungicides, heavy metals, natural toxicants or other contaminants and potentially harmful substances.

Subsection 5-13(2) provides that milk and milk products sourced in Australia that are to be prepared for export as food must be sourced only from the following:

• a registered establishment; or

- an establishment in relation to which an exemption from the requirement to be registered to carry out export operations in relation to the milk or milk products is in force under Part 2 of Chapter 2 of the Act; or
- in relation to milk—an establishment that stores and chills unpasteurised milk that is, before it is exported, to be further prepared at a registered establishment or exempt establishment.

The note following subsection 5-13(2) explains that the prescribed export conditions in section 2-4 of the Milk Rules have the effect that operations to store or chill unpasteurised milk are not required to be carried out at a registered establishment if the operations are carried out at an establishment where no other operations to prepare prescribed milk or milk products are carried out. All other operations to prepare the milk for export must be carried out at a registered establishment (unless an exemption is in force under Part 2 of Chapter 2 of the Act

Subsection 5-13(3) requires that prescribed milk that is to be sourced directly from an establishment that stores and chills milk after milking. This milk must be sourced only from an establishment with:

- disease management controls that ensure that only healthy animals are used for milking;
- measures that ensure animals for milking are not given or treated with anything that could adversely affect the fitness for human consumption of milk or milk products;
- measures that ensure the collection, storing and chilling of milk is done under conditions that ensure the fitness for human consumption is not adversely affected;
- measures that ensure as soon as practicable after milking, milk is placed under temperature controls that minimise the growth of pathogens that could adversely affect the fitness for human consumption of milk or milk products.

Subsections 5-13(4) and (5) prescribe requirements in relation to the traceability of prescribed milk or milk products, or milk or milk products that are to be prepared for export as food, and their ingredients.

Subsection 5-13(4) provides that prescribed milk or milk products, or milk or milk products that are to be prepared for export as food, and their ingredients, must be sourced only from a supplier with inventory and tracing systems to ensure that the milk or milk products and their ingredients are traceable, and can be recalled if required. This subsection does not limit the requirements in subsections 5-13(2) or (3).

Subsection 5-13(5) provides that the occupier of an establishment sourcing milk or milk products or their ingredients from an establishment referred to in subsection 5-13(3) must make records of each supplier of the milk or milk products and their ingredients.

The note following subsection 5-13(5) notifies the reader that the occupier of a registered establishment must keep each record made under 5-13(5) for 3 years (in accordance with subsection 11-7(2) of the Milk Rules).

5-14 Notifiable diseases

Section 5-14 prescribes requirements in relation to the notification of notifiable diseases by the holder of an approved arrangement for operations to prepare prescribed milk or milk products for export at a registered establishment.

Subsection 5-14(1) requires the holder of an approved arrangement to immediately notify an authorised officer, if the holder is aware that milk or milk products at the registered establishment are derived from an animal that is affected by, or is reasonably suspected to be affected by, a notifiable disease. The holder must not deal with the milk or milk products for export as food without the written approval of the authorised officer. Notifiable diseases are specific to the states or territories and lists of notifiable diseases are generally available from the relevant Department of Primary Industry (or the equivalent state or territory government body) websites and publications.

Subsection 5-14(2) provides that if the holder of an approved arrangement has given notification under subsection 5-14(1), the holder must as soon as practicable give notification in writing.

Notifiable disease is defined in section 1-5 of the Milk Rules as a disease the presence or suspected presence of which must be notified (however expressed) under a law of the State or Territory where the disease is or suspected of being located. Notifiable diseases are specific to the States or Territories, and information is available from the relevant State or Territory government body, through websites and publications, for example.

5-15 Temperature controls for preparing prescribed milk or milk products

Section 5-15 prescribes temperature controls for prescribed milk or milk products. The purpose of these provisions is to ensure that milk or milk products are kept at appropriate temperatures to minimise the growth of pathogens that could adversely affect the fitness for human consumption of the milk or milk products.

Subsection 5-15(1) provides that prescribed milk must be placed under temperature controls as soon as practicable after milking.

Subsections 5-15(2) to (4) specify the temperatures at which prescribed milk and milk products must be chilled. Subsection 5-15(2) requires prescribed milk and milk products that are to be chilled to be cooled to a temperature of 5 degrees Celsius or cooler. However, where an approved arrangement for operations to prepare the milk or milk products provides for different temperature controls, the milk or milk products must be cooled in accordance with those controls. Such control must require the milk or milk products to be cooled quickly enough to minimise the growth of pathogens that could adversely affect the fitness for human consumption of the milk or milk products. The approved arrangement must provide for measures to validate the effectiveness of the rate of cooling and the temperature controls in minimising the growth of pathogens that could adversely affect the fitness for human consumption of the milk or milk products.

Subsections 5-15(5) to (7) prescribe requirements for prescribed milk and milk products that are to be frozen. Prescribed milk or milk products that are to be frozen must be hard frozen and be done quickly enough to minimise the growth of pathogens that could adversely affect the fitness for human consumption of the milk or milk products. The approved arrangement must provide for measures to validate the effectiveness of the rate of achieving the required temperature.

Subsections 5-15(8) and (9) prescribe requirements in relation to the thawing and tempering of prescribed milk or milk products. This requires the milk or milk products to be thawed and tempered under temperature controls that minimise the growth of pathogens that could adversely affect the fitness for human consumption of the milk or milk products. The approved arrangement must provide for measures to validate the effectiveness of the temperature controls in minimising the growth of pathogens that could adversely affect the fitness for human consumption of the milk or milk products

5-16 Temperature controls for storing, handling, loading and transporting prescribed milk or milk products

Section 5-16 prescribes requirements for temperature controls for the storing, handling, loading and transporting of prescribed milk or milk products.

Subsections 5-16(1) and (2) relate to shelf-stable prescribed milk or milk products. Shelf-stable prescribed milk or milk products must be stored, handled, loaded and transported at the temperature required under the approved arrangement for operations to prepare the milk or milk products for export. The approved arrangement must also provide for measures to validate the effectiveness if the temperature controls in minimising the growth of pathogens that could adversely affect the fitness for human consumption of the milk or milk products.

Shelf-stable is defined in section 1-5 of the Milk Rules as meaning the milk or milk products can be safely stored and handled at ambient temperature.

Subsections 5-16(3) and (4) relate to prescribed milk or milk products other than shelf-stable milk or milk products. These milk or milk products must be stored, handled, loaded and transported at the temperatures required for chilling or freezing the milk or milk products under 5-15, or temperatures provided for in the approved arrangement. Where different temperature controls apply, the approved arrangement must provide for measures to validate the effectiveness of the temperature controls in minimising the growth of pathogens that could adversely affect the fitness for human consumption of the milk or milk products.

5-17 Preserving prescribed milk and milk products

Subsection 5-17(1) provides that, subject to any other requirements of Part 2 of Chapter 5 of the Milk Rules, a process applied to prescribed milk or milk products for the purpose of extending their shelf life must ensure the safety of the milk or milk products by destroying or preventing the growth of pathogens or reducing their growth to a level that does not adversely affect the microbiological safety of the milk or milk products.

Subsection 5-17(2) provides that an approved arrangement must provide for measures to validate the effectiveness of the process referred in subsection 5-17(1) in ensuring the safety of the milk or milk products.

5-18 Thermal processing of canned prescribed milk or milk products

Section 5-18 prescribes requirements for approved arrangements in relation to canning of prescribed milk or milk products.

Subsection 5-18(1) provides that, subject to any other requirement in the approved arrangement for operations to prepare the milk or milk products, canning of prescribed milk or milk products must result in milk or milk products that are commercially sterile.

Section 1-5 of the Milk Rules provides that *commercially sterile*, in relation to milk or milk products, means free of pathogens that are capable of growing under the conditions the milk or milk products are likely to encounter during storage and distribution at ambient temperature.

Subsection 5-18(2) provides that for canning of low acid prescribed milk or milk products, the approved arrangement must provide for measures to validate the effectiveness of the process resulting in milk or milk products that are commercially sterile.

Subsection 5-18(3) provides that before a thermal process designed from simulated manufacturing conditions is used for canning prescribed milk or milk products, the results of the process must be verified in the actual production of canned milk or milk products using the thermal processing equipment to be used for canning the milk or milk products, and under the commercial operating conditions under which the canning is to take place.

Subsection 5-18(4) provides that the canning process and canning materials used must prevent contamination affecting the contents of the can.

Subsection 5-18(5) provides that cans used for thermal processing must be inspected and evaluated in accordance with the Codex requirements.

The note following subsection 5-18(5) directs the reader to section 7.4.8 of Volume 1 of the Codex (*Recommended Internal Code of Hygiene Practice for Low-Acid and Acidified Low-Acid Canned Foods*) CAC/RCP 23-1979, which provides further guidance for canning low acid prescribed milk or milk products.

Subsection 5-18(6) provides that after thermal processing, the cans must be cooled and handled in a way that prevents the introduction of pathogens that could affect the commercial sterility of the contents of the can.

Subsection 5-18(7) provides that, if in accordance with the approved arrangement, the water used for cooling canned milk or milk products is made potable by chlorination, the water must show a measurable free residual chlorine level after contact with the cans.

The note following subsection 5-18(7) directs the reader to subsections 5-4(7) and (8) of the Milk Rules for requirements for water to be potable.

Subsection 5-18(8) provides that cans that have undergone thermal processing must be identified and separated from cans that have not undergone thermal processing.

5-19 Pasteurisation and other treatments

Section 5-19 sets out the requirements for temperature and time controls in relation to the pasteurisation and other treatment of prescribed milk, liquid milk products and cheese.

Subsection 5-19(1) requires that prescribed milk must:

- be pasteurised by being held at a temperature of not less than 72 degrees Celsius for not less than 15 seconds and immediately cooled to a temperature of 5 degrees Celsius or cooler (paragraph 5-19(1)(a)); or
- otherwise in accordance with the time and temperature controls set out in the approved arrangement for operations to prepare the milk, provided the different time and temperature controls have equal or greater lethal effect on bacteria in the milk (paragraphs 5-19(1)(b) and (c)).

Subsection 5-19(2) provides that where the approved arrangement specifies different time and temperature controls, it must also provide for measures to validate the effectiveness of the treatment as having equal or greater lethal effect on bacteria in the milk than would be achieved by the time and temperature controls set out in paragraph 5-19(1)(a).

The note following subsection 5-19(2) directs the reader to Australian Standard AS 3993-2003, *Equipment for the pasteurisation of milk and other liquid dairy products— Continuous flow systems*, for further information relating to pasteurisation standards and verification.

Subsection 5-19(3) requires that prescribed milk products that are liquid milk products must:

- be treated, as provided for in the approved arrangement, either using time and temperature controls that have equal or greater lethal effect on bacteria in the milk products as those referred to in paragraph 5-19(1)(a); or
- in another way that has equal or greater lethal effect on bacteria in the milk product.

Subsection 5-19(4) requires that the approved arrangement for operations to prepare the liquid milk products must provide for measures to validate the effectiveness of the treatment as having equal or greater lethal effect on bacteria in the milk than would be achieved if the time and temperature controls set out in paragraph 5-19(1)(a) were applied to milk products.

The note following subsection 5-19(4) directs the reader to Australian Standard AS 3993-2003, *Equipment for the pasteurisation of milk and other liquid dairy products— Continuous flow systems*, for further information relating to pasteurisation standards and verification.

Subsection 5-19(5) prescribes that the requirements in subsections 15-9(1) and (3) do not apply to milk or liquid milk products used in the manufacture of cheese.

Subsection 5-19(6) requires that milk or liquid milk products used in the manufacture of cheese meet one of the following conditions:

- be heat treated by being held at a temperature of not less than 72 degrees Celsius for not less than 15 seconds;
- be heat treated using a time and temperature combination that has equal or greater lethal effect on the bacteria in the milk or milk products than would be achieved by the time and temperature controls set out in subsection 5-19(1);
- be heat treated by being held at a temperature of not less than 62 degrees Celsius for not less than 15 seconds and the cheese must be stored at a temperature of not less than 2 degrees Celsius at the site of microbiological concern for not less than 90 days after the day the cheese is manufactured;
- in accordance with heat treatment as provided for in the approved arrangement for operations to prepare milk or liquid milk products.

The note following subsection 5-19(6) directs the reader to Australian Standard AS 3993-2003, *Equipment for the pasteurisation of milk and other liquid dairy products—Continuous flow systems*, for further information relating to pasteurisation standards and verification.

Subsection 5-19(7) has the effect that, if the approved arrangement specifies a different way to treat milk or liquid milk products used in the manufacture of cheese, the arrangement must also provide for measures to validate the effectiveness of the treatment:

- as having equal or greater lethal effect on bacteria in the milk than would be achieved if the time and temperature controls set out in paragraph 5-19(6)(a) were applied to milk products; and
- in achieving a level of food safety equivalent to that achieved for cheese prepared from milk or liquid milk products that are treated in accordance with paragraph 5-19(6)(a).

5-20 Packaging and identification

Section 5-20 prescribes requirements in relation to the packaging and identification of prescribed milk and milk products.

Subsection 5-20(1) provides that packaging, labels and other materials used to package or identify prescribed milk or milk products must be fit for the purpose for which they are used, not adversely affect the fitness for human consumption of the milk or milk products, and, in relation to packaging, effectively protect the milk or milk products from contamination in the conditions under which they are to be stored, handled, loaded and transported.

Subsection 5-21(2) provides that the prescribed milk or milk products must be packaged, labelled and identified in a way that does not adversely affect the fitness for human consumption of the milk or milk products.

5-21 Storage, handling and loading

Section 5-21 prescribes requirements in relation to the storage, handling and loading of prescribed milk and milk products.

Subsection 5-21(1) provides that prescribed milk or milk products must be stored, handled and loaded in a way that ensures they are protected from the likelihood of contamination, and the conditions (including humidity and atmosphere) under which they are stored, handled and loaded do not adversely affect their fitness for human consumption.

Subsection 5-21(2) provides that prescribed milk or milk products must not be loaded (including loaded for export) into or onto a conveyance unless the conveyance (including the food carrying compartment), the container system unit and the equipment used for loading comply with the applicable requirements of Part 2 of Chapter 5 of the Milk Rules.

5-22 Container system units and food carrying compartments of vehicles—construction etc.

Section 5-22 prescribes requirements in relation to the construction of container system units and food carrying compartments of vehicles. Section 1-5 of the Milk Rules defines *container system unit* as a container designed for use as a unit of cargo handling equipment in the transport of goods by aircraft or vessel. A *food carrying compartment* of a conveyance is defined as the part or area of the conveyance in which milk or milk products are carried.

Subsection 5-22(1) requires that container system units and the food carrying compartments of vehicles used to transport prescribed milk or milk products be constructed to protect the milk or milk products if there is a likelihood of their being contaminated during transport, and so that they can be effectively cleaned.

Subsection 5-22(2) requires that food contact surfaces of container system units and food carrying compartments must be able to be easily and effectively cleaned and, if necessary, sanitised if there is a risk they may cause contamination of prescribed milk or milk products.

Subsection 5-22(3) requires that the food contact surfaces of container system units and food carrying compartments must be effectively constructed, insulated and equipped to maintain prescribed milk or milk products at the temperatures required by Part 2 of Chapter 5 of the Milk Rules.

Subsection 5-22(4) provides that a food carrying compartment does not have to meet the requirements referred in subsection 5-22(1) or 5-22(3) if the milk or milk products are transported in a container system unit that meets the requirements.

5-23 Vehicles, container system units etc.—hygiene control

Section 5-23 provides that container system units, food carrying compartments and vehicles used to transport prescribed milk and milk products, and equipment used to handle prescribed milk and milk products during loading and transport, must:

 be cleaned and sanitised whenever necessary to prevent the contamination of prescribed milk or milk products; and • be maintained in a good state of repair and working order to the extent necessary to ensure the fitness for human consumption of prescribed milk and milk products is not adversely affected during transport.

5-24 Transport

Section 5-24 requires prescribed milk and milk products to be transported under temperature controls that ensure they are maintained during transportation (in accordance with the applicable requirements of Part 2 of Chapter 5 of the Milk Rules).

Transportation of prescribed milk and milk products must also take place in accordance with any other conditions necessary to ensure their fitness for human consumption is not adversely affected.

The note following subsection 5-24(1) refers the reader to section 5-16 of the Milk Rules, which deals with temperature controls for prescribed milk and milk products.

5-25 Identification as not for export as food—fitness for human consumption etc.

Section 5-25 prescribes requirements in relation to milk and milk products that are not fit for human consumption and how they are identified and treated.

Subsection 5-25(1) provides that milk and milk products that are not fit for human consumption (other than manufacturing grade milk or milk products) must be identified as not for export as food, must be kept in a way that does not contaminate prescribed milk and milk products, and must be either disposed of so they do not contaminate prescribed milk or milk products, their ingredients or water supply, or treated to make them fit for human consumption.

Subsections 5-25(2) and 5-25(3), respectively, relate to manufacturing grade milk and milk products that are not fit for human consumption, and milk and milk products for use as animal food. Such milk and milk products must be identified accordingly and be kept in a way that does not contaminate prescribed milk or milk products.

Section 1-5 of the Milk Rules defines *manufacturing grade*, in relation to milk or milk products, as milk or milk products that are not fit for human consumption but are suitable for further processing to make them fit for human consumption.

Subsection 5-25(4) provides that if, in relation to prescribed milk or milk products, an export permit for the milk or milk products is revoked, or the holder of an approved arrangement is given a direction under subsection 305(1) of the Act (direction to deal with non-compliance), that the milk or milk products are to be dealt with as not for export for food, the milk or milk products must be identified as not for export as food, must be kept in a way that ensures they are not a source of contamination of prescribed milk or milk products and must not be loaded for export. Subsection 305(1) of the Act allows any authorised officer to give a direction to deal with non-compliance with the requirements of the Act.

Subsection 5-25(5) captures generally any other milk or milk products that, under the Milk Rules, must be dealt with as not for export as food. Such milk or milk products must be identified accordingly and kept in a way that does not contaminate prescribed milk or milk products.

Subsection 5-25(6) makes provision for prescribed milk or milk products that do not meet importing country requirements of one or more countries, by requiring that the countries to which the milk or milk products are intended for export, and whether these importing country requirements are met, to be readily ascertainable.

5-26 Product standards—general

Section 5-26 prescribes requirements in relation to product standards (as set out in the Food Standards Code) for prescribed milk and milk products. Section 5-26 requires broadly that the Food Standards Code is adhered to, unless an approved arrangement is able to demonstrate how it will comply with differing requirements of an importing country. Subsections 5-26(1) to 5-26(4) relate to contaminants, chemicals additives and similar. Subsections 5-26(5) and 5-26(6) relate to microbiological limits. Subsections 5-26(7) to (8) relate to gene technology, irradiation and similar.

Section 1-5 of the Milk Rules defines *Food Standards Code* as the Australia New Zealand Food Standards Code. The Food Standards Code is available from the Food Standards Australia New Zealand website (https://www.foodstandards.gov.au).

Standard 1.5.3 of the Food Standards Code provides the definition of *irradiation*, in relation to food, means subjecting the food to ionising radiation, other than ionising radiation imparted to food by measuring or inspection instruments. Ionising radiation could be for example gamma rays, x-rays or electron beams that do not have direct contact with the food product. Irradiation is used to improve food safety by extending product shelf life, reducing the risk of foodborne illness, by sterilization of foods, and as a means of controlling insects and invasive pests.

Subsection 5-26(1) requires that prescribed milk and milk products and their ingredients must not contain certain substances that do not comply with a requirement of the Food Standards Code, being:

- a level of metal, non-metal or natural toxicant;
- an amount of agricultural or veterinary chemical;
- food additive, processing aid, vitamin, mineral, added nutrient, or other matter or substance.

The first note following subsection 5-26(1) refers the reader to Standards 1.4.1 and 1.4.4 (for contaminants and natural toxicants) of the Food Standards Code.

The second note following subsection 5-26(1) refers the reader to Standard 1.4.2 (for agriculture or veterinary chemicals) of the Food Standards Code.

The third note following subsection 5-26(1) refers the reader to Standards 1.3.1 to 1.3.3 (for food additives, processing aids and vitamins) of the Food Standards Code.

Subsection 5-26(5) provides that prescribed milk and milk products must meet the microbiological limits for milk and milk products and their ingredients set out in the Food Standards Code.

The note following subsection 5-26(5) refers the reader to Standard 1.6.1 (for microbiological limits) of the Food Standards Code.

Subsection 5-26(7) provides that prescribed milk and milk products and their ingredients must not be produced using gene technology, or be irradiated, or be produced using (or be subjected to) any other process that is contravention of the Food Standards Code.

The first note following subsection 5-26(7) refers the reader to Standard 1.5.2 (for gene technology) of the Food Standards Code.

The second note following subsection 5-26(7) refers the reader to Standard 1.5.3 (for food irradiation) of the Food Standards Code.

Subsections 5-26(2) to (4), (6) and (8) contain exceptions to the requirements in subsections 5-26(1), (5) and (7). These exceptions are if the importing country has different requirements than the Food Standards Code, and the approved arrangement to prepare the milk or milk products provides for a system of controls to ensure the different requirements are complied with, and the system of controls are implemented in accordance with the approved arrangement.

The note followings subsection 5-26(4) and 5-27(8) and the first note following subsection 5-27(6) refers the reader to section 5-7 of the Milk Rules which provides that it is a condition of an approved arrangement for export operations in relation to prescribed milk or milk products that all importing country requirements relating to the milk or milk products are met.

The second note following subsection 5-26(6) refers the reader to section 11-11 of the Milk Rules, which deals with taking, testing and analysing samples in relation to microbiological limits.

Division 5—Trade descriptions

Division 5 of Part 2 of Chapter 5 of the Milk Rules (sections 5-27 to 5-30) imposes conditions on approved arrangements concerning application of trade descriptions on prescribed milk and milk products

The note at the start of Division 5 refers the reader to Part 2 of Chapter 8 of the Act and Part 1 of Chapter 8 of the Milk Rules in relation to trade descriptions.

5-27 Trade description must be applied to prescribed milk and milk products

Section 5-27 imposes requirements relating to the application of trade descriptions for prescribed milk or milk products that are intended to be exported.

Subsection 5-27(1) requires a trade description that includes the information specified in subsection 5-27(3) to be applied to prescribed milk or milk products that are intended for export.

Subsection 5-27(2) provides that the trade description must be applied no later than the time the prescribed milk or milk products are packed in their immediate container before being loaded for export.

The first note following subsection 5-27(2) refers the reader to section 246 of the Act and Chapter 8 of the Milk Rules for the definition of *trade description*.

The second note following subsection 5-27(2) refers the reader to section 247 of the Act for the definition of *applied* in relation to a trade description.

The third note following subsection 5-27(2) refers the reader to section 161 of the Act and section 5-43 of the Milk Rules, where the Secretary may approve a variation of an approved arrangement to remove the requirement for a trade description where the relevant importing country authority does not it.

Subsection 5-27(3) prescribes the content of the trade description that must be applied to prescribed milk or milk products intended for export. The trade description must include:

- the description, net weight and country of origin of the milk or milk products;
- the registration number of the registered establishment where the milk or milk products were last carried out before export;
- the name and address of the occupier of the registered establishment, exporter or consignee of the milk or milk products;
- a list of ingredients (where the product contains 2 or more ingredients) in descending order of ingoing weight;
- the identity of the lot of the milk or milk products; and
- any directions for the use or storage of the milk or milk products that are necessary for reasons of food safety.

The first note following subsection 5-27(3) notifies the reader that the trade description must be accurate, as required by section 8-2 of the Milk Rules. Additionally, the note alerts the reader to Division 3 of Part 2 of Chapter 8 of the Act relating to offences and civil penalty provisions in relation to false trade descriptions.

The second note following subsection 5-27(3) refers the reader to Australian Consumer Law (within the meaning of the *Competition and Consumer Act 2010*), which contains prohibitions on engaging in conduct that is misleading or deceptive or is likely to mislead or deceive, and prohibitions on making false or misleading representations of the product (see sections 18, 29 and 151 of that Law).

Subsection 5-27(4) sets out that, for the purposes of paragraph 5-27(3)(d), the registration number must be clearly identifiable as being the registration number of the registered establishment.

Subsection 5-27(5) has specific requirements for milk or milk products that are packed if the exporter or consignee is not a person who prepared the milk or milk products for export. In these circumstances, the name of the exporter or consignee must be preceded by the words "PACKED FOR" or a statement of similar meaning.

Subsection 5-27(6) provides exceptions from the requirements in subsection 5-27(1) to apply a trade description. These exceptions are:

- milk or milk products transported from a registered establishment in cans without labels (if the cans comply with subsection 5-28(2));
- milk or milk products that have been bulk-loaded into container system units if the information in subsection 5-27(3) is applied to the outer container, or given to the consignee before the milk or milk products are loaded for export; and
- milk or milk products that are identified as not for retail sale if the information in subsection 5-27(3) is applied to the outer container or given to the consignee before the outer container is loaded for export.

Subsection 5-27(7) contains additional requirements for imported milk or milk products that are repacked but not further processed in Australian territory. In addition to any requirement in the Milk Rules in relation to trade descriptions, these milk or milk products must contain the name and registration number of the registered establishment where they were repacked, preceded by the words "PACKED BY" or a statement of similar meaning.

The inclusion of this information is important to ensure the identity of the prescribed milk or milk products can be ascertained and provides assurance of the integrity of the goods to trading partners.

5-28 Incomplete trade description—canned milk or milk products

Section 5-28 sets out the requirements for cans containing prescribed milk or milk products. Subsection 5-28(1) provides that if the cans are not permanently marked with the complete trade description at the time of filling, the registration number of the establishment where the canning took place, preceded by the letters "EX" must be embossed on the cans or indelibly applied directly to the cans.

Subsection 5-28(2) sets out requirements for cans containing prescribed milk or milk products that are to be transferred from a registered establishment without labels. These cans must have embossed on, or indelibly applied directly to, the cans a product code that can be used to identify the milk or milk products, the registration number of the registered establishment where the canning was carried out (preceded by "EX"), the country of origin of the milk or milk products, and the identity of the lot of the milk or milk products.

The inclusion of this information is important to ensure the identity of the prescribed milk or milk products can be ascertained and provides assurance of the integrity of the goods to trading partners.

5-29 Labelling and naming of ingredients

Subsections 5-29(1) and (2) require prescribed milk or milk products to meet each applicable requirement for the labelling and naming of ingredients and compound ingredients in Standard 1.2.4 of the Food Standards Code (if there are more than 2 ingredients, they must be listed in descending order of ingoing weight). Standard 1.2.4 of the Food Standards Code is available from the Food Standards Australia New Zealand website (http://www.foodstandards.gov.au).

Subsection 5-29(3) provides that if a claim is made as to composition of prescribed milk or milk products (i.e., how much of each ingredient is in the product), the trade description must include a quantitative statement supporting the claim.

5-30 Trade descriptions applied to packaging etc.

Section 5-30 requires that a trade description or any other information applied to any immediate container, or an outer container containing immediate containers, of prescribed milk or milk products must not be inconsistent with the information required to be included in a trade description under Division 5 of Part 2 of Chapter 5 of the Milk Rules.

Immediate container is defined in section 1-5 of the Milk Rules as the primary covering in which the milk or milk products are packed.

Division 6—Official marks

Division 6 of Part 2 of Chapter 5 of the Milk Rules (section 5-31) imposes conditions on approved arrangements for prescribed milk or milk products in respect of official marks.

The note at the beginning of Division 6 refers the reader to Part 3 of Chapter 8 of the Act, and Part 2 of Chapter 8 of the Milk Rules for further requirements relating to official marks.

5-31 Alteration of or interference with official mark

Section 5-31 sets out requirements that apply where the holder of an approved arrangement for operations to prepare prescribed milk or milk products for export at a registered establishment reasonably suspects an official mark has been altered or interfered with (in contravention of section 8-19 of the Milk Rules (alteration or interference with official marks)).

In these circumstances, the holder must notify an authorised officer immediately and not deal with the milk or milk products further for export as food without the written approval of an authorised officer. If the notification is given orally, the holder must as soon as practicable after giving the notification, also give the notification in writing.

Division 7—Segregation, identification, security, traceability and integrity

Division 7 of Part 2 of Chapter 5 of the Milk Rules (sections 5-32 to 5-34) sets out the conditions that apply to approved arrangements for prescribed milk or milk products in respect of segregation, identification, security, traceability and integrity.

These provisions are intended to ensure that the integrity of prescribed milk and milk products for export is maintained, including that they are easily identifiable and traceable, and are segregated from other milk and milk products.

5-32 Segregation, identification and traceability—general

Section 5-32 provides the general requirements for segregation, identification, and traceability of prescribed milk or milk products during preparation and transportation. Specifically, to the extent necessary to ensure one or more of the objects of the Act are met, milk and milk products meeting a particular description:

- must be identified and segregated during preparation and transport from other milk or milk products not meeting that description; and
- must not be confused with other milk or milk products not meeting that description;
 and
- must be prepared and transported under conditions of security.

Section 5-32 further sets out the general requirement that, to the extent necessary to ensure that one or more objects of the Act are met, inventory controls and tracing systems must be maintained.

This ensures milk and milk products are accurately identified and segregated from different kinds of products and, if necessary, can be effectively recalled. This is important for ensuring goods are fit for human consumption, meet the requirements of the Act and will meet importing country requirements.

The note following section 5-32 refers the reader to section 5-38 of the Milk Rules, which sets requirements for inventory controls.

5-33 Establishments where milk or milk products that are not for export etc. are prepared

Section 5-33 provides for segregation, identification and security in establishments where operations to prepare animal food or pharmaceutical material, or any other food (including milk or milk products) that is not prescribed milk or milk products, are also carried out. These rules are necessary to ensure the fitness for human consumption and integrity of the prescribed milk or milk products for export as food.

Subsection 5-33(1) operations to prepare prescribed milk or milk products at the same establishment where operations occur to prepare animal foods, pharmaceutical material, or any other food that is not prescribed milk or milk products, are carried out. This is the general rule.

The note following subsection 5-41(1) provides an example of operations to prepare any other food that is not prescribed milk or milk products, as being operations to prepare food for domestic consumption. This is because prescribed milk or milk products are intended for export (see section 2-1 of the Milk Rules).

However, subsection 5-33(2) provides an exception to the general rule, in that the prohibition in subsection 5-33(1) does not apply if the operations to prepare prescribed milk or milk products are carried out at a registered establishment in accordance with an approved arrangement, the fitness for human consumption and integrity of the prescribed milk or milk products are ensured, and the operations in subsection 5-33(1) to prepare milk or milk products at the establishment comply with the relevant requirements of the Act.

This is to ensure the prescribed milk or milk products are not contaminated by milk or milk products not fit for human consumption or do not meet importing country requirements.

5-34 Integrity—general

Section 5-34 sets requirements to ensure the integrity and identity of prescribed milk or milk products prepared in accordance with an approved arrangement at a registered establishment. These rules are necessary to ensure the integrity and fitness for human consumption of the prescribed milk or milk products.

Subsection 5-34(1) provides a general requirement that the integrity of prescribed milk or milk products must be able to be ensured.

The note following subsection 5-34(1) refers the reader to section 5-5 of the Milk Rules, which provides the approved arrangement must provide for certain measures for the identification, traceability and integrity of the milk and milk products.

Subsection 5-34(2) requires the identity of prescribed milk or milk products to be readily ascertainable and must not be lost or confused with the identity of any other milk or milk products.

The note following subsection 5-34(2) refers the reader to section 5-38 of the Milk Rules, which provides that records must be kept to ensure identification, traceability and integrity.

Subsection 5-34(3) provides that (without limiting subsection 5-34(2)) the following information that must be applied to the outer container of prescribed milk or milk products before the outer container is transferred from the establishment at which the outer container was packed. This information includes:

- a description of the milk or milk products, the net weight and the country of origin;
- the identity of the lot of the milk or milk products;
- the registration number of the registered establishment where the milk or milk products were packed into their immediate container, and

• any directions for the use or storage of the milk or milk products to ensure food safety.

The note following subsection 5-34(3) refers the reader to Division 5 of Part 2 of Chapter 5 of the Milk Rules (section 5-30), which provides that the description applied to an outer container must not be inconsistent with the information required to be included in the trade description.

Division 8—Transfers

Division 8 of Part 2 of Chapter 5 of the Milk Rules (sections 5-35 and 5-36) imposes conditions on approved arrangements relating to the transfer of prescribed milk or milk products from one registered establishment to another registered establishment.

5-35 Information and declarations relating to transferred prescribed milk or milk products

Section 5-35 details the information and declarations that are required to be given when a consignment of prescribed milk or milk products is transferred from one registered establishment (the *transferring establishment*) to another registered establishment (the *receiving establishment*). The information and declarations are necessary to ensure the integrity of prescribed milk or milk products that are transferred between registered establishments, and to ensure full traceability of prescribed milk or milk products to meet requirements.

Subsection 5-35(1) specifies the information and declarations that must be given to the occupier of the receiving establishment. These are:

- a full description of the milk or milk products in the consignment and its quantity, and information about storage conditions (i.e., whether the milk or milk products are chilled, frozen or shelf-stable);
- the name, address and registration number for both the transferring and receiving registered establishments;
- the number and kind of packages (if any),
- if the consignment contains milk or milk products that are transferred in cans without labels, or are milk or milk products that have been bulk-loaded into container system units any other information referred to in subsection 5-27(3);
- the name of the importing country (or the name of each importing country) for which applicable importing country requirements have been met; and
- a declaration stating that, at the day the declaration was made, the prescribed export conditions and any other relevant conditions of the Act have been complied with, and any relevant importing country requirements have been met, as well as a declaration stating that the information given in relation to the consignment is true and correct.

The note following subsection 5-35(1) refers to subsections 5-35(3) and (4) for matters relating to the declarations referred to in paragraphs 5-35(i) and (j).

Subsection 5-35(2) provides that the information and declarations specified in subsection 5-35(1) must be in writing. The declaration must be either provided to the occupier of the receiving establishment when the consignment leaves the transferring establishment or accompany the consignment when it arrives at the receiving establishment.

The first note following subsection 5-35(2) alerts the reader that electronic message formats should be compliant with the United Nations Rules for Electronic Data Interchange for Administration, Commerce and Transport. In 2021, these Rules can be accessed from the United Nations Economic Commission for Europe website (https://www.unece.org), which deals with electronic message formats.

The second note following subsection 5-35(2) refers the reader to section 9 of the *Electronic Transactions Act 1999*, which sets out when the requirements to give information (including a declaration) in writing can be met by electronic communication and directs the reader to section 10 of that Act for requirements in relation to electronic signatures. Subsection 5-35(3) requires that a declaration in relation to a consignment of prescribed milk or milk products under paragraphs 5-35(1)(i) or (j) must be made by either:

- the holder of the approved arrangement for operations to prepare the milk or milk products for export at the transferring establishment; or
- a person designated in the approved arrangement as a person who may make the declaration.

Subsection 5-35(4) provides that a declaration in relation to a consignment of prescribed milk or milk products under paragraphs 5-35(1)(i) or (j) must not be made if there are no reasonable grounds for making it, must not be false or misleading, and must be signed and dated by the person making the declaration.

The first note following subsection 5-35(4) directs the reader to sections 171 and 179 of the Act, which provide for the suspension or revocation of the approved arrangement if the requirements in subsection 5-35(4) are not met.

The second note following subsection 5-36(4) explains that a person may commit an offence or be liable to a civil penalty under the *Criminal Code* and the Act if the person provides false or misleading information or documents and directs reader to sections 137.1 and 137.2 of the *Criminal Code* and sections 368 and 369 of the Act.

Subsection 5-35(5) provides exemptions from the requirements to provide the information and declarations in subsection 5-35(1). The information and declarations are not required if the occupier of the transferring establishment is also the occupier of the receiving establishment and the approved arrangement provides for a system of controls to be implemented to ensure that the requirements of Division 7 of Part 2 of Chapter 5 of the Milk Rules (segregation, identification, security, traceability and integrity) are complied with during the transfer.

5-36 Information and declarations not received or inaccurate or incomplete

Section 5-36 sets out what action must be taken if a consignment of prescribed milk or milk products is transferred to a receiving establishment, and the information and declarations required under section 5-35 are not given to the occupier of the receiving establishment as required by subsection 5-35(2) or are inaccurate or incomplete.

In such circumstances, the holder of the approved arrangement must notify an authorised officer as soon as practicable after they become aware that section 5-36 applies to the consignment. In addition, the milk or milk products must be held at the receiving establishment under conditions of security and cannot be dealt with further for export as food until written approval is given by an authorised officer. The milk or milk products must also be identified as not for export as food and be segregated from prescribed milk and milk products. This ensures the integrity of prescribed milk or milk products for export.

Division 9—Management practices—export operations

Division 9 of Part 2 of Chapter 5 of the Milk Rules (sections 5-37 to 5-41) imposes conditions on an approved arrangement relating to management practices for operations to prepare prescribed milk or milk products for export.

5-37 Management practices, organisational structure, resources and personnel

Subsection 5-37(1) requires the holder of an approved arrangement for operations to prepare milk or milk products for export to ensure that the management practices, organisational structure, resources provided to carry out export operations and personnel who carry out those export operations, and the training those personnel receive, are appropriate to ensure compliance with the Act and the importing country requirements relating to the export operations and the prescribed milk or milk products.

Subsection 5-37(2) provides that the holder of the approved arrangement must also make a written record of the management practices, organisational structure, resources and personnel referred to in subsection 5-37(1).

The first note following subsection 5-37(2) refers the reader to subsection 11-8(2) of the Milk Rules, which provides that the required records must be kept for 3 years.

The second note following subsection 5-37(2) refers the reader to subsection 12(1) of the *Electronic Transactions Act 1999*, regarding the requirements for making electronic records.

5-38 Verification of compliance with the Act and other matters

Section 5-38 details the matters that must be verified, the requirement for a record of verification, and the necessary inventory controls to verify compliance.

Subsection 5-38(1) provides that the holder of an approved arrangement for a kind of export operations in relation to prescribed milk or milk products must verify that carrying out export operations at a registered establishment in accordance with the approved arrangement will ensure compliance with the applicable requirements of the Act, and with the conditions in

Divisions 2 to 7 of Part 2 of Chapter 5, and section 5-37 of the Milk Rules. This verification is necessary to demonstrate compliance with the regulatory controls in the Act.

Subsection 5-38(2) provides that a written record must be made of the methods, procedures, tests, monitoring and other evaluations used to verify compliance with the matters referred to in subsection 5-38(1), and the results of the verification.

The note following subsection 5-38(2) explains that the holder of the approved arrangement must retain each record made under this section of a period of 3 years and directs the reader to subsection 11-8(2) of the Milk Rules.

Subsections 5-38(3) and (4) set out the requirements for inventory controls. Subsection 5-38(4) requires the necessary inventory controls must be used in verifying compliance with the matters referred to in paragraphs 5-38(1)(b) and (c) (conditions in Division 2 to 7 of Part 2 of Chapter 5 of the Milk Rules and section 5-46 of the Milk Rules). Subsection 5-38(4) provides that the inventory controls must be in writing, comprehensive and able to be audited under the Part 1 of Chapter 9 of the Act and as required by section 5-40 of the Milk Rules.

5-39 Action must be taken to address non-compliance

Subsection 5-39(1) provides that corrective action must be taken to address any non-compliance or likely non-compliance with the matters referred to in subsection 5-38(1) when carrying out export operations in relation to prescribed milk or milk products in accordance with an approved arrangement. Corrective action must also be taken to ensure that the non-compliance does not occur again, or that the likely non-compliance is avoided. The effectiveness of the corrective action must also be assessed.

Subsection 5-39(2) provides that a written record to address non-compliance and ensure that the non-compliance does not reoccur and the assessment of the effectiveness of the corrective action must be made.

The note following subsection 5-39(2) refers the reader to subsection 11-8(2) of the Milk Rules, which has the effect that the holder of the arrangement must keep the required record for 3 years.

5-40 Internal audit and management review

Section 5-40 sets out the requirements for internal audits and management practice reviews, the records that must be made, and when internal audits are not required.

Subsection 5-40(1) provides that internal audits and management reviews must be conducted of the effectiveness of the management practices of the holder of an approved arrangement for a kind of export operations in relation to prescribed milk or milk products that are carried out at a registered establishment in ensuring compliance with the matters referred to in subsection 5-38(1). The purpose of the internal audits and management reviews are to measure the effectiveness of the management practices of the holder of an approved arrangement.

The note following subsection 5-40(1) explains that an internal audit under section 5-40 is not the same as an audit under Part 1 of Chapter 9 of the Act.

Subsection 5-40(2) provides that internal audits are not required to be conducted at a registered establishment if fewer than 3 people are employed at the registered establishment to carry out export operations in accordance with the approved arrangement, and management reviews are conducted in accordance with the approved arrangement. This is because an internal audit cannot be effectively undertaken where there are only one or2relevant people employed at the registered establishment. However, management reviews are still necessary.

Subsection 5-40(3) provides that a written record must be made of each internal audit and management review undertaken under subsection 5-40(1). The record must contain the results of the audit or review, each decision (if any) made to take action as a result of the audit or review, and each action taken as a result of the audit or review.

The note following section 5-40 refers the reader to subsection 11-8(2) of the Milk Rules, which has the effect that the holder of the arrangement must keep the required records for 3 years.

5-41 Authorised officer must be notified if prescribed milk or milk products are not fit for human consumption or integrity cannot be ensured etc.

Section 5-41 sets out the action required if prescribed milk or milk products are not fit for human consumption or that their integrity, traceability or identity cannot be ensured.

Section 5-41(1) provides that section 5-41 applies where the holder of an approved arrangement for operations to prepare prescribed milk or milk products for export at a registered establishment reasonably believes any of the following circumstances exist in relation to prescribed milk or milk products for which an export permit has been issued:

- there is, or there will be, a failure to meet importing country requirements relating to the prescribed milk or milk products;
- prescribed milk or milk products prepared for export at the registered establishment in accordance with the approved arrangement are not fit for human consumption;
- there is, or there has been, a failure of a procedure or another circumstance occurs or has occurred, at the registered establishment that has affected, or could affect the for human consumption of prescribed milk or milk products prepared for export at the registered establishment in accordance with the approved arrangement;
- the fitness for human consumption, identification, traceability or integrity of prescribed milk or milk products prepared for export at the registered establishment in accordance with the approved arrangement cannot be ensured;
- the information and declarations required by section 5-35 in relation to a consignment of prescribed milk or milk products that was transferred to the registered establishment (the *receiving establishment*) were not given to the occupier of the receiving establishment or did not accompany the consignment, or were inaccurate or incomplete, or the occupier of the receiving establishment is unable to obtain accurate and complete information and declarations.

Subsection 5-41(2) requires the holder of the approved arrangement, as soon as practicable after forming the belief, to notify an authorised officer.

Subsection 5-41(3) provides that if the holder of an approved arrangement gives a notification under subsection 5-41(2) orally, the holder must, as soon as practicable after giving the notification, also give the notification in writing.

Part 3—Renewal of approved arrangement

Part 3 of Chapter 5 of the Milk Rules (section 5-42) sets out requirements relating to the renewal of an approved arrangement for operations to prepare prescribed milk or milk products for export at a registered establishment.

5-42 Period within which application to renew approved arrangement must be made

Section 155 of the Act deals with an application to renew an approved arrangement. Subsection 155(2) allows the holder of an approved arrangement to apply to the Secretary to renew the approved arrangement. Subsection 155(4) requires an application for renewal to be made within the period prescribed by the rules (paragraph 155(4)(a)) or a longer period if allowed by the Secretary (paragraph 155(4)(b)).

Section 5-42 prescribes the timeframe in which an application to renew an approved arrangement for a kind of export operations in relation to prescribed milk or milk products must be made for the purposes of paragraph 155(4)(a) of the Act. This timeframe is 60 days starting on the day that is 180 days before the approved arrangement is due to expire. In other words, the application must be submitted when the approved arrangement is between 180 days and 120 days from expiring.

The first note following section 5-42 provides an example that, if an approved arrangement expires on 8 July in a year (other than a leap year), an application for renewal can be made in any time between 9 January and 10 March in that year. The period specified allows the Secretary sufficient time to consider the application before a decision is made.

The second note following section 5-42 explains that under subsection 155(1) of the Act, applications to renew approved arrangements will only need to be made for approved arrangements that have an expiry date.

Part 4—Variation of approved arrangement

Division 1 of Part 4 of Chapter 5 of the Milk Rules (sections 5-43 to 5-44) sets out requirements relating to the variation of an approved arrangement for operations to prepare prescribed milk or milk products for export at a registered establishment.

Division 1—Variations by holder

5-43 Requirements that must be met for variation to be approved or conditions varied

Section 161 of the Act deals with varying an approved arrangement. Subsection 161(1) allows the holder of an approved arrangement to apply to the Secretary to approve a variation of the approved arrangement in the following circumstances:

- where the proposed variation is to implement an alternative regulatory arrangement approved under paragraph 379C(1)(a) of the Act;
- where the holder and the Secretary consider that the proposed variation is significant; or
- where the proposed variation is to the conditions of the approved arrangement.

Subsection 161(3) of the Act allows the Secretary to refuse to approve the variation if the Secretary is not satisfied of one or more of the requirements listed in that subsection. Paragraph 161(3)(c) allows the rules to prescribe additional requirements.

Section 5-43(1) provides that section 5-43 applies in relation to an application made under subsection 161(1) of the Act to approve a variation of an approved arrangement for operations to prepare prescribed milk or milk products for export, or to vary the conditions of such an arrangement if:

- the application has been made because the relevant importing country authority does not require compliance with one or more conditions (the *relevant conditions*) in Divisions 3 to 7 of Part 2 of Chapter 5 of the Milk Rules; and
- the relevant importing country authority mandates different requirements to be met in relation to the prescribed milk or milk products.

The note following subsection 5-43(1) notifies the reader that variation of an approved arrangement, or of the conditions of an approved arrangement, may be needed to implement an alternative regulatory arrangement approved under section 379C(1)(a) of the Act or another significant variation (directing the reader to Subdivisions B and C of Division 1 of Part 4 of Chapter 5 of the Act).

Subsection 5-43(2) prescribes additional requirements for the purposes of paragraph 161(3)(c) of the Act. The Secretary may refuse to approve the variation if not satisfied that the following requirements will be met:

- compliance with the different importing country requirement will not result in the relevant requirements being met or the relevant conditions being complied with; and
- the approved arrangement provides for a system of controls to be implemented to ensure that the different importing country requirement will be complied with, and that system of controls will be implemented in accordance with the approved arrangement.

These measures are necessary so that the relevant importing country requirements are met and that market access to the importing country is enabled and maintained.

5-44 Significant variations

Section 164 of the Act lists the matters the holder of the approved arrangement and the Secretary must have regard to in considering whether a proposed variation, or the combined effect of 2 or more variations, is significant. Subparagraph 164(2)(c)(ii) allows the rules to prescribe kinds of variations.

Section 5-44 is made for the purposes of subparagraph 164(2)(c)(ii) of the Act and prescribes the following kinds of variations in relation to an approved arrangement for a kind of export operations in relation to prescribed milk or milk products. The prescribed variations include:

- a variation of the person who manages or controls the export operations;
- a variation of the functions a person is permitted to perform in accordance with approved arrangements, including making declarations, manufacturing or possessing an official marking device, and manufacturing, possessing, applying or interfering with an official mark;
- a variation of the export operations that might jeopardise the fitness for human consumption of the prescribed milk or milk products or affect the ability to ensure their integrity, or that might adversely affect the ability to assess whether the fitness for human consumption of the prescribed milk or milk products has been jeopardised;
- a variation that will provide for operations to prepare milk or milk products not for export or that are for animal food or pharmaceutical materials, in addition to operations to prepare prescribed milk or milk products;
- a variation that relates to or varies a variation of the approved arrangement implementing an alternative regulatory arrangement approved under paragraph 379C(1)(a) of the Act in relation to operations to prepare prescribed milk or milk products for export;
- a variation to an approved arrangement implementing an alternative regulatory arrangement approved under paragraph 379C(1)(a) of the Act in relation to operations to prepare prescribed milk or milk products for export.

Prescribing these variations is a transparency measure to assist industry to determine which variations are significant and to reassure importing countries of the integrity of approved arrangements for prescribed milk or milk products.

Division 2—Variations required by Secretary

5-45 Other reasons for requiring holder to vary approved arrangement

Subsection 165(1) of the Act allows the Secretary to make certain variations of an approved arrangement on his or her own initiative (including by requiring the holder of the approved arrangement to vary an aspect of the approved arrangement).

Subsection 165(2) of the Act sets out the grounds on which the Secretary must be satisfied before varying an approved arrangement under subsection 165(1). Paragraph 165(2)(h) enables the rules to prescribe additional grounds for the variation of an approved arrangement.

Subsection 5-45(1) provides that section 5-45 applies in relation to an approved arrangement for operations to prepare prescribed milk or milk products for export.

Subsection 5-45(2) provides, for the purposes of paragraph 165(2)(h) of the Act, that the Secretary may require the holder of an approved arrangement to vary an aspect of the arrangement if the Secretary is no longer satisfied that compliance with the system of control measures in the approved arrangement will ensure there will be reasonable grounds for issuing an export permit or a government certificate for prescribed milk or milk products that are prepared in accordance with the approved arrangement.

Part 5—Matters relating to applications

Part 5 of Chapter 5 of the Milk Rules (sections 5-46 to 5-48) deals with matters relating to applications under the Act concerning approved arrangements for a kind of export operations in relation to prescribed milk or milk products.

5-46 Application of this Part

Section 5-46 sets out the applications under the Act to which the requirements in Part 5 of Chapter 5 of the Milk Rules (sections 5-47 and 5-48) apply. These applications are:

- an application under section 150 of the Act to approve a proposed arrangement for a kind of export operations in relation to prescribed milk or milk products; or
- an application under section 155 of the Act to renew an approved arrangement for a kind of export operations in relation to prescribed milk or milk products; or
- an application under section 161 of the Act to approve a variation of an approved arrangement, or a variation of conditions of an approved arrangement, for a kind of export operations in relation to prescribed milk or milk products; or
- an application that is taken to be made under subsection 166(2) of the Act to approve a varied approved arrangement for a kind of export operations in relation to prescribed milk or milk products.

The first note following section 5-46 refers the reader to paragraphs 377(1)(a) and (b) of the Act which require that the application must be made in a manner approved by the Secretary and, if the Secretary has approved a form for the application, must include the information required by the form.

The second note following section 5-46 refers the reader to subsection 377(3) of the Act and explains that the Secretary may accept any information previously given to the Secretary in connection with an application made under the Act as satisfying any requirement to give that information under subsection 377(1) of the Act.

5-47 Initial consideration period

Section 379 of the Act details the requirements for dealing with applications made under the Act. Subsection 379(3) allows the rules to prescribe the initial consideration period in which an application must be considered by the Secretary. If the Secretary does not make a decision on the application within the prescribed initial consideration period (and the initial consideration period is not extended), the application is taken to have been refused.

Section 5-47 prescribes, for the purposes of subsection 379(3) of the Act, an initial consideration period for an application is 120 days. The initial consideration period may be extended under subsection 379(5) of the Act. The period of 120 days is appropriate, having regard to the matters the Secretary must consider in granting or refusing an application.

The note following section 5-47 explains that under subsection 379(4) of the Act, the consideration period for an application starts on the day after the day the Secretary receives the application.

5-48 Period within which request relating to application must be complied with

Subsection 379(9) of the Act allows the Secretary to make a number of requests in relation to a relevant application, including requesting additional information or requesting consent to enter premises. Paragraph 379(10)(b) allows the rules to prescribe a maximum period within which such a request must be complied with.

Section 5-48 prescribes, for the purposes of paragraph 379(10)(b) of the Act, that the period within which a request by the Secretary under subsection 379(9) to an applicant for information or documents relating to the application must be complied with is 6 months. The initial consideration period is indicative and can be extended under section 379 of the Act. The maximum period prescribed by this section is appropriate as it permits sufficient time to comply with matters provided in subsection 379(9) of the Act. The period provides certainty on the maximum amount of time required for an application to be processed. The time provided will also allow for abandoned applications to be deemed rejected after the period has elapsed.

CHAPTER 7—EXPORT PERMITS

An export permit is a document that confirms the eligibility of goods for export and facilitates the exit of those goods from Australia. A person may apply to the Secretary for an export permit for prescribed milk or milk products. The export permit must be issued in writing and will be in effect for a particular period. The permit may be varied, suspended or revoked, and may be required to be returned.

The prescribed export conditions in section 2-4 of the Milk Rules require the exporter of prescribed milk or milk products to hold an export permit covering the export.

Part 1—Issue of export permit

7-1 Conditions of export permit

Paragraph 227(1)(a) of the Act allows the rules to prescribe conditions of an export permit. Subsection 227(2) of the Act has the effect that conditions prescribed by the rules may be required to be complied with before or after the export of the goods to which the export permit relates.

Section 7-1 is made for the purposes of paragraph 227(1)(a) of the Act, and prescribes that a condition of an export permit for prescribed milk or milk products is that the holder must make written records of measures taken to ensure that the applicable requirements of the Act have been complied with.

The first note following section 7-1 refers the reader to examples of applicable requirements of Chapters 7 and 11 of the Milk Rules.

The second note following section 7-1 refers the reader to subsection 11-6(2) of the Milk Rules, which requires the holder of the export permit to retain each record made under section 7 of the Milk Rules for a period of three years.

The third note following section 7-1 refers the reader to subsections 227(4) and (5) of the Act which provide that the holder of an export permit that is in force may commit an offence or be liable to a civil penalty if a condition of the export permit is contravened.

7-2 Period of effect of export permit

Section 228 of the Act sets the period of effect of an export permit. An export permit takes effect when it is issued (paragraph 228(a) of the Act) and remains in force as prescribed by the rules, unless it is revoked earlier under section 233 of the Act (paragraph 228(b)).

Section 7-2 is made for the purposes of paragraph 228(b) of the Act and provides that an export permit for prescribed milk or milk products remains in force for 28 days (unless it is revoked under section 233 of the Act), starting on the day the permit is issued. The 28 day period is appropriate as export permits are often made in relation to perishable items.

The note following section 7-2 explains that under section 11-5 of the Milk Rules an export permit (other than an export permit that was issued by electronic means) must be retained in a secure place when it is not being used.

Part 2—Variation, suspension and revocation of export permit

7-3 Period of effect of varied export permit

Section 230 of the Act sets the period of effect of a varied export permit. A varied export permit takes effect when it is issued (paragraph 230(a)) and remains in force as prescribed by the rules, unless it is revoked earlier under section 233 of the Act (paragraph 230(b)).

Section 7-3 is made for the purposes of paragraph 230(b) of the Act and provides that an varied export permit for prescribed milk or milk products remains in force (unless it is revoked under section 233 of the Act) for the remainder of the period for which the export permit as originally issued was in force under section 7-2. A variation does not affect the original period of effect for a permit.

The note following section 7-3 explains that a varied export permit takes effect when it is issued (see paragraph 230(a) of the Act).

7-4 Circumstances in which export permit may be suspended

Subsection 231(1) of the Act provides that the Secretary may suspend an export permit if the Secretary reasonably believes that circumstances prescribed by the rules exist.

Section 7-4 is made for the purposes of subsection 231(1) of the Act and prescribes the circumstances in which the Secretary may suspend an export permit for prescribed milk or milk products. The prescribed circumstances are the same as the circumstances for revoking an export permit that are listed in paragraphs 233(a) to (f) of the Act and section 7-5 of the Milk Rules. This includes where the Secretary reasonably believes that:

- the integrity of the goods cannot be ensured;
- a condition of the permit has been, or is being, contravened;
- the requirements of the Act have not been complied with, or are not likely to be complied with, before the goods are imported into the importing country;
- an importing country requirement relating to the goods will not be, or is not likely to be, met before the goods are imported into the importing country;
- the holder of the permit made a false, misleading or incomplete statement in an application for the permit, or gave false, misleading or incomplete information to the Secretary or another person performing functions or exercising powers under the Act or a prescribed Agriculture law;
- the holder of the permit has contravened a requirement of the Act; or
- the additional circumstances set out below in section 7-5 of the Milk Rules exist.

These circumstances are likely to affect Australia's trading reputation and may affect access to importing country markets. The consequences may be serious and may affect several permit holders, so it is essential that export permits can be suspended in the prescribed circumstances to mitigate these consequences.

7-5 Other circumstances in which export permit may be revoked

Section 233 of the Act allows the Secretary to revoke an export permit if the Secretary reasonably believes that one or more of the circumstances listed in subsection 233(1) exist. Paragraph 233(1)(g) allows the rules to prescribe additional circumstances.

Section 7-5 is made for the purposes of paragraph 233(1)(g) and prescribes other circumstances, in addition to those specified in paragraphs 233(1)(a) to (f) of the Act, for revoking an export permit for prescribed milk or milk products. The additional circumstances are where:

- a person (other than the holder of the permit) has given the Secretary information or a document in relation to the milk or milk products that is false, misleading or incomplete;
- a condition or disease that is likely to affect the acceptability of the milk or milk products to the importing country is present in Australian territory; or
- the export of the milk or milk products could result in trade in, or the export of other goods from Australian territory, being adversely affected.

These circumstances are likely to affect Australia's trading reputation and may affect access to importing country markets. The consequences may be serious and may affect several permit holders, so it is essential that export permits can be revoked in the prescribed circumstances to mitigate these consequences.

The note following section 7-5 explains that if an export permit is revoked, the person to whom it was issued must return the permit to the Secretary withing 10 business days (unless it was issued by electronic means) and directs the reader to section 7-7 of the Milk Rules.

Part 3—Other matters

7-6 Changes that require additional or corrected information to be given to the issuing body

Section 235 of the Act requires the holder of an export permit to give the Secretary additional or corrected information in certain circumstances, including if a change prescribed by the rules occurs (paragraph 235(1)(b)).

Section 7-6 prescribes, for the purposes of paragraph 235(1)(b) of the Act, changes that require the holder of an export permit to provide the Secretary with additional or corrected information in relation to prescribed milk or milk products for which an export permit is in force but that have not been exported.

These changes are where there are reasonable grounds to suspect that:

- the fitness for human consumption of the prescribed milk or milk products has been jeopardised, or the integrity of the prescribed milk or milk products cannot be ensured;
- an importing country requirement relating to the milk or milk products will not be met
 or is not likely to be met before the milk or milk products are imported into the
 importing country;
- a prescribed export condition relating to the milk or milk products has not been complied with when the condition should have been complied with.

The purpose of this provision is to place an obligation on the exporter to ensure the permit continues to accurately reflect the circumstances for the issue of the permit. The consequences may be serious and may affect several permit holders, so it is essential that additional or corrected information is provided. This ensures export permits are only in force where the prescribed milk or milk products comply with the Act and the Milk Rules, enhancing Australia's reputation as a reliable trading partner.

The note following section 7-6 alerts the reader that an exporter may be liable to a civil penalty if the exporter fails to comply with a requirement under section 235 of the Act.

7-7 Return of export permit

Subsection 236(1) of the Act provides that the rules may require a person to whom an export permit was issued to return the permit to the Secretary in the circumstances prescribed by the rules and at the time, or within the period, prescribed by the rules.

Subsection 7-7(1) is made for the purposes of subsection 236(1) of the Act and requires an exporter to return an export permit for prescribed milk or milk products to the Secretary within 10 business days if the permit has been revoked. The 10 day period commences on the day the permit is revoked.

The purpose is to ensure export permits are not misused, by placing an obligation on the exporter to return the permit. This preserves the integrity of the export permit system by ensuring a permit is not used fraudulently to support the unauthorised export of prescribed milk or milk products. Ten business days is a reasonable time to allow the holder to return the permit to the Secretary, but is short enough to mitigate against the risk of the permit being misused.

Subsection 7-7(2) has the effect that the requirement to return an export permit does not apply to an export permit issued electronically, as there will not necessarily be a physical permit to return.

7-8 Notification that prescribed milk or milk products are not to be exported

Section 237 of the Act provides that the rules may require the holder of an export permit for a kind of prescribed goods to notify the Secretary, in writing, if it is no longer intended to export the goods in the circumstances prescribed by the rules, and at the time, or within the period, prescribed by the rules.

Section 7-8 is made for the purposes of section 237 of the Act, and requires the holder of an export permit for prescribed milk or milk products to notify the Secretary in writing, if it no longer intends to export the milk or milk products because of circumstance listed in section 7-4 of the Milk Rules (which lists the grounds for suspending an export permit). The notification must be given as soon as practicable but not later than 10 business days after the decision not to export the prescribed milk or milk products is made.

The purpose of section 7-8 is to preserve the integrity of the export permit system and ensures the Secretary is aware of when prescribed milk or milk products are no longer intended to be exported.

Part 4—Applications for export permits

7-9 Application of this Part

Section 7-9 provides that the requirements in Part 4 of Chapter 7 (sections 7-9 to 7-10) of the Milk Rules apply to applications for an export permit for prescribed milk or milk products (under section 224 of the Act), and applications under paragraph 229(3)(b) of the Act to vary an export permit or vary conditions of an export permit for prescribed milk or milk products.

7-10 Documents to accompany application

Section 239 of the Act sets the requirements for applications for export permits. Paragraph 239(1)(d) allows the rules to prescribe any documents that must accompany an application for an export permit.

Section 7-10 is made for the purposes of paragraph 239(1)(d) of the Act. Subsection 7-10(1) requires that an application for an export permit, or an application to vary an export permit or the conditions of an export permit, must be accompanied by a declaration stating that the applicant has in their possession:

- the information and declarations given to the occupier of the receiving establishment in relation to the milk and milk products under section 5-35 of the Milk Rules by the occupier of the registered establishment where operations to prepare the milk or milk products for export (other than storing, handling or loading) were last carried out;
- a declaration by a relevant person that identifies the milk or milk products, states that the requirements of the Act in relation to the export of the milk or milk products have been complied with, and importing country requirements in relation to the milk or milk products have been met, states that the information in the declaration is true and correct, and is signed and dated by the person who made it.

Subsection 7-10(2) provides that, if an assessor has given a notice to the applicant under subsection 9-20(2) of the Milk Rules, the declaration referred to in subsection 7-10(1) must also state that the applicant has the notice. Subsection 9-20(2) requires an assessor to give written notice to the relevant person for an assessment stating whether the assessor reasonably believes that, in relation to the prescribed milk or milk products, the requirements of the Act have been complied with, and that importing country requirements have been met before importation.

Subsections 7-10(3) and (4) provide that the declaration required by subsection 7-10(1) must be in the form approved by the Secretary, must not be made if there are no reasonable grounds for making it, must not be false or misleading, and must be signed and dated by the person who made it.

The note following subsection 7-10(4) alerts the reader that a person may commit an offence or be liable for a civil penalty under the Act or the *Criminal Code* if they provide false or misleading information or documents.

Subsection 7-10(5) sets out who is a relevant person for the purposes of paragraph 7-10(1)(b). A *relevant person* is the holder of the approved arrangement for operations to prepare the milk or milk products for export at the registered establishment where those operations (other than storing, handling, or loading) were last carried out, or a person designated in the approved arrangement as a person who may make the declaration required in paragraph 7-10(1)(b).

CHAPTER 8—OTHER MATTERS RELATING TO EXPORT

Part 1—Trade descriptions

The aim of trade description compliance management is to ensure that an occupier's approved arrangement is effective and operates in accordance with the Act to and that prescribed goods intended for export as food:

- are wholesome or are identified for further processing for foods;
- meet requirements to have an accurate trade description;
- meet importing country requirements necessary to maintain market eligibility; and
- are traceable, can be recalled if required and their integrity is ensured.

8-1 Purpose of this Part

Section 248 of the Act allows the rules to make provision for and in relation to trade descriptions for prescribed goods that are intended to be exported.

Section 8-1 provides that Part 1 of Chapter 8 (sections 8-1 to 8-3) of the Milk Rules is made for the purposes of section 248 of the Act, and makes provision for, and in relation to, trade descriptions for prescribed milk and milk products that are intended to be exported.

This ensures trade descriptions include relevant information and are used in a way that will ensure that the identity of prescribed milk or milk products can be ascertained and not confused with any other goods. The term *trade description* is defined in section 246 of the Act.

The note following section 8-1 notifies the reader that a person who engages in conduct that contravenes a provision in Part 1 of Chapter 8 of the Milk Rules may commit an offence or be liable to a civil penalty under section 249 of the Act.

8-2 General requirements for trade descriptions

The purpose of section 8-2 is to set out the general requirements for trade descriptions for prescribed milk or milk products that are intended to be exported.

Subsection 8-2(1) provides that trade descriptions must be accurate and unambiguous, legible, prominent, conspicuous, not obscured in any way and, to the extent practicable, be securely attached (unless the trade description is stated in any document relating to the milk or milk products) and tamper evident.

The note following subsection 8-2(1) refers the reader to section 247 of the Act, for a definition of when a trade description is *applied*.

Subsection 8-2(2) provides that information or pictures applied to prescribed milk or milk products, in addition to the trade description, must not be inconsistent with the information required to be included in trade descriptions under Division 5 of Part 2 of Chapter 5 of the Milk Rules (concerning approved arrangements for operations to prepare prescribed milk or milk products for export).

The requirements in section 8-2 help to ensure the prescribed milk or milk products are fit for human consumption, meet importing country requirements necessary to maintain market eligibility, are traceable, and can be recalled if required.

8-3 Trade descriptions in language other than English

Subsection 8-3(1) provides that section 8-3 applies in relation to a trade description that is applied to prescribed milk or milk products if any part of the trade description is in a language (the *foreign language*) other than English.

Subsection 8-3(2) provides that the foreign language part of the trade description must not be inconsistent with the English part of the trade description.

Subsection 8-3(3) requires:

- the occupier of the registered establishment where the prescribed milk or milk products are being held, or where the trade description was applied; or
- the exporter of the prescribed milk or milk products,

on request in writing by an authorised officer, to make available in writing to an authorised officer an English translation of the foreign language part of the trade description.

Subsection 8-3(4) requires the translation of the foreign language part of the trade description into English to be done by an appropriately qualified person who is not an employee of, and is independent of, the person who has been asked to make the translation available. This is necessary to independently verify that the foreign language part of the trade description is consistent with the English language part of the trade description.

Part 2—Official Marks

Official marks are market labels, tags or other seals applied to products exported from Australia. Each type of label has specific mark dimensions. There are strict conditions set out to comply with export requirements. Official marks indicate compliance with the Act and help to ensure products are not rejected when exported, which may result in large costs for business and the economy. Official marks are relied on by governments of importing countries as an assurance of the authenticity of a document or the origin, integrity and compliance of goods with importing country requirements or other relevant standards.

Division 1—Marks that are official marks

8-4 Purpose of this Division

Subsection 255(1) of the Act allows the rules to provide that a specified mark is an official mark for the purposes of this Act.

Section 8-4 provides that Division 1 of Part 2 of Chapter 8 of the Milk Rules (sections 8-4 to 8-12) is made for the purposes of subsection 255(1) of the Act and specifies the marks that are official marks for prescribed milk or milk products intended to be exported. An official mark is a mark that is applied to goods to confirm the identity, condition or status of the goods.

8-5 Tolerances for dimensions of official marks

Section 8-5 details the tolerances (or margins of error) for the dimensions of official marks, or a part of such a mark, that are specified in Division 1 of Part 2 of Chapter 8 of the Milk Rules. This is to ensure consistency in the dimensions of official marks.

For dimensions of up to 10 millimetres, the tolerance is plus or minus 1 millimetre. For dimensions of more than 10 millimetres, the tolerance is plus or minus 2 millimetres.

8-6 Official mark—foreign country identification

Subsection 8-6(1) provides a representation of the design of a 'foreign country identification' official mark, which is an official mark for the purpose of the Act. This kind of official mark must have the relevant foreign country identification mark inserted in where the letter 'A' is in the representation.

Subsection 8-6(2) provides that a *foreign country identification mark* is a mark that is required to be applied to milk or milk products that are to be imported into that country, as determined by the relevant importing country authority.

The note following subsection 8-6(2) refers the reader to the Manual of Importing Country Requirements (**MICoR**) for guidance on foreign country identification marks. In 2021, this manual could be viewed on the Department's website (https://www.awe.gov.au). Access to the document may require a password.

Subsection 8-6(3) provides the acceptable dimensions of a foreign country identification official mark. These dimension requirements relate to the diameter of the circle (50 millimetres), the minimum height of the letters in the word 'Australia' (6 millimetres) and the dimensions of the foreign country identification mark to be inserted into the official mark (as specified by the relevant importing country authority).

Where applicable, this mark enables the export of prescribed goods from Australia to the importing country.

The note following subsection 8-6(3) refers the reader to MICoR for guidance on the requirements for the dimensions of a foreign country identification mark.

8-7 Official mark—tamper-indicative metal strap seal

Section 8-7 provides that a tamper indicative metal strap seal is an official mark if it meets requirements of this section. The requirements are that the seal must:

- be a tamper-indicative metal strap seal that can be secured in a loop by inserting one end of the seal into or through a protected locking mechanism on the other end; and
- comply with ISO 17712:2013 Freight containers—Mechanical seals, as that document exists at the commencement of the Milk Rules. This international standard is a single source of information on mechanical seals and is available for a fee from the International Organization for Standardization (www.iso.org). The standard is an appropriate requirement as certain countries have compliance with the standard as a requirement to maintain market access. The manufacture and supply of tamperindicative metal straps are tightly controlled by the Department. The control of tamper-indicative metal straps combined with the requirement to meet international standards provides appropriate assurance to trading partners and facilitates trade; and
- bear the words 'Australian Government' and bear a unique number, or a unique combination of letters and numbers, provided to the manufacturer of the seal by the Department.

The purpose of mechanical seals, as part of the security system, is to determine whether a freight container has been tampered with, for example, whether there has been unauthorised access to the container.

8-8 Official mark—bolt seal

Section 8-8 provides that a bolt seal is an official mark if it meets the requirements of this section. A bolt seal is a tamper-evident locking device that requires a tool to be removed.. The requirements of the section are:

- the seal must be a high security bolt seal; and
- the seal must comply with ISO 17712:2013 Freight containers—Mechanical seals, as that document exists at the commencement of the Milk Rules. This international standard is a single source of information on mechanical seals and is available for a fee from the International Organization for Standardization (www.iso.org). The standard is an appropriate requirement as certain countries have compliance with the standard as a requirement to maintain market access. The manufacture and supply of bolt seals are tightly controlled by the Department. The control of bolt seals combined with the requirement to meet international standards provides appropriate assurance to trading partners and facilitates trade; and
- the seal must also bear the words 'Australian Government' and bear a unique number, or a unique combination of letters and numbers, provided to the manufacturer of the seal by the Department; and
- the seal must also be coated with green or blue plastic.

A bolt seal is required to be applied to a container system unit (other than a container system unit intended for transport by air) under Division 1 of Part 2 of Chapter 8 of the Milk Rules, and an official mark is required to be applied to the prescribed milk or milk products under Division 6 of Part 2 of Chapter 5 of the Milk Rules (approved arrangements).

The purpose of a bolt seal, as part of the security system, is to determine whether a freight container has been tampered with, for example, whether there has been unauthorised access to the container.

8-9 Official mark—European Union

Subsection 8-9(1) provides a representation of the design of an 'European Union' official mark, which is an official mark for the purposes of the Act. This kind of official mark must be in the design indicated in subsection 8-9(1) and contain the letter 'E' and meet the dimensions set out in subsection 8-9(2).

Subsection 8-9(2) provides the acceptable dimensions of the 'European Union' official mark. These dimensions relate to the width and height of the oval mark, and the height of the letter 'E'. The acceptable dimensions differ depending on whether the mark is a normal size mark, a small size mark or a computer-generated mark.

The 'European Union' official mark signifies that prescribed goods intended for export to the European Union have been inspected and are fit for human consumption.

8-10 Official mark—carton seal

Section 8-10 provides a representation of the design for a seal applied to a carton (a 'carton seal'), which is an official mark.

The 'carton seal' mark must meet the specifications in paragraphs 8-10(1)(a) to (c). This includes being printed in black (except for the Coat of Arms, which must be printed in red) on a white or security background, including the substitutions set out in subsection 8-10(3) and meeting the dimensions provided in subsection 8-10(2).

Subsection 8-10(2) provides the acceptable dimensions of the 'carton seal' official mark. These dimensions relate to the width (not less than 45 millimetres and not more than 75 millimetres) and height of the mark (not less than 125 millimetres and not more than 160 millimetres).

Subsection 8-10(3) sets out the information to be substituted at 'A', 'B' and 'C' in the design of the carton seal official mark. The registration number of a registered establishment where operations to prepare the relevant milk or milk products for export were carried out must be included where 'A' is in the representation, a number or combination of letters and numbers associated with the manufacturer of the mark must substitute the letter 'B', and a number or combination of letters and numbers that is unique to each mark must substitute the letter 'C'. This information is necessary to ensure the identification and traceability of the exported consignment of the prescribed milk or milk products.

8-11 Official mark—goods opened for assessment and resealed

Section 8-11 provides a representation of the design of a carton seal applied to a carton after it has been opened, inspected and re-sealed.

The mark must meet the specifications set out in paragraphs 8-11(1)(a) to (c) of the Act. These include being printed in green (except for the Coat of Arms which must be printed in red), be on a white or security background, including the substitutions set out in subsection 8-11(3) and meeting the dimensions provided in subsection 8-11(2).

Subsection 8-11(2) provides the required dimensions of the 'opened and resealed carton seal' official mark. These dimensions relate to the width (not less than 45 millimetres and not more than 75 millimetres) and height of the mark (not less than 125 millimetres and not more than 160 millimetres).

Subsection 8-11(3) sets out the information to be substituted at 'A' and 'B' in the design of the opened and resealed carton seal official mark. A number, or a combination of letters and numbers, associated with the manufacturer of a mark must be included where 'A' is in the representation. A number, or a combination of letters and numbers, which are unique to each official mark must be included where 'B' is in the representation. This information is necessary to ensure the identification and traceability of the exported consignment of the milk or milk products.

8-12 Official mark—Australian Government

Section 8-12 provides a representation of the design of an 'Australian Government' official mark, which is an official mark for the purposes of the Act. The mark must contain a number identifying the person that used the mark where 'XXXX' is included in the representation.

The note following section 8-12 explains that sections 8-15 to 8-19 and section 8-29 of the Milk Rules, which relate to the manufacture, supply, application and alteration or interference with an official mark, do not apply to an 'Australian Government' official mark.

Division 2—General rules relating to official marks

8-13 Purpose and application of this Division

Subsection 255(2) of the Act allows the rules to make provision for and in relation to:

- the persons or classes of persons, who may manufacture, possess, apply, alter or interfere with an official mark;
- the methods of applying official marks;
- the circumstances in which an official mark may, or must not, be applied;
- security of official marks;
- removal or defacement of official marks;

- making records in relation to official marks; and
- any other matter relating to official marks.

Subsection 8-13(1) provides that Division 2 of Part 2 of Chapter 8 of the Milk Rules (sections 8-13 to 8-24) is made for the purposes of subsection 255(2) of the Act and makes provision for and in relation to certain matters relating to the official marks specified in Division 1 of Part 2 of Chapter 8 of the Milk Rules for milk or milk products that are intended to be exported.

This is to ensure that official marks are not misused and only applied to eligible goods.

The note following subsection 8-13(1) notifies the reader that a person may commit an offence or be subject to a civil penalty under the Act if they engage in conduct that contravenes a provision in Division 2 of Part 2 of Chapter 8 of the Milk Rules (see section 258 of the Act) or other provisions in Division 3 of Part 3 of Chapter 8 of the Act (relating to false, misleading or deceptive official marks).

Subsection 8-13(2) provides that sections 8-15 to 8-19, which relate to the manufacture, supply, application and alteration of or interference with an official mark, do not apply to an 'Australian Government' official mark as provided for in section 8-12 of the Milk Rules.

8-14 Interpretation

Section 8-14 sets out when an official mark is *applied* to milk or milk products. This is fundamental to managing conduct in relation to that official mark.

An official mark will be applied to milk or milk products, for the purpose of the Milk Rules, if it is:

- applied directly to the milk or milk products, their packaging or any covering containing the milk or milk products; or
- applied to anything attached to the milk or milk products, their packaging or any covering containing the milk or milk products; or
- inserted into anything in which the milk or milk products are packaged or any covering containing the milk or milk products.

Subsection 8-14(2) specifies that a reference in Division 2 of Part 2 of Chapter 8 of the Milk Rules to a particular official mark is a reference to an official mark provided for in Division 1 of Part 2 of Chapter 8 of the Milk Rules.

8-15 Persons who may manufacture or supply official marks for milk or milk products

Section 8-15 specifies who may manufacture or supply a kind of official mark for milk or milk products. Limiting who may manufacture or supply official marks is necessary to ensure the integrity of the system for manufacturing official marks.

The persons who can manufacture or supply an official mark for milk or milk products are:

- authorised officers;
- persons who are able to manufacture or supply the official mark under an approved arrangement;
- persons acting in accordance with a direction given by an authorised officer; or
- a person who has been given a written approval by the Secretary to manufacture or supply the official mark in relation to specified milk or milk products and who is acting in accordance with that approval.

These restrictions do not apply to the manufacture or supply of the official mark specified in section 8-12 of the Milk Rules ('Australian Government' official mark).

8-16 Persons who may possess official marks that have not been applied to milk or milk products

Section 8-16 specifies who may possess official marks that have not been applied to milk or milk products. Limiting who can possess official marks ensures they are accounted for and only applied by nominated personnel.

The persons who can possess a kind of official mark for milk or milk products are:

- persons who are permitted, under section 8-15 of the Milk Rules, to manufacture or supply official marks;
- persons who are permitted, under section 8-17 of the Milk Rules, to apply the official mark;
- authorised officers;
- persons who are able to possess the official mark under an approved arrangement;
- persons acting in accordance with a direction given by an authorised officer; or
- a person who has been given a written approval by the Secretary to possess the official mark at a specified registered establishment and in relation to specified milk or milk products and who is acting in accordance with that approval.

These restrictions do not apply to the manufacture or supply of the official mark specified in section 8-12 of the Milk Rules ('Australian Government' official mark).

8-17 Persons who may apply official marks to milk or milk products etc.

Section 8-17 specifies who may apply official marks to milk or milk products. Limiting those who can apply official marks ensures that official marks are only applied to products passed as fit for human consumption and are used in accordance with the Act and Milk Rules.

The persons who can apply an official mark to milk and milk products are:

- persons acting in accordance with an approved arrangement in accordance with which the official mark is to be applied to the milk product; or
- persons acting in accordance with a direction given by an authorised officer; or
- authorised officers; or
- a person who has been given a written approval by the Secretary to apply the official mark at a specified registered establishment and in relation to specified milk or milk products and who is acting in accordance with that approval.

These restrictions do not apply to the application of the official mark specified in section 8-12 of the Milk Rules ('Australian Government' official mark).

8-18 Circumstances in which official mark must not be applied to milk or milk products

Section 8-18 provides circumstances where an official mark, (including a foreign country identification official mark or European Union official mark) must not be applied to milk and milk products.

Subsection 8-18(1) provides a person must not apply an official mark to milk or milk products if the goods are not fit for human consumption or have deteriorated.

Subsection 8-18(2) provides that a foreign country identification official mark (section 8-6) or a European Union official mark (section 8-9) must not be applied to milk or milk products if the circumstances in which that mark may be applied, as specified by the importing country, no longer exist.

The note following subsection 8-18(2) refers the reader to sections 8-6 and 8-9 of the Milk Rules for the requirements for the foreign country identification mark and the European Union official mark.

These restrictions do not apply to the application of the official mark specified in section 8-12 Milk Rules ('Australian Government' official mark).

8-19 Alteration of and interference with official marks

Section 8-19 details who may alter or interfere with an official mark, and in what circumstances, regardless of whether it has been applied to milk or milk products. This is necessary to ensure official marks can be relied upon by the relevant importing country authority as an assurance about the authenticity of a document or the origin, integrity and compliance of goods with importing country requirements.

An official mark (whether it has or has not been applied to any milk or milk products) can only be altered or interfered with in the following circumstances:

• where the alteration or interference is required or permitted by the Milk Rules; or

- where the alteration or interference is done by a person who is an authorised officer; or
- where the alteration or interference is done by a person who is acting in accordance with a direction given by an authorised officer; or
- where the alteration or interference is done in accordance with an approved arrangement and by a person who is designated in the arrangement as a person who may alter or interfere with an official mark; or
- where the alteration or interference is by a person who has been given a written approval by the Secretary to alter or interfere with the official mark at a specified registered establishment and in relation to specified milk or milk products and who is acting in accordance with that approval.

The first note following section 8-19 refers the reader to section 309 of the Act, which deals with directions given by authorised officers.

The second note following section 8-19 explains that altering or interfering with an official mark to make the mark false, misleading or deceptive may be an offence or the contravention of a civil penalty under sections 261 or 262 of the Act.

These restrictions do not apply to the alternation of or interference with the official mark specified in section 8-12 Milk Rules ('Australian Government' official mark).

8-20 Official marks must be legible and securely attached

Section 8-20 requires official marks applied to milk or milk products to be legible and securely attached. This enables the official mark to be identified when it is being used on milk and milk products and provides assurance of the authenticity of the official marks to trading partners.

8-21 Security of official marks

Section 8-21 requires a person who is in possession of an official mark that has not been applied to any milk or milk products (where permitted by section 8-16 of the Milk Rules) to ensure the official mark is securely stored. This ensures that all official marks can be accounted for when not in use.

8-22 Removal or defacement of official marks

Section 8-22 sets out requirements relating to the removal or defacement of official marks that have been applied to milk or milk products, including when the marks must be removed or defaced and who can take that action.

Subsection 8-22(1) requires an official mark to be removed or defaced if the milk or milk products to which it has been applied are no longer fit for human consumption or have deteriorated. This ensures products which are not fit for human consumption or that have deteriorated, do not enter or are removed from the export supply chain.

Subsection 8-22(2) requires official marks that have been applied to a carton in which milk or milk products are packed to be removed or defaced if the milk or milk products in the carton are no longer intended to be exported, or are no longer intended to be exported in that carton.

Subsection 8-22(3) requires a foreign country identification official mark or a European Union official mark to be removed or defaced if the circumstances in which that mark has been applied to milk or milk products, as specified by the importing country, no longer exist. The requirements in subsections 8-22(2) and (3) apply without limiting subsection 8-22(1).

Subsection 8-22(4) sets out who may remove or deface an official mark in accordance with a requirement in subsections 8-22(1), (2) or (3). This is limited to:

- an authorised officer; or
- a person acting in accordance with a direction from an authorised officer; or
- a person designated in an approved arrangement as a person who may remove or deface the official mark; or
- a person who has been given a written approval by the Secretary to remove or deface the official mark at a specified registered establishment and in relation to specified milk or milk products and who is acting in accordance with that approval.

The note following subsection 8-22(4) refers the reader to section 309 of the Act, which provides for how a direction may be given by an authorised officer.

The second note following subsection 8-22(4) alerts the reader to section 258 of the Act, which has the effect that a person may commit an offence or be liable to a civil penalty if the person contravenes a provision in Division 2 of Part 2 of Chapter 8 of the Milk Rules.

8-23 Records of official marks manufactured or supplied

Section 8-23 requires the holder of an approved arrangement that covers the manufacture or supply of official marks for use at establishments that are registered for operations to prepare prescribed milk or milk products for export to make a daily written record detailing each kind, and the number of each kind of official marks manufactured on that day.

The holder must also make a written record stating each day a consignment of official marks is supplied to an establishment registered for operations to prepare prescribed milk or milk products for export, each kind of official mark included in the consignment, and how the consignment is transported.

The note following section 8-23 explains that under section 11-8 of the Milk Rules, the holder of an approved arrangement must retain each record made under section 8-23 for 3 years (in accordance with subsection 11-8(2) of the Milk Rules).

8-24 Records of official marks received, applied, removed, defaced, destroyed or returned

Section 8-24 requires the holder of an approved arrangement for operations to prepare prescribed milk or milk products for export at a registered establishment to make a written record of consignments of official marks received at the establishment, official marks applied to, or removed from, milk or milk products at the establishment, official marks destroyed at the establishment and official marks returned from the establishment.

This ensures only goods that meet requirements have official marks applied and tracks official marks within a registered establishment.

The note following section 8-24 explains to the reader that under section 11-8 of the Milk Rules, the holder of an approved arrangement must retain each record made under section 8-24 for 3 years.

Division 3—Marks resembling official marks

8-25 Purpose of this Division

Section 256 of the Act allows the rules to make provision for and in relation to marks that resemble an official mark or are apparently intended to resemble or pass for an official mark.

Section 8-25 provides that Division 3 of Part 2 of Chapter 8 of the Milk Rules (sections 8-25 to 8-27) is made for the purposes of section 256 of the Act. It sets out the circumstances where a mark that resembles, or are apparently intended to resemble or pass for, an official mark specified in Division 1 of Part 2 of Chapter 8 of the Milk Rules (a *resemblance*) may be treated as an official mark, and who may apply a resemblance. A resemblance relates to milk or milk products that are intended for export.

The note following section 8-25 alerts the reader to section 258 of the Act, which provides that a person may commit an offence or be liable to a civil penalty if the person contravenes a provision in Division 3 of Part 2 of Chapter 8 of the Milk Rules.

8-26 Circumstances in which a mark resembles an official mark

Section 8-26 details circumstances in which a mark resembles an official mark. A mark will be considered to resemble an official mark set out in Division 1 of Part 2 of Chapter 8 of the Milk Rules (i.e. be a resemblance) if it is the same design as the official mark in all but its dimensions.

8-27 Persons who may apply a resemblance

Section 8-27 details who may apply a resemblance to milk or milk product, or to any thing containing milk or milk products.

This is limited to a person who is designated in an approved arrangement as a person who may apply the resemblance to milk or milk products or the thing containing milk or milk products, and where the application of the resemblance is in accordance with the arrangement.

Division 4—Official marking devices

An official marking device is defined in section 257 of the Act as a device that is capable of being used to apply an official mark but does not include a device prescribed by the Milk Rules.

8-28 Purpose of this Division

Subsection 257(2) of the Act allows the rules to make provision for and in relation to the following:

- the persons, or classes of persons, who may manufacture or possess an official marking device;
- the use of official marking devices;
- security of official marking devices;
- damaged official marking devices;
- destruction of official marking devices;
- making records of official marking devices;
- any other matter relating to official marking devices.

Section 8-28 provides that Division 4 of Part 2 of Chapter 8 of the Milk Rules (sections 8-28 to 8-33) is made for the purpose of subsection 257(2) of the Act. Division 4 makes provision for matters relating to official marking devices that are capable of being used to apply official marks as specified in Division 1 of Part 2 of Chapter 8 of the Milk Rules to milk or milk products that are intended to be exported. These requirements are necessary to ensure the security of official marking devices and preserve the integrity of official marks applied to milk or milk products.

The note following section 8-28 alerts the reader to section 258 of the Act, which has the effect that a person may commit an offence or be liable to a civil penalty if the person contravenes a provision in Division 4 of Part 2 of Chapter 8 of the Milk Rules.

8-29 Persons who may manufacture, supply or possess official marking devices

Section 8-29 specifies who can manufacture, supply or possess official marking devices for applying official marks. These are:

- an authorised officer; or a person acting in accordance with the direction of an authorised officer; or
- a person designated by an approved arrangement as a person who may manufacture, supply or possess an official marking device, and who is acting in accordance with the arrangement; or

• a person who has been given a written approval by the Secretary to manufacture, supply or possess the official marking device, and acts in accordance with the approval.

These restrictions ensure the security of the devices and preserve the integrity of official marks.

The note following subsection 8-29(1) refers the reader to section 309 of the Act, which deals with how directions may be given by authorised officers.

Subsection 8-29(2) has the effect that the requirements in this section do not apply to an 'Australian Government' official mark as provided by section 8-12 of the Milk Rules.

8-30 Security of official marketing devices

Section 8-30 requires a person permitted to possess an official marking device under section 8-29 to store the device securely when it is not being used. This is to avoid unauthorised use of the official marking device.

8-31 Damaged etc. official marking devices

Section 8-31 requires a person (other than an authorised officer) in possession of an official marking device who becomes aware the device is damaged or destroyed, worn or otherwise unfit for applying an official mark to milk or milk products, to notify an authorised officer in writing as soon as practicable after becoming aware of that fact.

The person must then retain the official marking device in secure place until otherwise directed by an authorised officer. This is to ensure the ability to manufacture official marks is not compromised in any way.

8-32 Records of official marking devices manufactured or supplied

Section 8-32 requires a person (other than an authorised officer) permitted under section 8-29 of the Milk Rules to manufacture or supply official marking devices for use at establishments that are registered for operations to prepare milk or milk products for export to make a daily written record stating:

- each kind of official marking device manufactured by the person on that day; and
- the number of each kind of official marking device manufactured by the person on that day; and
- the serial number of each official marking device manufactured by the person on that day.

A written record must also be made stating each day official marking devices were supplied by the person to establishments that are registered for operations to prepare prescribed milk or milk products for export and how they were transported on each day. The records provide evidence the manufacturer of official marking devices is satisfying regulatory requirements.

The note following section 8-32 explains that under section 11-9 of the Milk Rules, the person who is required to make a record under section 8-32 must retain each record for 3 years.

8-33 Records of official marking devices received, used, damaged, destroyed or returned

Section 8-33 requires the occupier of a registered establishment for operations to prepare milk or milk products for export to make a written record of the official marking devices that have been:

- received at the establishment;
- used to apply official marks to milk or milk products at the establishment;
- damaged or destroyed at the establishment; or
- returned from the establishment.

The note following section 8-33 explains that under subsection 11-7(2) of the Milk Rules, the occupier of the registered establishment must retain each record for 3 years.

CHAPTER 9—POWERS AND OFFICIALS

Part 1—Audits

Part 1 of Chapter 9 of the Milk Rules deals with matters relating to audits of export operations relating to milk or milk products.

Audits help retain wide access to overseas export markets by ensuring compliance with export requirements and importing country requirements. Under sections 266 and 267 of the Act, the Secretary may require an audit to be conducted of export operations carried out in certain circumstances, or in relation to the performance of functions under the Act. An audit under section 266 may be conducted by an authorised officer or an approved auditor, while an audit under section 267 may be conducted by a Commonwealth authorised officer or a person prescribed by the rules made for the purposes of subsection 267(3).

Division 1—General

9-1 References to audit in this Part

Section 9-1 provides that a reference in Part 1 of Chapter 9 of the Milk Rules to an audit is a reference to the following audits under Part 1 of Chapter 9 of the Act:

- an audit of export operations carried out in relation to milk and milk products; or
- an audit in relation to the performance by certain persons of their functions or the exercise of their powers under the Act in relation to milk or milk products. These persons are third party authorised officers, approved auditors and any other person (other than a Commonwealth authorised officer or a State or Territory authorised officer) who performs functions or exercises powers under the Act; or
- an audit in relation to compliance by a third party authorised officer, approved auditor
 or approved assessor of any conditions they are subject to when performing their
 functions and exercising their powers in relation to milk or milk products. Such
 conditions could be contained in their instruments of authorisations to be, for
 example, an approved auditor.

9-2 Audits of export operations

Subsection 266(2) of the Act sets out the matters to which an audit of export operations must relate. Paragraph 266(2)(f) allows the rules to prescribe any other matter relating to the operation of the Act prescribed by the rules.

Section 9-2 prescribes, for the purposes of paragraph 266(2)(f) of the Act, that an audit may be carried out in relation to whether the conditions of an exemption, under Part 2 of Chapter 2 of the Act, in relation to export operations carried out in relation to prescribed milk or milk products are being, have been, or are likely to be complied with. This means that an audit under subsection 266(1) of the Act may relate to such matters.

Division 2—Conduct of audit etc.

9-3 Purpose of this Division

Section 270 of the Act sets out matters relating to the conduct of audits under the Act. Subsection 270(4) of the Act allows the rules to make provision for and in relation to other matters relating to the conduct of audits, and the processes to be followed after an audit has been completed. Subsection 270(5) provides a non-exhaustive list of matters for which the rules may make provision for under subsection 270(4).

Section 9-3 provides that Division 2 of Part 1 of Chapter 9 of the Milk Rules (sections 9-3 to 9-6) is made for the purposes of subsections 270(4) and (5) of the Act and provides for and in relation to matters relating to the conduct of an audit, processes for dealing with non-compliance relating to audit requirements and audit reports.

Audits verify requirements are being met and export conditions are being complied with on an ongoing basis. This provides assurance to trading partners that import requirements are being met.

9-4 Manner in which audit must be conducted

Section 9-4 requires an audit to be conducted as expeditiously as reasonably practicable and in a way that results in minimal interference to the export operations, or performance of functions or the exercise of powers under the Act, to which the audit relates. This minimises the impact on industry, while still ensuring compliance with requirements is being verified.

The note following section 9-4 explains that under subsection 270(1) of the Act, the Secretary is not required to give notice of an audit.

9-5 Notice of non-compliance with requirements

Section 9-5 specifies what an auditor must do when, in the auditor's opinion following an audit of export operations under subsection 266(1) of the Act, there is or has been, a failure (or a combination of failures) that amount to non-compliance with a requirement to which the audit relates.

Subsection 9-5(1) requires that, in such circumstances, the auditor must provide written notification of the auditor's opinion. The notification must be given to the relevant person for the audit as soon as practicable after the audit is completed. The auditor must also assess whether the failure (or combination of failures) is a critical non-compliance. The relevant person for each type of audit of export operations is defined in section 269 of the Act.

Providing notice of non-compliance failures as soon as the audit is completed gives transparency in the process and enables remedial action to be undertaken to minimise potential impact on export operations.

The first note following subsection 9-5(1) clarifies that under section 12 of the Act, an *auditor* is an authorised officer or an approved auditor (as defined in section 12 of the Act).

The second note following subsection 9-5(1) refers the reader to section 269 of the Act for who is the *relevant person* for an audit.

Subsection 9-5(2) requires the auditor to notify the Secretary in writing as soon as practicable after forming an opinion that a failure, or combination of failures, is a critical non-compliance. It is necessary that the Secretary is aware of the critical non-compliance and can take the necessary action to minimise impacts on Australia's trading reputation.

Subsection 9-5(3) requires the auditor to also give notification as soon as practicable in writing if notification is given orally to the Secretary under subsection 9-5(2).

Subsection 9-5(4) specifies the failures which are *critical non-compliance* failures, for the purposes of sections 9-5 and 9-6 (audit reports). These are a failure (or combination of failures) that:

- results in, or is likely to result in the export or preparation for export of milk or milk products as food where the integrity of the goods cannot be ensured; or
- results in, or is likely to result in, the export, or the preparation for export of milk or milk products as food that are not fit for human consumption, not traceable, cannot be recalled if required, or do not meet an importing country requirement; or
- results in, or is likely to result in, the issuing of an export permit or a government certificate in relation to prescribed milk or milk products for which there are no reasonable grounds; or
- prevents, or is likely to prevent an accurate assessment of whether the integrity of the milk or milk products can be ensured; or
- prevents, or is likely to prevent an accurate assessment of whether the milk or milk products are fit for human consumption, traceable, can be recalled if required, or meet an importing country requirement; or
- prevents, or is likely to prevent an accurate assessment of whether there are, or will be, reasonable grounds for issuing an export permit for the prescribed milk or milk products, or a government certificate in relation to the prescribed milk or milk products.

These failures may have considerable impact on Australia's trading reputation and may result in impacts on other persons or businesses through action by importing country authorities. It is therefore critical that these non-compliance failures are reported to the Secretary immediately, so necessary corrective action can be implemented to mitigate consequences.

9-6 Audit reports

Section 9-6 sets out the requirements relating to audit reports, including how audit reports are to be provided, what they must entail and what they may also include. Audits verify relevant requirements are being met and conditions are being complied with on an ongoing basis. Audits provide assurance to trading partners that their import requirements are being met.

The audit report provides sufficient information is provided to enable an assessment of compliance with requirements.

Subsection 9-6(1) requires a completed audit report to be made in writing after the audit is completed or ends.

The note following section 9-6(1) refers the reader to the definition of *auditor* in section 12 of the Act. An *auditor* is an authorised officer or an approved auditor.

Subsection 9-6(2) specifies that an audit report must include the name of the auditor, the day the audit commenced, the day the audit was completed or ended, the total time spent conducting the audit (in hours), the names of the persons present at the entry and exit meetings for the audit, a description of the export operations or persons performing functions or exercising powers under the Act to which the audit relates, and a description of the nature and scope of the audit.

Subsection 9-6(3) requires the audit report to also contain the auditor's opinion regarding whether the audit was satisfactorily completed or whether the audit was ended before it could be satisfactorily completed, whether the requirements to which the audit relates are being, or have been, complied with, and the reasons for the auditor's opinion on these matters.

Subsection 9-6(4) requires all instances of non-compliance with the requirements to which the audit relates to be also included in the audit report. The report must describe each instance of non-compliance, including whether, in the auditor's opinion, the failure (either by itself or in combination with other failures) amounts to a critical non-compliance or has contributed to critical non-compliance. The report must include the reasons for the auditor's opinion on these matters.

Subsection 9-6(5) specifies that the audit report may also include recommendations for actions to be taken to address issues of non-compliance, to ensure that non-compliance does not recur, and to assess the effectiveness of such actions.

Subsection 9-6(6) requires the audit report to be given to the Secretary (in the approved manner) and to the relevant person for the audit within 14 business days after the audit is completed or ends.

The note following subsection 9-6(6) refers the reader to section 269 of the Act for who is the *relevant person* for an audit.

Division 3—Approved auditors

An approved auditor is a person approved by the Secretary under section 273 of the Act to carry out regulatory audits of export operations, including of registered establishments engaged in the preparation or storage and loading of products for export as food. Approved auditors can be engaged by the occupier of a registered establishment to conduct audits for compliance with legislative and importing country requirements and provide audit reports to the Secretary. The Secretary may, in writing, approve a person, or each person in a specified class of persons, to conduct audits under Part 1 of Chapter 9 of the Act.

9-7 Purpose of this Division

Subsection 273(1) of the Act allows the Secretary to approve a person, or each person in a specified class of persons, to conduct audits under Part 1 of Chapter 9 of the Act (approved auditors).

Subsection 273(6) of the Act allows the rules to make provision for and in relation to matters relating to the approval of persons, under subsection 273(1), as approved auditors. Subsection 273(7) provides a non-exhaustive list of examples of matters that may be the subject of rules made under subsection 273(6).

Section 9-7 provides that Division 3 of Part 1 of Chapter 9 of the Milk Rules (sections 9-7 to 9-17) is made for the purpose of subsections 273(6) and (7) of the Act and makes provision for and in relation to matters regarding the approval of individuals to conduct audits.

9-8 Application for approval

Section 9-8 relates to application requirements for an individual to become an approved auditor.

Subsection 9-8(1) provides that an individual may apply to the Secretary for approval, under subsection 273(1) of the Act to conduct audits.

Subsection 9-8(2) requires an application to be in a manner and form approved by the Secretary (if any). The application must also be accompanied by written evidence of the applicant's qualifications, a document detailing the applicant's audit experience, a document setting out procedures for the conduct of audits by the applicant and, if an application fee is prescribed by the *Export Control (Fees and Payments) Rules 2021*, that fee. This information and documentation will assist the Secretary in considering the application.

Subsection 9-8(3) provides that an application that does not comply with the requirements of subsection 9-8(2) is taken not to have been made. This means the application will not be considered unless and until all requirements are met.

The requirements for application for approval ensures the Secretary is provided with all relevant matters in considering whether applicants are suitably qualified and have the necessary skills to conduct audits into export operations.

9-9 Secretary must decide whether to approve applicant to conduct audits

Subsection 9-9(1) specifies that once a complete application from a person seeking approval to be an auditor is received, the Secretary must either approve or refuse to approve the applicant to conduct audits.

The note following subsection 9-9(1) explains that a decision to refuse the application is a reviewable decision under the Act (with reference to section 11-1 of the Milk Rules) and the Secretary must give the applicant written notice of the decision in accordance with section 382 of the Act.

Subsection 9-9(2) provides matters the Secretary must consider in approving an applicant to conduct audits. The Secretary must have regard to any matter the Secretary considers relevant, and must be satisfied that the applicant:

- is a 'fit and proper person' (having regard to the matters referred to in section 372 of the Act);
- has the necessary competency (for example, the knowledge, training, skills or experience) to conduct audits;
- is able to conduct audits objectively, independently, fairly and accurately;
- will comply with the requirements in Division 2 of Part 1 of Chapter 9 of the Milk Rules on the conduct of the audit (which deal with non-compliance and audit reports); and
- will comply with procedures to ensure that these requirements are met and can be accurately assessed.

Subsection 9-9(3) provides that the Secretary may, for the purposes of assessing whether audits will be conducted objectively, independently, fairly and accurately, consider any interests, pecuniary or otherwise, of the applicant that conflict or could conflict with the conduct of an audit by the applicant.

Subsection 9-9(4) sets out when the Secretary may refuse to approve an applicant to conduct audits. These include where the applicant has a relevant Commonwealth liability that has not been paid, or has made a false, misleading or incomplete statement, or provided false, misleading or incomplete information or documents in an application, or in a document under the Act or under a prescribed agriculture law, with no reasonable grounds for doing so.

Prescribed agriculture law has the same meaning as it does in section 12 of the Act.

The note following subsection 9-9(4) explains that the Secretary must not approve a person to conduct audits unless satisfied the person satisfies, or will satisfy, certain training and qualification requirements determined by the Secretary under subsections 273(3) and (4) of the Act.

9-10 Dealing with applications

Section 9-10 provides that the Secretary may request an applicant to provide further specified information or documents relevant to the application for the purpose of the Secretary making a decision on that application under section 9-8. The request must be in writing, must specify the timeframe in which to comply and must specify the manner in which the request is to be complied with.

This ensures that the Secretary can efficiently decide an application based on all relevant information or documents.

9-11 Conditions of approval

Subsection 9-11(1) specifies that the approval of an applicant under subsection 273(1) of the Act to conduct audits may be subject to any conditions the Secretary considers necessary.

The note following subsection 9-11(1) explains that a decision to approve the application subject to conditions is a reviewable decision under the Act (referring to section 11-1 of the Milk Rules) and the Secretary must give the applicant written notice of the decision in accordance with section 382 of the Act.

Subsection 9-11(2) provides that, without limiting subsection 9-11(1), the conditions of an approval to conduct an audit may relate to the scope of audits the auditor is approved to conduct (including by reference to the kind of export operations), aspects of the export operations (such as whether the operations comply with the requirements of the Act, are being carried out in accordance with an approved arrangement, or meet importing country requirements), or a kind of export operations carried out at a kind of establishment (for example, a registered establishment).

This provides the Secretary with the flexibility to specify the kinds of audits an approved auditor can undertake. It allows the Secretary to limit or broaden the scope of an approved auditor's functions and powers, in line with their experience, qualifications, the kind of audit and the requirements for export operation.

9-12 Notice of decision

Section 9-12 requires the Secretary to provide the applicant with a written notice of approval to conduct audits if the Secretary approves the applicant under subsection 273(1) of the Act. The notification must include that the applicant is approved to conduct audits, the scope of the audits covered, the date the approval takes effect, that it remains in force for 12 months unless revoked earlier under section 9-15 of the Milk Rules, and any conditions of the approval imposed under section 9-11 of the Milk Rules.

9-13 Period of effect of approval

Section 9-13 specifies that an approval of an individual under subsection 273(1) of the Act to conduct audits takes effect on the date stated in the notice given under section 9-12 of the Milk Rules and remains in force for 12 months unless revoked earlier under section 9-15 of the Milk Rules. This means that approved auditors maintain the currency of their qualifications to conduct audits.

9-14 Imposing or varying conditions of approval

Subsection 9-14(1) provides that, if an individual is approved under subsection 273(1) of the Act to conduct audits, the Secretary may, if they consider it necessary to do so, impose conditions on the approval or vary the conditions of an approval (including by imposing new conditions or removing conditions). A variation of conditions may include removing conditions or imposing new conditions.

The note following subsection 9-14(1) explains that a decision to impose conditions on, or vary the conditions of, an approval to conduct audits is a reviewable decision under the Act (referring to section 11-1 of the Milk Rules) and the Secretary must give the applicant holder of the approval written notice of the decision in accordance with section 382 of the Act.

Subsection 9-14(2) provides that, if the Secretary imposes conditions on, or varies the conditions of an approval, the Secretary must notify the individual, in writing, of the conditions imposed or the varied conditions (including any new conditions), the reasons for imposing or varying the conditions, and the date that the conditions or varied conditions take effect.

This ensures that the process is transparent and accountable, and provides the individual with adequate information about the decision to vary conditions of approval.

9-15 Revocation of approval

Sections 9-15 sets out the requirements for revoking an approval, granted under section 273 of the Act, of an individual to conduct audits.

Subsection 9-15(1) provides that the Secretary can revoke an approval of an individual to conduct audits where the individual requests the revocation or, where the Secretary is satisfied of any of the grounds listed.

The grounds for the Secretary to revoke an approval on their own initiative is that the Secretary is satisfied of any of the following:

- the individual is no longer a fit and proper person (having regard to section 372 of the Act);
- the individual does not have the necessary competency (for example, the knowledge, training, skills or experience) to conduct audits of the kind covered by the approval (including the conditions of the approval);
- the individual failed to show competency in conducting audits;
- an audit conducted by the individual, or an audit report given to the Secretary by the individual, was not objective, independent, fair or accurate;
- an audit conducted by the individual was not completed, and the audit report did not give any reasonable explanation why the audit was not completed;
- an audit report given to the Secretary by the individual was incomplete;
- the individual failed to comply with a relevant requirement prescribed by Division 2 of Part 1 of Chapter 9 of the Act;
- the individual contravened a condition of the approval;

 the individual made a false, misleading or incomplete statement, or provided false, misleading or incomplete information or documents, in an application for approval, or in a document under the Act or under a prescribed agriculture law, with no reasonable grounds for doing so.

The note following subsection 9-15(1) explains that a decision to revoke the approval is a reviewable decision under the Act (referring to section 11-1 of the Milk Rules) and the Secretary must give the holder of the approval written notice of the decision in accordance with section 382 of the Act.

The purpose of including these reasons for revoking approval to conduct audits is to ensure the integrity of the audit process, the necessary knowledge, training, skills and experience are maintained and that audits conducted are objective, independent and are fair and accurate.

Subsection 9-15(2) allows the Secretary to assess the competency of an approved auditor at any time and in any way the Secretary considers appropriate

Subsection 9-15(3) allows the Secretary, when considering revoking approval in circumstances where an audit failed to be objective, independent, fair or accurate, to consider any interests, pecuniary or otherwise of the individual that conflict or could conflict with the conduct of an audit by the individual.

Subsection 9-15(4) requires the Secretary, if they decide to revoke an individual's approval to conduct audits, to give to the individual a written notice stating the approval is to be revoked, the reasons for the revocation and the date the revocation takes effect. This ensures that the process is transparent and accountable and provides the individual with adequate information about the decision. Subsection 9-15(4) does not apply if the individual requests the revocation.

9-16 Register of approved auditors

Section 9-16 provides that the Secretary must keep a register of individuals who are approved under subsection 273(1) of the Act to conduct audits. The register may be kept by electronic means, may be kept at a place and in a form that the Secretary determines and must be publicly accessible. The register must include the names of the individuals approved under subsection 273(1) of the Act and any conditions on their approval to undertake audits.

The purpose of this provision is to ensure transparency and accountability in relation to individuals the Secretary approves to undertake audits. It also ensures that information about all approved auditors is publicly available so that anyone being audited can identify and verify these auditors and the conditions under which they operate. This is necessary as approved auditors perform functions and exercise powers under the Act.

9-17 Fit and proper person test

Subsection 372(1) of the Act sets out which provisions in the Act require the Secretary to comply with the requirements of section 372 of the Act when determining whether a person is a fit and proper person. Paragraph 372(1)(d) of the Act allows the rules to provide additional provisions of the Act for which the requirements in section 372 will apply (which includes instruments made under the Act, such as provisions of the Milk Rules).

Subsection 9-17(1) prescribes, for the purposes of paragraph 372(1)(d) of the Act, the provisions of the Milk Rules to which the fit and proper person test will apply. These are:

- section 9-9, relating to a decision to approve an individual to conduct audits; and
- section 9-15, relating to a decision to revoke an approval of an individual to conduct audits.

Paragraph 372(2)(e) of the Act requires the Secretary to have regard to whether certain applications by a person, or an associate of the person has been refused, when determining whether the person is a fit and proper person. Subparagraph 372(2)(e)(v) allows the rules to prescribe any other provision of the Act to be considered for this purpose.

Subsection 9-17(2) prescribes section 9-8 of the Milk Rules (application by an individual to conduct audits) for the purpose of paragraph 372(2)(e)(v) of the Act. This has the effect that when determining whether a person is a fit and proper person, the Secretary must consider whether an application under section 9-8 of the Milk Rules made by the person or an associate of the person was refused. It is important the Secretary consider the matter to determine whether an applicant is a fit and proper person.

Paragraph 372(4)(b) of the Act allows the rules to prescribe a person to whom the requirements under subsection 372(2) of the Act, which determine whether a person is a fit and proper person, will apply without reference to an associate of the person.

Subsection 9-17(3) prescribes an approved auditor for the purpose of paragraph 372(4)(b) of the Act. This means the requirements to determine whether an auditor is a fit and proper person under subsection 372(2) of the Act refer only to the auditor and not to an associate of the auditor

Section 374 of the Act relates to the notification that a person has been convicted of an offence or ordered to pay a pecuniary penalty. Paragraph 374(1)(g) provides that section 374 applies to any other person prescribed by the rules, and who carries out export operations, or performs functions or duties or exercises powers under the Act.

Subsection 9-17(4) prescribes, for the purposes of paragraph 374(1)(g) of the Act, an approved auditor. This has the effect that an approved auditor is required to notify of any conviction of offence or order to pay a pecuniary penalty for a contravention involving fraud or dishonesty in accordance with subsection 374(4) of the Act, or in relation to an associate of the person under subsection 374(5) of the Act. Failure to do so is a contravention of a civil penalty provision under subsection 374(6) of the Act.

Prescribing these provisions for the fit and proper person test is necessary to ensure that a prospective auditor is of a suitable character to conduct audits. Audits are necessary to establish whether export operations comply with the Act and the requirements of importing countries. Audits also involve access to business premises where commercially sensitive operations are conducted. It is essential that approved auditors are trustworthy and undertake audits with integrity. For these reasons, the fit and proper test applies when deciding whether to approve an individual to conduct audits and when deciding whether to revoke an approval to conduct audits.

Part 2—Assessment

An assessment of goods may be carried out under Part 2 of Chapter 9 of the Act if the assessment is required or permitted to be carried out under the Act and the Milk Rules (section 277 of the Act). This includes an assessment for the purpose of deciding whether to issue a government certificate (paragraph 68(c) of the Act) or export permit (paragraph 241(c) of the Act). The purpose of the assessment is to verify that:

- the requirements of the Act have been, or will be, complied with before the goods are imported into the importing country;
- importing country requirements have been, or will be, met before the goods are imported into the importing country; or
- a matter stated, or to be stated, in a government certificate in relation to the goods is true and correct.

Division 1—General

9-18 References to assessment in this Part

Section 9-18 provides that a reference in Part 2 of Chapter 9 of the Milk Rules to an assessment is a reference to an assessment of milk or milk products under Part 2 of Chapter 9 of the Act.

Division 2—Carrying out assessments etc

9-19 Circumstances in which assessment may be required or permitted

Subsection 277(2) of the Act provides that the rules may prescribe circumstances in which the Secretary may require or permit an assessment of goods to be carried out.

Section 9-19 is made for the purposes of subsection 277(2) of the Act and provides the Secretary may require or permit an assessment of prescribed milk or milk products to be carried out at any stage of operations to prepare the prescribed milk or milk products for export.

This provides the Secretary with flexibility to determine when it is necessary for an assessment of prescribed milk or milk products to be carried out. This reflects the possibility that the circumstances requiring an assessment are likely to change from time to time and may need to commence at short notice.

9-20 Process to be followed after assessment completed

Subsection 279 of the Act provides that the rules may make provision for the process to be followed after an assessment has been completed.

Section 9-20 is made for the purposes of subsection 279 of the Act and provides that the process to be followed after the completion of an assessment carried out under section 9-19 of the Milk Rules or under paragraph 241(c) of the Act for the purpose of making a decision in relation to an application for an export permit or to vary a permit (including the conditions) for prescribed milk or milk products.

Subsection 9-20(2) requires that the assessor give a written notice to the Secretary and the relevant person for the assessment stating whether the assessor reasonably believes that the requirements of the Act have been, or will be, complied with and whether the assessor reasonably believes that the importing country requirements have been, or will be met, before the milk or milk products are imported into the relevant importing country. Subsection 9-20(3) requires this notice to be signed and dated by the assessor.

The first note following subsection 9-20(2) refers the reader to section 12 of the Act for the definition of *assessor*, which is an approved assessor or authorised officer.

The second note following subsection 9-20(2) refers the reader to section 278 of the Act for the *relevant person* for an assessment, which is the applicant, holder of a government certificate, holder of an export permit, or person who gave a notice of intention to export.

Subsection 9-20(3) provides that the notice given by an assessor under subsection 9-20(2) must be signed and dated by the assessor.

The note following subsection 9-20(3) alerts the reader that a person may commit an offence or be liable for a civil penalty liability for providing false or misleading documents. The reader is directed to sections 137.1 and 137.2 of the *Criminal Code* and sections 368 and 369 of the Act.

Division 3—Approved assessors

9-21 Purpose of this Division

Subsection 281(1) of the Act allows the Secretary to approve a person, or each person in a specified class of persons, to carry out assessments of goods under Part 1 of Chapter 9 of the Act (approved assessors).

Subsection 281(6) of the Act allows the rules to make provision for and in relation to matters relating to the approval of persons, under subsection 281(1), as approved auditors. Subsection 281(7) provides for a non-exhaustive list of matters the rules may make provision for, without limiting subsection 281(6). These matters include applications for approval, dealing with applications, additional requirements to be met, matters to which the Secretary may or must have regard in considering applications, conditions and period of effect of approvals, assessment of the competency of applicants and suspension and revocation of approvals.

Section 9-21 provides that Division 3 of Part 2 of Chapter 9 of the Milk Rules (sections 9-21 to 9-31) is made for the purposes of subsections 281(6) and (7) of the Act, and makes provision for and in relation to matters relating to the approval of individuals to carry out assessments.

9-22 Application for approval

Section 9-22 relates to application requirements for an individual to become an approved assessor.

Subsection 9-22(1) provides that an individual may apply to the Secretary for approval under subsection 281(1) of the Act to carry out assessments.

Subsection 9-22(2) requires an application to be made in a manner and form approved by the Secretary (if any). The application must also include written evidence of the applicant's qualifications, a document detailing the applicant's assessment experience, a document setting out the procedures for the conduct of assessments, and, if an application fee is prescribed by the *Export Control (Fees and Payments) Rules 2021*, that fee. This information and documentation will assist the Secretary in considering the application.

Subsection 9-22(3) provides that if the application does not meet the requirements of subsection 9-22(2), the application is taken not to have been made. This means the application will not be considered unless and until all requirements are met.

The requirements for applications for approval ensures the Secretary is provided with all relevant matters in considering whether to approve a person, or each person in a specified class of persons, to carry out assessments of goods.

9-23 Secretary must decide whether to approve applicant to carry out assessments

Subsection 9-23(1) specifies that once a complete application from a person seeking approval to be an assessor is received, the Secretary must decide to either approve or refuse to approve the applicant to carry out assessments.

The note following subsection 9-23(1) explains that a decision to refuse the application is a reviewable decision under the Act (with reference to section 11-1 of the Milk Rules) and the Secretary must give the applicant written notice of the decision in accordance with section 382 of the Act.

Subsection 9-23(2) provides matters the Secretary must consider in approving an applicant to carry out assessments. The Secretary must have regard to any matter they consider is relevant, and must be satisfied that the applicant:

- is a 'fit and proper person' (under section 372 of the Act);
- has the necessary competency (for example, the knowledge, training, skills or experience) to carry out assessments;
- be able to carry out assessments objectively, independently, fairly and accurately.
- will comply with the requirements in Division 2 of Part 2 of Chapter 9 of the Milk Rules on the carrying out of the assessment; and
- will comply with procedures to ensure that these requirements are met and can be accurately assessed.

Subsection 9-23(3) allows the Secretary to consider, for the purposes of assessing whether audits will be conducted objectively, independently, fairly and accurately, any interests, pecuniary or otherwise, of the applicant that conflict or could conflict with the conduct of an assessment.

Subsection 9-23(4) sets out when the Secretary may refuse to approve an applicant to carry out assessments. These include where the applicant has:

- a relevant Commonwealth liability that has not been paid; or
- has made a false, misleading or incomplete statement or provided false, misleading or incomplete information, or documents in an application, or in aa document, under the Act or under a prescribed agriculture law, with no reasonable grounds for doing so.

Prescribed agriculture law has the same meaning as it does in section 12 of the Act.

The note following subsection 9-23(4) explains that, under the Act, the Secretary must not approve a person to conduct audits unless satisfied the person satisfies, or will satisfy, certain training and qualification requirements determined by the Secretary and directs the reader to subsections 281(3) and (4) of the Act.

9-24 Dealing with applications

Section 9-24 provides that the Secretary may request an applicant to provide further specified information or documents relevant to the application for the purpose of the Secretary making a decision on that application under section 9-22. The request must be in writing, specify the timeframe in which to comply and the manner in which the request is to be complied with.

This ensures that the Secretary can efficiently decide an application based on all relevant information or documents.

9-25 Conditions of approval

Subsection 9-25(1) specifies that the approval, under subsection 281(1) of the Act, of an applicant to carry out assessments may be subject to any conditions the Secretary considers necessary.

The note following subsection 9-25(1) explains that a decision to approve the application subject to conditions is a reviewable decision under the Act (referring to section 11-1 of the Milk Rules) and the Secretary must give the applicant written notice of the decision in accordance with section 382 of the Act.

Subsection 9-25(2) provides that, without limiting subsection 9-25(1), the conditions of an approval to conduct an assessment may relate to the scope of assessments the assessor is approved to carry out, including by reference to the kind of export operations, aspects of the export operations (such as whether the operations are being carried out in accordance with an approved arrangement) or a kind of export operations carried out at a kind of establishment (for example a registered establishment).

This provides the Secretary with the flexibility to specify the kinds of assessments an approved assessor can undertake. It allows the Secretary to limit or broaden the scope of an approved assessor's functions and powers, in line with their experience and qualifications and the kind of assessment and requirements for export operations.

9-26 Notice of decision

Section 9-26 requires the Secretary to provide the applicant with a written notice of approval if the Secretary approves the applicant under subsection 281(1) of the Act to carry out assessments. The notification must include that the applicant is approved to carry out assessments of milk or milk products under Part 2 of Chapter 9 of the Act, the scope of the assessments covered, the date the approval takes effect, that it remains in force for 12 months unless revoked earlier under section 9-29 of the Milk Rules, and any conditions of the approval imposed under section 9-25 of the Milk Rules.

9-27 Period of effect of approval

Section 9-27 specifies that an approval of an individual to carry out assessments under subsection 281(1) of the Act takes effect on the day stated in the notice under section 9-26 of the Milk Rules and remains in force for 12 months unless revoked earlier under section 9-29 of the Milk Rules. This ensures approved assessors maintain the currency of their qualifications to carry out assessments.

9-28 Imposing or varying conditions of approval

Subsection 9-28(1) provides that, if an individual is approved under subsection 281(1) of the Act to carry out assessments, the Secretary may, if they consider it necessary to do so, impose conditions on an approval or vary the conditions of an approval (including by imposing new conditions or removing conditions).

The note following subsection 9-28(1) explains that a decision to impose conditions on or vary the conditions of an approval is a reviewable decision under the Act (referring to section 11-1 of the Milk Rules) and the Secretary must give the holder of the approval written notice of the decision in accordance with section 382 of the Act.

Subsection 9-28(2) provides that, if the Secretary imposes conditions on, or varies the conditions of an individual's approval, the Secretary must notify the individual, in writing, of the conditions imposed or the varied conditions (including any new conditions), the reasons for imposing or varying the conditions and the date that the conditions or the varied conditions take effect.

This ensures that the process is transparent and accountable and provides the individual with adequate information about the decision to vary conditions of approval.

9-29 Revocation of approval

Section 9-29 sets out the requirements for revoking an approval, granted under section 281 of the Act, of an individual to carry out assessments.

Subsection 9-29(1) provides that the Secretary can revoke an approval of an individual to carry out assessments where the individual requests the revocation or, where the Secretary is satisfied of any of the grounds listed.

The grounds for the Secretary to revoke an approval on their own initiative is that the Secretary is satisfied of any of the following:

- the individual is no longer a fit and proper person (having regard to section 372 of the Act);
- the individual does not have the necessary competency (for example, the knowledge, training, skills or experience) to carry out assessments of the kind covered by the approval;
- the individual failed to show competency in carrying out assessments;
- an assessment carried out by the individual was not objective, independent, fair or accurate;
- the individual did not complete an assessment and did not give any reasonable explanation why it was not completed;
- the individual failed to comply with a relevant requirement prescribed by Division 2 of Part 2 of Chapter 9 of the Act;
- the individual contravened a condition of the approval;
- the individual made a false, misleading or incomplete statement, or provided false, misleading or incomplete information or documents, in an application for approval, or in a document under the Act or under a prescribed agriculture law, with no reasonable grounds for doing so.

The note following subsection 9-29(1) explains that a decision to revoke the approval is a reviewable decision under the Act (referring to section 11-1 of the Milk Rules) and the Secretary must give the holder of the approval written notice of the decision in accordance with section 382 of the Act.

The purpose of including these grounds for revoking approval to carry out assessments is to ensure the integrity of the assessment process, the necessary knowledge, training, skills and experience are maintained and that assessments carried out are objective, independent and are fair and accurate.

Subsection 9-29(2) allows the Secretary to assess the competency of an approved assessor for the purposes of subsection 9-29(1), at any time and in any way the Secretary considers appropriate.

Subsection 9-29(3) provides that the Secretary may consider any interests, pecuniary or otherwise, of the individual that conflict, or could conflict with carrying out of an assessment by the individual.

Subsection 9-29(4) requires the Secretary, if they decide to revoke an individual's approval to carry out assessments, to give to the individual a written notice stating the approval is to be revoked, the reasons for the revocation and the date the revocation takes effect. This ensures that the process is transparent and accountable and provides the individual with adequate information about the decision. Subsection 9-29(4) does not apply if the individual requests the revocation.

9-30 Register of approved assessors

Section 9-30 provides that the Secretary must keep a register of approved assessors. The register may be kept by electronic means, may be kept at a place and in a form that the Secretary determines, and must be publicly accessible. The register must include the names of the individuals approved (under subsection 281(1) of the Act to carry out assessments) and any conditions on their approval to undertake assessments. The intention is that the register will be available on the Department website (www.awe.gov.au).

The purpose of this provision is to ensure transparency and accountability in relation to individuals the Secretary approves to undertake assessments. It also ensures that all approved assessors are publicly available so that anyone being assessed can identify and verify these assessors and the conditions under which they operate. This is necessary as approved assessors perform functions and exercise powers under the Act.

9-31 Fit and proper person test

Subsection 372(1) of the Act sets out which provisions in the Act require the Secretary to comply with the requirements of section 372 when determining whether a person is a fit and proper person. Paragraph 372(1)(d) allows the rules to provide additional provisions of the Act for which the requirements in section 372 will apply (which includes instruments made under the Act, such as provisions of the Milk Rules).

Subsection 9-31(1) prescribes, for the purposes of paragraph 372(1)(d) of the Act, the provisions of the Milk Rules to which the fit and proper person test will apply. These are:

- section 9-23, relating to a decision to approve an individual to carry out assessments;
- section 9-29, relating to a decision to revoke an approval of an individual to carry out assessments.

Paragraph 372(2)(e) of the Act requires the Secretary to have regard to whether certain applications by a person, or an associate of the person has been refused, when determining whether the person is a fit and proper person. Subparagraph 372(2)(e)(v) allows the rules to prescribe any other provision of the Act to be considered for this purpose.

Subsection 9-31(2) prescribes section 9-22 of the Milk Rules (application by an individual to carry out assessments) for the purpose of paragraph 372(2)(e)(v) of the Act. This has the effect that when determining whether a person is a fit and proper person, the Secretary must consider whether an application under section 9-22 of the Milk Rules made by the person or an associate of the person was refused. It is important the Secretary consider the matter to determine whether an applicant is a fit and proper person.

Paragraph 372(4)(b) of the Act allows the rules to prescribe a person to whom the requirements under subsection 372(2) of the Act, which determine whether a person is a fit and proper person, will apply without reference to an associate of the person.

Subsection 9-31(3) prescribes an approved assessor for the purpose of paragraph 372(4)(b) of the Act. This means the requirements to determine whether an assessor is a fit and proper person under subsection 372(2) of the Act refer only to the assessor and not to an associate of the assessor.

Section 374 of the Act relates to the notification that a person has been convicted of an offence or ordered to pay a pecuniary penalty. Paragraph 374(1)(g) provides that section 374 applies to any other person prescribed by the rules, and who carries out export operations, or performs functions or duties or exercises powers under the Act.

Subsection 9-31(4) prescribes, for the purposes of paragraph 374(1)(g) of the Act, an approved assessor. This has the effect that an approved assessor is required to notify the Secretary of any conviction of offence or order to pay a pecuniary penalty for a contravention involving fraud or dishonesty in accordance with subsection 374(4) of the Act, or in relation to an associate of the person under subsection 374(5) of the Act. Failure to do so is a contravention of a civil penalty provision under subsection 374(6) of the Act.

Prescribing these provisions for the fit and proper person test is necessary to ensure that a prospective assessor is of a suitable character to carry out assessments. Assessments are necessary to establish whether export operations comply with the Act and the requirements of importing countries. Assessment also involve access to business premises where commercially sensitive operations are conducted. It is essential that approved assessors are trustworthy and undertake assessments with integrity. For these reasons, the fit and proper person test applies when deciding whether to approve an individual to carry out assessments and when deciding whether to revoke an approval to carry out assessments.

Part 3—Powers of the Secretary

9-32 Decisions that may be made by operation of computer program

Subsection 286(1) of the Act allows the Secretary to arrange for the use, under the Secretary's control, of computer programs for making certain decisions under the Act. Subsection 286(2) allows the rules to prescribe the kinds of decisions that may be made by the operation of a computer program, the persons or bodies that may use such a computer program, and the conditions of that use.

Subsection 9-32(1) prescribes, for the purposes of paragraph 286(2)(a) of the Act, the following decisions may be made by a computer program (an *authorised computer* program) under an arrangement made under subsection 286(1) of the Act in relation to milk or milk products:

- a decision under paragraph 67(1)(a) of the Act to issue a government certificate; and
- a decision under paragraph 225(1)(a) of the Act to issue an export permit.

Allowing computer programs to make certain decisions will provide administrative efficiency. An advantage of allowing a computer program to issue government certificates and export permits is that decisions are made efficiently, are not limited to being made during business hours, and are more accurate and consistent.

It is appropriate to enable a computer program to issue a government certificate because the decision under paragraph 67(1)(a) of the Act is based on objective criteria and would not require the computer program to weigh up discretionary factors. Only a decision to issue a certificate is prescribed for the purposes of the Milk Rules, and any decision to refuse to issue, including the consideration of any discretionary factors, would be made by a human decision maker.

It is appropriate to enable a computer program to issue an export permit as the decision under paragraph 225(1)(a) is based on objective criteria and does not require the computer program to weight up discretionary factors. Only a decision to issue an export permit is prescribed for the purposes of the Milk Rules and any decision to refuse to issue a permit, including the consideration of any discretionary factors, would be made by a human decision maker.

Under subsection 286(3) of the Act, the Secretary is required to take all reasonable steps to ensure decisions made by a computer program under the arrangement are correct. If the Secretary is satisfied that the decision made by the operation of the computer program is incorrect, the Secretary may make a decision in substitution for that made by the computer program (subsection 286(5)).

Paragraph 286(2)(b) of the Act allows the rules to prescribe the persons or bodies that may use computer programs under an arrangement in subsection 286(1).

Subsection 9-32(2) is made for the purposes of paragraph 286(2)(b) of the Act and details who may use an authorised computer program if the Secretary has given them a unique identifier to access the computer program. These persons are:

- the occupier of a registered establishment where operations to prepare milk or milk products for export are carried out;
- the holder of an approved arrangement for operations to prepare milk or milk products for export at a registered establishment;
- an exporter of milk or milk products;
- a person who provides services to, and is authorised in writing by, the occupier, holder or exporter to use the computer program to make the decision;
- an authorised officer;
- an APS employee in the Department; or
- a person performing services for the Department under a contract.

This ensures access to the computer program is only by those who require access to perform their functions.

Paragraph 286(2)(c) of the Act allows the rules to prescribe the conditions of the use of computer programs under an arrangement in subsection 286(1).

Subsection 9-32(3) is made for the purposes of paragraph 286(2)(c) of the Act and sets the conditions for use of the computer program by the persons listed under subsection 9-32(2). It provides that a person who has access to and uses the authorised computer program must be satisfied on reasonable grounds that the information entered into the computer program is true and correct and is accurately entered. This is to avoid, as far as practicable, incorrect or incomplete information being entered into the computer program which may result in an incorrect decision.

Part 4—Authorised officers

An authorised officer is able to perform a range of export functions on behalf of the Department. Authorised officers play an important role in ensuring the risk free, safe and trusted export of a variety of commodities, which helps maintain Australia's reputation as a trusted exporter of quality goods.

Division 1—Third party authorised officers

9-33 Requirement to be third party authorised officer—fit and proper person etc.

Subsection 291(3) of the Act provides that a person who is not an officer or employee of a Commonwealth body or a State or Territory body may apply to the Secretary to be a third party authorised officer. Subsection 291(7) of the Act allows the Secretary to authorise a person who is not an officer or employee of a Commonwealth body or a State or Territory body to be a third party authorised officer if the requirements of that subsection are met. Paragraph 291(7)(c) allows the rules to prescribe additional requirements that must be met for the Secretary to authorise a person to be a third party authorised officer.

Subsection 9-33(1) is made for the purposes of paragraph 291(7)(c) of the Act and sets out an additional requirement that a person be a fit and proper person (having regard to the matters referred to in section 372 of the Act) to be a third party authorised officer for the purpose of performing functions and exercising powers in relation to prescribed milk or milk products.

Third party authorised officers may have access to business premises where commercially sensitive operations are conducted. It is essential that they are trustworthy and undertake their roles with integrity. For these reasons, an individual is required to be a fit and proper person to be authorised to perform functions and exercise powers in relation to milk or milk products.

Subsection 372(1) of the Act sets out which provisions in the Act require the Secretary to comply with the requirements of section 372 when determining whether a person is a fit and proper person. Paragraph 372(1)(d) allows the rules to provide additional provisions of the Act for which the requirements in section 372 will apply (which includes instruments made under the Act, such as provisions of the Milk Rules).

Subsection 9-33(2) is made for the purposes of paragraph 372(1)(d) of the Act and prescribes subsection 9-33(1) as a provision to which the fit and proper person test applies. This means the fit and proper person requirements in section 372 of the Act apply in relation to a third party authorised officer. This is necessary to ensure that a prospective third party authorised officer is of a suitable character to perform functions or exercise powers under the Act.

Paragraph 372(2)(e) of the Act requires the Secretary to have regard to whether certain applications by a person, or by an associate of the person, have been refused, when determining whether the person is a fit and proper person. Subparagraph 372(2)(e)(v) allows the rules to prescribe any other provision of the Act to be considered for this purpose.

Subsection 9-33(3) is made for the purposes of subparagraph 372(2)(e)(v) of the Act and prescribes subsection 291(3) of the Act (application by person to be third party authorised officer for the purpose of performing functions and exercising powers in relation to prescribed milk or milk products). This means that in determining whether the applicant is a fit and proper person, the Secretary must have regard to whether the person, or an associate of the person, has made an application to be a third party authorised officer that has been refused. It is important the Secretary consider the reasons for refusing an application to be a third party authorised officer in determining whether an applicant is a fit and proper person.

Paragraph 372(4)(b) of the Act allows the rules to prescribe a person to whom the requirements under subsection 372(2) of the Act, which determine whether a person is a fit and proper person, will apply without reference to an associate of the person.

Subsection 9-33(4) is made for the purposes of paragraph 372(4)(b) of the Act and prescribes a person who is a third party authorised officer who may perform functions and exercise powers in relation to milk or milk products. This means the requirements in subsection 372(2) regarding the mandatory considerations when determining whether a third party authorised officer is a fit and proper person refers only to the third party authorised officer and not to an associate.

Section 374 of the Act relates to the notification that a person has been convicted of an offence or ordered to pay a pecuniary penalty. Paragraph 374(1)(g) provides that section 374 applies to any other person prescribed by the rules, and who carries out export operations, or performs functions or duties or exercises powers under the Act.

Subsection 9-33(5) is made for the purposes of paragraph 374(1)(g) of the Act and prescribes a third party authorised officer who may perform functions and exercise powers in relation to milk or milk products. This means that such a person is required to notify the Secretary of any conviction of offence or order pay a pecuniary penalty for a contravention of Australian law involving fraud or dishonesty for that person (under subsection 374(4) of the Act) or an associate (under subsection 374(5) of the Act). Failure to comply with this requirement is a contravention of a civil penalty provision under subsection 374(6) of the Act.

Division 2— Functions and powers

9-34 Purpose of this Division

Section 300 of the Act provides that the rules may confer functions or powers on authorised officers, or a class of authorised officers, that are necessary or convenient to be performed or exercised for the purposes of achieving the objects of the Act.

Section 9-34 is made for the purposes of section 300 of the Act and provides that Division 2 of Part 4 of Chapter 9 of the Milk Rules (sections 9-34 to 9-37) confers functions and powers on authorised officers, or classes of authorised officers. These powers and functions are necessary or convenient for the purposes of achieving the objects of the Act in relation to milk products for export.

The note following section 9-34 explains that under subsection 301(1) of the Act an authorised officer can only perform the functions or exercise the powers conferred on an authorised officer by the Act that are specified in that officer's instrument of authorisation.

9-35 Inspecting establishments and securing areas, equipment, facilities or other things

Subsection 9-35(1) allows an authorised officer to inspect an establishment (or area at the establishment), including any facilities or equipment or other things at the establishment (or area at the establishment) and any services provided at the establishment (or area of the establishment), where operations are being carried out to prepare or transport milk or milk products. This provision alone does not give an authorised officer the power of entry. Entry to the establishment will need to be exercised in accordance with the powers provided for in the Act.

The note following subsection 9-35(1) provides some examples of things that may be at an establishment or an area of an establishment.

Subsection 9-35(2) allows an authorised officer to secure an area of an establishment or facilities or equipment or any other thing at the establishment for the purpose of conducting an inspection under subsection 9-35(1), if the authorised officer considers it necessary to do so to enable functions to be performed, or powers exercised, under the Act. The area, facilities or equipment or other thing must be secured by attaching or applying an identification tag or similar means of identification. This is necessary to ensure all persons at the establishment are aware of areas that are secured to allow authorised officers to conduct inspections.

Subsection 9-35(3) requires the identification tag or other means of identification referred to in subsection 9-35(2) when securing an area of an establishment, or facilities, equipment or other thing, to be in a form approved by the Secretary. This ensures there is consistency with the means of identifying secured areas, facilities, equipment and other things.

Subsection 9-35(4) specifies that only an authorised officer, or a person acting in accordance with a direction from an authorised officer may remove an identification tag or other means of identification. This ensures the identification is only removed when the thing or area is no longer being inspected by an authorised officer.

The note following subsection 9-35(4) directs the reader to section 309 of the Act, for how a direction may be given by an authorised officer.

9-36 Securing and identifying establishment or conveyance etc.

Subsection 9-36(1) specifies the things and areas, including establishments or conveyances, which an authorised officer may secure, or retain and identify, for the purpose of carrying out an assessment or inspection of milk or milk products, or applying a treatment to milk or milk products. These are:

- a thing found at an establishment that is used, or is apparently used, for operations to prepare milk or milk products;
- a thing found in or on a conveyance that is used, or apparently used, to transport milk or milk products;
- an area of a registered establishment that is used or apparently used, for operations to prepare milk or milk products, including any facilities or equipment or services provided in that area;
- an establishment (other than a registered establishment) that is used, or apparently used, for operations to prepare milk or milk products; or
- a conveyance that is used, or apparently used, to transport milk or milk products.

The ability to secure or retain and identify these things or areas are necessary to ensure that milk or milk products for export are fit for human consumption and their integrity can be ensured

Subsection 9-36(2) requires a thing, area, establishment or conveyance referred to in subsection 9-36(1) to be identified by attaching or applying an identification tag or similar means of identification. This is necessary to ensure that all persons at the establishment are aware of the things and areas that are secured to allow authorised officers to deal with things or the area.

Subsection 9-36(3) provides that the identification tag or other means of identification used under subsection 9-36(2) must be in a form approved by the Secretary. This ensures there is consistency with the means of identifying secured areas.

Subsection 9-36(4) specifies that only an authorised officer or a person acting in accordance with a direction given by an authorised officer may remove the identification tag or other means of identification. This ensures the identification is only removed when the thing or area is no longer being dealt with by an authorised officer.

The note following subsection 9-36(4) refers the reader to section 309 of the Act, which deals with how a direction may be given by an authorised officer.

9-37 Interference with identified establishment or conveyance etc.

Section 9-37 provides only an authorised officer or a person acting in accordance with a direction given by an authorised officer can interfere with or use any area, thing, establishment or conveyance, or move a thing or conveyance identified under section 9-36.

Division 3—Directions to deal with non-compliance with the Act etc.

9-38 Other grounds for giving direction

Subsection 305(1) of the Act specifies the person (a relevant person) to whom an authorised officer may give a direction under the Act to deal with non-compliance, and the grounds for which the direction may be given. Item 8 of the table in subsection 305(1) allows the rules to prescribe additional kinds of persons and grounds for giving direction to those prescribed persons.

Section 9-38 is made for the purposes of item 8 of the table in subsection 305(1) of the Act and prescribes, specifically in relation to prescribed milk or milk products, additional persons who may be given a direction by an authorised officer to deal with non-compliance, and the grounds under which a direction may be given. These are in addition to the directions that can be given under the table in subsection 305(1) of the Act. Persons that may be given directions to deal with non-compliance are listed in column 1 of the table and the grounds for giving the directions are in column 2 of the table.

The additional persons to whom an authorised officer may give a direction are applicants for and holders of government certificate or export permits for prescribed milk or milk products.

The relevant grounds for giving a direction to applicants for, and holders of, government certificates are:

- some or all of the milk or milk products not complying, or not likely to comply, with a requirement of the Act that applies in relation to milk or milk products; or
- some or all of the milk or milk products not meeting, or not likely to meet, importing country requirements relating to milk or milk products; or
- where a matter to be stated in the government certificate is not true and correct in relation to the milk or milk products.

The relevant grounds for giving a direction to applicants for, and holders of export permits are:

- the fitness for human consumption of some or all of the milk or milk products being, or is likely to be, jeopardised; or
- whether it is likely that the integrity of some or all of the milk or milk products cannot be ensured.

Issuing directions enables authorised officers to deal with prescribed milk or milk products that may affect Australia's trading reputation or may not meet importing country requirements.

Division 4—Miscellaneous

9-39 Circumstances in which identity card need not be carried

Section 306 of the Act deals with identity cards. Subsection 306(5) provides that an authorised officer or approved auditor need not carry an identity card in the circumstances prescribed by the rules.

Section 9-39 is made for the purposes of subsection 306(5) of the Act and provides that an authorised officer or approved auditor is not required to carry an identity card at an establishment, or part of an establishment, where it would be unsafe or unhygienic to do so or there would be a risk the card or the milk or milk products at the establishment being contaminated.

CHAPTER 10—COMPLIANCE AND ENFORCEMENT

10-1 Samples taken in exercising monitoring or investigation powers

Section 326 of the Act triggers the standard suite monitoring powers in Part 2 of the *Regulatory Powers (Standard Provisions) Act 2014* (Regulatory Powers Act) for the purposes of the Act. Section 327 provides for additional monitoring powers on top of the standard monitoring powers. Those additional monitoring powers are taken to be monitoring powers under Part 2 of the Regulatory Powers Act.

Section 329 of the Act triggers the baseline investigation powers in Part 3 of the Regulatory Powers Act for the purposes of the Act. Section 330 provides for additional investigation powers on top of the standard investigation powers. Those additional investigation powers are taken to be investigation powers under Part 3 of the Regulatory Powers Act.

One of the additional monitoring and investigation powers provided by paragraph 327(2)(a) and subsection 330(2) of the Act is the power to take, test and analyse samples of any thing on premises entered under Parts 2 or 3 of the Regulatory Powers Act.

Section 10-1 provides requirements for the taking of a sample under paragraph 327(2)(a) or subsection 330(2) of the Act. The sample must be identified with a mark or tag and kept in the custody or control of an authorised officer until whichever of the following listed events occurs first. The listed events are where the sample is:

- destroyed during testing or analysis in accordance with section 412 of the Act;
- given to an analyst appointed under section 413 of the Act; or
- otherwise disposed of.

10-2 Dealing with things seized in exercising investigation powers

Section 10-2 sets out the requirements if a thing is seized at premises that has been entered by an authorised officer under an investigation warrant or under subsection 347(1) of the Act (where the authorised officer has reasonable grounds for suspecting there may be a thing on the premises that relates to an offence or contravention of a civil penalty provision).

The seized thing must be identified with a mark or tag and kept in the custody or control of an authorised officer until whichever of the listed events occurs first. The listed events are that the thing is:

- given to an analyst appointed under section 413 of the Act;
- destroyed during testing or analysis in accordance with section 412 of the Act;
- forfeited in accordance with the subsection 416(1) of the Act;
- destroyed or otherwise disposed of in accordance with section 418 of the Act; or

• returned or disposed of in accordance with, respectively, subsection 66(4) or section 68 of the Regulatory Powers Act.

The note following section 10-2 refers the reader to subsection 347(1) of the Act, which deals with entry to premises that are, or form part of, a registered establishment.

CHAPTER 11—MISCELLANEOUS

Part 1—Review of decisions

11-1 Reviewable decisions

Section 381 of the Act sets out the decisions under the Act that are *reviewable decisions* and who can seek a review of such decisions (the *relevant person*). A reviewable decision can be reviewed on its merits internally and, in certain circumstances, externally by the Administrative Appeals Tribunal.

Subsection 381(2) of the Act allows the rules to prescribe additional decisions to be reviewable decisions under the Act, and the relevant person for such decisions.

Section 11-1 is made for the purposes of subsection 381(2) of the Act and details the decisions made under the Milk Rules that are reviewable decisions. These decisions relate to the approval of a person to conduct audits and to carry out assessments.

The specified relevant person may apply in writing for review of these decisions. Section 383 of the Act sets out the process for internal review of reviewable decisions, other than decisions made by the Secretary personally. The review will be conducted by the Secretary or a delegate of the Secretary who has not been previously involved and who is senior to the original decision-maker. The Secretary or their delegate may affirm the decision, vary the decision, or set the decision aside and substitute a new decision. Review by the Administrative Appeals Tribunal is set out in section 385 of the Act.

Reviewable decisions are in column 1 of the table in section 11-1, the provisions of the Milk Rules under which the reviewable decision is made is in column 2 of the table and the relevant person for the decision is in column 3 of the table.

Prescribing the decisions and relevant persons is necessary to allow for review consistent with the Government's policy that an administrative decision that is likely to affect the rights or interests of an individual should be reviewable on its merits unless to do so would be inappropriate, or there are factors justifying the exclusion of merits review.

Part 2—Records

Retention of records is necessary for monitoring compliance with importing country requirements and government and industry standards. Records may also be relevant in relation to the traceability of goods if there is a need to recall those goods. Retaining records is essential for accountability and enables oversight of the export supply chain.

11-2 Purpose of this Part

Section 408 of the Act deals with requirements to retain records. Subsection 408(1) allows the rules to make provision for and in relation to requiring records to be retained by any of the following (relevantly):

- a person who carries out, or has carried out, export operations in relation to prescribed goods;
- a person who manages or controls, or who has managed or controlled, export operations at a registered establishment;
- a person who manages or controls, or has managed or controlled, export operations in accordance with an approved arrangement;
- a person who carries out, or has carried out, export operations in relation to nonprescribed goods for which an application for a government certificate has been made or a government certificate has been issued.

Subsection 408(2) sets out a non-exhaustive list of matters that may be the subject of rules made under section 408.

Section 11-2 is made for the purposes of subsections 408(1) and (2) of the Act and provides that Part 2 of Chapter 11 of the Milk Rules (sections 11-2 to 11-10) makes provision for and in relation to requiring the retention of records in relation to milk products.

The note following section 11-2 alerts the reader that a person may commit an offence of strict liability if the person is required to make a record in accordance with a provision of Part 2 of Chapter 11 of the Milk Rules and does not comply (subsection 408(3) of the Act).

11-3 General requirements for records

Section 11-3 sets out the general requirements for records required to be retained under Part 2 of Chapter 11 of the Milk Rules in relation to milk or milk products.

Subsection 11-3(1) requires records to be in English, be dated, accurate, legible and able to be audited. In addition, if the record was required to be in another language to meet importing requirements, it must also be kept in that other language (in addition to in English).

Subsection 11-3(2) specifies that a person is taken to have complied with a requirement to retain a record under Part 2 of Chapter 11 of the Milk Rules if they have retained a copy of a document where the original version was given to another person, as required, under a Commonwealth, State or Territory law or in accordance with ordinary commercial practice.

11-4 Government certificates

Subsection 11-4(1) requires a person to whom a government certificate in relation to milk or milk products is issued, to retain the certificate in a secure place when it is not being used.

Subsection 11-4(2) provides that this requirement does not apply in relation to a government certificate issued by electronic means.

This ensures, for example, that a government certificate is not misused or lost.

11-5 Export permits

Subsection 11-5(1) requires the person to whom an export permit for prescribed milk or milk products is issued to retain the permit in a secure place when it is not being used.

Subsection 11-5(2) provides that this requirement does not apply in relation to an export certificate issued by electronic means.

This ensures, for example, that an export permit is not misused or lost.

11-6 Records to be retained by exporter

Section 11-6 requires an exporter of prescribed milk or milk products to retain certain records for at least 3 years starting on the day the record is made or when it comes into their possession:

- each application by the exporter for a government certificate or export permit for prescribed milk or milk products;
- each declaration given under subsection 5-35(1)(i) or (j) of the Milk Rules that relates to prescribed milk or milk products for which the exporter made an application for a government certificate or export permit; and
- each other document that is made by the exporter or that comes into the exporter's possession that is relevant to showing whether they have complied, or are complying with the applicable requirements of the Act and importing country requirements.

The note following subsection 11-6(1) notifies the reader that a reference to the Act includes a reference to the Milk Rules (in accordance with section 1-5 of the Milk Rules and subsection 432(1) of the Act).

11-7 Records to be retained by occupier of registered establishment

Subsection 11-7(1) requires the occupier of a registered establishment that is registered for a kind of export operations in relation to prescribed milk or milk products to retain each document:

- that is made by the occupier or that comes into their possession; and
- that is relevant to showing whether they have complied or are complying with the applicable requirements of the Act (including the conditions of the establishment's registration).

The note following subsection 11-7(1) notifies the reader that a reference to the Act includes a reference to the Milk Rules (in accordance with section 1-5 of the Milk Rules and subsection 432(1) of the Act).

Subsection 11-7(2) provides that the occupier of the registered establishment must retain each record referred to in subsection 11-7(1) for at least 3 years, starting on the day the record is made or when it comes into the occupier's possession (as the case may be).

11-8 Records to be retained by holder of approved arrangement

Subsection 11-8(1) requires the holder of an approved arrangement for a kind of export operations in relation to prescribed milk or milk products to retain each document they make or that comes into their possession relevant to showing compliance with the applicable requirements of the Act, the approved arrangement and any conditions of the approved arrangement.

Subsection 11-8(2) provides that these records must be retained for at least 3 years starting from the day the record is made or when it comes into their possession.

The note following subsection 11-8(1) gives examples of records that the holder of an approved arrangement is required to keep.

11-9 Records relating to official marking devices

Section 11-9 requires a person who is required to make a record made under section 8-32 (records of official marking devices manufactured) of the Milk Rules must retain each record for 3 years after making the record.

Subsection 11-11(3) also provides that different methods are prescribed if importing country requirements relating to the milk or milk products, and an approved arrangement for operations to prepare the milk or milk products, provide for different methods and controls than those in subsection 11-11(1).

11-10 Records must not be altered or defaced during retention period

Subsection 11-10(1) provides that records that are required to be retained under Part 1 of Chapter 11 of the Milk Rules must not be altered or defaced during the period they are required to be kept (the *retention period*).

Subsection 11-10(2) provides that records can be marked up or have notations added to them in accordance with ordinary practice.

Subsection 11-10(3) clarifies that where a record (the *original record*) is altered or defaced during the retention period, the person who is required to retain the record must also retain additional documents. These are additional documents that come into the person's possession or are created by the person, which shows how the original record was altered or defaced.

Part 3—Samples

11-11 Microbiological limits—taking, testing and analysing samples

Paragraph 410(2)(a) of the Act allows the rules to prescribe a method for the taking, testing or analysis of kinds of samples of goods or any other thing that is to be taken, tested or analysed under the Act (other than in the performance of compliance and enforcement functions under Chapter 10 or the Regulatory Powers Act).

Section 11-11 is made for the purposes of paragraph 410(2)(a) of the Act.

Subsection 11-11(1) prescribes the methods for the taking, testing and analysis of samples of milk or milk products and their ingredients to verify compliance with microbiological limits in the Food Standards Code, subject to the exception in subsection 11-11(3).

These methods are those specified in the:

- Australian/New Zealand Standard (AS/NZS) 1766:1998, Methods for the Microbiological Examination of Food published jointly by, or on behalf of, Standards Australia and Standards New Zealand (as in force at the commencement of the Milk Rules); or
- an equivalent method of examination in accordance with the Australian New Zealand Standard AS/NZS 4659:1999, *Guide to Determining the Equivalence of Food Microbiology Test Methods* published jointly by, or on behalf of, Standards Australia and Standards New Zealand (as in force at the commencement of the Milk Rules).

Subsection 11-11(2) provides that the method must also comply with any additional requirements of the Food Standards Code.

Subsection 11-11(3) also provides that different methods are prescribed if importing country requirements relating to the milk or milk products, or an approved arrangement for operations to prepare the milk or milk products, provide for different methods or controls than those in subsection 11-11(1).

11-12 Storage of samples

Section 411 of the Act allows the rules to make provision for and in relation to the storage of samples that may be tested or analysed under the Act.

Subsection 11-12(1) is made for the purposes of section 411 of the Act and requires samples that may be tested or analysed under the Act to be held under conditions that are unlikely to affect the results of any testing or analysis of the samples. This is necessary to preserve the integrity of samples that may be used for regulatory purposes.

Subsection 11-12(2) provides that the requirement in subsection 11-12(1) does not apply in the context of samples that may be tested under Chapter 10 of the Act (compliance and enforcement) or the Regulatory Powers Act. This exception is necessary to allow for samples to be tested and analysed under those provisions in a manner that may destroy the sample.

Part 4—Damaged or destroyed milk or milk products

11-13 Division of compensation between owners

Section 419 of the Act allows the Secretary to approve the payment of a reasonable amount of compensation in respect of goods that are damaged or destroyed in the course of exercising powers or functions under the Act, if the Secretary considers it appropriate. Section 420 provides for matters relating to claims for compensation under section 419.

Subsection 420(2) of the Act sets out who can be paid compensation approved under section 419. Relevantly, paragraph 420(2)(b) provides that if there are 2 or more owners of the compensable goods, the compensation is to be divided among those owners as prescribed by the rules.

Section 11-13 is made for the purposes of paragraph 420(2)(b) of the Act and sets out how compensation is divided among2 or more owners of damaged or destroyed milk or milk products. The total compensation payable must be divided among those owners according to their proportion of interest in the milk or milk products at the time of destruction or damage.

The Secretary must be satisfied the proportion represents the owner's interest at the time the goods were damaged or destroyed. This ensures each owner is paid an amount of compensation equal to their share of ownership that the Secretary considers is equitable in the circumstances and no owner is disadvantaged because of the destruction of, or damage to, the goods.

11-14 Amount of compensation

Subsection 420(5) of the Act provides that the amount of compensation payable under subsection 419(1) is a reasonable amount prescribed by, or determined in accordance with, the rules.

Section 11-14 is made for the purposes of subsection 420(5) of the Act and prescribes the amount of compensation payable under subsection 419(1) of the Act to the owners of damaged or destroyed milk or milk products, where the damage or destruction occurred in the course of performing functions or duties, or exercising powers, under the Act.

Subsection 11-14(1) provides the amount of compensation payable for goods damaged by a person who is performing functions or duties or exercising powers under the Act is the lesser of either the amount the Secretary determines was the market value of the milk or milk products immediately before they were damaged, or the cost of repairing the damage.

The note following subsection 11-14(1) refers the reader to subsection 419(2) of the Act, which deals with when compensation is not payable in respect of goods that are damaged as a result of samples of the goods being taken during an audit, during an assessment or as permitted by subsection 327(2) or 330(2) of the Act.

Subsection 11-14(2) provides that the amount of compensation payable for destroyed milk or milk products is the amount the Secretary determines was the market value of the milk or milk products immediately before their destruction.

Part 5—Relevant Commonwealth liabilities

11-15 Circumstances in which relevant Commonwealth liability of a person is taken to have been paid

Section 431 of the Act provides that a relevant Commonwealth liability of a person is taken to have been paid for the purposes of a specified provision of the Act in the circumstances prescribed by the rules.

Subsection 11-15(1) provides that section 11-15 is made for the purposes of section 431 of the Act and prescribes circumstances in which a relevant Commonwealth liability of a person is taken to have been paid for the purposes of certain provisions of the Act (a *relevant provision*). The specified provisions of the Act are:

- paragraph 112(2)(b) (registration of establishment);
- paragraph 117(2)(b) (renewal of registration of establishment);
- paragraph 151(2)(b) (approval of proposed arrangement);
- paragraph 156(2)(b) (renewal of approved arrangement); or
- paragraph 161(3)(a) (variation of approved arrangement).

The note following subsection 11-15(1) refers the reader to the definition of *relevant Commonwealth liability* in section 12 of the Act.

Subsection 11-15(2) prescribes the circumstances that a relevant Commonwealth liability is taken to have been paid for the purposes of the provisions specified in subsection 11-15(1). These circumstances are where the person, or another person, has given a written undertaking (a *payment undertaking*) to the Secretary to pay the amount, the payment undertaking includes a term that the relevant Commonwealth liability is to be reduced by the amount paid in accordance with the undertaking, and the Secretary accepts the undertaking.

When accepting an undertaking, the Secretary must consider the financial position of the person who gave the payment undertaking, the nature and likely cost of the relevant export operations, whether the person will be able to comply with the undertaking and, if applicable, meet the cost of the export operations and any other relevant considerations (paragraph 11-15(2)(c)).

This ensures that the Secretary is able to approve, among other things, the registration of an establishment or a proposed arrangement even where the relevant Commonwealth liability of the applicant has person has not been paid, provided the requirements of this section are met.

Subsection 11-15(3) provides that the payment undertaking may be given by a person in relation to their relevant Commonwealth liability or the relevant Commonwealth liability of another person.

Subsections 11-15(4) and (5) allow for a single undertaking to relate to 2 or more Commonwealth liabilities. Should a single undertaking relate to 2 or more Commonwealth liabilities, or a person has provided 2 or more undertakings in relation to different relevant Commonwealth liabilities, then the Secretary may decide in which order payments are to be applied to reduce the outstanding Commonwealth liabilities.

Subsection 11-15(6) allows for a payment undertaking to be varied at any time by agreement between the Secretary and the person who gave the undertaking.

Subsection 11-15(7) allows the Secretary to agree to a variation to a payment undertaking if having considered the matters at paragraph 11-15(2)(c), the Secretary considers the variation appropriate, and the variation does not reduce the amount of the remaining Commonwealth liability.

The matters at paragraph 11-15(2)(c) are the same matters that the Secretary must consider when deciding whether to accept the undertaking in the first place, namely the financial position of the person who gave the undertaking, the nature and likely cost of the relevant export operations, whether the person will be able to comply with the undertaking and, if applicable, meet the cost of the export operations and any other relevant considerations.

CHAPTER 12—TRANSITIONAL PROVISIONS

The transitional provisions in Chapter 12 will ensure that:

- persons who have submitted applications under the old *Export Control (Milk and Milk Products) Orders 2005* (old Export Control (Milk) Orders) do not have to resubmit those applications for a decision or determination to be made;
- decisions or determinations made under the old Export Control (Milk) Orders remain effective;
- requests made by an authorised officer in relation to trade descriptions remain effective; and
- approvals for a person to make or possess an official mark or an official marking device remain effective.

These transitional provisions in Chapter 12 are in addition to transitional provisions provided for in the *Export Control (Consequential Amendments and Transitional Provisions) Act 2020* which provides transitional arrangements for matters that were under the old Export Control (Milk) Orders and the old *Export Control (Prescribed Goods—General) Order 2005* and are now dealt with under the Act. This includes, for example, the transition of registered establishments, approved arrangements and government certificates.

Part 1—Preliminary

12-1 Definitions

Section 12-1 defines terms that used in Chapter 12 of the Milk Rules (section 12-1 to 12-12).

The term *commencement time* is defined as the time when section 3 of the Act commences.

The term *old Export Control (Milk) Orders* is defined as the *Export Control (Milk and Milk Products) Orders 2005* as in force immediately before the commencement time. The Orders will be repealed at the commencement of the Milk Rules.

The term *old Export Control (General) Order* means the *Export Control (Prescribed Goods—General) Order 2005* as in force immediately before the commencement time.

Part 2—Approved arrangements

12-2 Information and declarations given before commencement time

Subsection 12-2(1) provides that section 12-2 applies if information and declarations had been given, under subclause 6.1 of Schedule 8 to the old Export Control (Milk) Orders to a consignee that is the occupier of a registered establishment in relation to milk or milk products that were at the establishment immediately prior to the commencement time.

Subsection 12-2(2) has the effect that, after the commencement time, such information and declarations are taken to be information and declarations that are required to be given to the occupier under section 5-35 of the Milk Rules, and are taken to have been given to the occupier in accordance with paragraph 5-35(2)(b) of the Milk Rules.

Part 3—Other matters relating to export

Division 1—Trade descriptions

12-3 Request for translation not complied with before commencement time

Section 12-3 has the effect that if an authorised officer had, by written notice to a person under suborder 76.1 of the old Export Control (Milk) Orders, requested a translation of part of a trade description or other information, but the request had not been complied with prior to the commencement time, the notice continues to have effect after the commencement time as if it had been given to the person under subsection 8-3(3) of the Milk Rules.

Division 2—Official marks

12-4 Person approved before commencement time to manufacture an official mark

Subsection 12-4(1) provides that section 12-4 applies in relation to a person who, immediately before the commencement time, was approved by the Secretary under subsection 13.18(2) of the old Export Control (General) Order to manufacture an official mark in relation to prescribed milk or milk products.

Subsection 12-4(2) has the effect that, at the commencement time, the person is taken to have been given a written approval by the Secretary under paragraph 8-15(c) of the Milk Rules to manufacture or supply the official mark in relation to prescribed milk or milk products.

12-5 Person approved before commencement time to possess an official mark

Subsection 12-5(1) provides that section 12-5 applies in relation to a person who, immediately before the commencement time, was approved by the Secretary under paragraph 13.18(3)(e) of the old Export Control (General) Order as a person who may possess an official mark in a specified registered establishment in relation to prescribed milk or milk products (other than an official mark that has been applied to the goods).

Subsection 12-5(2) has the effect that, at the commencement time, the person is taken to have been given a written approval by the Secretary under paragraph 8-16(d) of the Milk Rules to possess the official mark at the registered establishment in relation to prescribed milk or milk products.

12-6 Person approved before commencement time to apply an official mark

Subsection 12-6(1) provides that section 12-6 applies in relation to a person who, immediately before the commencement time, was approved by the Secretary under paragraph 13.18(3)(e) of the old Export Control (General) Order as a person who may apply an official mark in a specified registered establishment in relation to prescribed milk or milk products.

Subsection 12-6(2) has the effect that, at the commencement time, the person is taken to have been given a written approval by the Secretary under paragraph 8-16(d) of the Milk Rules to apply the official mark at the registered establishment in relation to prescribed milk or milk products.

Division 3—Official marking devices

12-7 Person approved before commencement time to manufacture an official marking device

Subsection 12-7(1) provides that section 12-7 applies in relation to a person who, immediately before the commencement time, was approved under subsection 13.18(2) of the old Export Control (General) Order to manufacture an official marking device that is capable of being used to apply an official mark to prescribed milk or milk products.

Subsection 12-7(2) has the effect that, at the commencement time, the person is taken to have been given a written approval by the Secretary under paragraph 8-29(1)(c) of the Milk Rules to manufacture or supply the official marking device.

12-8 Person approved before commencement time to possess an official marking device

Subsection 12-8(1) provides that section 12-8 applies in relation to a person who, immediately before the commencement time, was approved under subsection 13.18(2) of the old Export Control (General) Order to possess an official marking device that is capable of being used to apply an official mark to prescribed milk or milk products.

Subsection 12-8(2) has the effect that, at the commencement time, the person is taken to have been given a written approval by the Secretary under paragraph 8-29(1)(c) of the Milk Rules to possess the official marking device.

Part 4—Powers and officials

Division 1—Approved auditors

12-9 Application for approval as auditor not decided, or notice of decision not given, before commencement time

Subsection 12-9(1) provides that section 12-9 applies to an application by a person for approval as an approved auditor that had been made under subclause 2.1 of Schedule 10 to the old Export Control (Milk) Orders, and for which:

- no decision on the application was made; or
- a decision was made but written notice of that decision had not been given;

prior to the commencement time.

Subsection 12-9(2) deals with applications for which a decision was not made prior to the commencement time. Such applications are taken to have been made to the Secretary under subsection 9-8(1) of the Milk Rules to approve the individual under subsection 273(1) of the Act and will be decided in accordance with the Milk Rules. However, the requirements in subsections 9-8(2) and (3) (concerning application requirements) of the Milk Rules do not apply to such applications.

Subsections 12-9(3) to (5) deal with applications for which a decision was made prior to the commencement time but written notice of that decision had not been given by the Secretary to the applicant prior to the commencement time.

For such applications:

- if the decision that was made prior to the commencement time was to approve the person as an approved auditor, the decision is taken to have been a decision under paragraph 9-9(1)(a) of the Milk Rules. The Secretary must give the applicant written notice of the decision in accordance with section 9-12 of the Milk Rules as soon as practicable after the commencement time and also give the applicant a written notice in accordance with section 9-12 of the Milk Rules; or
- if the decision that was made prior to the commencement time was to refuse to approve the applicant as an approved auditor, the decision is taken to be a decision under paragraph 9-9(1)(b) of the Milk Rules. The Secretary must, as soon as practicable after the commencement time, give the applicant written notice of the decision.

The note following subsection 12-9(5) explains that a decision to refuse to approve the applicant is a reviewable decision under the Act (referring to section 11-1 of the Milk Rules) and the Secretary must give the applicant written notice of the decision in accordance with section 382 of the Act.

12-10 Request for further information not complied with before commencement time

Subsection 12-10(1) has the effect that if the Secretary had, under subclause 3.1 of Schedule 10 of the old Export Control (Milk) Orders, requested a person who applied for approval as an approved auditor provide further specified information or documents, but the request had not been complied with prior to the commencement time, the request must be complied with after the commencement time as if it had been given by the Secretary to the person under subsection 9-10(1) of the Milk Rules.

Subsection 12-10(2) provides that if the request did not specify the period within which the request must be complied with, it must be complied with as soon as practicable.

12-11 Decision to revoke approval as auditor decided, but notice not given before commencement time

Subsection 12-11(1) provides that where the Secretary had, prior to the commencement time, made a decision under subclause 11.1 of Schedule 10 to the old Export Control (Milk) Orders to revoke the approval of a person as an approved auditor, but written notice of the decision had not been given to the person prior to the commencement time, the Secretary is required to

give the person written notice of the decision as soon as practicable after the commencement time.

Subsection 12-27(2) has the effect that after the commencement time the decision is taken to have been given under subsection 9-15(1) of the Milk Rules.

The note following subsection 12-11(2) explains that a decision to revoke an individual's approval to conduct audits is a reviewable decision under the Act and the Secretary must give the applicant written notice of the decision in accordance with section 382 of the Act.

Division 2—Assessments

12-12 Verification by authorised officer before commencement time

Subsection 12-12(1) provides that section 12-12 applies where an authorised officer had given a written verification of matters under suborder 8.1 of Schedule 9 to the old Export Control (Milk) Orders in relation to prescribed milk or milk products that had not been exported before the commencement time.

Subsection 12-12(2) has the effect that at commencement time the written verification is taken to be a notice to the Secretary under subsection 9-20(2) of the Milk Rules.

Subsection 12-12(3) requires the Secretary to give a copy of the written verification to the person who would be the relevant person for an assessment of the prescribed milk or milk products if the assessment was carried out under Part 2 of Chapter 9 of the Act.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011(Cth)

Export Control (Milk and Milk Products) Rules 2021

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011* (Cth).

Overview of the instrument

The Export Control (Milk and Milk Products) Rules 2021 (the Milk Rules) has the following purposes:

- in conjunction with the *Export Control Act 2020* (the Act), it implements an improved regulatory framework for the export of prescribed goods, reducing complexity and strengthening compliance;
- it reduces duplication in the regulatory framework and provides streamlined and consolidated export-related requirements;
- it imposes regulatory controls on milk and milk products that are to be exported from Australia so that these products meet trade requirements and maintain overseas market access; and
- it provides a scheme of transitional and savings provisions that will preserve accrued rights and liabilities under the *Export Control (Milk and Milk Product) Orders 2005*. The provisions allow for decisions and approvals under the former Orders to continue, where applicable, under the Milk Rules.

List of human rights engaged

The Milk Rules engage the following rights:

International Covenant on Civil and Political Rights (ICCPR)

- Article 17 of the ICCPR Right to protection from arbitrary interference with privacy;
- Article 22 of the ICCPR Right to freedom of association.

Assessment of compatibility with human rights

Right to protection from arbitrary interference with privacy (Article 17 of the ICCPR) and right to freedom of association (Article 22 of the ICCPR)

Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual's privacy, family, home or correspondence, and protects a person's honour and reputation from unlawful attacks.

The right to privacy can be limited to achieve a legitimate objective where the limitations are lawful and not arbitrary. For an interference with the right to privacy to be permissible, the interference must be authorised by law, be for a reason consistent with the ICCPR and be reasonable in the circumstances. The United Nations Human Rights Committee has interpreted the requirement of 'reasonableness' as implying that any interference with privacy must be proportionate to a legitimate end and be necessary in the circumstances. While the United Nations Human Rights Committee has not defined 'privacy', the term is generally understood to comprise freedom from unwarranted and unreasonable intrusions into activities that society recognises as falling within the sphere of individual autonomy.

Chapters 4, 5, 7, 8, 9 and 11 of the Milk Rules require a person to provide information or documents, including for an assessment of whether the person is a fit and proper person under section 372 of the Act. Requiring persons to provide information or documents may incidentally require the provision of personal information. The collection, use, storage, and disclosure of personal information may engage the right to freedom from arbitrary or unlawful interference with privacy.

The collection of this information is necessary for the legitimate objective of assessing the suitability of a person to participate in export operations and to ensure those persons continue to comply with the legislative requirements in the Rules.

A person who provides information in an application 'opts in' to the regulatory system. A person who has opted in should expect that a certain amount of personal information about the way their business operates will need to be provided to the Secretary to gain the benefits of that system.

Article 22(1) of the ICCPR protects the right to freedom of association with others. Article 22(2) permits limitations which are prescribed by law and which are necessary in the interests of national security, public safety, public order, the protection of public health or morals or the protection of the rights and freedoms of others. This right may be engaged by the requirement to be a fit and proper person which incorporates an assessment of a person's associates.

Fit and proper person test

Participation in Australia's agricultural export markets is not a right; it is a privilege granted by the Australian Government to suitable persons. A person seeking the benefits of participating in those markets does so in the knowledge that the existence of certain prior conduct or associations may result in the rejection of an application, or suspension, variation or revocation of a registration or other approval.

The Milk Rules requires that approved auditors, approved assessors and third party authorised officers must be fit and proper persons. The Secretary must apply the fit and proper person test. Persons are required to notify the Secretary if they have been convicted of certain specific offences or ordered to pay a pecuniary penalty in relation to certain specified contraventions. When determining whether a person is a fit and proper person, the Secretary may consider the nature of the offences, the interest of the industry or industries relating to the person's export business, and any other relevant matter. While these factors are considered by the Secretary when applying the fit and proper person test, they may not automatically give rise to a negative finding. Rather, it will be up to the Secretary to consider whether a person is fit and proper after having regard to these matters, in addition to the other matters set out in section 372 of the Act.

A fit and proper person test can be used to consider a person's history of compliance with legislation and then deny approval to register an establishment, or to suspend, revoke or alter the conditions on an existing approved arrangement. This ensures that persons or companies are suitable entities to be responsible for the appropriate management of relevant risks.

Business associates and others may have influence over the primary person such that they may be able to compel them to undertake illegal activities on their behalf, through inducement or other means. Putting a 'fit and proper person' test in place will notify the Secretary of any associates of the primary person who may pose a risk and allow them to take action to ensure Australia's agricultural exports are not compromised.

The associates' test is designed to ensure that an applicant for a regulatory control under the Act (e.g., a registered establishment) is a suitable person to be responsible for managing relevant risks, considering potential consequences of non-compliance. It is appropriate for associates to be included in the consideration to ensure that the conduct of all types of entities may be considered where the Secretary considers it appropriate to do so.

Enabling the Secretary to take into account a broad range of matters is important when considering whether a person is a fit and proper person because such a person might be involved in the export of a wide range of goods, with varying degrees of risk. This ensures that the integrity of the regulatory framework is not compromised by limiting conduct that can be considered in this context. As the agricultural export sector is regularly changing and evolving, this is reasonable and proportionate and ensures that the current level of market access can be maintained and possibly even increased in future.

Australia's access to markets and the ability to export agricultural goods depends on its trading reputation and the confidence of its trading partners. To the extent these requirements engage Article 17 of the ICCPR, any interference with privacy is not arbitrary as the fit and proper person test is necessary, reasonable and proportionate for the legitimate objective of ensuring that persons who are involved in exporting goods from Australian territory are trustworthy and demonstrate the required integrity necessary to uphold Australian law and protect our trading reputation. In addition, any information collected under the Milk Rules and the Act is protected from unauthorised disclosure by confidentiality provisions in sections 388 to 397 of the Act.

While the fit and proper person test could be seen to restrict the associations a relevant person may have, it does not prevent or prohibit a person from holding any particular associations. Rather, holding certain association may mean that a person's circumstances are not compatible with participation in Australia's agricultural export markets. Australia's agricultural export industries are underpinned by trust. Importing country requirements relating to agricultural goods will often relate to the preservation of public health, with non-compliance representing a risk to Australia's participation in those markets.

Consideration of a person's associations is necessary because associates may leverage their personal relationship with the primary person to engage in non-compliant export activities. This may pose a risk to public health and safety. Therefore, to the extent that the fit and proper person test limits the right to freedom of association, it is permissible under Article 22(2) as it is for the purpose of protecting public health.

Summary

The Milk Rules are compatible with the right to protection from arbitrary interference with privacy under Article 17 and the right to freedom of association under Article 22 of the ICCPR. To the extent that the 'fit and proper person' test required by the Milk Rules limits these rights, this limitation is necessary, proportionate and reasonable to achieve the legitimate objectives of the Act.

Conclusion

The Milk Rules are compatible with human rights because, to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

Andrew Edgar Francis Metcalfe AO

Secretary of the Department of Agriculture, Water and the Environment