



Australian Government  
Department of Agriculture,  
Fisheries and Forestry

# Import risk review for dairy products for human consumption

## Second draft report

April 2024



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### **Acknowledgement of Country**

We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

### **Stakeholder submissions on draft reports**

This draft report allows interested parties to comment on relevant technical biosecurity issues. A final report will consider any comments received.

Submissions should be sent to the Department of Agriculture, Fisheries and Forestry and must meet the conditions specified in the relevant Biosecurity Advice notice.

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# Overview

The department received a number of submissions on the Import risk review for dairy products for human consumption: draft report. In consideration of these submissions and new available research, the department has made changes to the review, some of which are significant. The department is now releasing a second draft report for consultation in order for these changes to be considered by stakeholders.

# Introduction

## Australia's biosecurity policy framework

Australia's biosecurity policies aim to protect Australia against risks that may arise from exotic pests and diseases entering, establishing and spreading in Australia, thereby threatening Australia's unique flora and fauna, agricultural industries that are relatively free from serious pests and diseases, and human health.

Risk analysis is an important part of Australia's biosecurity policies. It enables the Australian Government to formally consider the level of biosecurity risk that may be associated with proposals to import goods into Australia. If the biosecurity risks do not achieve Australia's appropriate level of protection (ALOP), risk management measures are proposed to reduce the risks to an acceptable level. If the risks cannot be reduced to an acceptable level, the goods will not be imported into Australia until suitable measures are identified.

Successive Australian governments have maintained a conservative, but not a zero risk, approach to managing biosecurity risks. This approach is reflected in Australia's ALOP, which reflects community expectations through government policy and is currently described as providing a high level of protection aimed at reducing risk to a very low level, but not to zero.

Australia's risk analyses are undertaken by the Australian Government Department of Agriculture, Fisheries and Forestry (the department) using technical and scientific experts from relevant fields and involve consultation with stakeholders at various stages during the process.

Risk analyses conducted by the department are consistent with Australia's international biosecurity obligations including those under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the World Organisation for Animal Health (WOAH). Risk analyses go towards meeting our international obligations whilst addressing the various risks that goods may pose.

Risk analyses may take the form of a Biosecurity Import Risk Analysis (BIRA) or a non-regulated risk analysis (such as scientific review of existing policy and import conditions, or scientific advice).

More information about Australia's biosecurity framework is provided in the [Biosecurity Import Risk Analysis guidelines 2016](#).

The department recognises that new scientific information and technologies, or other combinations of measures, may provide an equivalent level of biosecurity protection for the disease agents identified as requiring risk management. The department will consider technical submissions that objectively demonstrate alternative biosecurity measures.

## Risk review

### Background

The [Importation of dairy products into Australia for human consumption: import risk analysis](#) (dairy IRA) was published in November 1999. This led to the development of import conditions for dairy products for human consumption, which have been updated over time as particular aspects were

revised. However, there has not been a consolidated review of the biosecurity risks associated with importing dairy products for human consumption since the dairy IRA was published. Since 1999, global supply chains for dairy products have become increasingly complex, import volumes have increased, and there is greater diversity in the range of dairy products available. Additionally, a large number of significant scientific advances have been published in the understanding of biosecurity risks which may be present in dairy.

In August 2001, [Animal Biosecurity Policy Memorandum 2001/22](#) advised of the adoption of conditions for the importation of colostrum. Importation of colostrum had not been included in the dairy IRA, other than as a human therapeutic.

The Australian Government has policies in place to meet both animal biosecurity and food safety requirements associated with imported foods for human consumption. While the department manages risks to animal health, the Director of Human Biosecurity in the Australian Government Department of Health and Aged Care manages risks to human health. Food safety risks are assessed by Food Standards Australia New Zealand (FSANZ), an independent statutory agency in the Health portfolio. All biosecurity requirements must be met before food safety requirements apply.

Food imported into Australia must meet Australia's food standards. Food imported into Australia must meet Australia's food standards (see section 4.7). This includes the requirements set down in the Australia New Zealand Food Standards Code (food standards code). The food standards code is developed and maintained by FSANZ and sets food standards, which apply to both domestic products and imported food. The department administers the [Imported Food Control Act 1992](#) and its subordinate legislation, operating the Imported Food Inspection Scheme to ensure food importers import food that is safe and compliant with Australia's food standards. In addition to the activities undertaken at the border, state and territory food enforcement agencies are responsible for enforcing the requirements of the food standards code for all food available for sale within their jurisdiction.

Chapter 4 of the food standards code includes [Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products \(Australia Only\)](#) (dairy standard). The dairy standard was developed following assessment of potential microbiological and chemical hazards and sets out a number of food safety requirements, including the implementation of documented food safety programs for dairy primary production, collection, transportation and processing.

Dairy products produced for human consumption must meet the Australian community's expectations for safe, wholesome food, covering the whole food production chain from paddock to plate. The dairy industry in Australia is a highly regulated sector with comprehensive food safety practices across the supply chain from farm to consumers.

Pasteurisation is the main process used for making dairy products safe for human consumption (FSANZ 2006). It is also a key risk management measure that can address many disease agents of animal biosecurity concern. Pasteurisation is defined in the [Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products](#) as 'a microbiocidal heat treatment aimed at reducing the number of any pathogenic micro-organisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard' (Codex Alimentarius Commission 2009).

In line with the FSANZ Guide to Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products (FSANZ 2009), the department defines pasteurisation as one of the following processes:

- high-temperature short-time (HTST) pasteurisation – a process applying a minimum temperature of 72°C for 15 seconds
- batch pasteurisation, also called low-temperature long-time (LTLT) pasteurisation – a process applying a minimum temperature of 63°C for 30 minutes
- ultra-high temperature (UHT) – a process applying a minimum temperature of 132°C for at least 1 second.

The major components of milk are water, lactose, fat, proteins and minerals (ash). Milk is processed into a wide range of dairy products for the retail industry and dairy-based ingredients intended for further processing. The equipment and processes used to transform raw milk, and the composition of the resulting dairy product, depend on the type of dairy product being produced. Some publicly available resources about the processes used to produce, and the composition of, dairy products are summarised in Table 1.

**Table 1 Publicly available resources about dairy products**

Title	Author	Content
<a href="#">Australian Manual for the Validation and Verification of Heat Treatment Equipment and Processes</a>	Australia New Zealand Dairy Authorities' Committee	A guideline to assist industry and regulators with the implementation of food safety standards and the application of good food safety practice
<a href="#">Australian Dairy Ingredient Reference Manual (PDF 4936 KB)</a>	Dairy Australia	Brief descriptions and composition information of dairy products and ingredients
<a href="#">Gateway to dairy production and products</a>	Food and Agriculture Organisation of the United Nations	Species-specific information about the composition of milk and brief descriptions of the manufacturing processes and characteristics of dairy products
<a href="#">Compendium of Microbiological Criteria for Food</a>	Food Standards Australia New Zealand	Best practice guidance for food regulators and the food industry which contains basic information on microorganisms (pathogens and indicators) significant to food safety, and microbiological criteria for food safety management. The dairy product chapter (chapter 5) was developed by experts from FSANZ and food regulatory agencies, in consultation with the dairy industry
<a href="#">Standards 2.5.1 to 2.5.7 of the food standards code</a>	Food Standards Australia New Zealand	Defines and sets compositional requirements for milk (2.5.1), cream (2.5.2), fermented milk products (2.5.3), cheese (2.5.4), butter (2.5.5), ice cream (2.5.6) and dried milk, evaporated milk and condensed milk (2.5.7)
<a href="#">Standard 4.2.4 of the food standards code</a>	Food Standards Australia New Zealand	Outlines requirements for primary production, dairy collection and transportation, dairy processing and additional requirements for the production, transport, and processing of milk for raw milk cheese



Title	Author	Content
<a href="#">A risk profile of dairy products in Australia</a>	Food Standards Australia New Zealand	The Risk Profile of Dairy Products in Australia brings together information on microbiological and chemical risks that may be associated with dairy products
<a href="#">The Codex Alimentarius standards for milk products, horizontal cheese standards and individual cheese standards</a>	The Codex Alimentarius Commission	Descriptions and essential composition and quality factors; the global reference for governments, the food industry, trade operators and consumers
<a href="#">The Dairy Processing Handbook</a>	Tetra Pal	Definitions and descriptions, composition information and detailed information on manufacturing processes
<a href="#">The milk making process</a>	Dairy Australia	Brief descriptions of common manufacturing processes

## Scope

The scope of this draft risk review is to consider the biosecurity risks that may be associated with importing dairy products into Australia for human consumption from any country.

This draft risk review is restricted to dairy products manufactured from milk and colostrum obtained from domestic cattle (*Bos taurus*), domestic water buffalo (*Bubalus bubalis*), domestic sheep (*Ovis aries*) and/or domestic goats (*Capra hircus*).

Dairy products manufactured from milk obtained from species other than domestic cattle, water buffalo, sheep and/or goats (such as camels, donkeys or horses) are not included in this draft risk review. If required, an assessment of the biosecurity risks and development of biosecurity measures for importing dairy products manufactured from milk obtained from other species will be undertaken in the future.

For the purpose of this draft risk review, the definition of dairy products is the same as that used in the [Biosecurity \(Conditionally Non-prohibited Goods\) Determination 2021](#) (Goods Determination).

Dairy products are milk and goods produced from milk:

- milk (including condensed, concentrated, dried and powdered milk); or
- goods produced from milk
  - butter
  - casein
  - cheese
  - cream
  - ghee
  - ice cream
  - milk albumin
  - whey
  - yoghurt.

The findings of the draft risk review will also inform risk management for:

- dairy products imported for personal use (personal consignments) or as food samples
- dairy products included in the Goods Determination
- raw milk cheese
- retorted dairy products.

This draft risk review specifically excludes:

- dairy products manufactured from milk obtained from animals other than domestic cattle, water buffalo, sheep and goats
- dairy products imported for any end use other than human consumption (such as animal feed, scientific, or industrial use).

### **Dairy products other than cheese**

All imported dairy products must meet the Imported Food Control Act, which includes a requirement for pasteurisation of milk and dairy products (except for cheese). As such, all imported dairy products (except for cheese) must be pasteurised. In estimating the unrestricted risk associated with importing dairy products for human consumption, this draft risk review assumes that the milk in dairy products (except for cheese) has been pasteurised with one of the following methods:

- high-temperature short-time (HTST) pasteurisation – a process applying a minimum temperature of 72°C for 15 seconds
- batch pasteurisation, also called low-temperature long-time (LTLT) pasteurisation – a process applying a minimum temperature of 63°C for 30 minutes
- ultra-high temperature (UHT) – a process applying a minimum temperature of 132°C for at least 1 second.

### **Cheese**

For the purposes of this draft risk review, cheese is defined as the ripened or unripened solid or semi-solid milk product, whether coated or not, that is obtained by wholly or partly coagulating milk, through the action of rennet or other suitable coagulating agents, and partially draining the whey which results from the coagulation. The product characteristics and processing factors of cheese, such as pH, salt concentration, water activity and ripening conditions, would be expected to reduce the likelihood of entry and the likelihood of susceptible animals being exposed to and consuming an infectious dose of disease agents of animal biosecurity concern. Where these factors did not sufficiently reduce the risk to achieve Australia's ALOP, risk management was required.

### **Alternative processing technologies**

Some alternative processing technologies to pasteurisation are now used commercially, although not widely. For example, high pressure processing is being used as an alternative to conventional heat pasteurisation (Horn et al. 2019).

A scientific evaluation of pasteurisation and alternative processes for pathogen reduction in milk and milk products from 2005 concluded that 'no single alternative technology has been shown to be capable of replacing heat – applied via the traditional thermal pasteurisation processes – as an

effective and reliable means of destroying all of the pathogenic vegetative bacteria that can be found in raw milk' (Juffs & Deeth 2007). The Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products states that non-thermal microbiocidal control measures 'are not yet applied at such intensities that will render the milk product safe at the point of application' (Codex Alimentarius Commission 2009).

Given the limited use of alternative processes compared with heat treatment for pasteurisation of dairy products, alternative processes as a risk management measure are not considered in this draft risk review. However, if there is interest in importing dairy products that have undergone an alternative process to heat treatment, an assessment of the alternative process will be undertaken in the future. Before biosecurity measures can be developed, scientific evidence needs to be available to demonstrate that the alternative process is able to manage disease agents of animal biosecurity concern to an appropriate level. This includes all disease agents identified as hazards (see section 1.1).

### **Dairy products of ovine and/or caprine origin**

Dairy products of ovine and/or caprine origin for human consumption are considered a niche market. The value of Australian bovine dairy production is forecast to increase to \$6.2 billion in 2022–23 (Read 2022), whereas the current Australian ovine and caprine dairy industries have an estimated total production value of \$30 million and \$4 million per annum, respectively (Stubbs & Abud 2009). This is consistent with dairy production figures in the European Union where dairy production from animals other than bovine accounts for around 3% of the total dairy production (Rossi 2017).

Imported dairy products of ovine and/or caprine origin are less likely to be disposed of or repurposed as animal feed, and at the household level, be discarded or fed to animals before human consumption. This was considered in the risk assessment for disease agents retained for risk review that could be imported in dairy products of ovine and/or caprine origin.

## **Existing regulation**

### **International requirements**

The Goods Determination includes alternative conditions for importing some dairy products and goods containing dairy ingredients. They are called 'alternative conditions' because they are an alternative to obtaining an import permit. The Goods Determination allows some dairy products to be imported without an import permit (Part 2, Division 1, section 18):

- dairy products, other than infant formula, containing one or more packets, with the total dry weight of the components of the goods (other than added water) containing less than 10% of dairy products
- dairy products (including infant formula) containing less than 10% by dry weight (other than added water) of dairy products
- commercially prepared and packaged chocolate
- commercially prepared and packaged clarified butter oil or ghee
- commercial dairy products from New Zealand, if the goods are brought in or imported directly from New Zealand and are made of ingredients that originated in, and were produced, processed and manufactured in, Australian territory or New Zealand only

The Goods Determination ([Part 2, Division 1, section 20](#)) allows biscuits, breads, cakes and pastries for human consumption to be imported for commercial use without an import permit if:

- the goods are shelf-stable and do not contain meat or meat product
- the goods, excluding any fillings or toppings, have been cooked throughout
- if the goods contain any fillings or toppings that are made of ingredients including 10% or more dairy products and/or 10% or more egg products, those fillings or toppings are cooked throughout.

Dairy products that are not included in the Goods Determination require a valid import permit and accompanying health certification. This is necessary for importation of the following dairy products for human consumption:

- dairy products (other than cheese and butter) of bovine origin from countries free from foot-and-mouth disease (FMD) and lumpy skin disease (LSD)
- dairy products (other than cheese and butter) of ovine and/or caprine origin from countries free from FMD and sheep pox and goat pox
- cheese or butter
- colostrum from the United States
- retorted dairy products.

Dairy products for human consumption, or any derivatives must not be distributed, sold or used for either:

- animal consumption, or
- use as bioremediation agents or fertiliser, or
- growing purposes, or
- veterinary therapeutic use.

For import conditions, see the [Australian Biosecurity Import Conditions database](#) (BICON).

### **Domestic arrangements**

The Australian Government is responsible for regulating the movement of animals and animal products into and out of Australia. However, the state and territory governments are responsible for animal health and environmental controls within their individual jurisdiction. Legislation on resource management or animal health may be used by state and territory government agencies to control interstate movement of animals and animal products. Once animals and animal products have been cleared by Australian Government biosecurity officers, they may be subject to interstate movement conditions. The importer is responsible for ensuring compliance with all requirements.

#### **1.1.1 Consultation**

Stakeholders were notified of the formal commencement of this risk review through [Animal Biosecurity Advice 2021-A01 on 13 January 2021](#). Stakeholders were invited to provide submissions on specific issues with Australia's current import conditions for dairy products for human

consumption. Submissions closed on 12 March 2021 and 17 submissions were received. Topics raised included:

- the need for biosecurity measures to be clear and flexible
- lists of countries free from certain diseases
- heat treatments equivalent to pasteurisation
- health certification procedures
- import permit procedures
- importing dairy products from New Zealand
- calculating and limits on the percentage of dairy
- highly refined minor dairy components
- diverting dairy products imported for human consumption to animal feed
- samples and personal consignments
- non-biosecurity requirements for importing raw milk cheese (outside the scope of this risk review)
- resourcing and funding for biosecurity (outside the scope of this risk review)
- tariffs (outside the scope of this risk review).

### **Next steps**

This draft risk review gives stakeholders the opportunity to comment and draw attention to any scientific, technical, or other gaps in the data, misinterpretations and errors.

The department will consider submissions received on this draft risk review and may consult informally with stakeholders. The department will then prepare a final report, taking into account stakeholder comments.

The final risk review will be published on the department's website with a notice advising stakeholders of the release. The department will also notify registered stakeholders and the World Trade Organization Secretariat about the release of the final Import risk review for dairy products for human consumption.

# 1 Method

## 1.1 Background

The WOA, in its [Terrestrial Animal Health Code](#) (the Terrestrial Code), describes 'General obligations related to certification' in Chapter 5.1. (WOAH 2022h).

In the Terrestrial Code, Article 5.1.2. states that:

The import requirements included in the international veterinary certificate should assure that commodities introduced into the importing country comply with the standards of WOA. Importing countries should align their requirements with the recommendations in the relevant standards of WOA. If there are no such recommendations or if the country chooses a level of protection requiring measures more stringent than the standards of WOA, these should be based on an import risk analysis conducted in accordance with Chapter 2.1.

Article 5.1.2. further states that:

The international veterinary certificate should not include measures against pathogenic agents or diseases which are not WOA listed, unless the importing country has demonstrated through import risk analysis, carried out in accordance with Section 2, that the pathogenic agent or disease poses a significant risk to the importing country.

The components of risk analysis as described in Chapter 2.1. of the Terrestrial Code (WOAH 2022j) are:

- hazard identification
- risk assessment (entry assessment, exposure assessment, consequence assessment and risk estimation)
- risk management
- risk communication.

Hazard identification, risk assessment and risk management are sequential steps within a risk analysis. Risk communication is conducted as an ongoing process and includes both formal and informal consultation with stakeholders.

## 1.2 Risk review

Although not defined or described in the Terrestrial Code, risk review is recognised by risk analysts as an essential component of the risk analysis process (Barry 2007; FSA 2006; Purdy 2010).

Australia applies a process of risk review to the biosecurity risks associated with the importation of an animal commodity (live animal or animal product) for which current biosecurity measures exist or where biosecurity measures have already been developed.

Australia sets its biosecurity measures in line with international standards where they exist and where they deliver the appropriate level of protection from pests and diseases. In general, Australia

will adopt the risk management measures recommended in the Terrestrial Code (WOAH 2022w) where they exist. However, where recommendations in the Terrestrial Code do not exist or do not achieve Australia's ALOP for a disease agent, Australia exercises its right under the SPS Agreement to determine appropriate sanitary measures, justified on scientific grounds and supported by risk analysis.

Risk review differs from the monitoring and review component of risk management, as described in the Terrestrial Code, in that each component of the risk analysis process (hazard identification, risk assessment and risk management) is reviewed under the risk review process. If a change (either an increase or a decrease) in the biosecurity risk associated with a live animal or animal product that is currently imported into Australia is identified based on updated scientific information, risk management measures can be revised accordingly.

This draft risk review has drawn on these sources of information (this list is not exhaustive):

- the Terrestrial Code (WOAH 2022w)
- the dairy IRA and current conditions for importing dairy products into Australia
- a review of relevant scientific literature.

Risk – defined by the Terrestrial Code (WOAH 2022i) as ‘the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health’ – is dynamic in nature; it changes with time. Consequently, risk should be regularly reviewed.

### **1.3 Review of hazard identification**

Hazard identification is described in the Terrestrial Code Article 2.1.2. (WOAH 2022j) as a classification step that is undertaken to identify potential hazards that may be associated with the importation of a commodity.

In accordance with the Terrestrial Code, a disease agent was considered to be a potential hazard relevant to the importation of dairy products if it was assessed to be:

- appropriate to dairy products manufactured from milk obtained from domestic cattle, water buffalo, sheep and/or goats
- WOAHL-listed, emerging and/or capable of producing adverse consequences in Australia.

A hazard was retained for risk review (hazard refinement) if:

- it was not present in Australia, or present in Australia and a notifiable disease or subject to official control or eradication
- there was scientific evidence that the disease agent is present in, and potentially transmissible in, dairy products.

Some disease agents were identified as hazards but were not retained for risk review as they were deemed to be sufficiently managed by the [minimum requirements](#).

Where evidence for the inclusion or exclusion of a particular disease agent was equivocal, a judgement was made based on the strength of the available evidence to implicate dairy products in disease transmission.

## 1.4 Review of risk assessment

Disease agents retained following hazard refinement were subjected to scientific review. Where the scientific review led to the conclusion that a risk assessment was required for the disease agent, this was conducted in accordance with Chapter 2.1 of the Terrestrial Code (WOAH 2022j).

Risk assessment is the evaluation of the likelihood and the biological and economic consequences of entry, establishment and/or spread of a hazard within the territory of an importing country.

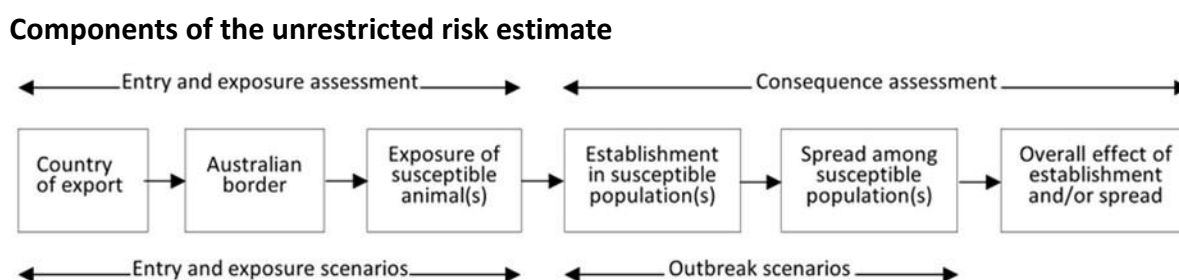
For each disease agent requiring risk assessment, the risk assessment resulted in an unrestricted risk estimate for the disease agent. For the purposes of this draft risk review, the unrestricted risk estimate was defined as the level of risk that would be present if there were no safeguards in place other than [minimum requirements](#).

Estimation of the unrestricted risk included consideration of:

- the likelihood of the disease agent entering Australia in dairy products imported for human consumption ([entry assessment](#))
- the likelihood of susceptible animals being exposed to the disease agent in dairy products imported for human consumption ([exposure assessment](#))
- the most likely outbreak scenario that could follow exposure to the disease agent and the likelihood of establishment and/or spread associated with the outbreak scenario ([consequence assessment](#))
- the overall effect of establishment and/or spread associated with the outbreak scenario ([consequence assessment](#)).

Steps in estimating the unrestricted risk are illustrated diagrammatically in Figure 1.

**Figure 1 Components of the unrestricted risk estimate**



If the unrestricted risk estimate for the disease agent did not achieve Australia’s ALOP, then risk management measures in addition to [minimum requirements](#) were recommended to reduce the risk to achieve Australia’s ALOP.

### 1.4.1 Evaluating and reporting likelihood

Risk assessments were conducted using a qualitative approach and the nomenclature in Table 2.



**Table 2 Nomenclature for qualitative likelihoods**

Likelihood	Description definition
High	The event would be very likely to occur
Moderate	The event is equally likely to occur or not occur
Low	The event would be unlikely to occur
Very low	The event would be very unlikely to occur
Extremely low	The event would be extremely unlikely to occur
Negligible	The event would almost certainly not occur

### 1.4.2 Entry assessment

Entry assessment consists of describing the pathways necessary for the importation of dairy products for human consumption to introduce the disease agent into Australia and estimating the likelihood of that complete process occurring.

The entry assessment considered a single-entry scenario defined as the period from milking, processing and export, up to arrival of dairy products in Australia. A number of factors were taken into account in determining the likelihood of the disease agent being present in imported dairy products, such as:

- prevalence of the disease agent in animals being milked in the source country
- visibility of clinical signs of disease associated with the disease agent
- presence of the disease agent in milk
- the effect of processing on the disease agent
- the possibility for post-processing contamination with the disease agent
- the effect of storage and transport on the disease agent.

A qualitative likelihood (Table 2) was assigned to describe the likelihood of the disease agent entering Australia in dairy products imported for human consumption.

### 1.4.3 Exposure assessment

Exposure assessment consists of describing the pathways necessary for exposure of susceptible animals in Australia to the disease agent in dairy products imported for human consumption and estimating the likelihood of the exposure occurring.

The exposure assessment commenced at the point of arrival of dairy products in Australia. The exposure assessment considered the different groups of animals that were susceptible to infection with the disease agent and the pathways by which these animals could be exposed to the disease agent in imported dairy products.

The exposure groups considered were:

- domestic ruminant species
- other susceptible non-ruminant species such as pigs, horses, poultry, dogs and cats
- feral animal and wildlife species.

The potential pathways for exposure of susceptible animals to dairy products imported for human consumption considered were:

- Product imported for human consumption is disposed as waste in such a way that it is accessible to animals, including feral and wild animals.
- Product imported for human consumption is repurposed for use in animal feed (for example, product becomes unfit for human consumption during further manufacture, product passes its use-by date or product is over-ordered)
- Product imported for human consumption is fed to animals (for example, milk powder fed to hand-reared animals, household scraps fed to animals)
- Product imported for human consumption that was always intended to be used as animal feed.

Exposure group and disease agent factors were also considered, including:

- whether susceptible animals in each exposure group would have direct or indirect contact with imported dairy products
- whether the disease agent would survive during the period before exposure of susceptible animals.

A qualitative likelihood (Table 2) was assigned to describe the likelihood of susceptible animals being exposed to the disease agent in dairy products imported for human consumption.

#### 1.4.4 Estimation of the likelihood of entry and exposure

The likelihood of entry and exposure for the disease agent was estimated by combining the likelihood of entry and the corresponding likelihood of exposure using the matrix shown in Figure 2.

**Figure 2 Matrix for combining qualitative likelihoods**

<b>Likelihood of entry</b>	<i>High</i>	Negligible	Extremely low	Very low	Low	Moderate	High
	<i>Moderate</i>	Negligible	Extremely low	Very low	Low	Low	Moderate
	<i>Low</i>	Negligible	Extremely low	Very low	Very low	Low	Low
	<i>Very low</i>	Negligible	Extremely low	Extremely low	Very low	Very low	Very low
	<i>Extremely low</i>	Negligible	Negligible	Extremely low	Extremely low	Extremely low	Extremely low
	<i>Negligible</i>	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
		<i>Negligible</i>	<i>Extremely low</i>	<i>Very low</i>	<i>Low</i>	<i>Moderate</i>	<i>High</i>
		<b>Likelihood of exposure</b>					

#### 1.4.5 Consequence assessment

The consequence assessment describes the potential effects of a given exposure and estimates the likelihood of the spread and establishment of the hazard (that is, the outbreak scenario) which could result in such effects occurring.

### **Identification of an outbreak scenario and likelihood of establishment and/or spread associated with the outbreak scenario**

Once exposure of susceptible animals has occurred, a number of possible outbreak scenarios could follow. These represent a continuum ranging from no spread to widespread establishment of disease.

The outbreak scenarios for this review are:

- establishment in the directly exposed population but does not spread to other populations of susceptible animals
- establishment in the directly exposed population and spread to other populations of susceptible animals within the local area
- establishment in the directly exposed population and spread to other populations of susceptible animals within the region
- establishment in the directly exposed population and spread to other populations of susceptible animals across multiple states or territories.

For risk assessment purposes, outbreak scenarios were considered based on the epidemiology of the disease agent. The most likely outbreak scenario following exposure of susceptible animals to the disease agent in imported dairy products was identified. The outbreak scenario considered was dependent on detection of the disease agent in susceptible animals. The most likely outbreak scenario was determined by the extent of establishment and/or spread at detection.

The likelihood of the identified outbreak scenario occurring was estimated to obtain the likelihood of establishment and/or spread of the disease agent associated with the identified outbreak scenario. A qualitative likelihood (Table 2) was assigned to describe the likelihood of establishment and/or spread.

### **Determination of overall effect of establishment and/or spread associated with outbreak scenario**

Effects of establishment and/or spread of the disease agent associated with the identified outbreak scenario were evaluated in terms of 7 (2 direct and 5 indirect) criteria.

Direct effects:

- Life or health (including production effects) of susceptible animals.
- The living environment, including life and health of wildlife, and any effects on the non-living environment.

Indirect effects:

- New or modified eradication, control, monitoring or surveillance and compensation strategies or programs.
- Domestic trade or industry, including changes in consumer demand and effects on other industries supplying inputs to, or using outputs from, directly affected industries.
- International trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand.

- The environment, including biodiversity, endangered species and the integrity of ecosystems.
- Communities, including reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any ‘side effects’ of control measures.

The overall effect of establishment and/or spread associated with the identified outbreak scenario took into account the increasing geographic level of these effects:

- local – restricted to a single locality or town
- regional – a recognised geographic area such as far north Queensland
- state or territory
- national.

and the magnitude of these effects:

- indiscernible – not usually distinguishable from normal day-to-day variation
- minor significance – recognisable, but minor and reversible
- significant – serious and substantive, but reversible and unlikely to have permanent economic effects
- highly significant – extremely serious and irreversible and likely to have permanent economic effects.

An outbreak may occur on a small geographical level but have significant national effects, and vice versa. Based on the geographic level and magnitude of effects, the overall effect of establishment and/or spread of the disease agent associated with the identified outbreak scenario was determined using the rules described in Table 3.

**Table 3 Rules for determining the overall effect of establishment and/or spread**

Overall effect	Description
Extreme	The effect is likely to be highly significant at the national level. Implies that economic stability, societal values or social well-being would be seriously affected.
High	The effect is likely to be significant at the national level and highly significant within affected zones. Implies that the effect would be of national concern. However, serious effects on economic stability, societal values or social well-being would be limited to a given zone.
Moderate	The effect is likely to be recognised on a national level and significant within affected zones. The effect is likely to be highly significant to directly affected parties.
Low	The effect is likely to be recognised within affected zones and significant to directly affected parties. It is not likely that the effect will be recognised at the national level.
Very low	The effect is likely to be minor to directly affected parties. The effect is unlikely to be recognised at any other level.
Negligible	The effect is unlikely to be recognised at any level within Australia.

#### **Derivation of likely consequences**

The likely consequences of establishment and/or spread of the disease agent were estimated by combining the likelihood of establishment and/or spread with the overall effect of establishment and/or spread using the matrix shown in Figure 3.

**Figure 3 Likely consequences matrix**

Likelihood of establishment and/or spread	High	Negligible	Very low	Low	Moderate	High	Extreme
	Moderate	Negligible	Very low	Low	Moderate	High	Extreme
	Low	Negligible	Negligible	Very low	Low	Moderate	High
	Very low	Negligible	Negligible	Negligible	Very low	Low	Moderate
	Extremely low	Negligible	Negligible	Negligible	Negligible	Very low	Low
	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Very low
		<i>Negligible</i>	<i>Very low</i>	<i>Low</i>	<i>Moderate</i>	<i>High</i>	<i>Extreme</i>

**Overall effect of establishment and/or spread**

### 1.4.6 Risk estimation

Risk estimation consists of integrating the results from the entry assessment, exposure assessment and consequence assessment to produce an unrestricted risk estimate of the disease agent.

The unrestricted risk for the disease agent was estimated by combining the likelihood of entry and exposure with the likely consequences of establishment and/or spread using the risk estimation matrix shown in Figure 4.

**Figure 4 Risk estimation matrix**

Likelihood of entry and exposure	High	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	Moderate	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	Low	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk	High risk
	Very low	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
	Extremely low	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
	Negligible	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk
		<i>Negligible</i>	<i>Very low</i>	<i>Low</i>	<i>Moderate</i>	<i>High</i>	<i>Extreme</i>

**Likely consequences of establishment and/or spread**

If the unrestricted risk of the disease agent was estimated to be ‘negligible’ or ‘very low’, this achieved Australia’s ALOP and risk management measures in addition to [minimum requirements](#) were not required.

If the unrestricted risk of the disease agent was estimated to be ‘low’, ‘moderate’, ‘high’ or ‘extreme’, this did not achieve Australia’s ALOP. As a result, risk management measures in addition to [minimum requirements](#) were required.

## 1.5 Risk management

Risk management is described in the Terrestrial Code Article 2.1.5. as the process of deciding upon and implementing measures to address the risks identified in the risk assessment, while ensuring that negative effects on trade are minimised (WOAH 2022j).

Components of risk management include risk evaluation – the process of comparing the risk estimated in the risk assessment with the reduction in risk expected from the proposed risk management measures – and option evaluation – the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences.

If the unrestricted risk estimate for a disease agent did not achieve Australia’s ALOP, then risk management measures in addition to [minimum requirements](#) were recommended to reduce the risk to achieve Australia’s ALOP.

The restricted risk estimate for a disease agent is the level of risk that would be present with a particular risk management measure or combination of measures applied. If the restricted risk of the disease agent was estimated to be ‘negligible’ or ‘very low’ following application of a particular risk management measure or combination of measures, this achieved Australia’s ALOP and that measure or combination of measures was considered acceptable.

If risk management measures were warranted, previous risk management measures were reviewed. Proposed risk management measures aimed to be practical, taking into account industry practices and operational feasibility, and no more trade-restrictive than necessary to achieve Australia’s ALOP.

## 1.6 Risk communication

Risk communication is defined in the Terrestrial Code as ‘the interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, risk communicators, the general public and other interested parties’ (WOAH 2022i).

In conducting import risk analyses and risk reviews, the department consults with the Department of Health and Aged Care where necessary to ensure that public health considerations are included in the development of Australia’s animal biosecurity policies. Consultation with external stakeholders is a standard procedure for all import risk analyses and risk reviews to enable stakeholder assessment and feedback on draft conclusions and recommendations about Australia’s animal biosecurity policies.

## 2 Hazard identification

The list of potential hazards (disease agents of potential biosecurity concern) was compiled from:

- Diseases, infections and infestations listed by the WOAHP included within the categories of multiple species diseases, infections and infestations; cattle diseases and infections; and sheep and goat diseases and infections (WOAH 2022d).
- Diseases identified in the dairy IRA and relevant previous import risk analyses and risk reviews conducted by the department.
- Other disease agents identified as occurring in milk obtained from domestic cattle, water buffalo, sheep and/or goats.

The method of hazard identification and refinement is described in section 1.3. The list of potential hazards is shown in Table 4. This table summarises the results of the hazard refinement process, including the reason for removal or retention of each disease agent.

Some disease agents were identified as hazards but were not retained for risk review as they were deemed to be sufficiently managed by [minimum requirements](#). Additional scientific information for these disease agents is summarised in Appendix A: Disease agents managed by minimum requirements.

Potential hazards included disease agents that may be shed directly into milk or may be present in milk through faecal/environmental contamination. Many disease agents are ubiquitous or common commensals and may be present in Australia. Others are opportunistic, not reported to be pathogenic or are of uncertain relevance in milk obtained from domestic cattle, water buffalo, sheep and goats due to limited or insufficient information. These disease agents were considered when compiling the list of potential hazards. Multicellular parasites (external and internal) were not considered to be relevant in milk and were not included in the list of potential hazards.

There are no domestic movement controls on milk or dairy products for disease agents that are present in Australia and are transmissible through milk. As such, potential hazards that are present in Australia were not retained for risk review.

**Table 4 Hazard identification and refinement**

Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Aino virus (Aino disease)	Cattle, sheep, goats	No	No	Yes	No	No: not present in milk
Akabane virus (Akabane disease)	Cattle, sheep, goats, possibly pigs	No	No	Yes	No	No: not present in milk
<i>Anaplasma bovis</i>	Cattle	No	No	Not reported	No	No: not present in milk
<i>Anaplasma marginale</i> (Bovine anaplasmosis)	Cattle	No	Yes	Yes	Yes (in tick-free areas)	No: not present in milk
<i>Babesia bovis</i> , <i>B. bigemina</i> , <i>B. divergens</i> (Bovine babesiosis)	Cattle, buffalo	No	Yes	<i>B. bovis</i> and <i>B. bigemina</i> present; <i>B. divergens</i> not present	Yes (in tick-free areas)	No: not present in milk
<i>Bacillus anthracis</i> (Anthrax)	Wild and domestic herbivores (natural hosts), all other warm-blooded animals including humans	May be present in milk, but no evidence of transmission through milk	Yes	Yes (subject to official control measures)	Yes	No: not transmissible through milk
<i>Besnoitia besnoiti</i> (Bovine besnoitiosis)	Cattle	No	No	Not reported	No	No: not present in milk
Bluetongue virus (bluetongue)	Cattle, sheep, goats, deer, buffalo, camelids	No	Yes	Yes (some serotypes not present)	Yes (clinical disease)	No: not present in milk
Border disease virus (Border disease)	Sheep and goats (primarily), cattle, pigs, deer, camels	No	No	Yes	No	No: not present in milk
Borna disease virus 1 (Borna disease)	Horses, cattle (rarely), goats, sheep, multiple other species	No	No	No	Yes	No: not present in milk



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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
<i>Borrelia burgdorferi</i> (Lyme disease)	Rodents (reservoir hosts); dogs, horses, cattle, humans (incidental hosts)	No evidence of presence in ruminant milk	No	Not reported	No	No: not present in milk of relevant species
Bovine encephalitis herpesvirus/bovine alphaherpesvirus 5	Cattle, sheep	Yes	No	Yes	No	No: present in Australia
Bovine enterovirus 1/enterovirus E1, bovine enterovirus 2/enterovirus F1	Cattle	No	No	Yes	No	No: not present in milk
Bovine ephemeral fever virus (bovine ephemeral fever)	Cattle, yaks, buffalo	No	No	Yes	No	No: not present in milk
Bovine herpesvirus 4/bovine gammaherpesvirus 4	Cattle	Yes	No	Not reported	No	No: not nationally notifiable, considered non-pathogenic
Bovine immunodeficiency virus (bovine immunodeficiency disease)	Cattle	Yes	No	Yes	No	No: present in Australia
Bovine kobuvirus	Cattle	No	No	Not reported	No	No: not present in milk
Bovine leukemia virus (Enzootic bovine leukosis)	Cattle, sheep (experimental infection only)	Yes	Yes	Australian dairy herd achieved freedom on 31 December 2012; very low prevalence in beef cattle	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
Bovine orthopneumovirus/bovine respiratory syncytial virus	Cattle, sheep, goats	No	No	Yes	No	No: not present in milk
Bovine parainfluenza virus 3	Cattle	No	No	Yes	No	No: not present in milk
Bovine parvovirus 1	Cattle	No	No	Yes	No	No: not present in milk
Bovine spongiform encephalopathy protease-resistant prion protein (PrP <sup>res</sup> ) (bovine spongiform encephalopathy)	Cattle, bison, cats, zoo felidae, antelope, humans	No	Yes	No	Yes	No: not present in milk

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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Bovine viral diarrhoea virus 1, bovine viral diarrhoea virus 2, HoBi-like pestivirus (bovine viral diarrhoea)	Bovine viral diarrhoea virus 1 and bovine viral diarrhoea virus 2: cattle, sheep, other ruminants, pigs; HoBi-like pestivirus: cattle, buffalo	May be present in milk, but no evidence of transmission through milk	Yes	Bovine viral diarrhoea virus 1 present; bovine viral diarrhoea virus 2 not present; HoBi like pestivirus not reported	Yes (bovine virus diarrhoea virus type 2 only)	No: not transmissible through milk
<i>Brucella abortus</i> , <i>B. melitensis</i> , <i>B. suis</i> (Brucellosis)	Multiple susceptible species including cattle, bison, buffalo, pigs, horses, deer, elk, camels, llamas, alpacas, humans	Yes	Yes	<i>B. abortus</i> and <i>B. melitensis</i> not present; <i>B. suis</i> present	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
<i>Brucella ovis</i> (Ovine epididymitis)	Sheep, red deer; goats and cattle susceptible to experimental infection	Yes	Yes	Yes	No	No: present in Australia
<i>Burkholderia pseudomallei</i> (Meliodosis)	Goats, sheep, camels, alpacas, multiple other species including cattle, humans	Yes	No	Yes	No	No: present in Australia
Cache Valley virus (Cache Valley fever)	Sheep and goats primarily, white-tailed deer potential reservoir, cows, horses; humans may also be susceptible	No	No	Not reported	No	No: not present in milk
<i>Campylobacter fetus</i> subsp. <i>venerealis</i> (Bovine genital campylobacteriosis)	Cattle	No	Yes	Yes	No	No: not present in milk
<i>Campylobacter jejuni</i> , <i>C. coli</i> (Campylobacter enteritis)	Cattle, multiple other species including humans	Yes	No	Yes	No	No: present in Australia
Caprine arthritis–encephalitis virus (caprine arthritis encephalitis)	Goats	Yes	Yes	Yes	No	No: present in Australia

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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
<i>Chlamydia (Chlamydophila) abortus</i> (Enzootic abortion of ewes/ovine chlamydiosis)	Sheep, goats (primary reservoir hosts), suspected to cause illnesses in multiple other species including humans	Yes	Yes	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
<i>Chlamydia pecorum</i>	Cattle, sheep, koalas	No	No	Yes	No	No: not present in milk
<i>Clostridium botulinum, C. perfringens</i>	Cattle, sheep, goats, pigs, humans, multiple other species	Yes	No	Yes	No	No: present in Australia
<i>Corynebacterium</i> spp.	Cattle, sheep, goats, pigs, dogs, cats, humans, multiple other species	Yes	No	Yes	No	No: present in Australia
Cowpox virus (cowpox)	Rodents (primary reservoir host), domestic cats, alpacas, zoo animals such as elephants and cheetahs, very rare in cattle	No	No	Not reported	No	No: not present in milk
<i>Coxiella burnetii</i> (Q fever)	Cattle, sheep, goats, buffalo, possibly camels, multiple other species including humans	Yes	Yes	Yes	No	No: present in Australia
Crimean-Congo haemorrhagic virus (Crimean-Congo haemorrhagic fever)	Cattle, sheep, goats, buffalo, camels, hares, dogs, mice, ostriches, humans, multiple other species	No evidence of presence in ruminant milk	Yes	No	Yes	No: not present in milk of relevant species
<i>Cryptosporidium parvum</i> (Bovine cryptosporidiosis)	Cattle, yaks, buffalo, camels, sheep, goats, horses, humans	Yes	No	Yes	No	No: present in Australia
Eastern equine encephalitis virus, western equine encephalitis virus, Venezuelan equine encephalitis virus	Birds, equids, rodents; occasionally other species	No	Yes	No	Yes	No: not present in milk

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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
(Eastern, Western and Venezuelan equine encephalomyelitis)	including cattle, sheep, camelids, pigs					
<i>Ehrlichia ruminantium</i> (Heartwater)	Cattle, buffalo, deer, sheep, goats	May be present in colostrum, transmission from dam to calf may occur	Yes	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
Epizootic haemorrhagic disease virus (epizootic haemorrhagic disease)	Cattle, deer, yaks, bison, sheep (experimental)	No	Yes	Clinical disease not present	Yes (clinical disease)	No: not present in milk
Foot-and-mouth disease virus (foot-and-mouth disease)	Cloven hooved animals	Yes	Yes	No	Yes	Yes: not present in Australia, present in and transmissible in milk, may not be managed by minimum requirements
<i>Francisella tularensis</i> (Tularaemia)	Mainly rabbits and other wild rodents; sheep, cattle (rarely), horses, dogs, cats, fish, birds, humans	No	Yes	Yes (suspected in wild animals, absent in domestic animals)	Yes	No: not present in milk
<i>Histophilus somni</i> (Histophilosis)	Cattle, bison, sheep	No	No	Yes	No	No: not present in milk
Infectious bovine rhinotracheitis virus/bovine alphaherpesvirus 1 (Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis)	Cattle, buffalo, sheep, goats	May be present in milk, but no evidence of transmission through milk	Yes	Yes (some subtypes not present)	No	No: not transmissible through milk
Influenza A virus (highly pathogenic avian influenza virus, subtype H5)	Mainly avian, multiple other mammalian species including humans	Yes	No (infection in cattle, sheep or goats is not WOAH-listed; 'Infection with influenza A viruses of high pathogenicity in	No	No (not nationally notifiable in cattle, sheep or goats. Influenza A virus infections are nationally notifiable in birds,	*Australia is currently monitoring the emerging issue of the detection of influenza A virus in milk following recent infections of ruminants with highly-pathogenic avian influenza virus, subtype H5

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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
			birds other than poultry including wild birds' is WOAHL-listed)		horses, and swine)	
Influenza D virus	Cattle, pigs, sheep, goats	No	No	Not reported	No	No: not present in milk
Jaagsiekte sheep retrovirus (Pulmonary adenomatosis)	Sheep, goats (rarely)	Yes	No	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
Japanese encephalitis virus (Japanese encephalitis)	Horses, donkeys, pigs primarily, rare clinical cases in cows, subclinical infections in many other mammals (including sheep, goats, rabbits, dogs), humans	No	Yes	Yes	Yes	No: not present in milk
Jembrana disease virus (Jembrana disease)	Bali cattle ( <i>Bos javanicus</i> ); cattle, buffalo and pigs susceptible to experimental infection	Yes	No	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
<i>Leptospira borgpetersenii</i> serovar hardjo type hardjo-bovis (Leptospirosis)	Cattle, multiple other species including humans	Yes	No	Yes	No	No: present in Australia
<i>Leishmania</i> spp. (Leishmaniasis)	Humans and dogs primarily; occasional reports in cattle, buffalo and goats	No	Yes	Yes (single novel species found in macropods in discrete location)	Yes	No: not present in milk
<i>Listeria monocytogenes</i> (Listeriosis)	Cattle, sheep, goats, camelids, buffalo, multiple other species including humans	Yes	No	Yes	No	No: present in Australia

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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Louping ill virus (louping ill)	Sheep (reservoir host), cattle, goats, horses, cervids, pigs, dogs, humans (rarely)	Yes	No	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
Lumpy skin disease virus (lumpy skin disease)	Cattle, buffalo, some wild ruminant species such as giraffes, springbok, impalas	Yes	Yes	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
Malignant catarrhal fever virus (Malignant catarrhal fever)	Cattle, bison, buffalo, sheep, wildebeest, deer	No	No	<i>Alcelaphine gammaherpesvirus-1</i> not present; <i>ovine gammaherpesvirus-2</i> present	Yes ( <i>alcelaphine herpesvirus-1</i> only)	No: not present in milk
Mammalian orthoreovirus	Pigs, cattle, sheep, goats, humans, multiple other species	No	No	Yes	No	No: not present in milk
<i>Mycobacterium avium</i> subsp. <i>paratuberculosis</i> (Paratuberculosis/Johne's disease)	Cattle, buffalo, sheep, goats, camelids, cervids, multiple other species including humans	Yes	Yes	Yes	Yes	No: present in Australia
<i>Mycobacterium bovis</i> , <i>M. caprae</i> , <i>M. tuberculosis</i> (Tuberculosis)	Cattle, bison, buffalo, multiple other species including humans	Yes	Yes	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
<i>Mycoplasma agalactiae</i> , <i>M. capricolum</i> subsp. <i>capricolum</i> , <i>M. mycoides</i> subsp. <i>capri</i> – also contains the former <i>M. mycoides</i> subsp. <i>mycoides</i> large colony type, <i>M. putrefaciens</i> (Contagious agalactia)	Sheep, goats	Yes	Yes	Clinical disease not present	Yes (clinical disease)	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
<i>Mycoplasma bovis</i> (Bovine mycoplasmosis)	Cattle	Yes	No	Yes	No	No: present in Australia

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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
<i>Mycoplasma capricolum</i> subsp. <i>capripneumoniae</i> (Contagious caprine pleuropneumonia)	Goats (primary), sheep (rarely), some wild ruminant species	No	Yes	No	Yes	No: not present in milk
<i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> small colony type (Contagious bovine pleuropneumonia)	Cattle, buffalo, sheep, goats	May be present in milk, but no evidence of transmission through milk	Yes	No	Yes	No: not transmissible through milk
Nairobi sheep disease virus (Nairobi sheep disease)	Sheep, goats	No	Yes	No	Yes	No: not present in milk
<i>Neospora caninum</i> (Neosporosis)	Cattle and dogs, occasionally horses, goats, sheep, deer	Yes	No	Yes	No	No: present in Australia
<i>Pasteurella multocida</i> serotypes 6:b and 6:e (Haemorrhagic septicaemia)	Cattle, buffalo, sheep, goats, pigs, camels, equids, yaks, deer, other wild ruminants	No	Yes	No	Yes	No: not present in milk
Pathogenic <i>Escherichia coli</i> including E. coli O157:H7	Cattle, multiple other species including humans	Yes	No	Yes	No	No: present in Australia
Peste des petits ruminants virus (peste des petits ruminants)	Sheep and goats primarily; few outbreaks in camels and buffalo reported	Yes	Yes	No	Yes	Yes: not present in Australia, present in and transmissible through milk, may not be managed by minimum requirements
Pseudocowpox virus (pseudocowpox)	Cattle	No	No	Yes	No	No: not present in milk
Pseudorabies virus/suid alphaherpesvirus 1 (Aujeszky's disease/pseudorabies)	Pigs (natural host); multiple species (including cattle, sheep and goats) are dead-end hosts	Only present in milk of pigs	Yes	No	Yes	No: not present in milk of relevant species

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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Rabies virus (rabies)	All mammals including humans	May be present in milk, but no evidence of transmission through milk	Yes	No	Yes	No: not transmissible through milk
Rift Valley fever virus (Rift Valley fever)	Cattle, buffalo, sheep, goats, camelids, multiple other species including humans	May be present in milk, but no evidence of transmission through milk	Yes	No	Yes	No: not transmissible through milk
Rinderpest virus (rinderpest)	Most cloven-hooved animals including cattle, buffalo, yaks, giraffe, sheep, goats, pigs; rarely camels	Yes	Yes	No (globally eradicated in 2011)	Yes	No: globally eradicated
Rotaviruses	Cattle, sheep, goat, humans, multiple other species	No	No	Yes	No	No: not present in milk
<i>Salmonella</i> Abortusovis (Salmonellosis)	Sheep (primarily), goats (few reports)	May be present in milk, but no evidence of transmission through milk	Yes	No	Yes	No: not transmissible through milk
<i>Salmonella</i> spp. (Salmonellosis)	Broad range of hosts including humans	Yes	No	Yes	No	No: present in Australia
Schmallenberg virus	Cattle, bison, sheep, goats, deer, dogs, alpacas, mouflons, wild boar	No	No	Not reported	No	No: not present in milk
Scrapie protease-resistant prion protein (PrP <sup>Sc</sup> ) (scrapie)	Sheep, goats (less frequently)	Yes	Yes	No	Yes	Yes: not present in Australia, present in and transmissible through milk, may not be



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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
						managed by minimum requirements
Sheeppox virus, goatpox virus (Sheep pox and goat pox)	Sheep, goats	Yes	Yes	No	Yes	Yes: not present in Australia, present in and transmissible through milk, may not be managed by minimum requirements
<i>Shigella</i> spp.	Humans (primarily), monkeys, cattle, sheep, goats (rare)	Yes	No	Yes	No	No: present in Australia
<i>Staphylococcus aureus</i>	Cattle, sheep, goats, camelids, horses, dogs, cats, rabbits, multiple other species including humans	Yes	No	Yes	No	No: present in Australia
<i>Streptococcus</i> spp.	Cattle, sheep, goats, pigs, multiple other species	Yes	No	Yes	No	No: present in Australia
Tick-borne encephalitis virus (Encephalitides – tick-borne)	Rodents (reservoir host), dogs, horses, cattle, sheep, goats, humans	May be present in milk, but no evidence of transmission through milk	No	No	Yes	No: not transmissible through milk
<i>Trypanosoma evansi</i> (Surra)	Mainly camels, equids, buffalo, cattle	Yes	Yes	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
<i>Theileria annulata</i> – Mediterranean theileriosis, <i>T. parva</i> – East Coast fever (Theileriosis)	Cattle, buffalo, yaks, camels	No	Yes	No	Yes	No: not present in milk
<i>Toxoplasmosis gondii</i> (Toxoplasmosis)	Cats (definitive hosts), small ruminants, pigs, camelids, cattle (rare or absent),	Yes	No	Yes	No	No: present in Australia

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Disease agent	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
	multiple other species including humans					
<i>Tritrichomonas foetus</i> (Trichomoniasis)	Cattle	No	Yes	Yes	No	No: not present in milk
<i>Trypanosoma brucei</i> , <i>T. congolense</i> , <i>T. simiae</i> , <i>T. vivax</i> (Trypanosomosis – tsetse fly associated)	Cattle (main reservoir hosts), sheep, goats, pigs, wild buffalo, camels, horses, alpacas, multiple other species	No	Yes	No	Yes	No: not present in milk
<i>Trypanosoma cruzi</i> (Chagas disease)	Dogs, cats, sheep, goats, cattle, humans, multiple other species	No	No	No	Yes	No: not present in milk
<i>Ureaplasma diversum</i>	Cattle	No	No	Yes	No	No: not present in milk
Vaccinia virus (Bovine vaccinia and buffalopox)	Buffalo, cattle, humans	Yes	No	Not reported	No	Yes: not reported in Australia, present in and transmissible through milk, may not be managed by minimum requirements
Vesicular stomatitis virus (vesicular stomatitis)	Cattle, horses, pigs, sheep, goats (rarely), humans	No	No	No	Yes	No: not present in milk
Visna-maedi virus (Maedi-visna)	Sheep, goats	Yes	Yes	No	Yes	No: managed by minimum requirements (see Appendix A: Disease agents managed by minimum requirements)
Wesselsbron virus (Wesselsbron disease)	Sheep and goats; possibly cattle; humans	No	No	No	Yes	No: not present in milk
West Nile virus (West Nile fever)	Birds, equids, sheep, camel, cattle (rarely), multiple other species including humans	No	Yes	Yes (Australian variants)	Yes (clinical disease)	No: not present in milk

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<b>Disease agent</b>	<b>Susceptible species</b>	<b>Present or transmissible in milk</b>	<b>WOAH-listed disease</b>	<b>Present in Australia</b>	<b>Nationally notifiable in Australia</b>	<b>Retained for risk review</b>
<i>Yersinia enterocolitica</i> (Yersiniosis)	Sheep, goats, cattle, pigs, humans	Yes	No	Yes	No	No: present in Australia
<i>Yersinia pestis</i> (Plague)	Rodents primarily; sheep, goats, camels and humans	No	No	No	No	No: not present in milk

## 2.1 Disease agents retained for risk review

The disease agents retained for risk review based on the information provided in Table 4 were:

- foot-and-mouth disease virus
- peste des petits ruminants virus
- scrapie protease-resistant prion protein
- sheeppox virus and goatpox virus
- vaccinia virus.

The following disease agents were identified as hazards but were not retained for risk review as they were deemed to be sufficiently managed by [minimum requirements](#) – additional scientific information for these agents is summarised in Appendix A: Disease agents managed by minimum requirements:

- bovine leukemia virus
- *Brucella* spp.
- *Chlamydia (chlamydophilia) abortus*
- *Ehrlichia ruminantium*
- jaagsiekte sheep retrovirus
- Jembrana disease virus
- louping ill virus
- lumpy skin disease virus
- *Mycobacterium tuberculosis*
- *Mycoplasma* spp.
- *Trypanosoma evansi*
- visna-maedi virus.

## 3 Risk reviews

### 3.1 Foot-and-mouth disease virus

#### 3.1.1 Background

Foot-and-mouth disease virus (FMDV) (species *Foot-and-mouth disease virus*; genus *Aphthovirus*; family *Picornaviridae*) is the cause of FMD, a highly contagious viral vesicular disease of cloven-hoofed animals (Alexandersen et al. 2003; Bøtner & Belsham 2012; Pharo 2002). There are 7 distinct serotypes of FMDV and there are numerous strains within each serotype. Serotype O is the most prevalent and occurs in many parts of the world (Pharo 2002). There is no cross-protection between different serotypes (Sutmoller et al. 2003).

FMD is endemic and is prevalent in many countries in Africa, Asia, and the Middle East, and in limited areas of South America (FAO 2021). Many countries have zones recognised by the WOA as FMD-free, either with or without vaccination (Alexandersen et al. 2003; WOA 2021a). Traditional grazing methods, movement of livestock and circulating virus in wildlife and feral species are the main causes of FMDV crossing international borders. Uncontrolled animal movement across borders is common in countries with endemic FMD and contributes to FMD spread (Allepuz et al. 2013; Balinda et al. 2010; MacPhillamy et al. 2022).

All domestic and wild cloven-hoofed ungulates, and over 70 species of wildlife, are susceptible to FMD (Alexandersen et al. 2003; Thomson, Vosloo & Bastos 2003), including cattle, buffalo, African buffalo (*Syncerus caffer*), sheep, goats, pigs, deer, antelope, gazelle, moose, impala, wildebeest, eland, wild pigs, elephants, giraffe, camelids (camels, llamas and alpacas), and hedgehogs (AHA 2014; Alexandersen & Mowat 2005; McLauchlan & Henderson 1947; WOA 2021c). Other species in which experimental infection with high titres of FMDV has been demonstrated include capybaras, wombats, brush tail possums, red-necked wallabies, red kangaroos, eastern grey kangaroos, long-nosed bandicoots, water rats, echidnas, feral European rabbits, and tree kangaroos (AHA 2014; Gomes & Rosenberg 1984; Snowdon 1968). Rare cases of human infection have been documented and are usually mild, short-lived, and self-limiting (CFSPH 2021; Prempeh, Smith & Muller 2001).

Infection with FMDV is a WOA-listed disease of multiple species (WOA 2022d). The WOA maintains a list of member countries and zones that are officially recognised as free from FMD, and Australia maintains a [FMD-Free Country List](#) for countries that have been assessed by the department and approved by the Director of Biosecurity as being FMD-free. Australia is officially recognised by the WOA as FMD-free where vaccination is not practised (WOA 2022s). In Australia, infection with FMDV is nationally notifiable and FMD has not occurred since 1872 (AHA 2021a; DAFF 2024).

#### 3.1.2 Technical information

##### Agent properties

FMDV remains viable for weeks to months in cool and humid environments, particularly in the presence of organic matter (AHA 2014; Bartley, Donnelly & Anderson 2002; Brown et al. 2021). FMDV is pH-labile and is rapidly inactivated below pH 6.0 and above pH 9.0 (Bachrach et al. 1957). FMDV is progressively inactivated at temperatures above 50°C and is inactivated at 70°C for 30 minutes; however, FMDV survives freezing and drying (WOA 2021c).

## **Epidemiology**

The incubation period of FMD varies with the strain of the virus, number of viral particles ingested or inhaled, species infected, and age and health of the animal. The incubation period can be 1 to 12 days in sheep, 2 to 14 days in cattle, 2 or more days in pigs and up to 21 days in buffalo (AHA 2014; CFSPH 2021). The incubation period of FMD in the Terrestrial Code is 14 days and WOA reports that excretion of FMDV begins up to 4 days before the onset of clinical signs of disease (AHA 2014; WOA 2022m). Virus is excreted in exhaled air, in secretions such as milk, saliva, semen, faeces and urine, and from ruptured vesicles (Alexandersen et al. 2003).

FMDV may be transmitted by ingestion, inhalation, direct contact through a break in the skin or via artificial insemination (Callis 1996; CFSPH 2021). Transmission is predominantly via aerosols in cattle and via oral exposure in pigs, which are the amplification host (AHA 2014; Donaldson & Alexandersen 2001; Garner & Cannon 1995). Indirect transmission through fomites and mechanical transmission through vectors such as birds and rodents can occur, and airborne spread has been considered a significant route of transmission in past outbreaks (Pharo 2002; Tomasula & Konstance 2004).

Although FMD has a wide host range, the significance of each species in viral spread varies depending on their susceptibility to infection and the amount of virus they excrete (Sutmoller et al. 2003). FMD infection in sheep and goats is generally mild and they may be important in the undetected maintenance and spread of disease (AHA 2014; Alexandersen & Mowat 2005; Alexandersen et al. 2003; Barnett & Cox 1999; Sutmoller et al. 2003; WOA 2021c). Susceptibility of several Australian wildlife species to FMDV has been demonstrated in experimental studies, and FMDV has been reported as the cause of severe disease and death in eastern grey kangaroos (*Macropus giganteus*), residing in a zoo located in an FMD-prevalent area of India (AHA 2014; Bhattacharya et al. 2003).

FMDV is known to persist in the oropharyngeal region of infected animals. Persistent infection has been observed for up to 3.5 years in cattle and 12 months in sheep; however, the role of sub-clinical animals in persistence and reoccurrence of FMD is considered to be minimal (Ahmed et al. 2017; Sutmoller et al. 2003).

## **Presence in milk**

Raw (unpasteurised) milk is a well-recognised source for the spread of FMDV during outbreaks (Angelidis 2014; Donaldson, 1997; Tomasula & Konstance 2004). Infectious FMDV has been isolated from the milk of clinically normal cows and from milk of other ruminants, including sheep and goats (Aly & Gaber 2007; Donaldson, 1997; Pharo 2002; Spickler & Roth 2012). It has also been isolated in apparently healthy vaccinated Asian buffaloes (Ahmed et al. 2017). Therefore, it is possible that healthy vaccinated animals could also excrete FMDV in milk.

FMDV is excreted in milk during the incubation period, between 1 and 4 days after infection, and may be excreted without clinical signs (Ahmed et al. 2017; Reid, et al. 2006; Spickler & Roth 2012; Tomasula & Konstance 2004). Infectious FMDV in cow's milk may persist for more than 3 weeks post-infection (Armson et al. 2018; Reid, et al. 2006). FMDV titres in milk collected from infected cows during an outbreak can approximate the infectious oral dose for pigs and cattle (Donaldson, et al. 1982; Donaldson, 1997; Sellers 1971; Spickler & Roth 2012).

There is limited published information available about FMDV in milk from countries where FMD is endemic. Several reviews assume that there will be a high level of viral dilution in bulk milk tanks because infected farms will be quarantined during an outbreak (Donaldson, 1997; Tomasula et al. 2007). However, management practices in countries where FMD is endemic are likely to be different with regard to isolation of infected animals, and the number of infected animals contributing to the milk supply at any given time may be higher than in countries where FMD is not endemic. Thus, the assumed increased dilution factor of FMDV in bulk milk tanks may not be applicable in endemic countries (Ahmed et al. 2017; Ansari-Lari et al. 2017; Armson et al. 2020).

The dilution of milk from infected animals in a bulk milk tank with milk from uninfected animals may reduce the FMDV titre. Additionally, in countries that have control measures in place for FMD, infected animals are likely to be recognised and the farm quarantined further reducing the FMDV titre in the bulk milk tank (Donaldson, 1997). Nevertheless, if enough susceptible animals are exposed to milk products with low levels of virus there is a chance of one animal being infected and, for a highly contagious disease like FMD, this would lead to further disease spread to susceptible contact animals (Sutmoller & Vose 1997).

### **Inactivation in milk**

The interpretation of FMDV-infectivity and inactivation studies can be difficult due to the different routes of inoculation, the different sample types used for testing, and the different detection methods employed. Inactivation studies are often undertaken following intravenous, intramammary, or intranasal inoculation or contact exposure to FMDV. Although intranasal and contact exposure may be considered more representative of natural infection under field conditions, the mammary gland is an important replication site for FMDV and FMDV titres in milk from intramammarily inoculated cattle have been demonstrated to be similar to those from experimental contact exposure (Armson et al. 2018; Blackwell, et al. 1982; Blackwell, Wool & Kosikowski 1981; Burrows et al. 1971; Donaldson, 1997).

During the viremic stage, virus titre may be below the detection limit of cell culture, and so animal bioassays using steer inoculation are used as a more sensitive method of FMDV detection (Blackwell & Hyde 1976; Spickler & Roth 2012; Tomasula & Konstance 2004; Tomasula et al. 2007). Although inoculation is not representative of natural infection in the field, it is a sensitive method for detection of infectious FMDV in milk samples when determining if FMDV has been inactivated.

The interpretation of inactivation data for FMDV in dairy products is further complicated by the protective effect conferred by milk. Virus that is shed from the mammary gland is incorporated into the casein micelles and fat globules, which provide protection from inactivation (Spickler & Roth 2012; Tomasula & Konstance 2004). Due to the protective effect of fat in milk, data obtained for one type of dairy product may not be applicable to another due to differing fat compositions. For example, FMDV is more readily inactivated in skim milk compared to whole milk, and dairy products with high fat content such as cream or butter may require more severe heat treatment to inactivate FMDV than products with a lower fat content (Blackwell & Hyde 1976; Reid et al. 2006; Spickler & Roth 2012).

Inactivation of FMDV in whole and skim milk has repeatedly failed using parameters equal to or exceeding HTST and batch pasteurisation, including parameters considered suitable by WOAHP for management of FMDV in milk or milk products intended for human consumption (Bohm 1982; de

Leeuw & van Bakkum 1979; Dhennin & Labie 1976; El-Alfy 1998; Spickler & Roth 2012; Tomasula et al. 2007). However, inactivation of FMDV has been demonstrated in whole milk following treatment at 100°C for 27 minutes or 148°C for at least 3 seconds (Cunliffe et al. 1979; de Leeuw & van Bakkum 1979; Walker et al. 1984).

During the 1982 FMD outbreak in Denmark, milk was treated by HTST pasteurisation followed by heat treatment of 80°C for 3 seconds. This was sometimes followed by lowering the pH to below 4.5. Approximately 18 million kilograms of milk treated this way was fed to FMDV-susceptible domestic animals without causing outbreaks (Danish Veterinary Service 1982), as cited in (Alexandersen 2005; Donaldson, AI 1997). Although effective, double pasteurisation and acidification may be difficult to implement commercially (Aly & Gaber 2007).

Milk can be processed into a wide variety of dairy products using many different commercial processing methods (Chandan 2015; Pires et al 2021; Roobab et al 2021). A combination of processing methods may facilitate inactivation of FMDV in processed dairy products. However, interpretation of data regarding the inactivation potential of manufacturing processes for different types of dairy products is complicated by the significant variation in commercial processes used and the differing fat composition in each type of product (Chandan 2015). Importantly, FMDV can survive the drying process used to make dehydrated dairy products when the initial treatment of the milk does not completely inactivate the virus (Cottral 1969; Spickler & Roth 2012).

Acidification alone is not consistently effective for inactivation of FMDV in milk. Alteration in pH can precipitate milk components into an insoluble form that protect the virus instead of facilitating inactivation (Spickler & Roth 2012). FMDV infectivity can remain in milk following 6 hours at pH 1.97 (Sonder et al. 1990). Inactivation of infectious FMDV is seen in production of acid whey (pH 4.5 to 4.6) but not sweet whey (pH 6.1 to 6.7) (Spickler & Roth 2012). The acidification and ripening processes used in cheese manufacture are likely to facilitate the inactivation of FMDV. This has been demonstrated in cheese manufactured using milk subjected to a thermal treatment insufficient to inactivate FMDV; infectious virus persisted immediately after thermal treatment but was eliminated following 30 days of ripening at 2°C in cheddar cheese, and after 35 days (but not 21 days) at 4°C at pH 5.2 (Blackwell 1976).

Information on the effects of the processes used for casein and caseinate manufacture on inactivation of FMDV is sparse. In a 1977 study, casein, and sodium caseinates produced from pasteurised skim milk, sourced from cattle infected with FMDV, produced infection when inoculated into steers. Cytopathic effects were not observed in cell cultures and the authors reported that very low titres of infectious FMDV were present in the casein and caseinate. The production methods used in this study are representative of commercial processing techniques. The authors postulated that FMDV survival in casein and caseinates may be due to the protective effect of casein micelles against inactivation (Cunliffe & Blackwell 1977).

### **Pathogenesis**

The most common portal of entry of FMDV is through the respiratory tract. Virus can also gain entry through the integument of the feet, mouth, muzzle, nose, and udder. The virus primarily replicates in the epithelial cells of the pharynx and dorsal soft palate and then spreads via the blood to secondary sites, such as the mammary gland (AHA 2014; Pacheco et al. 2015).



## **Diagnosis**

The severity of clinical signs of FMD varies with the virus strain and exposure dose, and the age and species of the animal (WOAH 2021c).

Clinical signs of FMD are most apparent in cattle. Commonly described clinical signs of FMD in cattle are pyrexia (40–41°C) and vesicular lesions in the mouth, between hooves, coronary band, and teats. There is also a prolonged reduction in milk yield and mortality in calves can reach up to 50% (AHA 2014; Ghanem & Abdel-Hamid 2010; Horsington et al. 2018). In pigs, the main clinical sign of FMD is lameness, and snout and mouth lesions may develop. Abortion is also common and significant mortality can occur in piglets. Adult pigs generally recover from the disease, although severe foot lesions may cause chronic lameness (AHA 2014; Stenfeldt et al. 2016). Clinical signs of disease in sheep and goats are frequently mild or inapparent, which can make the clinical diagnosis of FMD difficult. Significant mortalities may occur in young animals (Kitching & Hughes 2002).

Several other viral vesicular diseases, including swine vesicular disease, vesicular stomatitis, and vesicular exanthema of swine, cannot be distinguished from FMD solely by clinical examination. Demonstration of specific antigen or nucleic acid is required to confirm FMDV. Enzyme-linked immunosorbent assay (ELISA), lateral flow devices (LFD) and reverse transcription polymerase chain reaction (RT-PCR) are used for diagnosis (Alexandersen et al. 2003; WOAH 2022g).

## **Treatment**

There is no specific treatment for animals infected with FMDV (CFSPH 2021).

## **Control**

Vaccination has been successfully used in many parts of the world to control FMD. Inactivated vaccines against the circulating serotype effectively control clinical disease in infected animals. Vaccinated animals that are exposed to infection within a few days of vaccination can become carriers (AHA 2014; Backer et al. 2012; Moonen et al. 2004).

### **3.1.3 Current biosecurity measures**

The dairy IRA included risk management measures for FMD for the importation of dairy products of bovine, ovine and/or caprine origin – the milk or the milk from which the dairy product was made originated from a country/zone recognised by the WOAH as FMD-free (with or without vaccination) and the products were processed in an FMD-free country/zone. The dairy IRA also included risk management measures for FMD for specified cheeses (that is, cheese that attained a pH of less than 6, and has aged for 30 days or more if made from pasteurised milk, or has aged for 120 days or more at a temperature not less than 2°C if made from unpasteurised milk) from countries/zones not free from FMD.

For importation from FMD-free countries, to manage the small risk that milk could be collected in the period immediately after an FMD incursion and before detection/official notification, the dairy IRA recommended that for all dairy products the milk should be pasteurised, or the imported milk/dairy product should not be released from quarantine control until at least 30 days from the date of manufacture.

Since the dairy IRA was published, the import conditions have been updated to reflect changes in Australia's approach towards determining the FMD status of trading partners. Apart from legislated exemptions, retorted products and specified cheeses; dairy ingredients may only be sourced from,

and products containing dairy ingredients manufactured and exported from, countries/zones on the department's [FMD-Free Country List](#).

The dairy IRA also considered the importation of dairy products from countries/zones not free from FMD, subject to individual assessment and provided that the dairy products were manufactured (under specified controls) from raw materials obtained in an FMD-free country/zone or were processed in a manner that would be expected to inactivate FMDV.

The Terrestrial Code recommends risk management for milk and milk products intended for human consumption (WOAH 2022m) imported from:

- FMD free countries or zones where vaccination either is or is not practised or FMD free compartments (Article 8.8.24.). These recommendations are that the products come from animals which have been kept in a FMD free country, zone, or compartment, or which have been imported in accordance with Terrestrial Code recommendations (Article 8.8.10., Article 8.8.11. or Article 8.8.12.).
- FMD infected countries or zones where an official control programme exists (Article 8.8.25.). These recommendations are that the products originate from establishments which were not infected or suspected of being infected with FMD at the time of milk collection, the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV, and the products have been processed to ensure the destruction of FMDV in accordance with one of the following procedures for the inactivation of FMDV in milk and cream
  - a process applying a minimum temperature of 132°C for at least 1 second (UHT), or
  - if the milk has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (HTST pasteurisation), or
  - if the milk has a pH of 7.0 or greater, the HTST process applied twice.

### **3.1.4 Conclusion**

FMD is not present in Australia and is a nationally notifiable and WOAHL-listed disease.

Australia's current import conditions for dairy products for human consumption for FMD are more stringent than the recommendations in the Terrestrial Code. Therefore, a risk assessment was required.

### **3.1.5 Risk assessment**

#### **Entry assessment**

The following factors were considered relevant to an estimate of the likelihood of FMDV being present in dairy products imported for human consumption.

- FMD is endemic in many countries in Africa, Asia, and the Middle East, and in limited areas of South America. Many countries have zones that are recognised by the WOAHL as FMD-free, either with or without vaccination.
- FMDV can be present in milk and colostrum of infected cattle, buffalo, sheep and goats.
- Clinical signs of FMD are most apparent in cattle. Clinical signs of FMD are often mild in sheep and goats.

- Excretion of FMDV begins up to 4 days before the onset of clinical signs of disease. FMDV has been reported to be excreted in milk for greater than 3 weeks post-infection.
- Fat globules and casein micelles in milk provide protection for FMDV against inactivation.
- Levels of FMDV in milk collected from infected animals may get reduced due to dilution in bulk milk tanks.
- Dairy products may be imported from countries where FMD is endemic or from countries that have a vaccinated population. There is limited published information available about FMDV transmission in milk from these countries.
- The presence of FMDV in dairy products imported for human consumption depends on the type of dairy product and processing parameters applied to the product. However, residual FMDV is likely to be present in many dairy products, as HTST pasteurisation (or equivalent heat treatment) and many other dairy product processing techniques do not completely inactivate the virus.
- Viable virus could be introduced into processed product if contamination with raw milk or other dairy ingredients sourced from infected animals occurs after processing.

**Conclusion:** Based on these considerations, the likelihood of FMDV entering Australia in dairy products imported for human consumption from a country/zone where the disease agent is present was estimated to be **moderate**.

#### **Exposure assessment**

The exposure groups considered for FMDV were wildlife and domestic and feral ruminant species and pigs.

The following factors were considered relevant to an estimate of the likelihood of susceptible animals being exposed to FMDV in dairy products imported for human consumption.

- All domestic and wild cloven-hoofed ungulates, and over 70 species of wildlife, are susceptible to FMD.
- FMDV can persist for extended periods when chilled or frozen, and has been known to remain viable for weeks to months in cool and humid environments.
- Virus shed from the mammary gland is incorporated into the casein micelles and fat globules which provide the virus protection from inactivation.
- As only dairy products for human consumption would be imported, most imported dairy products would move from the distributor/retailer to household consumers or to the food industry. However, susceptible animals could be exposed to dairy products imported for human consumption if
  - product was disposed of in such a way that it was accessed by animals, including feral and wild animals. This could result in exposure of susceptible animals, such as feral pigs, to FMDV
  - product was repurposed for use in animal feed. Susceptible animals would readily consume feed that included imported dairy products. This could result in exposure of susceptible animals to FMDV

- product was fed directly to animals, such as feeding milk powder to hand-reared animals or feeding household scraps to animals, including pigs. This could result in exposure of susceptible animals to FMDV.

**Conclusion:** Based on these considerations, the likelihood of susceptible animals being exposed to FMDV in dairy products imported for human consumption was estimated to be **moderate**.

#### **Estimation of the likelihood of entry and exposure**

The likelihood of entry was estimated to be moderate and the likelihood of exposure was estimated to be moderate. Using Figure 2, the likelihood of entry and exposure for FMDV was estimated to be **low**.

#### **Consequence assessment**

##### *Identification of an outbreak scenario and likelihood of establishment and/or spread associated with the outbreak scenario*

The most likely outbreak scenario following exposure of susceptible animals to FMDV in dairy products for human consumption was considered to be establishment in the directly exposed population and spread to other populations of susceptible animals across multiple states and territories.

The following factors were considered relevant to an estimate of the likelihood of the identified outbreak scenario occurring:

- FMDV may be transmitted by ingestion, inhalation, direct contact through a break in the skin or via artificial insemination. The virus can also be spread by indirect transmission through fomites such as clothing and vehicles. Airborne spread can also be a route of transmission.
- FMD is highly contagious. Whilst the level of FMDV in contaminated imported dairy products for human consumption may be relatively low, exposure of susceptible animals to dairy products with small amounts of FMDV could still result in an infected animal, which would mean high likelihood of spread to susceptible contact animals. Animal and fomite movement across states and territories occurs easily and can happen within a few days.
- A wide range of dairy products, including pasteurised milk and cheeses, from infected cattle have been demonstrated to be highly effective vehicles for transmission of FMD. No studies have investigated the transmissibility of FMDV in dairy products sourced from sheep or goats.
- Pigs are highly susceptible to infection with FMDV by ingestion and are primarily infected from consuming contaminated animal products.
- Virus can be excreted in exhaled air, in secretions such as milk, saliva, semen, faeces and urine, and from ruptured vesicles.
- Cattle are most susceptible to aerosol infection.
- In contrast to the severe, acute infection that occurs in cattle and pigs, FMD infection in sheep and goats is generally milder and they may be important in the undetected maintenance and spread of disease.

Based on these considerations, the likelihood of establishment and/or spread of FMDV associated with the identified outbreak scenario was estimated to be **moderate**.

*Determination of overall effect of establishment and/or spread associated with outbreak scenario*

The following factors were considered relevant to the effects of establishment and/or spread of FMDV associated with the identified outbreak scenario.

The effect on the life or health (including production effects) of susceptible animals:

- The severity of clinical signs of FMD varies with FMDV strain, exposure dose, age and species of the animal.
- Most pigs recover from the disease, although severe foot lesions may cause chronic lameness. Mortality in cattle is rare. Clinical signs of disease in sheep and goats may be mild. Significant mortalities may occur in calves and lambs.
- Production losses due to FMD include reduced milk production, reduced growth rates and abortion.
- Rare cases of mild, short-lived and self-limiting infections have been reported in humans.

The effect on the living environment, including life and health of wildlife, and any effects on the non-living environment:

- Susceptibility to FMDV in several Australian wildlife species has been demonstrated. The possible spread of FMD through wildlife populations is unknown, but it can be expected that an infection in wildlife would be difficult to control.

The effect on new or modified eradication, control, monitoring or surveillance and compensation strategies or programs:

- If FMD was identified in Australia, the response strategy as outlined in the AUSVETPLAN disease strategy manual for FMD is eradication in the shortest possible time, while minimising economic effects using stamping out. This would be supported by a combination of strategies including a livestock standstill, quarantine and movement controls, tracing and surveillance, disposal of destroyed animals and animal products, decontamination, recalls of animal products, relief and recovery programs, and a public awareness campaign. Vaccination may also be used (AHA 2014).
- FMD is scheduled as Category 2 under Australia's EADRA for cost-sharing arrangements. Should it be activated, EADRA states that costs of the response would be covered by government and relevant industries by contributions of 80% and 20%, respectively (AHA 2019b).
- Depending on the location and size of an FMD outbreak and the control strategy used, the Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES) estimates control costs to be between \$61 million and \$96 million, and between \$6.3 million and \$16.4 million in compensation to farmers for animals destroyed during control procedures (Buetre et al. 2013).

The effect on domestic trade or industry, including changes in consumer demand and effects on other industries supplying inputs to, or using outputs from, directly affected industries:

- Following a detection of FMD, a national livestock standstill, lasting at least 72 hours, would be immediately enforced for FMD-susceptible animals. Following this, further movement

restrictions would be implemented during the control and eradication programme. This would disrupt domestic markets.

- Along with affected livestock producers, associated industries would suffer losses, such as transporters, stockfeed manufacturers and processors of animal products.
- With export market disruptions, relevant animal products destined for export would be redirected to the domestic market and domestic prices would fall. As a result, revenue for affected and associated industries would decrease.
- Domestic consumers may be concerned about the safety of animal products. An awareness campaign may be needed to educate consumers that FMD does not affect food safety.

The effect on international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand:

- An outbreak of FMD would result in instant loss of much of Australia's agricultural exports and the competitive advantage of having an FMD-free status.
- Most of the economic costs from a FMD outbreak would arise from revenue losses due to immediate and prolonged export bans by Australia's FMD-sensitive markets. ABARES estimates that over 10 years, minimal trade restrictions (assuming that export bans are lifted quickly) following a small outbreak would result in expected revenue losses of around \$6 billion, compared with losses of up to \$52 billion (in present value terms) with extended trade restrictions following a large outbreak (Buetre et al. 2013).
- Resumption of trade would depend on demonstration of freedom and renegotiations with importing countries. Additional biosecurity measures may need to be met.
- Zoning may enable trade to recommence earlier. However, export markets for relevant commodities from affected zones may be lost or restricted, and access to new export markets could be affected.

The effect on the environment, including biodiversity, endangered species and the integrity of ecosystems:

- Disposal of large numbers of destroyed animals and animal products, and increased use of disinfectants, may have effects on the environment.

The effect on communities, including reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures:

- Psychological distress could occur due to implementation of control and eradication measures, such as for owners of animals that are destroyed as part of disease control measures.
- Ongoing financial distress could occur for owners of affected premises if the disease situation prevents timely restocking.
- The economic viability of communities within affected areas may be compromised due to effects on directly affected and associated industries.
- Tourists may avoid affected regions due to negative media portrayal and due to incorrect perceptions of public health risks from FMD.

- Disruption of events due to movement controls could have social consequences for people involved.

Based on the geographic level and magnitude of effects, using the rules in Table 3, the overall effect of establishment and/or spread of FMDV associated with the identified outbreak scenario was estimated to be **extreme**. The effect is likely to be highly significant at the national level. Implies that economic stability, societal values or social well-being would be seriously affected.

#### *Derivation of likely consequences*

The likelihood of establishment and/or spread was estimated to be moderate and the overall effect of establishment and/or spread was estimated to be extreme. Using Figure 3, the likely consequences of establishment and/or spread of FMDV were estimated to be **extreme**.

#### **Risk estimation**

The likelihood of entry and exposure was estimated to be low and the likely consequences of establishment and/or spread were estimated to be extreme. Using Figure 4, the unrestricted risk of FMDV was estimated to be **high**.

#### **Conclusion**

The unrestricted risk of FMDV was estimated to be high. As the unrestricted risk estimate does not achieve Australia's ALOP, risk management measures in addition to [minimum requirements](#) are required.

### **3.1.6 Risk management measures**

The Terrestrial Code recommendations for milk and milk products for human consumption only require milk with a pH of 7.0 or higher to be double pasteurised. Milk generally has a pH below 7.0 (M'Hamdi et al. 2018). Based on the Terrestrial Code recommendations, most milk and milk products from FMD-infected countries or zones where an official control program exists would only require a single HTST pasteurisation treatment, which would not completely inactivate FMDV in milk. Additionally, based on the findings of the literature review, the UHT treatment recommended by the Terrestrial Code may not reliably inactivate FMDV.

This section describes the various risk management options for FMDV associated with the importation of dairy products for human consumption that are considered to achieve Australia's ALOP.

#### **Dairy products from countries free from FMD**

To manage the risk of FMDV associated with the importation of dairy products for human consumption, country/zone freedom as recognised by the department is required for the source, manufacture and export countries to achieve Australia's ALOP. This means that dairy products containing dairy ingredients of bovine, ovine and/or caprine origin are sourced from animals born and raised in, manufactured in, and exported from countries/zones on the department's FMD-Free Country List.

#### **Dairy ingredients sourced from a country not free from FMD**

Alternatively, to manage the risk of FMDV associated with the importation of dairy products (except for cheese) using dairy ingredients sourced from animals in countries/zones not on the department's FMD-Free Country List, the dairy products (except for cheese) will require additional heat treatment to achieve Australia's ALOP. This may be either application of a moist heat treatment process (in

addition to minimum requirements) to the milk or the dairy ingredients involved to reach a core temperature (or heating throughout in the case of liquid product) of no less than 100°C retained for no less than 30 minutes, or in addition to minimum requirements, at a temperature of no less than 148°C retained for no less than 3 seconds.

### **Cheese**

To manage the risk of FMDV associated with the importation of cheese using milk sourced from animals in countries/zones not on the department's FMD-Free Country List, additional measures are required to achieve Australia's ALOP. For cheese made from pasteurised milk, the pH throughout the product must be 5.2 or less prior to and after being ripened, and must be ripened at a temperature of no less than 4°C for no less than 30 days from the date of processing. For cheese made from unpasteurised milk, the pH throughout the product must be 5.2 or less prior to and after being ripened, and the cheese must be ripened at a temperature of no less than 7°C for no less than 120 days from the date of processing. For cheese, the date of processing is equivalent to the date the curd was set.

For cheese made from unpasteurised milk sourced from animals in countries/zones on the department's FMD-Free Country List, to address the possible risk that milk could be collected in the period immediately after an FMD incursion and before detection, cheese made from unpasteurised milk matured/ripened/stored for at least 30 days from the date of processing (the date the curd was set). This represents approximately 2 incubation periods of FMDV.

### **Dairy products manufactured or exported from a country not free from FMD**

Additional risk management measures for FMDV associated with the importation of dairy products manufactured in and/or exported from countries/zones not on the department's FMD-Free Country List are required to achieve Australia's ALOP. Dairy products must be manufactured in and/or exported from countries/zones that have current approval by Australia, and the supply chain and manufacturing facilities must have current approval by Australia. These measures ensure the risk associated with substitution or contamination of product or production line is adequately managed. This applies to dairy products manufactured using dairy ingredients sourced from any country/zone.

### **Dairy products stored or transhipped via a country not free from FMD**

Additional risk management measures for FMDV associated with the importation of dairy products that have been stored or transhipped via countries/zones not on the department's FMD-Free Country List are required to achieve Australia's ALOP. Dairy products containing dairy ingredients of bovine, ovine and/or caprine origin must be sourced from animals born and raised in, manufactured in, and exported from countries/zones on the department's FMD-Free Country List, or meet the manufacturing conditions above, and the goods may only be unloaded during transhipment and stored without manipulation. The supply chain must also have current approval by Australia.

### **Commercially prepared and packaged**

To achieve Australia's ALOP, dairy products sourced from and/or manufactured in and/or exported from and/or stored (or transhipped) in countries that are not on the department's FMD-Free Country List must also be commercially prepared and packaged and ready for retail sale to the final consumer without any further processing. This lowers the likelihood of susceptible animals being exposed to and consuming an infectious dose of FMDV compared with dairy ingredients imported in bulk due to



the relatively increased packaging and smaller volumes of individual units, and by stopping waste streams associated with further manufacture onshore.

Alternatively, to manage the risk of FMDV associated with the importation of dairy products (except for cheese) using dairy ingredients sourced from animals in countries/zones not on the department's FMD-Free Country List, the dairy products (except for cheese) will require additional heat treatment to achieve Australia's ALOP. This may be either application of a moist heat treatment process (in addition to minimum requirements) to the milk or the dairy ingredients involved to reach a core temperature (or heating throughout in the case of liquid product) of no less than 100°C retained for no less than 30 minutes, or in addition to minimum requirements, at a temperature of no less than 148°C retained for no less than 3 seconds.

Furthermore, this additional heat treatment is used as a measure to manage the risk of contamination and substitution of dairy ingredients within finished dairy products. As the literature review demonstrates, pasteurisation alone does not guarantee inactivation of FMDV in milk, and the additional heat treatment provides an alternative risk management measure other than retorting, which is currently the only alternative option to country freedom.

## **3.2 Peste des petits ruminants virus**

### **3.2.1 Background**

Peste des petits ruminants virus (species *Small ruminant morbillivirus*; genus *Morbillivirus*; family *Paramyxoviridae*) is the cause of peste des petits ruminants (PPR), a highly contagious, acute viral disease of goats and sheep of all ages (Clarke et al. 2018; Idoga et al. 2020; Kumar et al. 2014; Zhao et al. 2021). PPR is considered the most important WOAHA-listed disease of domestic small ruminants in the developing world, as these regions are home to over 80% of the global sheep and goat population and rely heavily on small ruminant production for sustaining livelihoods (Clarke et al. 2018; Idoga et al. 2020). Following the eradication of rinderpest, which is caused by a closely related virus in the genus *Morbillivirus*, PPR has been identified by the Food and Agriculture Organization of the United Nations and the WOAHA as the next target for global eradication by 2030 (Clarke et al. 2018; WOAHA 2022t).

In 1942, PPR was first described in Côte d'Ivoire, located on the south coast of West Africa (Clarke et al. 2018; Kumar et al. 2014). Of the 12,757 outbreaks that were reported to the WOAHA between 2015 and 2019, 75.1% were in Asia, 24.8% were in Africa and 0.1% were in Europe (Bulgaria only) (Zhao et al. 2021). The disease is now endemic in many countries of Africa, Asia and the Middle East, with prevalence reaching over 80% in some endemic countries (Ahaduzzaman 2020; Baloch et al. 2021; EFSA Panel on Animal Health and Welfare 2015).

All strains of PPR virus belong to one serotype, but the different strains are grouped into 4 different lineages (I to IV). Generally, lineages I and II are found in Africa (mainly in West Africa), III is found in Arabia and East Africa. Lineage IV is termed the Asian lineage as it usually found in Asia (Zhao et al. 2021).

Animals susceptible to PPR are primarily goats and sheep (Idoga et al. 2020; Zhao et al. 2021). Other animals that are susceptible to disease include wild small ruminants, gazelle, gemsbok, ibex and camels. Cattle, buffalo and suids can be infected but do not show clinical signs of disease (EFSA Panel on Animal Health and Welfare 2015; Rahman et al. 2020).

Infection with PPR virus is a WOAHA-listed disease of sheep and goats (WOAH 2022d). The WOAHA maintains a list of member countries/zones that are officially recognised as free from PPR. Australia is officially recognised by the WOAHA as free from PPR (WOAH 2022p). In Australia, infection with PPR virus is nationally notifiable (DAFF 2024). PPR has never occurred in Australia (AHA 2021a).

### **3.2.2 Technical information**

#### **Agent properties**

PPR virus is readily destroyed by heat and sunlight (EFSA 2006; EFSA Panel on Animal Health and Welfare 2015; Kumar et al. 2014; Scott Williams Consulting Pty Ltd 2017), and is susceptible to most disinfectants such as alcohol, ether, and common detergent (EFSA 2006; EFSA Panel on Animal Health and Welfare 2015; Scott Williams Consulting Pty Ltd 2017). The virus can survive up to 72 hours in shaded conditions (EFSA Panel on Animal Health and Welfare 2015; Kozat & Sepehrizadeh 2017). PPR virus is relatively stable at refrigeration temperatures around 4°C (Latif et al. 2016).

Inactivation data available for PPR virus is limited and is generally extrapolated from the closely related rinderpest virus (EFSA Panel on Animal Health and Welfare 2015; Scott Williams Consulting Pty Ltd 2017). PPR virus is reported to be stable between pH 5 and pH 10, and inactivated below pH 4 or above pH 11 (EFSA 2006; EFSA Panel on Animal Health and Welfare 2015; Kumar et al. 2014; WOAHA 2020). The virus has been reported to be completely inactivated after heat treatment at 50°C or 60 minutes (Coetzer, Thomson & Tustin 1994), as cited in (Kumar et al. 2014; Scott Williams Consulting Pty Ltd 2017). However, the experimental data to support thermal inactivation data provided by Coetzer (1994) is unclear.

The closely related rinderpest virus, in the form of tissue culture supernatant fluid, at pH 7.3 had around a 10<sup>5</sup> reduction within seconds at 70°C, and around a 10<sup>6</sup> reduction in 5 minutes. A further increase in temperature to 75°C resulted in absence of cytopathic changes in tissue cultures taken at zero time, and did not cause infection when inoculated into cattle (Boer & Barber 1964).

#### **Epidemiology**

The incubation period of PPR is often 5 to 6 days, but can range from 2 to 7 days (EFSA 2006; Kumar et al. 2014). The incubation period of PPR in the Terrestrial Code is 21 days (WOAH 2022o). No carrier state has been identified (EFSA 2006).

PPR is highly infectious and has a high within-flock transmission rate (EFSA Panel on Animal Health and Welfare 2015; Idoga et al. 2020). The virus is easily transmitted through direct contact with infected animals, or secretions and/or excretions of infected animals, or by contact with fomites (Idoga et al. 2020). Primary infection usually occurs through inhalation but may also be through ingestion (EFSA 2006).

Virus is shed in secretions from the nose, throat, mouth and conjunctiva, as well as in faeces, urine and milk, from approximately 3 to 22 days post-infection. Excretion of virus can start before clinical signs of disease are apparent (EFSA 2006; EFSA Panel on Animal Health and Welfare 2015).

Sheep may be less susceptible to PPR than goats and exhibit a milder form of the disease; however, mild or subclinical infection in sheep may contribute to the undetected spread of disease (EFSA Panel on Animal Health and Welfare 2015; Idoga et al. 2020).

The role of species other than goats and sheep in the spread of PPR is unknown (Zhao et al. 2021). Experimental findings suggest that suids could transmit PPR virus (Schulz et al. 2018). Sera collected from cattle and camels contained PPR virus antibodies; however, clinical disease has not been observed in these species (Mdetele et al. 2021; Schulz et al. 2019). PPR virus antibodies have also been detected in several African wildlife species; however, there is little evidence of disease in free-ranging wildlife populations. The role of wildlife in the epidemiology of PPR is not well understood – available data suggests that wildlife species are not a reservoir of PPR virus (Aguilar et al. 2020).

### **Presence in milk**

PPR virus could be present in milk from affected sheep or goats. A 2018 experimental study isolated virus in 3 out of 4 goat milk samples collected during PPR outbreaks in Bangladesh (Clarke et al. 2018). The closely related rinderpest virus is excreted in the milk of animals for up to 45 days after recovery from infection (EFSA Panel on Animal Health and Welfare 2015; Spinage 2003).

PPR virus in milk and milk products would not be amplified during storage or transport, but any virus not inactivated during processing may be relatively stable (EFSA 2006).

There is no information available on the survival and/or infectivity of PPR virus in milk. Transmission of PPR virus through milk has not been reported (Clarke et al. 2018; EFSA 2006).

There are no studies available that investigate the inactivation of PPR virus in milk. Pasteurisation alone may not be sufficient to completely inactivate PPR virus in milk (AHA 2020b; Scott Williams Consulting Pty Ltd 2017). The closely related rinderpest virus is reported to be rapidly inactivated at temperatures above 70°C (Boer & Barber 1964); however, there is no confirmation that rinderpest virus in milk is inactivated by pasteurisation (AHA 2020b).

### **Pathogenesis**

The pathogenesis of PPR virus is not well understood and is assumed to be like that of other morbilliviruses. Infection is thought to be initiated by the virus being taken up by antigen presenting cells, which are present in the respiratory mucosa. These cells transport the virus to regional lymphoid tissues where virus replication takes place. The infected lymphocytes disseminate the virus throughout the body via the lymphatic and vascular system (Kumar et al. 2014).

### **Diagnosis**

The morbidity and mortality rate of PPR varies depending on species infected, age and prevalence of secondary infectious agents (EFSA Panel on Animal Health and Welfare 2015). The morbidity and mortality rate in susceptible populations can reach between 90 and 100% and 50 and 100%, respectively. The disease is characterised by fever, oculo-nasal discharge, diarrhoea and erosions in the mouth. There is a very high case fatality in severe cases (WOAH 2019). Death usually occurs between 4 and 6 days after the onset of fever. Pregnant animals may abort (Idoga et al. 2020; Kumar et al. 2014).

The most common and reliable laboratory techniques for detection of PPR virus use PCR and ELISA tests (EFSA Panel on Animal Health and Welfare 2015; WOAH 2019).

### **Treatment**

There is no specific treatment for animals infected with PPR virus (Balamurugan et al. 2014).

## **Control**

There are two commercial live attenuated vaccines available for control of PPR. Nigeria 75/1 is based on a lineage II strain of PPR virus and is commonly used in African countries. Sungri 96 is based on a lineage IV strain of PPR virus and is commonly used throughout India (Kumar et al. 2014; Zhao et al. 2021). Either of these vaccinations will provide effective immunity against all 4 lineages of PPR virus (Zhao et al. 2021). A single dose of vaccine is believed to provide protective immunity in sheep and goats for approximately 4 years (Kumar et al. 2014).

Issues with Nigeria 75/1 and Sungri 96 include their low thermal tolerance and the inability to differentiate infected from vaccinated animals (Zhao et al. 2021). Routine use of vaccination prevents serosurveillance, which makes it impossible to maintain a status of freedom from PPR (EFSA Panel on Animal Health and Welfare 2015).

### **3.2.3 Current biosecurity measures**

The dairy IRA included risk management measures for PPR for the importation of dairy products of ovine and/or caprine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that meets WOAHP requirements for freedom from PPR, or the milk or the milk from which the dairy product was made was subjected to pasteurisation or an equivalent heat treatment.

The Terrestrial Code recommends risk management for PPR for milk and milk products from sheep and goats (WOAH 2022a) imported from:

- PPR free countries or zones (Article 14.7.18.). These recommendations are that these products come from animals which have been kept in a PPR free country or zone for at least the 21 days prior to milking.
- countries or zones considered infected with PPR virus
  - The recommendations for milk are that the milk: originates from flocks which were not subjected to any restrictions due to PPR at the time of milk collection; or has been processed to ensure the destruction of the PPR virus in accordance with one of the procedures recommended by the WOAHP for the inactivation of FMDV in milk (see section 3.1.3); and the necessary precautions were taken to avoid contact of the products with any potential source of PPR virus (Article 14.7.19.).
  - The recommendations for milk products are that these products are derived from milk complying with the requirements of Article 14.7.19.; and the necessary precautions were taken after processing to avoid contact of milk products with any potential source of PPR virus (Article 14.7.20.).

### **3.2.4 Conclusion**

PPR is not present in Australia and is a nationally notifiable and WOAHP-listed disease.

Australia's current import conditions for dairy products for human consumption for PPR are less stringent than the recommendations in the Terrestrial Code. Pasteurisation alone may not be sufficient to inactivate PPR virus in milk. Therefore, a risk assessment was required.

### 3.2.5 Risk assessment

#### Entry assessment

The following factors were considered relevant to an estimate of the likelihood of PPR virus being present in dairy products imported for human consumption:

- PPR is a highly infectious disease that is easily transmitted through direct contact with infected animals or their secretions, and fomites.
- PPR is endemic in many countries of Africa, Asia and the Middle East, with prevalence reaching over 80% in some endemic countries.
- PPR virus is likely to be present in sheep and goat milk.
- If milk for human consumption were only sourced from clinically healthy animals, the possibility of contamination of milk with PPR virus would be reduced; however, excretion of PPR virus can start before clinical signs are apparent and, in some animals, particularly in sheep, subclinical infection or only mild clinical signs of disease occurs. It is possible that these animals will be undetected while shedding virus into milk.
- Definitive data on inactivation of PPR virus is limited. Pasteurisation alone may not be sufficient to completely inactivate PPR virus in milk.
- Post-processing contamination with raw milk or other dairy ingredients sourced from infected animals could introduce viable virus into processed product.
- Any virus not inactivated during processing may be relatively stable, PPR virus would be expected to survive storage and transport.

**Conclusion:** Based on these considerations, the likelihood of PPR virus entering Australia in dairy products imported for human consumption from a country/zone where the disease agent is present was estimated to be **moderate**.

#### Exposure assessment

The exposure groups considered for PPR virus were domestic and feral sheep and goats.

The following factors were considered relevant to an estimate of the likelihood of susceptible animals being exposed to PPR virus in dairy products imported for human consumption:

- PPR affects sheep and goats of all ages.
- PPR virus present in imported dairy products will likely survive during the period before exposure of susceptible animals.
- Dairy products of ovine and/or caprine origin imported for human consumption into Australia are considered a niche market.
- Susceptible animals could be exposed to dairy products imported for human consumption if
  - product was disposed of in such a way that it was accessed by animals, including feral and wild animals. This is unlikely to result in exposure of susceptible animals to PPR virus
  - product was repurposed for use in animal feed. Susceptible animals would readily consume feed that included imported dairy products. This could result in exposure of susceptible animals to PPR virus

- product was fed directly to animals, such as feeding milk powder to hand-reared animals. This could result in exposure of susceptible animals to PPR virus.

**Conclusion:** Based on these considerations, the likelihood of susceptible animals being exposed to PPR virus in dairy products imported for human consumption was estimated to be **low**.

#### **Estimation of the likelihood of entry and exposure**

The likelihood of entry of PPR virus was estimated to be moderate. The likelihood of exposure of PPR virus was estimated to be low. Using Figure 2, the likelihood of entry and exposure for PPR virus was estimated to be **low**.

#### **Consequence assessment**

##### *Identification of an outbreak scenario and likelihood of establishment and/or spread associated with the outbreak scenario*

The most likely outbreak scenario following exposure of susceptible animals to PPR virus in dairy products for human consumption was considered to be establishment in the directly exposed population and spread to other populations of susceptible animals across multiple states or territories.

The following factors were considered relevant to an estimate of the likelihood of the identified outbreak scenario occurring:

- There is limited information about transmission of PPR virus through milk. However, virus has been isolated in milk from goats and pasteurisation alone may not be sufficient to completely inactivate PPR virus in milk.
- PPR is highly contagious, and transmission of PPR virus is primarily via direct contact between infected and susceptible animals.
- Movement of infected animals is the main pathway for long-distance dispersal of PPR virus. Animal movement between state and territories occurs frequently.
- On a newly affected farm, it is likely some animals would exhibit clinical signs of PPR within a week after infection. Clinical signs may be non-specific which could lead to delayed detection of PPR.

Based on these considerations, the likelihood of establishment and/or spread of PPR virus associated with the identified outbreak scenario was estimated to be **moderate**.

##### *Determination of overall effect of establishment and/or spread associated with outbreak scenario*

The following factors were considered relevant to the effects of establishment and/or spread of PPR virus associated with the identified outbreak scenario:

- The effect on the life or health (including production effects) of susceptible animals.
- High morbidity and mortality rates of PPR have been reported.
- High animal morbidity and mortality would lead to reduced productivity on affected farms.

The effect on the living environment, including life and health of wildlife, and any effects on the non-living environment:

- PPR is not considered to have any direct effects on the environment.

The effect on new or modified eradication, control, monitoring or surveillance and compensation strategies or programs:

- If PPR was identified in Australia, the response strategy as outlined in the AUSVETPLAN disease strategy manual for PPR is eradication in the shortest possible time using stamping out. This would be supported by a combination of strategies including sanitary disposal of destroyed animals and contaminated animal products, quarantine and movement controls, decontamination and/or disposal of fomites, zoning and/or compartmentalisation, and an awareness campaign. It is unlikely that vaccination would be used in Australia (AHA 2020b).
- PPR is scheduled as Category 2 under Australia's EADRA for cost-sharing arrangements. Should it be activated, EADRA states that costs of the response would be covered by government and relevant industries by contributions of 80% and 20%, respectively (AHA 2019b).

The effect on domestic trade or industry, including changes in consumer demand and effects on other industries supplying inputs to, or using outputs from, directly affected industries:

- Following a detection of PPR, domestic movement restrictions would disrupt domestic markets.
- Along with affected livestock producers, associated industries in affected regions would suffer losses, such as transporters, stockfeed manufacturers and processors of animal products.
- With export market disruptions, relevant animal products destined for export would be redirected to the domestic market and domestic prices may fall. As a result, revenue for affected and associated industries would decrease.
- Domestic consumers may be concerned about the safety of animal products. This could reduce sales of products derived from relevant species. An awareness campaign may be needed to educate consumers that PPR does not affect food safety.

The effect on international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand:

- An outbreak of PPR in Australia would disrupt exports of relevant animals and animal products from Australia. Resumption of trade would depend on renegotiations with importing countries and additional biosecurity measures may need to be met.
- If PPR were to become established, zoning could be used to maintain or regain access to international markets. However, export markets for relevant commodities from affected zones may be lost or restricted, and access to new export markets could be affected.

The effect on the environment, including biodiversity, endangered species and the integrity of ecosystems:

- Disposal of destroyed animals and animal products, and increased use of disinfectants, may have effects on the environment.

The effect on communities, including reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures:

- Psychological distress could occur due to implementation of control and eradication measures, such as for owners of animals that are destroyed as part of disease control measures.
- Ongoing financial distress could occur for owners of affected premises if the disease situation prevents timely restocking.
- Where the relevant species were important to the local economy, if PPR were to become established, the economic viability of communities within affected regions may be compromised due to effects on directly affected and associated industries.
- Disruption of events due to movement controls could have social consequences for people involved.

Based on the geographic level and magnitude of effects, using the rules in Table 3, the overall effect of establishment and/or spread of PPR virus associated with the identified outbreak scenario was estimated to be **high**. The effect is likely to be significant at the national level and highly significant within affected zones. Implies that the effect would be of national concern. However, serious effects on economic stability, societal values or social well-being would be limited to a given zone.

#### *Derivation of likely consequences*

The likelihood of establishment and/or spread of PPR virus was estimated to be moderate. The overall effect of establishment and/or spread for PPR virus was estimated to be high. Using Figure 3, the likely consequences of establishment and/or spread of PPR virus was estimated to be **high**.

#### **Risk estimation**

The likelihood of entry and exposure of PPR virus was estimated to be low. The likely consequences of establishment and/or spread of PPR virus was estimated to be high. Using Figure 4, the unrestricted risk of PPR virus was estimated to be **moderate**.

#### **Conclusion**

The unrestricted risk of PPR virus was estimated to be **moderate**. As the unrestricted risk estimate does not achieve Australia's ALOP, risk management measures in addition to [minimum requirements](#) are required.

### **3.2.6 Risk management measures**

This section describes the various risk management options for PPR virus associated with the importation of dairy products for human consumption that are considered to achieve Australia's ALOP.

To manage the risk of PPR virus associated with the importation of dairy products for human consumption, country/zone freedom as recognised by the department is required to achieve Australia's ALOP. This means that dairy products (except for cheese) containing dairy ingredients of ovine and/or caprine origin are sourced from animals born and raised in, manufactured in, and exported from countries/zones on the department's PPR-Free Country List.

Alternatively, to manage the risk of PPR virus associated with the importation of dairy products (except for cheese) using dairy ingredients of ovine and/or caprine origin sourced from countries/zones not on the department's PPR-Free Country List, to achieve Australia's ALOP, the dairy products will require approved treatments. This is UHT at a temperature of no less than 132°C and retaining at such temperature for no less than 1 second, or equivalent thermal treatment.



To manage the risk of PPR virus associated with the importation of dairy products (except for cheese) using dairy ingredients of ovine and/or caprine origin manufactured in and/or exported from countries/zones not on the department's PPR-Free Country List, to achieve Australia's ALOP, the goods must be manufactured in and/or exported from countries/zones that have current approval by Australia, and the supply chain and manufacturing facilities must have current approval by Australia. This applies to dairy products manufactured using dairy ingredients of ovine and/or caprine origin sourced from any country/zone.

Additional risk management measures for PPR virus associated with the importation of dairy products (except for cheese) that have been stored or transhipped via countries/zones not on the department's PPR-Free Country List, are required to achieve Australia's ALOP. Dairy products containing dairy ingredients of ovine and/or caprine origin must be sourced from animals born and raised in, manufactured in, and exported from countries/zones on the department's PPR-Free Country List, or meet the manufacturing conditions above and the goods may only be unloaded during transhipment and stored without manipulation. The supply chain must also have current approval by Australia.

To achieve Australia's ALOP, dairy products (except for cheese) sourced from and/or manufactured in and/or exported from and/or stored (or transhipped) in countries/zones that are not on the department's PPR-Free Country List must also be commercially prepared and packaged and ready for retail sale to the final consumer without any further processing. This lowers the likelihood of susceptible animals being exposed to and consuming an infectious dose of PPR virus compared with dairy ingredients imported in bulk due to the relatively increased packaging and smaller volumes of individual units, and by stopping waste streams associated with further manufacture onshore.

Risk management is not required for PPR virus for imported cheese for human consumption, as the [minimum requirements](#) will effectively manage the biosecurity risk, to achieve Australia's ALOP.

### **3.3 Scrapie protease-resistant prion protein**

Scrapie protease-resistant prion protein (PrP<sup>Sc</sup>) is the cause of classical scrapie (scrapie), a transmissible fatal neurodegenerative disease of sheep and goats (CFSPH 2016; Greenlee 2019; Madsen-Bouterse et al. 2018; WOA 2022u). PrP<sup>Sc</sup> is a misfolded isoform of the cellular prion protein (PrP<sup>C</sup>) that is infectious and naturally transmissible (Ligios et al. 2011). Infected animals do not usually become ill for years; however, once clinical signs of disease develop, the disease is progressive and always fatal (Aguilar-Calvo et al. 2015; CFSPH 2016; Detwiler & Baylis 2003). Failure to prevent the introduction of disease, or eradicate the disease quickly, allows the silent spread of scrapie due to the prolonged incubation period. In countries or regions where the disease has become endemic, efforts to eliminate the disease are usually unsuccessful (Detwiler & Baylis 2003).

Atypical scrapie is recognised as a separate disease from scrapie (Greenlee 2019). It arises spontaneously in older sheep and goats and is poorly transmissible under natural conditions (CFSPH 2016; Fediaevsky et al. 2010). Atypical scrapie is not a WOA-listed disease and is excluded from the scrapie chapter in the Terrestrial Code, as the condition is clinically, pathologically, biochemically and epidemiologically unrelated to classical scrapie and may not be infectious (WOAH 2023). Atypical scrapie will not be considered in this review.

Scrapie belongs to a group of neurodegenerative diseases affecting humans and animals called transmissible spongiform encephalopathies (TSEs). Scrapie was the first TSE to be identified and other TSEs include bovine spongiform encephalopathy (BSE) in cattle, chronic wasting disease in cervids and Creutzfeldt-Jakob disease in humans (Garza et al. 2014).

Scrapie is endemic in many European countries, Canada and the United States and has been reported throughout most of the world (CABI 2019b; Detwiler & Baylis 2003). The reported prevalence of scrapie in affected countries is generally low; however, reported prevalence data is likely to be an under-estimate of the true prevalence due to the long incubation period and inability to detect early infection using currently available diagnostic tests (Fediaevsky et al. 2008; USDA 2020). In Europe, prevalence has been reported at an average of 0.32% of sheep killed in abattoirs, and 1.5% of sheep not intended for human consumption (Fediaevsky et al. 2008). Australia and New Zealand successfully eradicated scrapie after it was introduced through imported animals (Detwiler & Baylis 2003).

Animals susceptible to scrapie are sheep and goats, and possibly other animals closely related to sheep and goats (CFSPH 2016). There is no evidence that scrapie is transmissible to humans (Detwiler & Baylis 2003).

Scrapie is a WOAHL-listed disease of sheep and goats (WOAH 2022d). In Australia, scrapie is nationally notifiable and classical scrapie has not occurred since 1952 (AHA 2019a; DAFF 2024).

### **3.3.1 Technical information**

#### **Agent properties**

PrP<sup>Sc</sup> is highly resistant to the thermal and chemical treatments considered suitable to inactivate most pathogens. Inactivation of prion infectivity has only been demonstrated following extreme treatments such as 20,000 ppm sodium hypochlorite for 1 hour (Fichet et al. 2004) (which is highly corrosive to certain surfaces), 1 gram-equivalent per litre sodium hydroxide for 60 minutes followed by autoclaving at 121°C for 30 minutes (Taguchi et al. 1991), or incineration at 1,000°C (Brown et al. 2004). Although there are reports of other treatments successfully inactivating prions, many of these have been demonstrated to be insufficient for complete inactivation in subsequent studies (Taylor 1999). Inactivation studies of prions are further complicated by the sometimes-marked difference in susceptibility to inactivation treatments observed between different prion strains and sample types (e.g. brain macerates or intact brain tissue) (Taylor 1999).

PrP<sup>Sc</sup> can bind to soil particles and retain infectivity for decades (Brown & Gajdusek 1991; Seidel et al. 2007). Persistent infectivity has been demonstrated on many objects and materials (Konold et al. 2015; Weissmann et al. 2002). PrP<sup>Sc</sup> has reportedly survived and retained infectivity for up to 16 years in a barn previously housing infected animals (Georgsson, Sigurdarson & Brown 2006).

#### **Epidemiology**

The incubation period of scrapie typically ranges from 2 to 5 years (Aguilar-Calvo et al. 2015; Detwiler & Baylis 2003). Due to the variability of the incubation period, an incubation period is not specified in the Terrestrial Code (WOAH 2023).

The long incubation period between exposure and clinical disease may allow infected animals to shed PrP<sup>Sc</sup> for a long period of time. Introduction of preclinically infected animals through the

purchase of breeding animals is the most consistent risk factor for the introduction of scrapie into naïve flocks or herds (Detwiler & Baylis 2003).

Transmission occurs primarily through oral ingestion of PrP<sup>Sc</sup> from the contaminated environment (Greenlee 2019). Transmission from dams to neonates via contaminated placenta and placental fluids immediately post-partum is considered epidemiologically important (CFSPH 2016; Greenlee 2019). PrP<sup>Sc</sup> is also excreted in urine, faeces, saliva, through the skin, and in colostrum and milk (Gough & Maddison 2010; Konold et al. 2013). Infected goats usually come from herds that are comingled with sheep. Less frequently, scrapie has been reported in herds containing only goats (Greenlee 2019).

Older animals are much less susceptible to scrapie (Greenlee 2019). Cases of scrapie have been reported in animals aged over 5 years; however, this could have been due to an unusually long incubation period, rather than infection of PrP<sup>Sc</sup> later in life (Detwiler & Baylis 2003).

In sheep, polymorphisms of the prion protein gene (PRNP) have a major role in determining the host susceptibility to scrapie, the incubation period, and the transmission potential by the host (Goldmann 2018; Konold et al. 2016). In goats, the role of polymorphisms of the PrP gene in host susceptibility to scrapie is not definitive and requires further research (Greenlee 2019; Konold et al. 2016).

#### **Presence in milk**

Infected sheep can secrete PrP<sup>Sc</sup> in milk at least 20 months before showing clinical signs of disease (Maddison et al. 2009). PrP<sup>Sc</sup> is transmissible through milk from preclinically infected sheep and goats and in colostrum from preclinically infected sheep (Konold et al. 2013; Konold et al. 2016). There is no experimental data available regarding the infectivity of PrP<sup>Sc</sup> in colostrum from infected goats.

It is common for hand-reared young animals to be fed colostrum from ewes and goats due to its beneficial effects on survival and development (Agenbag et al. 2021; Hernández-Castellano et al. 2015) It is recommended that colostrum from potentially infected sheep or goats should not be fed to scrapie-free flocks (CFSPH 2016).

There are no studies available that investigate inactivation of PrP<sup>Sc</sup> in milk. Milk processing would have little or no effect on the structure of prions, except for diluting and decreasing their concentrations (Guan et al. 2017).

#### **Pathogenesis**

Unlike BSE in cattle, where most tissue infectivity is confined to the central nervous system, the distribution of PrP<sup>Sc</sup> is widespread in sheep and goats infected with scrapie, and in sheep experimentally infected with BSE (Jeffrey et al. 2006). Following entry into the gut associated lymphoid tissue, PrP<sup>Sc</sup> spreads to other lymphoreticular tissue including the spleen, lymph nodes and tonsils, then to the enteric nervous system and the CNS. Following replication in the CNS, there is centrifugal spread of PrP<sup>Sc</sup> via the peripheral nervous system to sites of secondary replication. There is prolonged persistence and replication within the lymphoid tissues throughout disease incubation (Gough & Maddison 2010). It is likely that young animals are more susceptible to infection with scrapie as they have a greater density of gut-associated lymphoid tissues compared to older animals (Greenlee 2019; Konold et al. 2008).

## **Diagnosis**

There are a wide range of clinical signs associated with scrapie. Not all affected animals will exhibit the full range of clinical signs of disease and there can be extreme variation between individual animals (Detwiler & Baylis 2003). Most animals die within 2 weeks to 6 months after the onset of clinical signs of disease (Aguilar-Calvo et al. 2015).

Clinical signs include incoordination, gait abnormalities progressing to severe hindlimb ataxia, hyperaesthesia, hyperexcitability, altered mentation, neurological deficits, pruritus causing self-trauma, alopecia and wool loss, progressive loss of body condition, recumbency, and death (Aguilar-Calvo et al. 2015; Detwiler & Baylis 2003; Konold & Phelan 2014).

Diagnosis of scrapie is based on detection of PrP<sup>Sc</sup> (Greenlee 2019). Definitive diagnosis may be made by histopathological or immunohistochemical examination of the brainstem for fixed brainstem samples, or an enzyme-linked immunosorbent assay followed by confirmatory western blot for fresh brainstem samples (AHA 2020a). Ante-mortem testing consists of immunohistochemistry on biopsies of the nictitating membrane, palatine tonsils, superficial lymph nodes or recto-anal mucosa associated lymphoid tissue (WOAH 2022u). However, many infected animals will not have detectable lymphoreticular involvement and confirmatory diagnosis is through post-mortem sampling as described above (Greenlee 2019).

Protein misfolding cyclic amplification is a widely used and highly sensitive technique to detect PrP<sup>Sc</sup> in fluids, including milk. In this test, PrP<sup>C</sup> is added to the substrate, which can convert and amplify minute amounts of PrP<sup>Sc</sup> to detectable amounts through serial cycles of incubation and sonification (CFSPH 2016; Konold et al. 2013). In a study performed in 2009, milk from both clinically and preclinically infected sheep tested positive for PrP<sup>Sc</sup> in at least one protein misfolding cyclic amplification reaction (Maddison et al. 2009). The use of protein misfolding cyclic amplification is not currently recommended by the WOAH as a diagnostic test for scrapie (WOAH 2022u).

Failure to detect PrP<sup>Sc</sup> in tissues, secretions or excretions of sheep and goats does not necessarily confirm its absence. Current tests to detect animals preclinically infected with scrapie are more appropriate on a flock basis rather than for testing of individual animals (Detwiler & Baylis 2003).

## **Treatment**

There is no specific treatment for animals infected with PrP<sup>Sc</sup> (CFSPH 2016; Detwiler & Baylis 2003; Madsen-Bouterse et al. 2018).

## **Control**

Scrapie is difficult to eradicate and control (Detwiler & Baylis 2003). Vaccinations are not possible since infection with PrP<sup>Sc</sup> does not elicit an immune response (Greenwood 2002).

Breeding sheep for genetic resistance using the PRNP genotype is an important tool for many control and eradication programs (Detwiler & Baylis 2003). Genotype-based breeding programs designed to increase resistant PRNP genotypes in sheep populations, in conjunction with the removal of affected animals, occurs in the European Union and the United States (Greenlee 2019).

### **3.3.2 Current biosecurity measures**

The dairy IRA did not include risk management measures for scrapie as at the time it was not considered to be transmitted via milk. Although there are no import conditions for scrapie for dairy

products for human consumption, imported dairy products containing milk from sheep or goats are not eligible for repurposing as animal feed.

The Terrestrial Code recommends risk management for importation of milk and milk products of sheep or goat origin from countries/zones not considered free from scrapie and intended for use in feeding of sheep and goats (Article 14.8.10.) (WOAH 2023). These recommendations are that the milk and milk products come from scrapie-free establishments (as described in Article 14.8.5.).

### 3.3.3 Conclusion

Scrapie is not present in Australia and is a nationally notifiable and WOAHL-listed disease.

Australia's current import conditions for dairy products for human consumption do not include scrapie. The Terrestrial Code does not include recommendations for dairy products for human consumption for scrapie. PrP<sup>Sc</sup> can be present in milk of infected animals and may be transmissible in dairy products. Therefore, a risk assessment was required.

### 3.3.4 Risk assessment

#### Entry assessment

The following factors were considered relevant to an estimate of the likelihood of PrP<sup>Sc</sup> being present in dairy products imported for human consumption:

- Scrapie is widespread globally. It is reported on all major continents and islands, except for Australia and New Zealand.
- The reported prevalence in affected countries is generally low; however, reported prevalence data is likely to be an under-estimate of the true prevalence due to the long incubation period and inability to detect early infection through laboratory testing.
- PrP<sup>Sc</sup> can be present in the milk and colostrum of infected sheep and goats, including those that are clinically healthy at the time of milking.
- PrP<sup>Sc</sup> in milk and colostrum would not be inactivated by HTST pasteurisation or any other milk processing technique.
- PrP<sup>Sc</sup> is highly stable outside of the host. If present in dairy products, PrP<sup>Sc</sup> would be expected to survive storage and transport.

**Conclusion:** Based on these considerations, the likelihood of PrP<sup>Sc</sup> entering Australia in dairy products imported for human consumption from a country/zone where the disease agent is present was estimated to be **moderate**.

#### Exposure assessment

The exposure groups considered for PrP<sup>Sc</sup> was domestic and feral sheep and goats.

The following factors were considered relevant to an estimate of the likelihood of susceptible animals being exposed to PrP<sup>Sc</sup> in dairy products imported for human consumption:

- Animals susceptible to scrapie are sheep, goats, and possibly other animals closely related to sheep and goats. Older animals are much less susceptible to scrapie than young animals.

- PrP<sup>Sc</sup> is highly stable outside of the host. PrP<sup>Sc</sup> present in dairy products would be expected to survive the period before exposure of susceptible animals.
- Dairy products of ovine and/or caprine origin imported for human consumption into Australia are considered a niche market.
- Colostrum is much more likely to be used as a food than other dairy products for hand rearing young animals.
- As only dairy products for human consumption would be imported, most imported dairy products would move from the distributor/retailer to household consumers or to the food industry. However, susceptible animals could be exposed to dairy products imported for human consumption if
  - product was disposed of in such a way that it was accessed by animals, including feral and wild animals. This is unlikely to result in exposure of susceptible animals to PrP<sup>Sc</sup>
  - product was repurposed for use in animal feed. Susceptible animals would readily consume feed that included imported dairy products. This could result in exposure of susceptible animals to PrP<sup>Sc</sup>
  - product was fed directly to animals, such as feeding milk powder to hand-reared animals. This could result in exposure of susceptible animals to PrP<sup>Sc</sup>.

**Conclusion:** Based on these considerations, the likelihood of susceptible animals being exposed to PrP<sup>Sc</sup> in dairy products other than colostrum imported for human consumption was estimated to be **very low**. Based on these considerations, the likelihood of susceptible animals being exposed to PrP<sup>Sc</sup> in colostrum imported for human consumption was estimated to be **low**.

#### **Estimation of the likelihood of entry and exposure**

For dairy products other than colostrum imported for human consumption, the likelihood of entry was estimated to be moderate and the likelihood of exposure was estimated to be very low. Using Figure 2, the likelihood of entry and exposure for PrP<sup>Sc</sup> was estimated to be **very low**.

For colostrum imported for human consumption, the likelihood of entry was estimated to be moderate and the likelihood of exposure was estimated to be low. Using Figure 2, the likelihood of entry and exposure for PrP<sup>Sc</sup> was estimated to be **low**.

#### **Consequence assessment**

##### *Identification of an outbreak scenario and likelihood of establishment and/or spread associated with the outbreak scenario*

The most likely outbreak scenario following exposure of susceptible animals to PrP<sup>Sc</sup> in dairy products for human consumption was considered to be establishment in the directly exposed population and spread to other populations of susceptible animals across multiple states or territories.

The following factors were considered relevant to an estimate of the likelihood of the identified outbreak scenario occurring:

- Milk from infected sheep and goats, and colostrum from sheep, has been demonstrated experimentally as highly effective vehicles for scrapie transmission.

- Most sheep and goats are thought to be infected as neonates when they are exposed to placenta and placental fluids from infected dams, which contain high levels of PrP<sup>Sc</sup>.
- Host susceptibility may be influenced by age, genetics, breed and strain of scrapie. Older animals are less susceptible to infection than younger animals. A study investigating the PrP genotypes of two common Australian sheep breeds (merino and Poll Dorset) confirmed that animals of highly susceptible PrP genotypes are found in Australia (Hunter & Cairns 1998).
- Infected animals shed PrP<sup>Sc</sup> long before clinical signs of disease occur, and clinical signs of scrapie may not be evident until several years after infection.
- Transmission of PrP<sup>Sc</sup> could occur if young sheep or goats ingested imported dairy products made from milk or colostrum sourced from infected sheep or goats.
- There is no information available about the minimum infectious dose of PrP<sup>Sc</sup> in sheep or goats through consumption of milk.
- Large populations of feral goats are present in some parts of Australia. However, it is unlikely that scrapie would be maintained in the feral goat population. It is not common for scrapie to be reported in herds containing only goats.

Based on these considerations, the likelihood of establishment and/or spread of PrP<sup>Sc</sup> associated with the identified outbreak scenario was estimated to be **low**.

*Determination of overall effect of establishment and/or spread associated with outbreak scenario*

The following factors were considered relevant to the effects of establishment and/or spread of PrP<sup>Sc</sup> associated with the identified outbreak scenario.

The effect on the life or health (including production effects) of susceptible animals:

- Scrapie is always fatal once clinical signs of disease develop. However, the long incubation period means that many infected sheep and lambs are slaughtered before the onset of clinical signs of disease.
- Increased animal mortality would lead to reduced productivity on affected farms.

The effect on the living environment, including life and health of wildlife, and any effects on the non-living environment:

- Scrapie is not considered to have any direct effects on the environment.

The effect on new or modified eradication, control, monitoring or surveillance and compensation strategies or programs:

- If scrapie was identified in Australia, the response strategy as outlined in the AUSVETPLAN disease strategy manual for scrapie is control and eradication in the shortest possible time while minimising economic effects. Where the disease is limited to a manageable number of premises and there is a high level of confidence that the known extent of spread represents the actual extent of spread, control and eradication would be through short-term stamping out or modified stamping out. This would be supported by a combination of strategies including tracing and surveillance; quarantine and movement controls; enhanced biosecurity; sanitary disposal of

destroyed animals, contaminated animal products and waste; awareness campaigns; and long-term management of contaminated and potentially contaminated premises (AHA 2020a).

- Scrapie is scheduled as Category 3 under Australia's EADRA for cost-sharing arrangements. Should it be activated, EADRA states that costs of the response would be covered by government and relevant industries by contributions of 50% each (AHA 2019b).
- ABARES estimates that scrapie could be eradicated an average of 8 years after detection of the first case, which would mean likely regaining negligible-risk status according to WOA requirements after around 15 years on average (ABARES. 2017).
- Based on a sheep meat and beef market ban of 3 months, ABARES estimated the cost to livestock industries of a scrapie outbreak to be \$75 million, comprising \$5 million in control costs (ABARES. 2017).
- International experience shows that scrapie is very difficult to eradicate once it is established. Failure to eradicate scrapie could cause prolonged productivity losses, increased costs and operational procedures associated with implementing control and surveillance measures for scrapie. If scrapie continued to spread despite eradication efforts, ABARES estimates the cost of managed spread, where control measures that slow the spread of disease are implemented, to be between \$119 million and \$150 million (ABARES. 2017).

The effect on domestic trade or industry, including changes in consumer demand and effects on other industries supplying inputs to, or using outputs from, directly affected industries:

- Following a detection of scrapie, domestic movement controls may be implemented that would disrupt domestic markets.
- Along with affected livestock producers, associated industries in affected regions would suffer losses, such as transporters, stockfeed manufacturers and processors of animal products.
- With export market disruptions, relevant animal products destined for export would be redirected to the domestic market and domestic prices may fall. As a result, revenue for affected and associated industries would decrease.
- Domestic consumers may be concerned about the safety of animal products because of the link of scrapie to BSE. This could reduce sales of products derived from sheep and goat origin. An awareness campaign may be needed to educate consumers that scrapie does not affect food safety.

The effect on international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand:

- Scrapie is present in most countries. However, an outbreak of scrapie in Australia would disrupt exports of relevant animals and animal products from Australia to importing countries that are either free of scrapie or sensitive to scrapie regardless of its presence in their own country. Resumption of trade would depend on renegotiations with importing countries and additional biosecurity measures may need to be met.



- Depending on the extent of international trade bans imposed on Australia following detection of scrapie, economic effects on the Australian sheep and goat industries may be significant as they are largely export orientated industries (ABARES. 2017).
- ABARES estimated that a sheep meat and beef market ban of 3 months following a scrapie outbreak would cost livestock industries \$70 million because of trade disruptions. ABARES estimated a cost of scrapie to trade of \$152 million based on a year-long sheep meat ban and \$2.2 billion based on a sheep meat ban extended until Australia regained negligible-risk status (15 years average) (ABARES. 2017).
- If scrapie were to become established, zoning could be used to maintain or regain access to international markets. However, export markets for relevant commodities from affected zones may be lost or restricted, and access to new export markets could be affected.

The effect on the environment, including biodiversity, endangered species and the integrity of ecosystems:

- Disposal of large numbers of destroyed animals and animal products, and increased use of disinfectants, may have effects on the environment.

The effect on communities, including reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures:

- Psychological distress could occur due to implementation of control and eradication measures, such as for owners of animals that are destroyed as part of disease control measures.
- Where sheep and goats were important to the local economy, if scrapie were to become established, the economic viability of communities within affected regions may be affected due to effects on directly affected and associated industries.
- Disruption of events due to movement controls could have social consequences for people involved.
- Public concerns about the zoonotic potential of scrapie, due to its link with BSE, may have a detrimental effect on tourism in affected rural and regional communities.

Based on the geographic level and magnitude of effects, using the rules in Table 3, the overall effect of establishment and/or spread of PrP<sup>Sc</sup> associated with the identified outbreak scenario was estimated to be **high**. The effect is likely to be significant at the national level and highly significant within affected zones. Implies that the effect would be of national concern. However, serious effects on economic stability, societal values or social well-being would be limited to a given zone.

#### *Derivation of likely consequences*

The likelihood of establishment and/or spread was estimated to be low and the overall effect of establishment and/or spread was estimated to be high. Using Figure 3, the likely consequences of establishment and/or spread of PrP<sup>Sc</sup> were estimated to be **moderate**.

#### **Risk estimation**

For dairy products other than colostrum imported for human consumption, the likelihood of entry and exposure was estimated to be very low and the likely consequences of establishment and/or

spread were estimated to be moderate. Using Figure 4, the unrestricted risk of PrP<sup>Sc</sup> was estimated to be **very low**.

For colostrum imported for human consumption, the likelihood of entry and exposure was estimated to be low and the likely consequences of establishment and/or spread were estimated to be moderate. Using Figure 4, the unrestricted risk of PrP<sup>Sc</sup> was estimated to be **low**.

### **Conclusion**

The unrestricted risk of PrP<sup>Sc</sup> in dairy products other than colostrum imported for human consumption was estimated to be **very low**. As the unrestricted risk estimate achieves Australia's ALOP, risk management measures for dairy products other than colostrum imported for human consumption in addition to [minimum requirements](#) are not required.

The unrestricted risk of PrP<sup>Sc</sup> in colostrum imported for human consumption was estimated to be low. As the unrestricted risk estimate does not achieve Australia's ALOP, risk management measures for colostrum imported for human consumption in addition to [minimum requirements](#) are required.

### **3.3.5 Risk management measures**

This section describes risk management for PrP<sup>Sc</sup> associated with the importation of dairy products for human consumption that is considered to achieve Australia's ALOP.

As older sheep and goats are considerably less susceptible to PrP<sup>Sc</sup>, risk management measures are required to reduce the likelihood of young sheep and goats being exposed to PrP<sup>Sc</sup> in dairy products imported for human consumption. Colostrum is much more likely to be used as a food than other dairy products for hand-rearing young animals.

Scrapie is present worldwide and there are no practical heat treatment options that would inactivate PrP<sup>Sc</sup> in milk. Ingestion of only a small volume of colostrum may result in infection. As such, the risk of PrP<sup>Sc</sup> associated with the importation of dairy products for human consumption will need to be managed to achieve Australia's ALOP. Colostrum of ovine and/or caprine origin will not be eligible for import due to the increased likelihood of young sheep and goats being exposed to PrP<sup>Sc</sup>, and a statement that the goods do not contain colostrum will be included in health certification for exporting dairy products of ovine and/or caprine origin for human consumption to Australia.

Other dairy products not containing colostrum of ovine and/or caprine origin imported for human consumption into Australia are considered a niche market and are less likely to be exposed to susceptible animals. As such, risk management for dairy products of ovine and/or caprine origin (except for colostrum) is not required to achieve Australia's ALOP.

## **3.4 Sheeppox virus and goatpox virus**

### **3.4.1 Background**

Sheeppox virus and goatpox virus (species *Sheeppox virus* and *Goatpox virus*; genus *Capripoxvirus*; family *Poxviridae*) cause pox disease in sheep and goats (CFSPH 2017b). These viruses can cause heavy production losses and mortalities (CFSPH 2017b).

Sheeppox and goatpox virus strains are serologically indistinguishable, however strains of sheeppox and goatpox viruses generally express host preferences for either sheep or goats; although, there are some isolates that infect both sheep and goats equally (EFSA 2006; Kitching 2004). Serological

techniques have also shown sheeppox and goatpox viruses to be cross-protective between the two species. It has been demonstrated that serum against goatpox virus can protect sheep against sheeppox virus and vice versa (Kitching 1986, 2004).

Studies have shown that recombination of capripoxviruses in the field is possible (Sprygin et al. 2018). In 2017, a recombinant vaccine-like lumpy skin disease virus (LSDV) strain was detected in cattle in Russia, where only the sheeppox virus vaccine is used. This was following the initiation of vaccination campaigns using LSDV vaccines in neighbouring countries, demonstrating that recombination of capripoxvirus strains can occur, which may further complicate the epidemiology of the disease (Kononov et al. 2019; Sprygin et al. 2020).

Sheeppox and goatpox viruses are prevalent in Bangladesh, India, the Middle East, North and Central Africa and much of Central Asia (Carn 1993; Yune & Abdela 2017). Outbreaks have occurred in Bulgaria (2013), Greece (2013 to 2018), Egypt (2017), Indonesia (2018) and Spain (2022) and sporadic outbreaks have occurred in Israel, Kazakhstan, Mongolia, Russia and Tajikistan (WOAH 2022x). High prevalence of sheep pox and goat pox has been reported in affected countries. For example, an overall flock prevalence of 14% was reported in Algeria (Kardjadj 2017), a seroprevalence of 73.4% was reported in the Kordofan region of Sudan (Mansour et al. 2021) and a prevalence of 79.69% was reported in North Vietnam (Pham et al. 2020).

All breeds of domestic sheep and goats are susceptible to sheep pox and goat pox. Morbidity and mortality rates in sheep and goats vary according to factors such as breed, level of immunity, age of the animal and strain of the virus (AVA 2017; Bhanuprakash et al. 2006; WOA 2013). There is no evidence of sheeppox and goatpox viruses in wildlife, although it cannot be excluded that wild sheep and goats can be infected (EFSA Panel on Animal Health and Welfare 2014).

Sheep pox and goat pox is a WOA-listed disease of sheep and goats (WOAH 2022d). In Australia, infection with sheeppox virus or goatpox virus is nationally notifiable (DAFF 2024). Sheep pox and goat pox have never occurred in Australia (AHA 2021a).

### **3.4.2 Technical information**

#### **Agent properties**

Sheeppox and goatpox viruses can remain viable for many months in the environment, especially in dark environmental conditions such as contaminated animal sheds, and can remain viable in wool for up to 3 months (WOAH 2013).

The WOA considers 56°C for 2 hours or 65°C for 30 minutes suitable to inactivate sheeppox and goatpox viruses (WOAH 2013). A 1973 study found that sheeppox virus suspended in buffer was not detectable after heat treatment of 55°C for 1 hour, 60°C for 1 hour and 65°C for 30 minutes (Ferreira 1973).

The sensitivity of sheeppox and goatpox viruses to heat differs among strains. Inactivation of virus strains has been reported following various time, temperature and substrate combinations including 55°C for 60 minutes, 60°C for 30 minutes and 60°C for 5 minutes (El-Awar and El-Zein 1986; Kavitha, Chetty & Sreenivasulu 2009; Wolff, Beer & Hoffmann 2020).

Sheeppox and goatpox viruses are susceptible to highly acidic or alkaline pH (EFSA Panel on Animal Health and Welfare 2014). A study demonstrated that sheeppox virus was no longer detectable after

2 hours at pH 3 and pH 11 (Ferreira 1973). The viruses may be more sensitive to acids than to alkalis. In the same experiment, a  $10^5$  reduction in infectivity was achieved when goatpox virus was exposed to pH 3 for 1 hour, in contrast to a  $10^1$  reduction in infectivity at pH 8 (Datta & Soman 1991).

Thermal inactivation studies comparing the sensitivity of capripoxviruses are rare. A thermal inactivation study using four different capripoxvirus isolates (LSDV field strain, LSDV Neethling vaccine strain, sheep pox vaccine strain, and goat pox virus field strain) demonstrated similar susceptibility to thermal treatments between the different isolates in different substrates following treatment at 56°C for 30 minutes or 60°C for 10 minutes (Wolff, Beer & Hoffmann 2020). Although inactivation of four goatpox virus strains has been reported following various time/temperature combinations including 55°C for 60 minutes and 60°C for 30 minutes (Datta & Soman 1991; Kavitha, Chetty & Sreenivasulu 2009), goatpox virus has also been demonstrated to retain infectivity following treatment at 56°C for 60 minutes and 60°C for 30 minutes (Tantawi et al. 1980). These studies indicate greater thermal resistance for goatpox virus than for LSDV (Wolff, Beer & Hoffmann 2020).

The Institute of Diagnostic Virology at the Friedrich-Loeffler Institute recommends uniform thermal inactivation parameters (56°C for 1 h) for all capripoxvirus isolates prior to removal from BSL-3 facilities based on their data (Wolff, Beer & Hoffmann 2020). Although they recognise there may be variation in thermal susceptibility between different isolates, they do not consider LSDV to require different parameters for inactivation from sheeppox and goatpox viruses. In order to account for the potential differences in thermal susceptibility between capripoxvirus isolates, they recommend an increased exposure time to ensure inactivation. Their recommendation is based on doubling the exposure time demonstrated to inactivate capripoxviruses in their laboratory. These recommendations are impracticable for the inactivation of sheeppox and goatpox viruses in dairy production. There is currently insufficient evidence to conclude that sheeppox and goatpox viruses will be inactivated by the same conditions which inactivate LSDV in milk.

### **Epidemiology**

The incubation period of sheep pox and goat pox ranges from 1 to 2 weeks, but clinical signs of disease have developed as early as 2 days in experimentally infected animals (CFSPH 2017b). The incubation period of sheep pox and goat pox in the Terrestrial Code is 21 days (WOAH 2022v).

Movement of infected animals and direct contact with susceptible animals are the main methods of spreading sheeppox and goatpox viruses (EFSA Panel on Animal Health and Welfare 2014). Transmission of sheep pox and goat pox via the respiratory route and through contact has been demonstrated (Kitching & Taylor 1985). Extremely high viral titres are found in the skin of infected animals and there is evidence that stable flies (*Stomoxys calcitrans*) can act as an efficient mechanical vector (Bowden et al. 2008; Kitching & Mellor 1986). However, the role of insect vectors in the field remains unclear (Tuppurainen et al. 2017). Virus shed in saliva, ocular and nasal discharge, skin lesions and scabs, urine and faeces may contaminate feed, water, wool and the environment, leading to indirect transmission orally or via skin abrasions (EFSA Panel on Animal Health and Welfare 2014). Indirect transmission through wildlife (insects or wild birds) may also occur (EFSA Panel on Animal Health and Welfare 2014).

### **Presence in milk**

There is no experimental evidence that sheeppox and goatpox viruses are present in milk. However, as the presence of LSDV has been detected in milk samples, it is generally agreed in the literature

that they are present in milk (Bedeckovic et al. 2018; Bhanuprakash et al. 2006; CFSPH 2017b; Rao & Bandyopadhyay 2000; Sharawi & Abd El-Rahim 2011). It is possible that physical contamination of milk with sheeppox and goatpox viruses could occur during milking if infected animals have lesions on or close to the udder as there are large quantities of virus within the scabs of lesions (EFSA 2006).

Whether capripoxviruses would be present in sufficient titres in contaminated milk to cause infection is unknown. There have been no recorded cases of transmission of capripoxviruses in milk. The Food and Agriculture Organization of the United Nations lumpy skin disease field manual for veterinarians states that the virus may be transmitted to suckling calves through infected milk or from skin lesions on the teats (Tuppurainen, Alexandrov & Beltrán-Alcrudo 2017). Although, there is no direct experimental confirmation of this assumption, sheeppox and goatpox virus has been isolated in milk, and maternal antibodies have been detected in lambs vaccinated with a sheeppox and goatpox vaccine in a challenge trial (Abd-Elhafeiz 2021; Gulyaz 1999; Murcia, Donachie & Palmarini 2009; Précausta, Kato & Vellut 1979; WOAAH 2013).

There are currently no studies available that directly investigate inactivation of sheeppox and goatpox virus in milk.

### **Pathogenesis**

Following experimental intradermal infection of sheeppox and goatpox virus in sheep and goats, virus was shed in nasal and oral secretions from day 6 post-inoculation. Peak shedding occurred between 10 and 14 days post-inoculation. Most animals ceased shedding virus by day 21; however, a small number of animals continued to shed low levels of virus until day 64 post-inoculation. In the same experiment, viral genomes were first detected in the blood of sheep and goats at 6 days and 4 days post-inoculation, respectively. Peak viraemia occurred between days 10 and 14 post-inoculation and ceased by day 14 post-inoculation in sheep and day 28 in goats (Bowden et al. 2008).

### **Diagnosis**

Capripoxviruses cause systemic disease in cattle, sheep and goats, with fever, generalised skin nodules, lesions in the mucous membranes and internal organs, emaciation, enlarged lymph nodes and cutaneous oedema (Bowden et al. 2008; EFSA 2006). Pox lesions can be seen on mucous membranes of the eyes, mouth, nose, pharynx, epiglottis, trachea; on the ruminal and abomasal mucosae; on the muzzle, nares, prepuce, testicles, udder and teats; in the vulva and under the tail (WOAH 2013).

Mortality rates for sheep pox and goat pox may reach 10% in endemic areas and 100% in introduced animals and younger animals (Boshra et al. 2015), with morbidity rates in endemic areas between 70% and 90% (WOAH 2013). Animals affected by sheep pox and goat pox may have permanent scars reducing the quality of hides and wool (CFSPH 2017b).

Subclinical infections can occur in animals affected by sheeppox and goatpox viruses (WOAH 2013). Mild infections can be difficult to recognise even by the most experienced veterinarians (Saegerman et al. 2019; Tuppurainen, Alexandrov & Beltrán-Alcrudo 2017).

The use of ELISA tests for serological diagnosis has not been validated by the WOAHA for sheeppox and goatpox viruses (WOAH 2022q, 2024). Because immunity to capripoxviruses is predominately cell-mediated, vaccinated or mildly affected animals may not be detected by serological tests as the

level of antibody produced may be below the detection limit (Tuppurainen 2018a; Tuppurainen et al. 2015; WOAH 2022q, 2024).

#### **Treatment**

There is no specific treatment for animals infected with capripoxviruses (CFSPH 2017b).

#### **Control**

In countries where sheeppox and goatpox viruses are endemic, vaccination is commonly used for disease control. The most commonly used sheep pox and goat pox vaccines are either attenuated live or inactivated strains of sheep pox and goat pox. Homologous vaccines provide optimal protection. Inactivated vaccines do not provide adequate or long-term immunity (Madhavan & Kumar 2016).

Sheeppox and/or goatpox virus strain vaccines are used for LSD control in some countries. They are not recommended for use in countries that are free from LSD due to the risk of disease introduction associated with the use of a live attenuated vaccine (Tuppurainen et al. 2015).

### **3.4.3 Current biosecurity measures**

The dairy IRA included risk management measures for sheep pox and goat pox for the importation of dairy products of ovine and/or caprine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that meets WOAH requirements for freedom from sheep pox and goat pox.

Since the dairy IRA was published, the import conditions have been updated to reflect changes in Australia's approach towards determining the sheep pox and goat pox status of trading partners, and in response to identified biosecurity risks. Apart from legislated exemptions, retorted products, and cheese and butter, goods containing ovine and/or caprine dairy ingredients must only be sourced, manufactured and exported from, countries/zones on the department's [Sheep Pox and Goat Pox-Free Country List](#).

The Terrestrial Code does not recommend risk management for sheep pox and goat pox for importation of milk and milk products intended for human consumption (Chapter 14.9.) (WOAH 2022v).

### **3.4.4 Conclusion**

Sheep pox and goat pox are not present in Australia and are nationally notifiable and WOAH-listed diseases.

The Terrestrial Code does not include recommendations for dairy products for sheep pox and goat pox. Therefore, a risk assessment was required.

### **3.4.5 Risk assessment**

#### **Entry assessment**

The following factors were considered relevant to an estimate of the likelihood of sheeppox and goatpox viruses being present in dairy products imported for human consumption.

- The geographic distribution of sheep pox and goat pox has remained relatively stable but is widespread and prevalent in countries where the agent occurs.

- Sheeppox and goatpox viruses may be present in milk and colostrum of sheep and goats following natural infection or vaccination.
- After infection, sheeppox and goatpox viruses may be shed from skin lesions for up to 64 days. Animals with skin lesions close to the udder or teat may shed crusts, containing virus, into milk during milk collection.
- If milk for human consumption was only sourced from clinically healthy animals, the possibility of contamination of milk with crusts would be reduced; however, 50% of animals are likely to have subclinical infection or only mild clinical signs of disease. It is highly likely that infection in these animals will be undetected while shedding virus into milk.
- There is evidence that heat treatments equivalent to batch pasteurisation and UHT, are likely to inactivate capripoxviruses in milk. However, there is no evidence to show that heat treatment equivalent to HTST pasteurisation will inactivate sheeppox and goatpox viruses in milk. Post-processing contamination with raw milk or other dairy ingredients sourced from infected animals could introduce viable virus into processed product.

**Conclusion:** Based on these considerations, the likelihood of sheeppox and goatpox viruses entering Australia in ovine and/or caprine dairy products imported for human consumption from a country/zone where the disease agent is present was estimated to be **low**.

#### **Exposure assessment**

The exposure groups considered for sheeppox and goatpox viruses were domestic and feral sheep and goats.

The following factors were considered relevant to an estimate of the likelihood of susceptible animals being exposed to sheeppox and goatpox viruses in dairy products imported for human consumption:

- Sheep pox and goat pox only affects sheep and goats.
- Capripoxviruses can survive many years in dried scabs at ambient temperatures and survive in the environment or premises for up to 6 months. Sheeppox and goatpox viruses present in imported dairy products may survive during the period before exposure of susceptible animals.
- Dairy products of ovine and/or caprine origin imported for human consumption into Australia are considered a niche market.
- Susceptible animals could be exposed to dairy products imported for human consumption if
  - product was disposed of in such a way that it was accessed by animals, including feral and wild animals
  - product was repurposed for use in animal feed. Susceptible animals would readily consume feed that included imported dairy products. This could result in exposure of susceptible animals to sheeppox and goatpox viruses
  - product was fed directly to animals, such as feeding milk powder to hand-reared animals. This could result in exposure of susceptible animals to sheeppox and goatpox viruses.

**Conclusion:** Based on these considerations, the likelihood of susceptible animals being exposed to sheeppox and goatpox viruses in ovine and/or caprine dairy products imported for human consumption was estimated to be **very low**.

#### **Estimation of the likelihood of entry and exposure**

The likelihood of entry of sheeppox and goatpox viruses was estimated to be low. The likelihood of exposure of sheeppox and goatpox viruses was estimated to be very low. Using Figure 2, the likelihood of entry and exposure for sheeppox and goatpox viruses was estimated to be **very low**.

#### **Consequence assessment**

##### *Identification of an outbreak scenario and likelihood of establishment and/or spread associated with the outbreak scenario*

The most likely outbreak scenario following exposure of susceptible animals to sheeppox and goatpox viruses in dairy products for human consumption was considered to be establishment in the directly exposed population and spread to other populations of susceptible animals across multiple states or territories.

The following factors were considered relevant to an estimate of the likelihood of the identified outbreak scenario occurring:

- It remains unknown if sheeppox and goatpox viruses would be present in sufficient amounts in contaminated milk to cause infection.
- Transmission of sheeppox and goatpox viruses is primarily via direct contact between infected and susceptible animals.
- Movement of infected animals is the main pathway for long-distance dispersal of capripoxviruses. Animal movements between states and territories occurs frequently.
- Clinical signs of sheep pox and goat pox may not be evident for several weeks after infection. However, on a newly affected farm it is likely that some animals would display clinical signs of disease within the first or second week of infection.

Based on these considerations, the likelihood of establishment and/or spread of sheeppox and goatpox viruses associated with the identified outbreak scenario was estimated to be **moderate**.

##### *Determination of overall effect of establishment and/or spread associated with outbreak scenario*

The following factors were considered relevant to the effects of establishment and/or spread of sheeppox and goatpox viruses associated with the identified outbreak scenario.

The effect on the life or health (including production effects) of susceptible animals:

- Mortality rates between 5% and 10% are expected for sheep pox and goat pox. However, the mortality rate for sheep pox and goat pox may reach 100% in naïve and younger animals.
- Animals affected by sheep pox and goat pox may have permanent scars reducing the quality of hides and wool.

The effect on the living environment, including life and health of wildlife, and any effects on the non-living environment:

- Sheep pox and goat pox are not considered to have any direct effects on the environment.



The effect on new or modified eradication, control, monitoring or surveillance and compensation strategies or programs:

- If sheep pox or goat pox was identified in Australia, the response strategy as outlined in the AUSVETPLAN disease strategy for sheep pox and goat pox is eradication in the shortest possible time using stamping out. This would be supported by a combination of strategies including sanitary disposal of destroyed animals and contaminated animal products, quarantine and movement controls, decontamination of fomites, tracing and surveillance, zoning and/or compartmentalisation and an awareness campaign. Vaccination may be used as part of a modified stamping-out strategy (AHA 2021c).
- Sheep pox and goat pox are scheduled as Category 2 under Australia's EADRA for cost-sharing arrangements. Should it be activated, EADRA states that costs of the response would be covered by government and relevant industries by contributions of 80% and 20%, respectively (AHA 2019b).

The effect on domestic trade or industry, including changes in consumer demand and effects on other industries supplying inputs to, or using outputs from, directly affected industries:

- Following a detection of sheep pox and goat pox, domestic movement restrictions would disrupt domestic markets.
- Along with affected livestock producers, associated industries in affected regions would suffer losses, such as transporters, stockfeed manufacturers and processors of animal products.
- With export market disruptions, relevant animal products destined for export would be redirected to the domestic market and domestic prices may fall. As a result, revenue for affected and associated industries would decrease.
- Domestic consumers may be concerned about the safety of animal products. This could reduce sales of products derived from relevant species. An awareness campaign may be needed to educate consumers that sheep pox and goat pox does not affect food safety.

The effect on international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand:

- An outbreak of sheep pox and goat pox in Australia would significantly disrupt exports of relevant animals and animal products from Australia. Resumption of trade would depend on renegotiations with importing countries and additional biosecurity measures may need to be met.
- In 2021, Australian sheepmeat exports were valued at \$4 billion respectively (MLA 2022).
- Over the 2020-21 financial year, Australian wool exports were valued at \$3.6 billion (DAFF 2022).
- If sheep pox and goat pox were to become established, zoning could be used to maintain or regain access to international markets. However, export markets for relevant commodities from affected zones may be lost or restricted, and access to new export markets could be affected.

The effect on the environment, including biodiversity, endangered species and the integrity of ecosystems:

- Disposal of destroyed animals and animal products, and increased use of disinfectants, may have effects on the environment.
- Increased use of insecticides for insect vector control could have an effect on a range of insect species and disrupt food sources of wildlife, lead to environmental contamination (including water sources) and resistance to insecticides.

The effect on communities, including reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures:

- Psychological distress could occur due to implementation of control and eradication measures, such as for owners of animals that are destroyed as part of disease control measures.
- Ongoing financial distress could occur for owners of affected premises if the disease situation prevents timely restocking.
- Where the relevant species were important to the local economy, if sheep pox and goat pox were to become established, the economic viability of communities within affected regions may be compromised due to effects on directly affected and associated industries.
- Disruption of events due to movement controls could have social consequences for people involved.

Based on the geographic level and magnitude of effects, using the rules in Table 3, the overall effect of establishment and/or spread of sheeppox and goatpox viruses associated with the identified outbreak scenario was estimated to be **high**. The effect is likely to be significant at the national level and highly significant within affected zones. Implies that the effect would be of national concern. However, serious effects on economic stability, societal values or social well-being would be limited to a given zone.

#### *Derivation of likely consequences*

The likelihood of establishment and/or spread of sheeppox and goatpox viruses was estimated to be moderate. The overall effect of establishment and/or spread for sheeppox and goatpox viruses was estimated to be high. Using Figure 3, the likely consequences of establishment and/or spread of sheeppox and goatpox viruses was estimated to be **high**.

#### **Risk estimation**

The likelihood of entry and exposure of sheeppox and goatpox viruses was estimated to be very low. The likely consequences of establishment and/or spread of sheeppox and goatpox viruses was estimated to be high. Using Figure 4, the unrestricted risk of LSD virus and sheeppox and goatpox viruses was estimated to be **low**.

#### **Conclusion**

The unrestricted risk of sheeppox and goatpox viruses was estimated to be **low**. As the unrestricted risk estimate does not achieve Australia's ALOP, risk management measures in addition to [minimum requirements](#) are required.

#### **Risk management measures**

This section describes the various risk management options for sheeppox and goatpox viruses associated with the importation of dairy products for human consumption that are considered to achieve Australia's ALOP.

To manage the risk of sheeppox and goatpox viruses associated with the importation of dairy products for human consumption, country/zone freedom as recognised by the department is required to achieve Australia's ALOP. This means that dairy products (except for cheese) containing dairy ingredients of ovine and/or caprine origin, are sourced from animals born and raised in, manufactured in, and exported from countries/zones on the department's [Sheep Pox and Goat Pox-Free Country List](#).

Alternatively, to manage the risk of sheeppox and goatpox viruses associated with the importation of dairy products of ovine and/or caprine origin (except for cheese) using dairy ingredients sourced from animals in countries/zones not on the department's [Sheep Pox and Goat Pox-Free Country List](#), to achieve Australia's ALOP the dairy products will require approved treatments. This is either application of batch pasteurisation at a temperature of no less than 63°C and retaining at such temperature for no less than 30 minutes, or UHT at a temperature of no less than 132°C and retaining at such temperature for no less than 1 second, or equivalent thermal treatment.

To manage the risk of sheeppox and goatpox viruses associated with the importation of dairy products of ovine and/or caprine origin (except for cheese) manufactured in and/or exported from countries/zones not on the department's [Sheep Pox and Goat Pox-Free Country List](#), to achieve Australia's ALOP, the goods must be manufactured in and/or exported from countries/zones that have current approval by Australia, and the supply chain and manufacturing facilities must have current approval by Australia. This applies to dairy products manufactured using dairy ingredients sourced from any country/zone.

Additional risk management measures for sheeppox and goatpox viruses associated with the importation of dairy products of ovine and/or caprine origin (except for cheese) that have been stored or transhipped via countries/zones not on the department's [Sheep Pox and Goat Pox-Free Country List](#), are required to achieve Australia's ALOP. Dairy products containing dairy ingredients of ovine and/or caprine origin must be sourced from animals born and raised in, manufactured in, and exported from countries/zones on the department's [Sheep Pox and Goat Pox-Free Country List](#), or undergo an approved heat treatment; and the goods may only be unloaded during transhipment and stored without manipulation. The supply chain must also have current approval by Australia.

To achieve Australia's ALOP, dairy products of ovine and/or caprine origin (except for cheese) sourced from and/or manufactured in and/or exported from and/or stored (or transhipped) in countries/zones that are not on the department's [Sheep Pox and Goat Pox-Free Country List](#) must also be commercially prepared and packaged and ready for retail sale to the final consumer without any further processing. This lowers the likelihood of susceptible animals being exposed to and consuming an infectious dose of sheeppox and goatpox viruses compared with dairy ingredients imported in bulk due to the relatively increased packaging and smaller volumes of individual units, and by stopping waste streams associated with further manufacture onshore.

Risk management is not required for sheeppox and goatpox viruses for imported cheese for human consumption, as the [minimum requirements](#) will effectively manage the biosecurity risk, to achieve Australia's ALOP.

## 3.5 Vaccinia virus

### 3.5.1 Background

Vaccinia virus (species *Vaccinia virus*; genus *Orthopoxvirus*; family *Poxviridae*) and buffalopox virus (strain Buffalopox virus, species *Vaccinia virus*; genus *Orthopoxvirus*; family *Poxviridae*) cause the diseases bovine vaccinia and buffalopox respectively (Eltom et al. 2020; Rehfeld et al. 2015; Silva et al. 2021). The diseases are characterised by exanthematous lesions on the teats and udders of lactating cattle and buffalo and affected animals can develop secondary mastitis, which leads to a significant reduction in productivity (de Oliveira et al. 2018; de Oliveira et al. 2010; Eltom et al. 2020; Matos et al. 2018; Silva et al. 2021). Vaccinia virus and buffalopox virus are transmissible to humans who are in direct contact with affected animals, such as farmers and milkers, causing pox-like lesions on the hands and forearms, malaise, fever and lymphadenopathy (Eltom et al. 2020; Megid et al. 2012). Human-to-human transmission is considered possible (Batista et al. 2009; Matos et al. 2018).

Variola virus, the causative agent of smallpox, is also a member of the genus *Orthopoxvirus*. Due to the immunological cross reactivity within the genus *Orthopoxvirus*, vaccinia virus was used in smallpox vaccines. Mass vaccination against smallpox was discontinued following global eradication in 1980 and most of the world's population no longer has protective immunity against orthopoxviruses. Since then, increasing incidence of disease caused by vaccinia virus in humans and animals has led to concern about its zoonotic potential (D'Anunção et al. 2012; Essbauer et al. 2007; Gurav et al. 2011).

The geographic distribution of vaccinia virus and buffalopox virus seems to be restricted and stable; however, the factors that restrict the spread of disease are unknown and further spread to new geographical areas cannot be excluded (Silva et al. 2021). Bovine vaccinia has occurred exclusively in Brazil since 1999 and is endemic throughout most of the territory (Ferreira et al. 2008; Matos et al. 2018; Rehfeld, Fraiha, et al. 2017). A seroprevalence of 75.7% in dairy cows in the State of Minas Gerais, the largest dairy-producing state in Brazil, was reported in 2017 (Borges et al. 2017). Buffalopox mainly occurs in India, where the first recorded case occurred in 1934 (Rehfeld et al. 2015; Singh et al. 2007). Information on the current prevalence of buffalopox in India is not readily available, but it has been reported to infect up to 79.35% of adult buffaloes in 2 districts of India during outbreaks in 1982 (Muraleedharan et al. 1989; Numan 2015). A prevalence of 50% was reported for one district of Pakistan in 2009 (Khan 2010; Numan 2015). Sporadic outbreaks of buffalopox have been reported in Bangladesh, Egypt, India, Indonesia, Italy, Nepal, Pakistan and Russia (Eltom et al. 2020; Matos et al. 2018; Silva et al. 2021).

Bovine vaccinia primarily affects dairy cattle (Megid et al. 2012; Rivetti Jr et al. 2013; Silva et al. 2021). Buffalopox affects buffalo and cattle (Eltom et al. 2020; Gurav et al. 2011). Although vaccinia virus has been detected in other domestic animals, including horses, donkeys, pigs, dogs, cats and mice, their involvement in the spread of disease has not been demonstrated. Vaccinia virus genomes and antibodies against orthopoxviruses have been detected in a broad range of wild animals including non-human primates, cingulates, marsupials and wild rodents. It is possible that transmission of vaccinia virus can occur between wild and domestic animals, although it has not been demonstrated to date (Silva et al. 2021).

Bovine vaccinia and buffalopox are not WOA-listed diseases. In Australia, bovine vaccinia and buffalopox are not nationally notifiable and have never been reported.

### 3.5.2 Technical information

#### Agent properties

Vaccinia virus is highly stable in the environment, especially in low humidity and low temperature environments (Essbauer et al. 2007; Rivetti Jr et al. 2013). Organic matter, such as faeces, is likely to protect vaccinia virus from environmental exposure to ultraviolet radiation, temperature and humidity (Abrahão, Trindade, et al. 2009; Rivetti Jr et al. 2013).

Vaccinia virus is sensitive to disinfectants such as sodium hypochlorite and is readily inactivated within a few seconds of exposure to ultraviolet radiation (Matos et al. 2018; Rivetti Jr et al. 2013).

Vaccinia virus suspended in media required dry heat treatment of 95°C for 2 hours to be inactivated. It has been demonstrated that dry heat treatment between 75°C and 95°C for 1 hour is not able to reduce the titre of vaccinia virus significantly (Sauerbrei & Wutzler 2009).

The presence of a protein-rich environment is likely to protect vaccinia virus from inactivation (de Oliveira et al. 2010). Vaccinia virus remained viable for more than 166 days in storm water stored at 4°C when supplemented with foetal bovine serum, but only 56 days without foetal bovine serum. The storm water used in the study ranged between pH 5.4 and 5.7, suggesting the stability of vaccinia virus in a slightly acidic environment (Essbauer et al. 2007).

#### Epidemiology

The incubation period of bovine vaccinia and buffalopox ranges from 2 to 4 days (Matos et al. 2018; Singh et al. 2007).

Transmission of vaccinia virus is primarily through direct contact with affected animals or indirect contact with contaminated hands of milkers or milking equipment. Calves are usually infected during suckling and disease can spread between farms through the introduction of infected animals or by milkers who have had contact with sick animals on other affected farms (D'Anuniação et al. 2012; Matos et al. 2018). In Brazil, bovine vaccinia spreads rapidly on affected farms, partially due to the hand-milking of small dairy herds. It has been reported that morbidity of a herd can reach 100% for lactating cows and calves (Matos et al. 2018; Silva et al. 2021).

Apart from direct contact, it is not known whether there are other modes of vaccinia virus transmission among bovines (Rivetti Jr et al. 2013). Results from experimental studies suggest that milk and faeces from affected animals are possible sources of vaccinia virus exposure and transmission (Abrahão, Oliveira, et al. 2009; D'Anuniação et al. 2012). In an environment contaminated with faeces containing viable vaccinia virus, transmission could occur through ingestion of contaminated food and water. Following oral inoculation of mice with experimentally contaminated milk, vaccinia virus DNA was detected in faeces, blood, oral swabs and tissues. However, extremely high titres (10<sup>7</sup> PFU) were used, no clinical symptoms were observed, and no viable vaccinia virus particles were isolated in any of the samples collected (Rehfeld et al. 2015). Whether bovines are susceptible to infection through oral ingestion of contaminated dairy products other than milk has not been confirmed (Matos et al. 2018; Rivetti Jr et al. 2013).

The role of non-lactating cattle, such as dry cows, bulls and heifers, in the spread of bovine vaccinia is unclear. Viable vaccinia virus has been isolated in the blood of subclinical dry cows and bulls. It is uncommon for these animals to show clinical signs of disease when infected (Rehfeld, Matos, et al. 2017). Information about the occurrence of buffalopox in non-lactating buffalo is not available.

Domestic and wild rodents may be natural reservoirs of vaccinia virus and facilitate disease spread. Vaccinia virus particles and DNA has been detected at 20 and 60 days post-environmental exposure, in faeces from intranasally infected mice (Abrahão, Trindade, et al. 2009). Furthermore, horizontal transmission has been suggested as possible following the detection of infectious vaccinia virus particles in faeces of mice in direct contact with wood shavings contaminated with faeces from cattle experimentally infected with vaccinia virus (Abrahão, Trindade, et al. 2009; D'Anuniação et al. 2012).

### **Presence in milk**

First reported in 2009, the presence of vaccinia virus in milk has been confirmed by multiple studies (Abrahão, Oliveira, et al. 2009). Vaccinia virus DNA has been detected in milk collected from teats absent of lesions as well as from animals with no clinical signs (Rehfeld, Matos, et al. 2017). Information about the presence of vaccinia virus in colostrum is not available and it has been suggested that virus may only be activated in stressed or immunosuppressed animals (de Oliveira et al. 2015).

There is no information available about whether vaccinia virus is transmissible to cattle and buffalo through ingestion of contaminated dairy products. Ingestion of food, such as contaminated dairy products, is not a known natural route of vaccinia virus transmission (Matos et al. 2018). The minimum infectious dose of vaccinia virus through consumption of milk has not been determined (Rehfeld et al. 2015).

Vaccinia virus may not be completely inactivated after pasteurisation or from the ripening process during cheese production. Vaccinia virus may be associated with somatic cells in milk, which could provide protection against inactivation. Inactivation studies using milk inoculated with virus after collection should be interpreted with caution, as vaccinia virus could remain viable for longer in dairy products sourced from naturally or experimentally infected cows (Rehfeld, Fraiha, et al. 2017).

Pasteurisation of milk may significantly reduce the titre of vaccinia virus in milk, but residual virus may still be present. In experimental studies, heat treatment with parameters similar to batch pasteurisation have demonstrated a reduction in viral titre (de Oliveira et al. 2018; de Oliveira et al. 2010).

Experimental studies have also demonstrated that vaccinia virus is able to survive the cheese production process. After HTST pasteurisation (72°C for 15 seconds), cheese produced from experimentally contaminated milk demonstrated only a small reduction in viral titre, and virus was recoverable from whey (de Oliveira et al. 2010). Studies using both heat treated and raw milk demonstrated that vaccinia virus can survive the cheese ripening process (de Oliveira et al. 2018; Rehfeld, Fraiha, et al. 2017).

### **Pathogenesis**

Experimental detection of vaccinia virus in blood, faeces and milk of clinically and subclinically infected animals, and after the complete healing of lesions, suggests systemic spread of the virus (Matos et al. 2018; Rehfeld, Matos, et al. 2017; Rivetti Jr et al. 2013).

It is proposed that intradermal vaccinia virus infection occurs due to virus penetrating the local epithelium of teats through a previous wound or through microscopic breakage of the skin barrier, with viral replication at the entry site leading to formation of exanthematous lesions. The virus could

penetrate the dermis and spread rapidly through the blood and lymphatic vessels, reaching the regional lymph nodes and spreading to the mesenteric lymph nodes and ileum lymphoid tissues, epithelia and goblet cells. Vaccinia virus could disseminate to other lymphoid tissues (such as spleen, liver, tonsils and other lymph nodes) as it migrates through the blood and lymphatic pathway (Matos et al. 2018; Rivetti Jr et al. 2013).

### **Diagnosis**

In cattle and buffalo herds, vaccinia virus infections are characterised by exanthematous lesions on the udder and teats of lactating animals (Matos et al. 2018). Infected buffalo may also develop lesions in the inguinal region, over the parotid and on the base and inner surface of the ear and eyes (Singh et al. 2007). Severe local lesions lead to mastitis and other secondary infections in more than 40% of affected animals, which can reduce milk yield by 40 to 80% (Matos et al. 2018; Singh et al. 2007). Vaccinia virus infection is usually self-limiting, and lesions heal about 20 days after infection (Matos et al. 2018; Silva et al. 2021). In farms where suckling calves are in direct contact with cows, it is common to observe calves with lesions in the mouth, which can reduce food intake and lead to weight loss (Matos et al. 2018).

Clinical examination and collection of specimens (swabs and serum) from buffalo and cattle are the first steps for diagnosis of bovine vaccinia and buffalopox. Infection can be confirmed through electron microscopy examination, inoculation in cell culture for isolation of virus, plaque reduction and neutralisation testing, polymerase chain reaction (PCR) and partial genome sequencing (Eltom et al. 2020; Medeiros-Silva et al. 2010).

### **Treatment**

There is no specific treatment for animals infected with vaccinia virus (Eltom et al. 2020; Oliveira et al. 2014). Measures to aid the clinical recovery of affected animals can be taken, such as disinfection of lesions to prevent secondary infections (Matos et al. 2018).

### **Control**

There is no commercial vaccination available for prevention of vaccinia virus infection in cattle or buffalo (Eltom et al. 2020; Gurav et al. 2011; Matos et al. 2018; Oliveira et al. 2014).

## **3.5.3 Current biosecurity measures**

Bovine vaccinia was not considered in the dairy IRA. The dairy IRA included risk management measures for buffalopox for the importation of dairy products of bovine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that is free from buffalopox. However, risk management measures for buffalopox were removed in 2000.

The WOAHP does not have recommendations for bovine vaccinia or buffalopox.

## **3.5.4 Conclusion**

Bovine vaccinia and buffalopox have never been reported in Australia. They are not nationally notifiable or WOAHP-listed diseases.

Australia's current import conditions for dairy products for human consumption do not include bovine vaccinia or buffalopox. The Terrestrial Code does not include recommendations for bovine

vaccinia or buffalopox. Vaccinia virus can be present in milk of infected animals and may be transmissible in dairy products. Therefore, a risk assessment was required.

### 3.5.5 Risk assessment

#### Entry assessment

The following factors were considered relevant to an estimate of the likelihood of vaccinia virus being present in dairy products imported for human consumption:

- Bovine vaccinia and buffalopox are mainly restricted to Brazil and India, respectively, where they are endemic, and high prevalence rates have been reported in some regions.
- Vaccinia virus can be present in milk and colostrum of infected cattle and buffalo due to virus being shed in milk or due to contamination from lesions and scabs on teats.
- Vaccinia virus may be excreted in the milk of affected animals for long periods of time.
- If milk for human consumption were only sourced from clinically healthy animals, the possibility of contamination of milk with lesions and scabs would be reduced. However, animals with subclinical infection or mild clinical signs of disease may go undetected and may still shed virus into milk.
- Somatic cells in milk may protect vaccinia virus from inactivation.
- Pasteurisation of milk would significantly reduce the titre of vaccinia virus in milk, but residual virus may still be present.
- Post-processing contamination with raw milk or other dairy ingredients sourced from infected animals could introduce viable virus into processed product.

**Conclusion:** Based on these considerations, the likelihood of vaccinia virus entering Australia in dairy products imported for human consumption from a country where the disease agent is present was estimated to be **moderate**.

#### Exposure assessment

The exposure group considered for vaccinia virus was domestic and feral cattle and buffalo.

The following factors were considered relevant to an estimate of the likelihood of susceptible animals being exposed to vaccinia virus in dairy products imported for human consumption:

- Bovine vaccinia primarily affects dairy cattle and buffalopox affects buffalo and cattle. Although vaccinia virus has been detected in other domestic animals, their involvement in disease spread has not been demonstrated.
- Vaccinia virus is highly stable in protein-rich media stored at low temperatures. Vaccinia virus which remains present in dairy products post processing will likely survive during the period before exposure of susceptible animals.
- There is limited evidence that transmission through milk is a significant factor for the transmission of bovine vaccinia.
- As only dairy products for human consumption would be imported, most imported dairy products would move from the distributor/retailer to household consumers or to the food



industry. However, susceptible animals could be exposed to dairy products imported for human consumption if

- product was disposed of in such a way that it was accessed by animals, including feral and wild animals. This is unlikely to result in exposure of susceptible animals to vaccinia virus
- product was repurposed for use in animal feed. Susceptible animals would readily consume feed that included imported dairy products. This could result in exposure of susceptible animals to vaccinia virus
- product was fed directly to animals, such as feeding milk powder to hand-reared animals. This could result in exposure of susceptible animals to vaccinia virus.

**Conclusion:** Based on these considerations, the likelihood of susceptible animals being exposed to vaccinia virus in dairy products imported for human consumption was estimated to be **low**.

#### **Estimation of the likelihood of entry and exposure**

The likelihood of entry was estimated to be moderate and the likelihood of exposure was estimated to be low. Using Figure 2, the likelihood of entry and exposure for vaccinia virus was estimated to be **low**.

#### **Consequence assessment**

##### *Identification of an outbreak scenario and likelihood of establishment and/or spread associated with the outbreak scenario*

The most likely outbreak scenario following exposure of susceptible animals to vaccinia virus in dairy products for human consumption was considered to be establishment in the directly exposed population and spread to other populations of susceptible animals within the local area.

The following factors were considered relevant to an estimate of the likelihood of the identified outbreak scenario occurring:

- Transmission of vaccinia virus is primarily via direct contact and fomite spread.
- Information about whether vaccinia virus is transmissible to cattle and buffalo through ingestion of contaminated dairy products is not available. Experimental infection through oral inoculation has occurred in mice; however, no clinical signs of disease occurred.
- The minimum infectious dose of vaccinia virus through consumption of milk has not been determined.
- Vaccinia virus can spread rapidly on affected farms, particularly those with poor hygiene and biosecurity practices.
- Spread of disease between farms could occur due to introduction of infected animals or fomites, such as people and equipment.
- The incubation period of bovine vaccinia and buffalopox is short (between 2 and 4 days). In an outbreak, lactating animals and suckling calves in the exposed population would be expected to present clinical signs of disease shortly after exposure to vaccinia virus.
- Detection of bovine vaccinia may be delayed in exposed populations of non-lactating cattle, such as dry cows, bulls and heifers, as clinical signs of disease in these animals are not as common. The role of these animals in the spread of bovine vaccinia is unclear.

- Information about the occurrence of infection and/or clinical signs of buffalopox in buffalo other than lactating animals is not available.
- Domestic and wild rodents may be natural reservoirs of vaccinia virus and facilitate silent spread of disease.

Based on these considerations, the likelihood of establishment and/or spread of vaccinia virus associated with the identified outbreak scenario was estimated to be **low**.

*Determination of overall effect of establishment and/or spread associated with outbreak scenario*

The following factors were considered relevant to the effects of establishment and/or spread of vaccinia virus associated with the identified outbreak scenario.

The effect on the life or health (including production effects) of susceptible animals:

- In regions affected by bovine vaccinia or buffalopox, a loss in productivity of buffalo and cattle occurs due to reduced milk yield caused by mastitis.
- Lesions in the mouth of calves can lead to weight loss due to reduced food intake.
- Bovine vaccinia and buffalopox are zoonotic diseases. Farmers or animal handlers in direct contact with lesions on infected animals can develop pox-like lesions on the hands and forearms, malaise, fever and lymphadenopathy.

The effect on the living environment, including life and health of wildlife, and any effects on the non-living environment:

- In areas where bovine vaccinia or buffalopox are endemic, there is serological evidence of infection with vaccinia virus in a wide range of wildlife species. However, clinical signs of disease in wildlife species have not been reported.
- It is not known if Australian native fauna would be susceptible to infection with the virus.

The effect on new or modified eradication, control, monitoring or surveillance and compensation strategies or programs:

- Bovine vaccinia and buffalopox are not nationally notifiable diseases in Australia. There is no AUSVETPLAN disease strategy manual for bovine vaccinia or buffalopox. These diseases are not scheduled under Australia's Emergency Animal Disease Response Agreement (EADRA) for cost-sharing arrangements.
- If bovine vaccinia or buffalopox were detected in Australia, control measures could include implementation of disinfection protocols and strict hygienic practices on affected farms, tracing and surveillance, movement controls on animals and animal products, supportive treatment of infected animals (including humans) and a public awareness campaign.

The effect on domestic trade or industry, including changes in consumer demand and effects on other industries supplying inputs to, or using outputs from, directly affected industries:

- Vaccinia virus is a zoonotic pathogen. Detection of bovine vaccinia or buffalopox in Australia could affect domestic trade and industries associated with susceptible animals. Resources would be required to manage public health issues.

- Productivity losses and increased costs could result due to the temporary removal of infected individuals from the work environment and medical expenses required for their treatment.
- Due to concerns about human health risks associated with the consumption of contaminated dairy products, affected farms and periferical farms could be temporarily prohibited from supplying milk for commercial processing.
- Australian consumers could decrease consumption of dairy products following detection of bovine vaccinia or buffalopox in Australia. An awareness campaign may be needed to address consumer concerns.

The effect on international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand:

- Bovine vaccinia and buffalopox are not WOAHA-listed diseases.
- If bovine vaccinia or buffalopox were detected in Australia, there may be disruption to exports of relevant animals and animal products to countries where these diseases are not known to occur.
- If bovine vaccinia or buffalopox were to become established, zoning could potentially be used to maintain or regain access to international markets.

The effect on the environment, including biodiversity, endangered species and the integrity of ecosystems:

- Bovine vaccinia and buffalopox are not considered likely to have any indirect effects on the environment.

The effect on communities, including reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures:

- There could be productivity losses, increased costs and operational procedures associated with implementing control measures for bovine vaccinia or buffalopox.
- Minor disruption to cattle and buffalo events (for example, due to movement restrictions and concerns about zoonotic diseases) could have social consequences for people involved.
- Where cattle and buffalo, particularly those supplying milk, were important to the local economy, if bovine vaccinia or buffalopox were to become established, the economic viability of communities within affected regions may be affected due to effects on directly affected and associated industries.
- Public concern about a zoonotic disease may have a detrimental effect on tourism in affected rural and regional communities.

Based on the geographic level and magnitude of effects, using the rules in Table 3, the overall effect of establishment and/or spread of vaccinia virus associated with the identified outbreak scenario was estimated to be **low**. The effect is likely to be recognised within affected zones and significant to directly affected parties. It is not likely that the effect will be recognised at the national level.

*Derivation of likely consequences*

The likelihood of establishment and/or spread was estimated to be low and the overall effect of establishment and/or spread was estimated to be low. Using Figure 3, the likely consequences of establishment and/or spread of vaccinia virus were estimated to be **very low**.

**Risk estimation**

The likelihood of entry and exposure was estimated to be low and the likely consequences of establishment and/or spread were estimated to be very low. Using Figure 4, the unrestricted risk of vaccinia virus was estimated to be **negligible**.

**Conclusion**

The unrestricted risk of vaccinia virus was estimated to be **negligible**. As the unrestricted risk estimate achieves Australia's ALOP, no specific risk management measures in addition to [minimum requirements](#) are required.

## 4 Proposed biosecurity risk management measures

The following details the proposed biosecurity risk management measures for dairy products for human consumption imported into Australia.

### 4.1 Minimum requirements for imported dairy products

Risk management measures are applied to all imported dairy products to ensure food safety, and there are some components of the dairy standard that also manage animal biosecurity risk. These, in addition to specific heat treatments applied to the milk or dairy ingredients, are referred to as the minimum requirements for managing animal biosecurity risk in imported dairy products.

The components of the dairy standard that also manage animal biosecurity risks include:

- milk is sourced only from healthy animals
- documented quality assurance programs (such as food safety programs) for dairy primary production, collection, transportation and processing are implemented
- all facilities involved in manufacture (other than labelling and storage) are either registered, approved or recognised as required by the relevant national authority for food safety.

The minimum requirement for all dairy products (except for cheese), includes one of the following heat treatment options applied to the milk or the dairy ingredients during processing:

- HTST pasteurisation at a temperature of no less than 72°C and retaining at such temperature for no less than 15 seconds, or
- batch pasteurisation at a temperature of no less than 63°C and retaining at such temperature for no less than 30 minutes, or
- UHT at a temperature of no less than 132°C and retaining at such temperature for no less than 1 second, or
- the milk or the dairy ingredients underwent an alternative heat treatment equivalent to pasteurisation of milk as stated on the Australian import permit.

Applications for alternative heat treatments to the above will be assessed by the department during the import permit application assessment. If approved, the alternative heat treatment will be specified in the import permit for the product. Heat treatments applied to dry products are less effective than those applied to liquids and therefore, a heat treatment applied to a dry product will not be considered equivalent to pasteurisation of milk.

#### 4.1.1 Cheese

Cheese will not be required to be made from milk that has been pasteurised (or undergone an equivalent heat treatment) if it has undergone one of the following heat treatments in accordance with clause 16 of the [dairy standard](#):

- Thermisation with additional measures
  - Milk used to make cheese or cheese products has been processed by being held at a temperature of no less than 64.5°C for a period of no less than 16 seconds, and the cheese or cheese product stored at a temperature of no less than 7°C for a period of no less than 90 days from the date of processing.
- High temperature curd cook with additional measures
  - Milk or dairy products used to make cheese or cheese products have been processed such that: the curd is heated to a temperature of no less than 48°C and the cheese or cheese product has a moisture content of less than 39%, after being stored at a temperature of no less than 10°C for a period of no less than 120 days from the date of processing.

The product characteristics and processing factors, such as pH, salt concentration, water activity and ripening conditions, are expected to reduce the likelihood of entry and the likelihood of susceptible animals being exposed to and consuming an infectious dose of disease agents of animal biosecurity concern. Together these factors sufficiently reduce the likelihood of entry and exposure of disease agents of animal biosecurity concern to a similar level as pasteurisation— other than for FMDV, which requires additional risk management measures to achieve Australia’s ALOP.

Please note that raw milk cheese is not within the scope of this review (see section 4.4).

## 4.2 Disease agent-specific animal biosecurity measures

The following describes the animal biosecurity measures, in addition to the [minimum requirements](#), for dairy products for human consumption imported into Australia.

### 4.2.1 Foot-and-mouth disease virus

Animal biosecurity measures for FMDV apply to all dairy products containing dairy ingredients of bovine origin or ovine and/or caprine origin.

#### Country/zone of origin

Either the country/zone is on the department’s FMD-Free Country List, or the following animal biosecurity measures apply.

For all dairy products except for cheese:

- The final dairy products are commercially prepared and packaged and ready for retail sale to the final consumer without any further processing.
- For all dairy products (except for cheese), in addition to the pasteurisation requirements outlined in the [minimum requirements](#) for imported dairy products, one of the following options for heat treatment must be applied to the milk or the dairy ingredients during processing
  - application of a thermal moist heat treatment process to the milk or the dairy ingredients involved. For example, moist heat treatment to reach a core temperature (or even heating throughout in the case of liquid product) of no less than 100°C and retained at such temperature for no less than 30 minutes, or
  - application of a thermal moist heat treatment of not less than 148°C and retaining at such temperature for no less than 3 seconds.

For cheese made from pasteurised milk:

- the cheese has attained a pH of 5.2 or less throughout the product prior to and after being ripened
- the cheese has been ripened at a temperature of no less than 4°C for a period of no less than 30 days from the date of processing (the date the curd was set).

For cheese made from unpasteurised milk:

- the milk used to make cheese has undergone one of the following heat treatments
  - thermisation - a temperature of no less than 64.5°C for a period of no less than 16 seconds
  - high temperature curd cook - the curd is heated to a temperature of no less than 48°C.
- the cheese has
  - attained a pH of 5.2 or less throughout the product prior to and after being ripened
  - been ripened at a temperature of no less than 7°C for a period of no less than 120 days from the date of processing (the date the curd was set).

For cheese made from unpasteurised milk, if the country/zone of origin is on the department's FMD-Free Country List, the cheese has been matured/ripened/stored for at least 30 days from the date of processing (the date the curd was set). Cheese made from unpasteurised milk produced according to the requirements of the dairy standard will already have been stored (during maturation/ripening) for over 30 days.

#### **Country/zone of manufacture or export**

Either the country/zone is on the department's FMD-Free Country List, or the following animal biosecurity measures apply:

- The final dairy products are commercially prepared and packaged and ready for retail sale to the final consumer without any further processing.
- The dairy products were manufactured in and/or exported from only countries/zones that have current approval by Australia.
- The supply chain and manufacturing facilities have current approval by Australia.

#### **Country/zone of storage or transshipment en route to Australia**

Either the country/zone is on the department's FMD-Free Country List, or the following animal biosecurity measures apply:

- The final dairy products are commercially prepared and packaged and ready for retail sale to the final consumer without any further processing.
- The supply chain has current approval by Australia.
- The only operations that are performed on dairy products are transshipment and storage.

### **4.2.2 Peste des petits ruminants virus**

Animal biosecurity measures for PPR virus apply only to dairy products (except for cheese) containing dairy ingredients of ovine and/or caprine origin.

### **Country/zone of origin**

Either the country/zone is on the department's PPR-Free Country List, or one of the following options for heat treatment must be applied to the milk or the dairy ingredients during processing:

- UHT at a temperature of no less than 132°C and retaining at such temperature for no less than 1 second, or
- the milk or the dairy ingredients underwent an alternative heat treatment equivalent to UHT of milk as stated on the Australian import permit.

### **Country/zone of manufacture or export**

Either the country/zone is on the department's PPR-Free Country List, or the following animal biosecurity measures apply:

- The final dairy products are commercially prepared and packaged and ready for retail sale to the final consumer without any further processing.
- The dairy products were manufactured in and/or exported from only countries/zones that have current approval by Australia.
- The supply chain and manufacturing facilities have current approval by Australia.

### **Country/zone of storage or transshipment en route to Australia**

Either the country/zone is on the department's PPR-Free Country List, or the following animal biosecurity measures apply:

- The final dairy products are commercially prepared and packaged and ready for retail sale to the final consumer without any further processing.
- The supply chain has current approval by Australia.
- The only operations that are performed on dairy products are transshipment and storage.

Specific requirements for peste des petits ruminants virus are not required for imported cheese for human consumption, as the [minimum requirements](#) will effectively manage the biosecurity risk, to achieve Australia's ALOP.

## **4.2.3 Sheeppox virus and goatpox virus**

Animal biosecurity measures for sheeppox virus and goatpox virus apply only to dairy products (except for cheese) containing dairy ingredients of ovine and/or caprine origin.

### **Country/zone of origin**

Either the country/zone is on the department's [Sheep Pox and Goat Pox-Free Country List](#), or one of the following options for heat treatment must be applied to the milk or the dairy ingredients during processing:

- batch pasteurisation at a temperature of no less than 63°C and retaining at such temperature for no less than 30 minutes, or
- UHT at a temperature of no less than 132°C and retaining at such temperature for no less than 1 second, or



- the milk or the dairy ingredients underwent an alternative heat treatment equivalent to batch pasteurisation or UHT of milk as stated on the Australian import permit.

#### **Country/zone of manufacture or export**

Either the country/zone is on the department's [Sheep Pox and Goat Pox-Free Country List](#), or the following animal biosecurity measures apply:

- The final dairy products are commercially prepared and packaged and ready for retail sale to the final consumer without any further processing.
- The dairy products were manufactured in and/or exported from only countries/zones that have current approval by Australia.
- The supply chain and manufacturing facilities have current approval by Australia.

#### **Country/zone of storage or transshipment en route to Australia**

Either the country/zone is on the department's [Sheep Pox and Goat Pox-Free Country List](#), or the following animal biosecurity measures apply:

- The final goods are commercially prepared and packaged and ready for retail sale to the final consumer without any further processing.
- The supply chain has current approval by Australia.
- The only operations that are performed on dairy products are transshipment and storage.

Specific requirements for sheeppox virus and goatpox virus are not required for imported cheese for human consumption, as the [minimum requirements](#) will effectively manage the biosecurity risk, to achieve Australia's ALOP.

### **4.3 Dairy products containing colostrum**

For animal biosecurity risk management purposes, colostrum is defined as the substance secreted from the udder for the first 4 days following parturition.

Some disease agents are excreted in as high, if not higher, concentrations in colostrum than in milk. Whilst HTST pasteurisation or equivalent heat treatment would be expected to destroy these pathogens, claims by manufacturers that colostrum products are fully pasteurised may not be accurate as this level of heat treatment may destroy the immunoglobulins, which is an important component of the immunological activity found in colostrum (Hurley & Theil 2011). Additionally, compared to milk, colostrum is more likely to be used as a food for hand-rearing young animals, increasing the likelihood of exposure of susceptible animals to these pathogens.

Pasteurisation does not inactivate the scrapie agent and younger sheep and goats are more susceptible to scrapie than older animals. Ingestion of only a small volume of colostrum or milk may result in infection.

To manage the animal biosecurity risk associated with the importation of dairy products containing colostrum, in addition to the [minimum requirements](#), the following animal biosecurity measures apply to achieve Australia's ALOP:

- Colostrum of bovine origin will be eligible for import if the country/zone of origin is on the department's [FMD-Free Country List](#); the country/zone of manufacture and export is approved to export dairy products to Australia; an approved heat treatment, as per section 4.1, has been applied and certified for; and all facilities involved in manufacture (other than labelling and storage) are either registered, approved or recognised as required by the relevant national authority for food safety.
- Colostrum of ovine and/or caprine origin will not be eligible for import due to the increased likelihood of susceptible animals being exposed to the scrapie agent. A statement that the goods do not contain colostrum will be included in health certification for exporting dairy products of ovine and/or caprine origin for human consumption to Australia.

## 4.4 Raw milk cheese

Raw milk cheese is defined in the Imported Food Control Order 2019 and is covered by a foreign government certification arrangement under the Imported Food Control Act. It is cheese made from milk that has not undergone pasteurisation, thermisation with additional measures, or high temperature curd cook with additional measures during production.

Under imported food legislation, imports of raw milk cheese must be covered by a foreign government certificate under a government-to-government certification arrangement. Countries wanting to export raw milk cheese to Australia can apply for assessment of whether their country's system for the production, collection, transportation and processing of raw milk cheese provides an equivalent food safety outcome to the system in Australia. A foreign government certification arrangement and foreign government certificate is negotiated if equivalence is determined (noting that all biosecurity requirements must be met before food safety requirements apply). Case-by-case assessment of biosecurity risk will apply to raw milk cheese. Raw milk cheese is not within the scope of this review.

## 4.5 Allowances for whey protein fractions

In response to stakeholder comments, this risk review considers the biosecurity risks associated with importation of whey protein fractions, for human consumption. Whey protein fractions are:

- $\alpha$ -lactalbumin
- $\beta$ -lactoglobulin
- bovine immunoglobulins
- bovine serum albumin
- glycomacropeptide
- lactoferrin
- lactoperoxidase.

A risk assessment was conducted for whey protein fractions (Appendix B: Risk assessment for whey protein fractions). The risk assessment determined that whey protein fractions will not need to meet the biosecurity requirements for dairy products that would otherwise apply if:

- whey protein fractions are included as an ingredient in dairy products

- the dairy products are manufactured in and exported from countries/zones that have current approval by Australia.

## 4.6 Repurposing imported dairy products for human consumption as animal feed

The current import conditions for dairy products imported for human consumption do not allow the goods or any derivatives to be distributed, sold or used for animal consumption, use as bioremediation agents or fertiliser, growing purposes or veterinary therapeutic use. Legally the importer must use the imported goods as required by the import permit. Information about the volume of dairy products imported for human consumption and subsequently consumed by animals (not in accordance with current import conditions) is lacking.

Animal biosecurity and human food safety are not the same. Many disease agents of animal biosecurity concern do not affect humans and are unlikely to be considered during the development of human food manufacturing systems.

Dairy products imported for human consumption that enter or are intended to enter the human food chain may become unfit for human consumption and are withdrawn from sale. Currently, dairy products (except for colostrum) of bovine origin from countries/zones that are free from FMD and LSD may be eligible for repurposing from human consumption to animal feed. A different import permit is required for dairy products imported for human consumption that are repurposed as animal feed.

Recognising the need to reduce food waste, in some circumstances the department will continue to allow dairy products that have been imported for human consumption to be repurposed as animal feed. Dairy products imported for human consumption are not to be fed to animals in Australia unless the department has authorised this end use as import permit conditions for the specific goods. Non-dairy ingredients of animal biosecurity concern also need to be considered.

Repurposing dairy products that were imported for human consumption as animal feed increases the level of animal biosecurity risk due to the increase in the likelihood of exposure. As such, the department will consider whether dairy products imported for human consumption are suitable for repurposing as animal feed on a case-by-case basis, considering the following factors:

- Countries/zones of origin, manufacture and export will need to be on the department's [FMD-Free Country List](#).
- Imported dairy products of ovine and/or caprine origin will not be eligible for repurposing as animal feed. Few countries are free from scrapie and the scrapie agent can be transmitted in milk to susceptible animals.
- Imported cheeses that have been made from milk that has not been pasteurised (or undergone an equivalent heat treatment) will not be eligible for repurposing as animal feed.
- Imported colostrum will not be eligible for repurposing as animal feed.
- At least 30 days will need to have passed from the date the milk was sourced until dairy products for imported for human consumption are repurposed as animal feed, to address the

possible risk that milk could be collected before detection and official notification of a disease outbreak.

Other factors may also be considered, such as non-dairy ingredients stored or used in or at the manufacturing facilities. Dairy products imported for human consumption that contain non-dairy ingredients are not eligible for repurposing as animal feed if they contain restricted animal material (RAM) in accordance with the Australian Ruminant Feed Ban, National Uniform Rules and in accordance with all state and territory legislation.

Data may be collected, and verification activities may be undertaken to ensure the requirements remain appropriate (for example, relating to the volume of imported dairy products being repurposed for animal feed and checks on the best-before or use-by date at the time of arrival in Australia).

## **4.7 Meeting Australia's food laws**

In addition to meeting Australia's biosecurity laws, imported food for human consumption must comply with the requirements of the Imported Food Control Act, as well as Australian state and territory food laws. Among other things, these laws require all food, including imported food, to meet the standards set out in the food standards code.

The department administers the Imported Food Control Act, which supports the inspection and testing of imported food to verify its safety and compliance with Australia's food standards, including the food standards code. This is undertaken through a risk-based border inspection program, the Imported Food Inspection Scheme. More information about the Imported Food Inspection Scheme is available on the department's website.

FSANZ is responsible for developing and maintaining the food standards code. The food standards code is available on the Federal Register of Legislation or through the FSANZ website.

Standard 1.4.2 and Schedules 19, 20, 21 and 22 of the food standards code set out the maximum levels of contaminants and natural toxicants, maximum residue limits and extraneous residue limits for agricultural and veterinary chemicals that are permitted in foods for sale, including imported food. Standard 1.6.1 and Schedule 27 provides requirements for microbiological limits in foods for sale, including a range of dairy products.

## **4.8 Recognition of country free status**

When assessing country freedom, the department evaluates information derived from the exporting country, the Terrestrial Code, the World Animal Health Information System (WAHIS), and other sources regarding the animal health status and competent authority of the exporting country and its neighbours.

Certification of country freedom will be required for countries recognised by the department as free from these diseases, as specified on the country lists prepared by the Director of Biosecurity and published on the department's website.

## 4.9 Documentation

A written application to import dairy products and goods containing dairy ingredients must be lodged with the department before any import can occur.

Each consignment must be accompanied by:

- a valid import permit issued by the Director of Biosecurity
- a health certificate consistent with 'Model veterinary certificate for international trade in products of animal origin' as described in Chapter 5.10. (WOAH 2022r) of the Terrestrial Code, signed by an official veterinarian (unless otherwise agreed).

An official veterinarian means a veterinarian authorised by the veterinary authority of the country to perform certain designated official tasks associated with animal health or public health and inspections of commodities and, when appropriate, to certify in accordance with Chapters 5.1. and 5.2. of the Terrestrial Code (WOAH 2022w).

All documents presented to the department when lodging an import declaration must meet the department's minimum documentary and import declaration requirements.

## 4.10 Health certification

Before being eligible to export, a country will need to have an agreed health certificate for exporting dairy products to Australia. The appropriate competent authority for issuing health certificates for dairy products, and a mechanism for notifying the department of any changes to the competent authority and/or the documentation being issued, will be identified during development of the agreed health certificate.

Dairy supply chains, from production of milk through to a dairy product arriving in Australia, can be complicated and may involve multiple different countries. Health certificates will need to state the countries of origin of the milk from which dairy ingredients were made and the countries of manufacture of dairy ingredients and goods containing dairy ingredients.

The country of origin is the country where the animals that produced the milk were domiciled at the time of milk production.

The countries of manufacture in this context includes all countries where steps applied in transforming raw liquid milk into the final goods that are being exported to Australia. This includes, but is not limited to:

- combining with other ingredients (including non-dairy ingredients)
- heat treatments such as pasteurisation
- labelling
- other processes applied after combining with other ingredients (including non-dairy ingredients)
- packaging
- physical processes such as separation, aeration, homogenisation, drying, churning and acidification

- storage.

The country of export is the country where the goods were exported from.

Health certificates generally need to be issued by the competent authority of the country from which the goods are being exported.

If health certificates are issued by the competent authority in the country where the final packaging and labelling of the dairy products occurs rather than the country of export, a non-manipulation certificate will need to be issued by the veterinary authority of the country from which the goods are being exported, if the exporting country is not eligible to export that type of dairy product to Australia. Non-manipulation certificate is defined in the department's 'Minimum documentary and import declaration requirements policy', version 4.0 (effective from 2 August 2021) as follows:

'a government-to-government certificate issued by the competent government authority of the exporting country that provides assurance that goods being exported from that country but were produced or manufactured in an alternative country have not been manipulated since the goods were originally manufactured or produced.'

#### **4.11 Verification of biosecurity measures**

Imported dairy products will be subject to documentary assessment at the border for compliance with import permit conditions. In addition, imported dairy products may be subject to other verification measures, such as visual checks. The compliance-based intervention scheme may be applied to dairy products in the future.

Where risk management measures require dairy products to be processed to achieve a specific parameter, imported dairy products may be randomly sampled at the border for verification that the parameter has been achieved. For example, for goods that require a certain pH to be achieved, the pH of the goods may be tested before release from biosecurity control.

Other methods may be used to verify compliance with import permit conditions, such as using tools to determine the provenance of dairy products and using technology to provide supply chain information.

#### **4.12 Review of processes**

The department reserves the right to review the biosecurity measures after the first year of trade, or when there is reason to believe that the disease or sanitary status of an approved country/zone has changed, or if there is evidence of new or emerging diseases. The department may also review the biosecurity measures if there is any change in the nature or understanding of a disease/disease agent (hazard), entry pathways or exposure pathways.

# Appendix A: Disease agents managed by minimum requirements

## **Bovine leukemia virus**

Bovine leukemia virus (species *Bovine leukemia virus*; genus *Deltaretrovirus*; family *Retroviridae*) causes the cattle disease enzootic bovine leukosis. Malignant tumours (lymphosarcomas), which lead to death within months, occur in 2% to 5% of affected cattle over 3 years of age (EFSA 2015; WOA 2022f).

The disease appears to be widespread globally (EFSA 2015). A small number of countries, particularly in Western Europe, are free from disease (EFSA 2015; WOA 2022f). Following a national eradication program, the Australian dairy herd achieved freedom from enzootic bovine leukosis on 31 December 2012. It is present in the Australian beef herd at a very low prevalence (AHA 2021a).

Iatrogenic spread is considered an important mode of disease transmission. Transplacental transmission and/or peripartum infections can also occur. Transmission through feeding of colostrum and milk from affected cows has also been demonstrated (EFSA 2015).

Enzootic bovine leukosis is a WOA-listed disease of cattle (WOA 2022d). The Terrestrial Code does not have recommendations for importation of dairy products for enzootic bovine leukosis.

The dairy IRA did not include risk management measures for enzootic bovine leukosis as the disease was endemic in Australia in 1999.

Since the dairy IRA was published, enzootic bovine leukosis has been eradicated in dairy cattle in Australia.

Experimental studies have demonstrated that pasteurisation inactivates bovine leukemia virus in milk (Baumgartener, Olson & Onuma 1976; Chung et al. 1986; Rubino & Donham 1984). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for bovine leukemia virus.

## ***Brucella* spp.**

Organisms in the genus *Brucella* spp. cause the bacterial disease brucellosis. It is a significant cause of reproductive loss in animals (CFSPH 2018a). Most *Brucella* species have a limited range of reservoir hosts, but other animals can be infected, particularly when they are in close contact (CFSPH 2018a). Brucellosis in cattle is usually caused by *B. abortus* and less frequently by *B. melitensis* (Corbel 2006; WOA 2022c). Buffalo, bison, African buffalo, feral pigs and sheep have also been reported to be affected by *B. abortus* (CFSPH 2018a). Brucellosis in sheep and goats is usually caused by *B. melitensis* (WOA 2022c). Brucellosis in pigs is usually caused by *B. suis*. Although *B. suis* can occasionally cause disease in cattle, they are unable to transmit disease (WOA 2022c).

Brucellosis is prevalent in China, India, the Mediterranean region, Mexico, the Middle East, Peru and Sub-Saharan Africa (WOA 2022b). Bovine brucellosis, caused by *B. abortus*, was eradicated from

Australia in 1989. *B. melitensis* has never occurred in Australia. *B. suis* is present in Australia (AHA 2021a).

*Brucella* spp. are shed in milk, birth products (placenta, foetus, foetal fluids), vaginal discharges, semen and urine (CFSPH 2018a). Transmission usually occurs from ingestion of bacteria from these products or through contaminated feedstuffs. Other possible routes of transmission include inhalation, contamination of abrasions or mucosal surfaces, and sexual transmission (CFSPH 2018a; Corbel 2006).

Brucellosis is a zoonotic disease and a nationally notifiable human health disease (Department of Health and Aged Care 2022).

Infection with *B. abortus*, *B. melitensis* and *B. suis* is a WOAHL-listed disease of multiple species (WOAH 2022d). For the purposes of the Terrestrial Code, 'Brucella' means *B. abortus*, *B. melitensis*, or *B. suis*, excluding vaccine strains. The Terrestrial Code has recommendations for importation of milk and milk products for *Brucella* spp. The recommendations are that the milk or the milk products have been derived from animals in a country, zone, herd or flock free from infection with *Brucella* spp. as relevant or were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products (WOAH 2022k).

The dairy IRA included risk management measures for bovine brucellosis and ovine brucellosis (*B. abortus* and *B. melitensis*) for the importation of dairy products of bovine, ovine and/or caprine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that meets WOAHL requirements for freedom from bovine brucellosis and ovine brucellosis, or the milk or the milk from which the dairy product was subjected to pasteurisation or an equivalent heat treatment.

Since the dairy IRA was published, pasteurisation remains the recommended and scientifically validated method to destroy *Brucella* spp. in milk products (CFSPH 2018a; Van den Heever, Katz & Te Brugge 1982). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for *Brucella* spp.

## ***Chlamydia (Chlamydophila) abortus***

*Chlamydia (Chlamydophila) abortus* is a globally distributed obligate intracellular bacterium, which causes enzootic abortion of ewes or ovine chlamydiosis. It is a cause of abortion and foetal loss predominantly in sheep and goats, typically occurring in the last 2 to 3 weeks of pregnancy, characterised by placentitis and stillborn lambs or kids (Aitken & Longbottom 2007). Cattle, pigs, horses and wild ruminants can also be affected, although less commonly (WOAH 2022e).

*C. abortus* is prevalent and contributes to significant economic losses in most sheep-rearing countries of the world, including many parts of Africa, Europe, North America and the UK (Longbottom & Coulter 2003). Enzootic abortion of ewes or ovine chlamydiosis caused by *C. abortus* has never occurred in Australia (AHA 2021b; WOAHL 2022x).

*C. abortus* is commonly shed in milk and colostrum, as well as vaginal secretions, placental membranes or abortions that contaminate the environment (Martínez-Serrano et al. 2022; Taheri,



Ownagh & Mardani 2021). Transmission to susceptible animals is primarily by ingestion of infectious material (WOAH 2022i).

*C. abortus* is zoonotic, with pregnant women and immunocompromised individuals particularly at risk (Essig & Longbottom 2015; Longbottom & Coulter 2003). Chlamydial infection caused by *C. trachomatis* is a nationally notifiable human health disease (Department of Health and Aged Care 2022).

Enzootic abortion of ewes or ovine chlamydiosis is a WOAHL-listed disease of sheep and goats (WOAH 2022d). The Terrestrial Code does not have recommendations for importation of dairy products for infection with *C. abortus*.

The dairy IRA did not include risk management measures for *C. abortus*. It noted that although some references mentioned milk as a source of infection, no experimental transmission through milk had been demonstrated.

Since the dairy IRA was published, there is still no information available on the transmissibility of *C. abortus* in milk. However, fatty acids in milk have demonstrated remarkable antichlamydial activity. Lauric acid, which is a type of fatty acid, demonstrates rapid antichlamydial activity at concentrations substantially lower than the lauric acid concentrations found in the milk of cows, goats, and sheep (Bergsson et al. 1998; German & Dillard 2010; Pikhtirova et al. 2020; Zhu et al. 2014). This antichlamydial effect has also been demonstrated for other fatty acids found in milk (Bergsson et al. 1998). Additionally, *Chlamydia* spp. used in laboratory studies are routinely inactivated using temperatures below those used for pasteurisation (Byrne 1976; Zeichner 1983). The combination of the antichlamydial effects of milk constituents and the effects of [minimum requirements](#) are considered appropriate risk management for *C. abortus*.

## **Ehrlichia ruminantium**

The bacterium *Ehrlichia ruminantium* (formerly *Cowdria ruminantium*), is an obligate intracellular parasite that causes heartwater, a disease of ruminants (CFSPH 2015a; WOAHL 2021b). All domestic and wild ruminants are susceptible to infection. Acute disease with pyrexia, followed by inappetence, diarrhoea, dyspnoea and nervous signs is the most common form of heartwater in domestic animals; these animals usually die within a week (WOAH 2021b).

Heartwater occurs in nearly all countries of Sub-Saharan Africa and in the surrounding islands. It has also been reported in the Caribbean (CFSPH 2015a). It has never occurred in Australia (AHA 2021a).

Transmission of *E. ruminantium* primarily occurs by ticks in the genus *Amblyomma*. Ticks become infected by feeding on affected cattle and remain infected for at least 15 months (WOAH 2021b). Although primarily transmitted via ticks, *E. ruminantium* has been detected in colostrum (CFSPH 2015a). Vertical transmission has been demonstrated from domestic cattle to their calves, thought to be due to ingestion of the organism within infected cells in colostrum (Allsopp 2010; Deem et al. 1996).

Evidence that *E. ruminantium* may be zoonotic is limited to reports of positive PCR results for the agent in 3 fatal cases of human ehrlichiosis in Africa. It remains to be determined whether the agent causes disease in humans (CFSPH 2015a).

Heartwater is a WOAHA-listed disease of multiple species (WOAHA 2022d). The Terrestrial Code does not have recommendations for importation of dairy products for heartwater.

The dairy IRA did not include risk management measures for heartwater as it was not considered to be naturally transmitted via milk.

Since the dairy IRA was published, vertical transmission of *E. ruminantium* through colostrum has been recognised as a mode of transmission in numerous reviews (Allsopp 2010; CFSPH 2015a).

*E. ruminantium* would not survive pasteurisation as it is heat labile, extremely fragile and does not survive outside a host for more than a few hours at room temperature (CFSPH 2015a; WOAHA 2021b). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for *E. ruminantium*.

## Jaagsiekte sheep retrovirus

Jaagsiekte sheep retrovirus (species *Jaagsiekte sheep retrovirus*; genus *Betaretrovirus*; family *Retroviridae*) is the cause of pulmonary adenomatosis. It mainly affects sheep and rare cases have been reported in goats. The virus causes tumours to develop in the respiratory system. Clinical signs of disease, which occur only in animals with tumours, include weight loss, emaciation and respiratory compromise (CFSPH 2019a). Subclinically infected animals can shed the virus.

Pulmonary adenomatosis has been reported in Africa, Asia, the Americas and Europe (CFSPH 2019a). It has never been reported in Australia (AHA 2019a).

Transmission mainly occurs by the respiratory route. The virus is also shed in milk and colostrum, which can transmit the virus to nursing animals (Borobia et al. 2016; CFSPH 2019a; Grego et al. 2008).

Pulmonary adenomatosis is not a WOAHA-listed disease.

The dairy IRA did not include risk management measures for pulmonary adenomatosis as it considered that jaagsiekte sheep retrovirus had not been shown to be excreted in milk.

Since the dairy IRA was published, experimental studies have demonstrated that jaagsiekte sheep retrovirus is excreted in milk and colostrum, and that transmission to nursing lambs can occur under natural conditions (Borobia et al. 2016; Grego et al. 2008).

No data is available for the effects of pasteurisation on jaagsiekte sheep retrovirus. However, viruses from the family *Retroviridae* are heat labile and readily inactivated at 56°C; therefore, pasteurisation would be sufficient to inactivate the virus in milk (Venables et al. 1997). Additionally, raising lambs on heat-treated colostrum is a recommended control measure (Borobia et al. 2016; Grego et al. 2008). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for jaagsiekte sheep retrovirus.

## Jembrana disease virus

Jembrana disease virus (species *Jembrana disease virus*; genus *Lentivirus*; family *Retroviridae*) is the cause of Jembrana disease. Overt clinical disease with significant mortalities have only occurred in Bali cattle (*Bos javanicus*). Clinical signs of disease include fever, lethargy, anorexia and enlargement

of the superficial lymph nodes. The case fatality rate is about 20% and recovered Bali cattle can remain viraemic for at least 2 years after infection. The disease can also be transmitted to cattle and buffalo, although a milder form of disease occurs (Wilcox 1997; Wilcox, Chadwick & Kertayadnya 1995).

Jembrana disease is endemic in Bali and has spread to other islands in Indonesia. It has never been reported in cattle outside of Indonesia (CABI 2019a).

The virus has been detected in saliva, milk and nasal discharge. Transmission via the conjunctival, intranasal and oral route occurs when susceptible cattle are in close contact with acutely infected animals. The disease may also be transmitted mechanically by haematophagous arthropods (Kusumawati et al. 2014; Soeharsono et al. 1995).

Jembrana disease is not a WOAHL-listed disease.

The dairy IRA included risk management measures for Jembrana disease for the importation of dairy products of bovine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that is free from Jembrana disease, or the milk or the milk from which the dairy product was made was subjected to pasteurisation or an equivalent heat treatment.

Since the dairy IRA was published, there is still no data available for the effects of pasteurisation on Jembrana disease virus. However, a study which investigated the effects of pasteurisation on a different lentivirus, bovine immunodeficiency virus, found that there was no evidence of transmission when HTST pasteurised virus-spiked milk was inoculated into calves (Venables et al. 1997). An earlier study also demonstrated inactivation of bovine immunodeficiency virus in milk by batch pasteurisation and HTST pasteurisation (Moore, Keil & St.Cyr Coats 1996). Lentiviruses appear to be quite unstable and heat labile. Experimental inactivation of other lentiviruses suggests that Jembrana disease virus would be inactivated by pasteurisation (Kriesel et al. 2020; Scott Williams Consulting Pty Ltd 2017). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for Jembrana disease virus.

## Louping ill virus

Louping ill virus (species *Louping ill virus*; genus *Flavivirus*; family *Flaviviridae*) is the cause of louping ill, a disease that mainly affects sheep, although clinical cases have been documented in goats, cattle, horses, llama, alpacas, pigs, dogs, deer and other animals. Red grouse are also susceptible natural infection. In a naïve sheep flock, louping ill can cause neurological signs and up to 60% of the flock can die (CFSPH 2020).

Louping ill mainly occurs in the United Kingdom. It has also been reported in Norway, Russia and on the island of Bornholm in Denmark (CFSPH 2020). It has never occurred in Australia (AHA 2019a).

The primary method of transmission of louping ill is via ticks. The main vector is the three-host tick *Ixodes ricinus* (CFSPH 2020). The virus has been found in the milk of goats and sheep. Results from experimental studies suggest that goats are more susceptible than sheep to transmission through milk (Reid et al. 1984; Reid & Pow 1985).

Humans can possibly acquire virus through drinking of unpasteurised milk from small ruminants, especially goats (CFSPH 2020).

Louping ill is not a WOAH-listed disease.

The dairy IRA did not include risk management measures for louping ill as it considered that transmission only occurs by *Ixodes ricinus* ticks, which are not present in Australia.

Since the dairy IRA was published, consumption of unpasteurised milk and milk products from infected animals has been recognised as a possible mode of transmission of louping ill (CFSPH 2020; Reid et al. 1984).

Pasteurisation of milk inactivates louping ill virus in dairy products (CFSPH 2020; Scott Williams Consulting Pty Ltd 2017). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for louping ill virus.

## Lumpy skin disease virus

Lumpy skin disease virus (LSDV) (species Lumpy skin disease virus; genus Capripoxvirus; family Poxviridae) causes a pox disease in cattle and buffalo (CFSPH 2017a). LSDV can cause heavy production losses and mortalities (CFSPH 2017a).

LSDV strains of capripoxviruses are antigenically indistinguishable from strains of sheeppox and goatpox viruses (EFSA 2006). Although LSDV naturally causes disease in only cattle and buffalo, it has been demonstrated experimentally that some virus strains can cause clinical disease in sheep (Kukushkina et al. 2016; Namazi & Tafti 2021).

LSDV is present throughout much of Africa and Russia. It is also endemic in Egypt, Turkey and many Middle Eastern countries. Since 2014, LSD has spread to countries within southeastern Europe and Asia that were previously free from the disease. As LSD is primarily transmitted through biting arthropod vectors, the prevalence of LSD in affected countries depends on the presence of suitable climatic conditions. In Africa, Europe and the Middle East, there is seasonality in LSD incidence due to vectors being less active during the dry season or cold winters. However, there may be no vector-free seasons in some countries due to suitable climatic conditions year-round (Roche et al. 2020).

Infection with LSDV is a WOAH-listed disease of cattle (WOAH 2022d). In Australia, infection with LSDV is nationally notifiable (DAFF 2024). LSD has never occurred in Australia (AHA 2021a).

The presence of LSDV in milk and colostrum from cattle is likely (Davies 1991; EFSA 2006; Scott Williams Consulting Pty Ltd 2017). Although there have been no recorded cases of transmission of capripoxviruses in milk. The Food and Agriculture Organization of the United Nations lumpy skin disease field manual for veterinarians states that the virus may be transmitted to suckling calves through infected milk or from skin lesions on the teats (Tuppurainen, Alexandrov & Beltrán-Alcrudo 2017). However, there is no experimental confirmation of this assumption (Sprygin et al. 2019).

A 2020 study reported that an LSD virus field strain and LSD virus vaccine strain were inactivated by heating to 56°C for 30 minutes or 60°C for 10 minutes (Wolff, Beer & Hoffman 2020). Experimental inactivation of LSD virus by heating to 65°C for 10 minutes has been validated at The Pirbright Institute, a reference laboratory for LSD (WOAH laboratory expert for capripoxviruses 2022, pers.

comm., 04 May). Recent research has also demonstrated that LSDV is inactivated in milk after heating at 72°C for 7.5 seconds, which is half the duration of HTST pasteurisation (Riddell 2023).

The dairy IRA included risk management measures for LSD for the importation of dairy products of bovine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that meets WOAHP requirements for freedom from LSD.

Since the dairy IRA was published, the import conditions have been updated to reflect changes in Australia's approach towards determining the LSD status of trading partners, and in response to identified biosecurity risks. Apart from legislated exemptions, retorted products, and cheese and butter; dairy ingredients of bovine origin may only be sourced from, and products containing dairy ingredients manufactured and exported from, countries/zones on the department's LSD-Free Country List.

## **Mycobacterium tuberculosis**

*Mycobacterium tuberculosis* species, known as the *M. tuberculosis* complex which includes *M. bovis*, *M. caprae* and *M. tuberculosis*, cause the disease tuberculosis. Cattle are the primary hosts for *M. bovis* and infection causes bovine tuberculosis. Clinical cases of *M. bovis* have also been recorded in many other mammals and marsupials including sheep, goats, pigs, deer and camels. Tuberculosis in goats is usually caused by *M. caprae*; however, *M. caprae* has also been found in cattle herds that have no apparent contact with small ruminants (CFSPH 2019b). *M. caprae* was previously classified as *M. tuberculosis* subsp. *caprae* and reclassified as *M. bovis* subsp. *caprae* before being elevated to species status (Aranaz et al. 2003). *M. tuberculosis* is maintained in humans, but it can occasionally affect animals (CFSPH 2019b; WOAHP 2022a).

Tuberculosis in cattle is usually a chronic debilitating disease. Common clinical signs of disease include emaciation, weakness, inappetence, fever and a moist, intermittent cough. Clinical signs of tuberculosis are similar in other species, but the main clinical signs and course of disease can differ between species (CFSPH 2019b).

Transmission of disease is caused by inhalation, ingestion or direct contact through mucous membranes or breaks in the skin. The organisms are shed in respiratory secretions, exudates from lesions, urine, faeces, milk, vaginal secretions and semen (CFSPH 2019b).

Bovine tuberculosis is common in cattle in parts of Africa, Asia, the Middle East and Latin America including Mexico. A limited number of countries have reported being completely free of *M. bovis* including Greenland, Iceland, Israel, Singapore and some European nations. *M. caprae* has been reported in China, Europe and North Africa (CFSPH 2019b). Tuberculosis in animals caused by *M. tuberculosis* is known to occur in Africa and Asia, where the highest incidences of human tuberculosis are reported (Hlokwe, Said & Gcebe 2017). Infection by *M. tuberculosis* complex in animals is not present in Australia (WOAHP 2022x). Australia has been free from bovine tuberculosis caused by *M. bovis* since 1997; the last case of *M. bovis* was reported in buffalo in 2002 (AHA 2019a).

Tuberculosis is a zoonotic disease and a nationally notifiable human health disease (Department of Health and Aged Care 2022).

Infection with *Mycobacterium tuberculosis* complex is a WOAHL-listed disease of multiple species (WOAH 2022d). For the purposes of the Terrestrial Code, *M. tuberculosis* complex comprises *M. bovis*, *M. caprae* and *M. tuberculosis*, but excludes vaccine strains. The Terrestrial Code has recommendations for importation of milk and milk products of bovids for *M. tuberculosis* complex. The recommendations are that the milk or milk products have been derived from bovids in a herd free from infection with *M. tuberculosis* complex or were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products (WOAH 2022n).

The dairy IRA included risk management measures for bovine tuberculosis (*M. bovis*) for the importation of dairy products of bovine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that meets WOAHL requirements for freedom from bovine tuberculosis, or the milk or the milk from which the dairy product was made was subjected to pasteurisation or an equivalent heat treatment.

Since the dairy IRA was published, pasteurisation remains the accepted method to inactivate causative agents of tuberculosis in dairy products (FSANZ 2006; Lake et al. 2009). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for infection with *M. tuberculosis*.

## **Mycoplasma spp.**

*Mycoplasma* species *M. agalactiae*, *M. capricolum* subsp. *capricolum*, *M. mycoides* subsp. *capri* (includes the formerly known *M. mycoides* subsp. *mycoides* large colony type) and *M. putrefaciens* cause contagious agalactia, a disease of sheep and goats. The latter three organisms mainly affect goats (CFSPH 2018b). All four mycoplasmas affect the host similarly; they have a triple mammary, articular and ocular tropism and cause mastitis, arthritis and keratoconjunctivitis (Bergonier, Berthelot & Pourmarat 1997; CFSPH 2018b). *M. mycoides* subsp. *mycoides* small colony type is closely related to *M. mycoides* subsp. *capri* and has also been isolated from milk of sheep with clinical signs of mastitis. However, *M. mycoides* subsp. *mycoides* is the causative agent of contagious bovine pleuropneumonia rather than contagious agalactia (Bergonier, Berthelot & Pourmarat 1997; Brandao 1995).

Contagious agalactia is widespread globally. It is particularly prevalent in the Middle East and southern Europe. Cases have also been documented in parts of Asia and the Americas (CFSPH 2018b). Strains of *M. agalactiae* have been isolated in Australia, but these Australian strains do not produce clinical disease (AHA 2021a).

The organisms that cause contagious agalactia are shed in milk, and nasal and ocular secretions (CFSPH 2018b). Subclinical animals may be carriers for long periods of time, and females can shed organisms in milk for more than one lactation cycle (Bergonier, Berthelot & Pourmarat 1997; CFSPH 2018b). Ingestion of milk and colostrum from affected animals is a significant mode of transmission (Bergonier, Berthelot & Pourmarat 1997; CFSPH 2018b).

Contagious agalactia is a WOAHL-listed disease of sheep and goats (WOAH 2022d). The Terrestrial Code does not have recommendations for importation of dairy products for contagious agalactia.

The dairy IRA included risk management measures for contagious agalactia for the importation of dairy products of ovine and/or caprine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that meets WOAHP requirements for freedom from contagious agalactia, or the milk or the milk from which the dairy product was made was subjected to pasteurisation or an equivalent heat treatment.

Since the dairy IRA was published, pasteurisation of colostrum and milk remains the globally accepted method for prevention of vertical transmission in affected herds (CFSPH 2018b; DaMassa 1996). Presence of *M. agalactiae* and *M. mycoides* subsp. *capri* in pasteurised colostrum was demonstrated in an experimental study; however, the number of organisms in pasteurised colostrum seemed to be less than the infective dose for oral transmission (CFSPH 2018b; Paterna et al. 2013). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for *Mycoplasma* species.

## ***Trypanosoma evansi***

*Trypanosoma evansi* is the protozoal parasite that causes the disease surra. Camels, equids, buffalo and cattle are generally considered to be the major hosts among domesticated animals. Infections are usually mild or subclinical in cattle, buffalo and related species in Africa or Latin America, whereas cattle and buffalo regularly become ill in Asia. Clinical cases have also been reported in most other domesticated mammals and some wild species. Common clinical signs of disease include fever, weight loss, lethargy, signs of anaemia and enlarged lymph nodes. The disease can be acute, subacute or chronic (CFSPH 2015b).

Surra occurs in Africa, Asia, Central and South America, and the Middle East (CFSPH 2015b). It has never been reported in Australia (AHA 2019a).

Transmission mainly occurs mechanically by biting insects. It can also be transmitted via the iatrogenic and transplacental routes. Transmission in milk and colostrum has been demonstrated in experimentally infected sheep (Campigotto et al. 2015; CFSPH 2015b).

Surra is a WOAHP-listed disease of multiple species (WOAHP 2022d). The Terrestrial Code does not have recommendations for importation of dairy products for surra.

Surra was not considered in the dairy IRA.

Since the dairy IRA was published, presence of *T. evansi* in sheep's milk and colostrum has been demonstrated experimentally. The milk and colostrum from the sheep in this experiment successfully infected mice orally (Campigotto et al. 2015).

No data is available for the effects of pasteurisation on *T. evansi*. However, trypanosomes are extremely fragile in the environment and sensitive to heat (CFSPH 2015b). A closely related organism, *T. brucei*, was inactivated when treated at 50°C for 5 minutes (Wang et al. 2008). Based on this data, *T. evansi* would not survive pasteurisation. Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for *Trypanosoma evansi*.



## Visna-maedi virus

Visna-maedi virus (species *Visna-maedi virus*; genus *Lentivirus*; family *Retroviridae*) is the cause of maedi-visna, a disease that affects sheep and occasionally goats. Most infections are subclinical; however, some animals develop untreatable dyspnea (maedi) or neurological signs (visna) (CFSPH 2007).

Maedi-visna is present worldwide, apart from Australia, Iceland and New Zealand (Kalogianni et al. 2020). It has never occurred in Australia (AHA 2019a).

Infection through consumption of colostrum and milk from infected animals is a well-known mode of transmission. Transmission through the respiratory route can also occur when animals are in close contact (CFSPH 2007; Kalogianni et al. 2020).

Maedi-visna is a WOAHL-listed disease of sheep and goats (WOAH 2022d). The Terrestrial Code does not have recommendations for importation of dairy products for maedi-visna.

The dairy IRA included risk management measures for maedi-visna for the importation of dairy products of ovine and/or caprine origin, other than cheese and butter – the milk or the milk from which the dairy product was made originated from a country/zone that meets WOAHL requirements for freedom from maedi-visna, or the milk or the milk from which the dairy product was made was subjected to pasteurisation or an equivalent heat treatment.

Since the dairy IRA was published, there is still no information available about the effects of pasteurisation on visna-maedi virus. However, a study which investigated the effects of pasteurisation on a different lentivirus, bovine immunodeficiency virus, found that there was no evidence of transmission when HTST pasteurised virus-spiked milk was inoculated into calves (Venables et al. 1997). An earlier study also demonstrated inactivation of bovine immunodeficiency virus in milk by batch pasteurisation and HTST pasteurisation (Moore, Keil & St.Cyr Coats 1996). Lentiviruses appear to be quite unstable and heat labile. Experimental inactivation of other lentiviruses suggests that visna-maedi virus would be inactivated by pasteurisation (Kriesel et al. 2020; Scott Williams Consulting Pty Ltd 2017). Additionally, raising lambs on pasteurised milk is a recommended method to prevent vertical transmission in affected herds (CFSPH 2007). Therefore, the [minimum requirements](#) of dairy products is considered appropriate risk management for visna-maedi virus.



# Appendix B: Risk assessment for whey protein fractions

## Introduction

In response to stakeholder comments, this risk review considers the biosecurity risks associated with importation of protein fractions for human consumption. A risk assessment was conducted for whey protein fractions.

## Method

A risk assessment was conducted for whey protein fractions, consistent with the method described in section 1.

Foot-and-mouth disease virus (FMDV) presents the highest level of biosecurity risk associated with imported dairy products. Unless otherwise stated, for practical purposes this risk assessment focussed on factors associated with the production processes and properties of the relevant goods to estimate the restricted risk of FMDV.

For each type of relevant goods, if the restricted risk of FMDV with existing alternative conditions in place was estimated to be 'negligible' or 'very low', this was assumed to achieve Australia's ALOP for all diseases of biosecurity concern and additional risk management measures were not required. If not, modified and/or additional alternative conditions were considered to further reduce the restricted risk. For goods where the management of the biosecurity risk was deemed too complex or variable to enable the use of alternative conditions, risk management measures were considered that could be applied as conditions on an import permit. Modifications to alternative conditions for some types of relevant goods were proposed where difficulties with implementation or interpretation have been identified.

## Background

Whey protein is made up of  $\beta$  lactoglobulin (50 to 55%),  $\alpha$ -lactalbumin (20 to 25%), bovine serum albumin (5 to 10%), glycomacropeptide (10 to 15%), immunoglobulins (10 to 15%), lactoferrin (1 to 2%) and lactoperoxidase (0.5%) (Wang & Guo 2019).

As each whey protein fraction has unique functional properties, there is an increasing desire to make purified whey protein fractions to meet specific nutritional and functional needs for many food and nutrition applications. Common applications of whey protein fractions include being added to infant formulas, used as a supplement for prevention and treatment of human diseases such as diseases of the liver or immune system, and used as a binder or natural preservative.  $\beta$ -lactoglobulin has also been used in yoghurt and salad dressings, and for egg replacement due to its functional properties such as gelling, emulsifying and foaming (Madureira et al. 2007; Wang & Guo 2019).

Currently, importation of whey protein fractions into Australia for human consumption is not considered any differently from other dairy products.

There is no Codex standard for whey protein fractions.

## Technical information

Whey protein fractions can be extracted from whey using membrane separation technology (Tetra Pak 2021). Within the dairy industry, there are 4 different membrane separation (also known as fractionation or filtration) processes used: microfiltration, ultrafiltration, nanofiltration and reverse osmosis. Each of these processes allows different components of whey and milk to pass through the membrane due to different densities of the membrane. For example, reverse osmosis is the tightest possible membrane process where only water can pass through the membrane, whereas microfiltration is the most open type of membrane where all components of the milk and whey can pass through the membrane except for bacteria, spores and fat globules (Tetra Pak n.d.). The components that pass through the membrane during the filtration process are referred to as permeate and the components that do not pass through the membrane are referred to as retentate. Depending on the type of whey product being produced, water may be added to the feed as filtration proceeds to wash out lactose and minerals, which will pass through the membranes – this process is called diafiltration (Tetra Pak n.d.).

Before isolation of whey protein fractions can occur, the whey is first clarified, separated, pasteurised and cooled (Tetra Pak 2021). Whey clarification removes casein fines from the whey before it reaches the whey separator. The cream is separated from the whey using a whey cream separator. These steps should occur as soon as possible after whey is drawn from the cheese curd as its temperature and composition promotes the growth of bacteria, leading to protein degradation and lactic acid formation. If the whey requires storage for over 8 hours before further processing, or if it is being used for infant formula and sports nutrition applications, it is usually pasteurised directly after the removal of fat and fines (Tetra Pak 2021). To reduce heat denaturation of whey protein fractions during production, non-thermal technologies and low temperature drying treatments are emerging as alternatives to pasteurisation.

Ultrafiltration of the pre-treated whey is performed to separate the whey into two streams: the water, dissolved salts, lactose and acids pass through the membrane (permeate) and the proteins and fat are retained (retentate). The retentate undergoes further membrane separation techniques to produce whey protein fractions (Tetra Pak 2021).

Individual whey proteins (such as lactoferrin and lactoperoxidase) can be individually isolated from whey using repetitive membrane separation processes with the addition of a chromatographic process. The pre-treated whey is subjected to cross-flow microfiltration and the particle free permeate is then subjected to a chromatographic process to isolate the desired whey protein. Lactoferrin and lactoperoxidase are positively charged at the normal pH of sweet whey, which is between pH 6.2 and pH 6.6, and the rest of the whey proteins ( $\alpha$ -lactalbumin,  $\beta$ -lactoglobulin and bovine serum albumin) are negatively charged in the same pH range. To isolate lactoferrin and lactoperoxidase, a specially designed cation exchange resin is used to bind the positively charged proteins to the ion exchange resin while the other whey proteins pass through because of their negative charge. Further processing by ultrafiltration and diafiltration (addition of water to the filtration process to wash out remaining lactose and minerals) yields pure protein products of approximately 95% purity. After a final cross-flow microfiltration, the protein concentrates are spray-dried or freeze-dried (Tetra Pak n.d.). Ion-exchange chromatography is the most used technique for whey protein fractionation (Vasiljevic & Duke 2016).

Another method for whey protein fractionation is selective precipitation through salt. Such methods were reported as early as 1934 (Bonnaillie & Tomasula 2008). When salt concentration of a solution exceeds a critical limit, the water is displaced from the protein, thereby leaving the protein dehydrated. This method is unlikely to be used commercially as the separated protein is contaminated with large quantities of salt and purification may be costly (Vasiljevic & Duke 2016).

Isoelectric focusing can also be used to induce protein precipitation through heat and pH adjustment. This method takes advantage of differences in isoelectric pH to separate a mixture of proteins into their individual fractions (Vasiljevic & Duke 2016). Precipitation of  $\alpha$ -lactalbumin has been reported using gentle heat treatment with the addition of hydrochloric acid, at temperatures between 55°C and 70°C and pH between 3.8 to 5.5 (Bonnaillie & Tomasula 2008). An example of a process used for separation of  $\alpha$ -lactalbumin from whey using heat and pH adjustment is: pH of whey is adjusted through addition of chemicals (such as sodium sulfate, ferric chloride, polyphosphates or sodium chloride); whey is heated between 90°C and 120°C; proteins are recovered through centrifugation and microfiltration; recovered proteins are washed and further processed using ultrafiltration and diafiltration; and the final product is then concentrated and dried (Vasiljevic & Duke 2016).

Membrane separation and chromatographic techniques are used to extract immunoglobulins from colostrum and cheese whey. Immunoglobulins are recovered from pre-treated whey or colostrum through repetitive membrane separation techniques (such as ultrafiltration, microfiltration and reverse osmosis) alone or in combination with chromatography. The addition of chromatography facilitates better recovery of immunoglobulins (El-Loly 2007; Mehra, Marnila & Korhonen 2006). The final products are usually spray-dried or freeze-dried powders. As the antibody activity of immunoglobulins may be reduced from thermal processing, non-thermal technologies such as pulsed electric fields are emerging as an alternative to thermal processing during the production of these products (Mehra, Marnila & Korhonen 2006).

There is limited information available about the effects of whey protein fraction isolation and production on inactivation of FMDV. In a 1978 study,  $\alpha$ -lactalbumin and  $\beta$ -lactoglobulin extracted from infectious whey did not contain viable FMDV, even by inoculation into steers. In this study, the whey was obtained as a by-product from the manufacture of cheese using pasteurised milk collected from cows inoculated with FMDV. Membrane separation processes were not used to produce  $\alpha$ -lactalbumin and  $\beta$ -lactoglobulin, rather separation was performed through precipitation using hydrochloric acid and then solubilized with ammonium hydroxide solution. The authors postulated that FMDV was successfully inactivated due to the final product containing negligible fat and casein, which, if present, protect the virus from inactivation. The use of continuous heating, precipitation and solubilisation at pH extremes was also thought to facilitate FMDV inactivation (Blackwell 1978).

## **Risk assessment and risk management**

If FMDV was present in the milk from which whey protein fractions were produced, the processing required to produce the whey protein fractions would reduce the viral titre in the final product. FMDV was successfully inactivated in several whey protein fractions recovered from infectious sweet whey produced from pasteurised milk in a 1978 experimental study, noting that the process used in this study may not be consistent with current commercial processes. A higher FMD viral titre would be expected in the final product if non-thermal technologies or low temperature treatments were used in the production of whey protein fractions.

Compared with many other dairy products, importation of whey protein fractions for human consumption presents a reduced likelihood of entry of FMDV and likelihood of susceptible animals being exposed to and consuming an infectious dose of FMDV. This is due to the processing involved in the manufacture of these products.

The likelihood of FMDV entering Australia in imported whey protein fractions for human consumption was estimated to be very low. The likelihood of susceptible animals being exposed to FMDV, with sufficient residual infectivity to initiate infection, in imported whey protein fractions for human consumption was estimated to be very low. This results in a restricted risk estimate of low, which does not achieve Australia's ALOP. Therefore, risk management measures for imported whey protein fractions for human consumption are required.

Generally, when whey protein fractions are added as an ingredient, they are typically present at levels of less than 1% of the final product however in specific formulation this percentage may increase. If whey protein fractions from any country were included in small quantities as an ingredient in dairy products and goods containing dairy ingredients for human consumption from countries that are recognised by the department as free from FMD, this would further reduce the likelihood of entry of FMDV and likelihood of susceptible animals being exposed to and consuming an infectious dose of FMDV, due to the lower proportion of whey protein fractions per unit volume entering and potentially being consumed by susceptible animals.

The likelihood of FMDV entering Australia in such goods was estimated to be extremely low. The likelihood of susceptible animals being exposed to FMDV, with sufficient residual infectivity to initiate infection, in such goods was estimated to be extremely low. This results in a restricted risk estimate of very low, which achieves Australia's ALOP.

## Recommendations

Whey protein fractions are:

- $\alpha$ -lactalbumin
- $\beta$ -lactoglobulin
- bovine immunoglobulins
- bovine serum albumin
- glycomacropeptide
- lactoferrin
- lactoperoxidase.

Whey protein fractions will not need to meet the biosecurity requirements for dairy products that would otherwise apply if:

- whey protein fractions are included as an ingredient in dairy products
- the dairy products are manufactured in and exported from countries/zones that have current approval by Australia.

# Glossary

Term	Definition
ABARES	Australian Bureau of Agricultural and Resource Economics and Sciences
ALOP	Appropriate level of protection
Appropriate level of protection (ALOP) for Australia	The Biosecurity Act 2015 defines the appropriate level of protection (or ALOP) for Australia as a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to very low, but not to zero.
AUSVETPLAN	Australian Veterinary Emergency Plan
Australian territory	Australian territory as referenced in the Biosecurity Act 2015 refers to Australia, Christmas Island and Cocos (Keeling) Islands.
Batch pasteurisation	A process applying a minimum temperature of 63°C for 30 minutes, also known as low-temperature long-time pasteurisation
BICON	Australian Biosecurity Import Conditions database
Biosecurity	The prevention of the entry, establishment or spread of unwanted pests and infectious disease agents to protect human, animal or plant health or life, and the environment.
Biosecurity import risk analysis (BIRA)	The Biosecurity Act 2015 defines a BIRA as an evaluation of the level of biosecurity risk associated with particular goods, or a particular class of goods, that may be imported, or proposed to be imported, into Australian territory, including, if necessary, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or the class of goods, to a level that achieves the ALOP for Australia. The risk analysis process is regulated under legislation.
Biosecurity measures	The Biosecurity Act 2015 defines biosecurity measures as measures to manage any of the following: biosecurity risk, the risk of contagion of a listed human disease, the risk of listed human diseases entering, emerging, establishing themselves or spreading in Australian territory, and biosecurity emergencies and human biosecurity emergencies.
Biosecurity risk	The Biosecurity Act 2015 refers to biosecurity risk as the likelihood of a disease or pest entering, establishing or spreading in Australian territory, and the potential for the disease or pest causing harm to human, animal or plant health, the environment, economic or community activities.
Bovine	Ungulates of the subfamily Bovinae. For the purpose of this review limited to domestic cattle ( <i>Bos taurus</i> ) and domestic water buffalo ( <i>Bubalus bubalis</i> ).
BSE	Bovine spongiform encephalopathy
Caprine	Ungulate of the genus <i>Capra</i> . For the purpose of this review limited to domestic goats ( <i>Capra hircus</i> ).
Cheese	The ripened or unripened solid or semi-solid milk product, whether coated or not, that is obtained by wholly or partly coagulating milk, through the action of rennet or other suitable coagulating agents, and partially draining the whey which results from the coagulation.
Colostrum	The substance secreted from the udder for the first 4 days following parturition
Competent Authority	The Veterinary Authority or other Governmental Authority of a country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations.
Dairy IRA	Importation of dairy products into Australia for human consumption: import risk analysis, November 1999
Dairy standard	Standard 4.2.4 of the food standards code – Primary Production and Processing Standard for Dairy Products (Australia Only)
Department (the)	Australian Government Department of Agriculture, Fisheries and Forestry

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<b>Term</b>	<b>Definition</b>
EADRA	Emergency Animal Disease Response Agreement
ELISA	Enzyme-linked immunosorbent assay
Endemic	Belonging to, native to, or prevalent in a particular geography, area or environment.
Feral animal	A domestic species that is not confined or under control (e.g. cattle, goats, horses, pigs).
FMD	Foot-and-mouth disease
Food standards code	Australia New Zealand Food Standards Code
FSANZ	Food Standards Australia New Zealand
Goods	The Biosecurity Act 2015 defines goods as an animal, a plant (whether moveable or not), a sample or specimen of a disease agent, a pest, mail or any other article, substance or thing (including, but not limited to, any kind of moveable property).
Goods determination	Biosecurity (Conditionally Non-prohibited Goods) Determination 2021
Host	An organism that harbours a parasite, mutual partner, or commensal partner, typically providing nourishment and shelter.
HTST	High-temperature short-time; a process applying a minimum temperature of 72°C for 15 seconds
ID50	Mouse median infectious dose; quantifies the amount of virus required to produce infection in 50% of inoculated animals (Diteepeng et al. 2016).
Import permit	Official document authorising a person to bring or import particular goods into Australian territory in accordance with specified import requirements.
Imported Food Control Act	Imported Food Control Act 1992
LSD	Lumpy skin disease
LTLT	Low-temperature long-time, also called batch pasteurisation; a process applying a minimum temperature of 63°C for 30 minutes
Non-regulated risk analysis	Refers to the process for conducting a risk analysis that is not regulated under legislation (Biosecurity import risk analysis guidelines 2016).
OIE	Previous name for the World Organisation for Animal Health
Ovine	Ungulate of the genus <i>Ovis</i> . For the purpose of this review limited to domestic sheep ( <i>Ovis aries</i> ).
Pathogen	A biological agent that can cause disease to its host.
PCR	Polymerase chain reaction
PFU	Plaque forming unit; represents the number of infectious virus particles, based on the assumption that each plaque formed is representative of one infective virus particle (Diteepeng et al. 2016).
PPRV	Peste des petits ruminants virus
PrP	Prion protein
PrP <sup>C</sup>	Normal prion protein
PrP <sup>Sc</sup>	Scrapie agent prion protein
Quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing or treatment.
Restricted risk	Risk estimate with sanitary measure(s) applied.
Risk analysis	Refers to the technical or scientific process for assessing the level of biosecurity risk associated with the goods, or the class of goods, and if necessary, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or class of goods to a level that achieves the ALOP for Australia.

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<b>Term</b>	<b>Definition</b>
SPS Agreement	World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures
Stakeholders	Government agencies, individuals, community or industry groups or organisations, in Australia or overseas, including the proponent/applicant for a specific proposal, which have an interest in the policy issues.
Surveillance	An official process that collects and analyses information related to animal health.
TCID50	Median tissue culture infectious dose; quantifies the amount of virus required to produce a cytopathic effect in 50% of inoculated tissue culture cells (Diteepeng et al. 2016).
Terrestrial Code	World Organisation of Animal Health Terrestrial Animal Health Code
TSE	Transmissible spongiform encephalopathy
UHT	Ultra-high temperature; a process applying a minimum temperature of 132°C for at least 1 second
Unrestricted risk	Unrestricted risk estimates apply in the absence of risk mitigation measures.
Vector	An organism that does not cause disease itself, but which causes infection by conveying pathogens from one host to another.
WOAH	World Organisation for Animal Health

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