Import risk review for dairy products for human consumption: draft report

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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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Summary

The Australian Government Department of Agriculture, Fisheries and Forestry has prepared this draft risk review to consider the biosecurity risks associated with the importation of dairy products (from any country) into Australia for human consumption. In 1999, the department completed an import risk analysis on dairy products for human consumption from all countries. This led to the development of import conditions for dairy products, which have been updated over time as particular aspects were revised.

Australia permits the importation of dairy products for human consumption (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 and butter from countries free from FMD, some cheeses from countries not free from FMD, colostrum from the United States for human consumption, and retorted dairy products.

This draft risk review aims to modernise Australia's dairy import conditions to reflect the current and future trading environment. It takes into account new and relevant peer-reviewed scientific information, international standards, relevant changes in industry practices and operational practicalities. Only dairy products for human consumption manufactured from milk obtained from domestic cattle, water buffalo, sheep and/or goats are included. It does not include dairy products imported for personal use (personal consignments), as food samples, or retorted dairy products.

This draft risk review proposes that the importation of dairy products to Australia continues to be permitted, subject to a range of biosecurity measures. It proposes some modifications to current biosecurity measures.

Hazards that require biosecurity measures to manage risks to a very low level in order to achieve Australia's appropriate level of protection (ALOP) have been identified. The hazards requiring measures, in addition to the minimum requirements for imported dairy products, are FMD, LSD, sheep pox and goat pox, peste des petits ruminants (PPR) and scrapie.

This draft risk review contains details of the risk review for the identified hazards and the proposed biosecurity measures to allow interested parties to provide comments and submissions to the department within the consultation period.

This draft risk review proposes a combination of risk management measures and operational systems that will reduce the risk associated with the importation of dairy products into Australia to achieve Australia's ALOP, including:

- milk is sourced only from healthy animals
- documented food safety programs for dairy primary production, collection, transportation and processing are implemented
- all the facilities involved in manufacture have current approval for the relevant operations from the competent authority of the country where manufacture occurred

- milk and dairy products are processed to meet specific requirements
- for dairy products of bovine origin, the countries/zones of origin of the milk from which dairy ingredients were made, countries/zones of manufacture of dairy ingredients and goods containing dairy ingredients, and the country/zone of export must all be on the department's FMD-Free Country List and the department's LSD-Free Country List (except for cheese), and there must be no opportunity for contamination or substitution with potentially contaminated goods from the time of export to the time of arrival in Australia
- for dairy products of ovine and/or caprine origin the countries/zones of origin of the milk from which dairy ingredients were made, countries/zones of manufacture of dairy ingredients and goods containing dairy ingredients, and the country/zone of export must all be on the department's FMD-Free Country List, the department's Sheep Pox and Goat Pox-Free Country List (except for cheese), and the department's PPR-Free Country List (except for cheese), and there must be no opportunity for contamination or substitution with potentially contaminated goods from the time of export to the time of arrival in Australia
- alternatively, for importation of dairy products for human consumption from countries not recognised by the department as free from FMD, LSD, sheep pox and goat pox, and PPR, heat treatment in addition to minimum requirements will be required
- an appropriate heat treatment will be required for colostrum of bovine origin, and all facilities involved in manufacture must have current approval for the relevant operations from the competent authority of the country where manufacture occurred
- colostrum of ovine and/or caprine origin is not permitted.

The proposed biosecurity measures recommended in this draft risk review differ from current import conditions, the key changes include:

- risk management options available for countries of origin and/or manufacture and export and/or for storage which are not recognised by the department as free from FMD and/or LSD and/or sheep pox and goat pox have been expanded
- addition of risk management measures for PPR in imported dairy products (except for cheese) of ovine and/or caprine origin
- butter will no longer be considered differently from other dairy products
- allowances for whey protein fractions.

Release of Peste des Petits Ruminants-Free Country List

The list will be published on the department's website prior to the finalisation of the Import risk review for dairy products for human consumption.

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.

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 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
Australian Manual for the Validation and Verification of Heat Treatment Equipment and Processes	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
Australian Dairy Ingredient Reference Manual	Dairy Australia	Brief descriptions and composition information of dairy products and ingredients
Gateway to dairy production and products	Food and Agriculture Organization of the United Nations	Species-specific information about the composition of milk and brief descriptions of the manufacturing processes and characteristics of dairy products
Standards 2.5.1 to 2.5.7 of the food standards code	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)
The Codex standards for milk products, horizontal cheese standards and individual cheese standards	The Codex Alimentarius Commission	Descriptions and essential composition and quality factors; the global reference for governments, the food industry, trade operators and consumers
The Dairy Processing Handbook	Tetra Pak	Definitions and descriptions, composition information and detailed information on manufacturing processes
The milk making process	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 (including colostrum), 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. These laws require all food, including imported food, to meet the standards set out in the food standards code, 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 2.1).

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).

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.

Under standard conditions for dairy products for human consumption, these goods 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.

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 WOAH, 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 the OIE. Importing countries should align their requirements with the recommendations in the relevant standards of the OIE. If there are no such recommendations or if the country chooses a level of protection requiring measures more stringent than the standards of the OIE, 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 OIE 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 2022z) 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 2022z)
- 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
- WOAH-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.

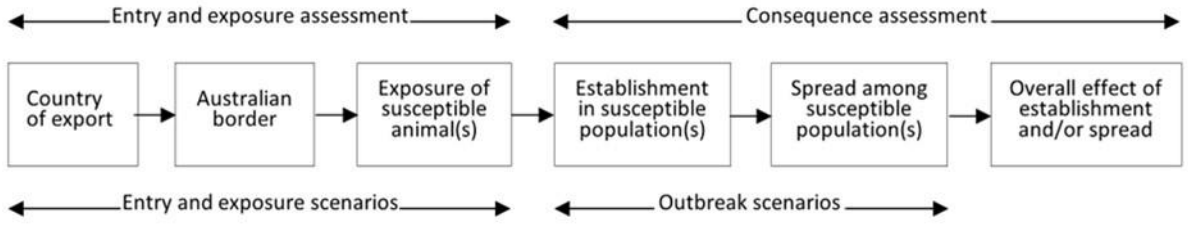
For each disease agent requiring risk assessment, the risk assessment resulted in an unrestricted risk estimate for the disease agent. For the purposes of this draft risk review, the unrestricted risk estimate was defined as the level of risk that would be present if there were no safeguards in place 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	Descriptive 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 enters or is meant to enter the human food chain but is subsequently 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

Likelihood of entry	Negligible	Extremely low	Very low	Low	Moderate	High
High	Negligible	Extremely low	Very low	Low	Moderate	High
Moderate	Negligible	Extremely low	Very low	Low	Low	Moderate
Low	Negligible	Extremely low	Very low	Very low	Low	Low
Very low	Negligible	Extremely low	Extremely low	Very low	Very low	Very low
Extremely low	Negligible	Negligible	Extremely low	Extremely low	Extremely low	Extremely low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
	Negligible	*Extremely low*	*Very low*	*Low*	*Moderate*	*High*

Likelihood of exposure

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	Negligible	Very low	Low	Moderate	High	Extreme
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

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	Negligible	Very low	Low	Moderate	High	Extreme
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

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 WOAH 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.

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 (disease)	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
Anaplasma bovis	Cattle	No	No	Not reported	No	No: not present in milk
Anaplasma marginale (Bovine anaplasmosis)	Cattle	No	Yes	Yes	Yes (in tick-free areas)	No: not present in milk
Babesia bovis, B. bigemina, B. divergens (Bovine babesiosis)	Cattle, buffalo	No	Yes	*B. bovis* and *B. bigemina* present; *B. divergens* not present	Yes (in tick-free areas)	No: not present in milk
Bacillus anthracis (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
Besnoitia besnoiti (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

Disease agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Borrelia burgdorferi (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)
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^{res}) (bovine spongiform encephalopathy)	Cattle, bison, cats, zoo felidae, antelope, humans	No	Yes	No	Yes	No: not present in milk

Disease agent (disease)	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
Brucella abortus, B. melitensis, B. suis (Brucellosis)	Multiple susceptible species including cattle, bison, buffalo, pigs, horses, deer, elk, camels, llamas, alpacas, humans	Yes	Yes	*B. abortus* and *B. melitensis* not present; *B. suis* present	Yes	No: managed by minimum requirements (see Appendix A)
Brucella ovis (Ovine epididymitis)	Sheep, red deer; goats and cattle susceptible to experimental infection	Yes	Yes	Yes	No	No: present in Australia
Burkholderia pseudomallei (Melioidosis)	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
Campylobacter fetus subsp. *venerealis* (Bovine genital campylobacteriosis)	Cattle	No	Yes	Yes	No	No: not present in milk
Campylobacter jejuni, C. coli (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

Disease agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Chlamydia (Chlamydophila) abortus (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)
Chlamydia pecorum	Cattle, sheep, koalas	No	No	Yes	No	No: not present in milk
Clostridium botulinum, C. perfringens	Cattle, sheep, goats, pigs, humans, multiple other species	Yes	No	Yes	No	No: present in Australia
Corynebacterium 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
Coxiella burnetii (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
Cryptosporidium parvum (Bovine cryptosporidiosis)	Cattle, yaks, buffalo, camels, sheep, goats, horses, humans	Yes	No	Yes	No	No: present in Australia

Disease agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Eastern equine encephalitis virus, western equine encephalitis virus, Venezuelan equine encephalitis virus (Eastern, Western and Venezuelan equine encephalomyelitis)	Birds, equids, rodents; occasionally other species including cattle, sheep, camelids, pigs	No	Yes	No	Yes	No: not present in milk
Ehrlichia ruminantium (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)
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
Francisella tularensis (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
Histophilus somni (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	No	Yes	Yes (some subtypes not present)	No	No: not present in milk
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 agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
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 (*Bos javanicus*); cattle, buffalo and pigs susceptible to experimental infection	Yes	No	No	Yes	No: managed by minimum requirements (see Appendix A)
Leptospira borgpetersenii serovar hardjo type hardjo-bovis (Leptospirosis)	Cattle, multiple other species including humans	Yes	No	Yes	No	No: present in Australia
Leishmania 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
Listeria monocytogenes (Listeriosis)	Cattle, sheep, goats, camelids, buffalo, multiple other species including humans	Yes	No	Yes	No	No: present in Australia
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)
Lumpy skin disease virus (lumpy skin disease)	Cattle, buffalo, some wild ruminant species such as giraffes, springbok, impalas	Yes	Yes	No	Yes	Yes: not present in Australia, present in and transmissible through milk, may not be managed by minimum requirements

Disease agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Malignant catarrhal fever virus (Malignant catarrhal fever)	Cattle, bison, buffalo, sheep, wildebeest, deer	No	No	*Alcelaphine gammaherpesvirus-1* not present; *ovine gammaherpesvirus-2* present	Yes (*alcelaphine herpesvirus-1* 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
Mycobacterium avium subsp. *paratuberculosis* (Paratuberculosis/Johne's disease)	Cattle, buffalo, sheep, goats, camelids, cervids, multiple other species including humans	Yes	Yes	Yes	Yes	No: present in Australia
Mycobacterium bovis, M. caprae, M. tuberculosis (Tuberculosis)	Cattle, bison, buffalo, multiple other species including humans	Yes	Yes	No	Yes	No: managed by minimum requirements (see Appendix A)
Mycoplasma agalactiae, M. capricolum subsp. *capricolum, M. mycoides* subsp. *capri* – also contains the former *M. mycoides* subsp. *mycoides* large colony type, *M. putrefaciens* (Contagious agalactia)	Sheep, goats	Yes	Yes	Clinical disease not present	Yes (clinical disease)	No: managed by minimum requirements (see Appendix A)
Mycoplasma bovis (Bovine mycoplasmosis)	Cattle	Yes	No	Yes	No	No: present in Australia
Mycoplasma capricolum subsp. *capripneumoniae* (Contagious caprine pleuropneumonia)	Goats (primary), sheep (rarely), some wild ruminant species	No	Yes	No	Yes	No: not present in milk

Disease agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Mycoplasma mycoides subsp. *mycoides* 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
Neospora caninum (Neosporosis)	Cattle and dogs, occasionally horses, goats, sheep, deer	Yes	No	Yes	No	No: present in Australia
Pasteurella multocida 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 *Escherichia coli* including E. coli 0157: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

Disease agent (disease)	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
Salmonella 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
Salmonella 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

Disease agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Scrapie protease-resistant prion protein (PrP^{Sc}) (scrapie)	Sheep, goats (less frequently)	Yes	Yes	No	Yes	Yes: not present in Australia, present in and transmissible through milk, may not be 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
Shigella spp.	Humans (primarily), monkeys, cattle, sheep, goats (rare)	Yes	No	Yes	No	No: present in Australia
Staphylococcus aureus	Cattle, sheep, goats, camelids, horses, dogs, cats, rabbits, multiple other species including humans	Yes	No	Yes	No	No: present in Australia
Streptococcus 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
Trypanosoma evansi (Surra)	Mainly camels, equids, buffalo, cattle	Yes	Yes	No	Yes	No: managed by minimum requirements (see Appendix A)
Theileria annulata – Mediterranean theileriosis, *T. parva* – East Coast fever (Theileriosis)	Cattle, buffalo, yaks, camels	No	Yes	No	Yes	No: not present in milk

Disease agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Toxoplasmosis gondii (Toxoplasmosis)	Cats (definitive hosts), small ruminants, pigs, camelids, cattle (rare or absent), multiple other species including humans	Yes	No	Yes	No	No: present in Australia
Tritrichomonas foetus (Trichomoniasis)	Cattle	No	Yes	Yes	No	No: not present in milk
Trypanosoma brucei, T. congolense, T. simiae, T. vivax (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
Trypanosoma cruzi (Chagas disease)	Dogs, cats, sheep, goats, cattle, humans, multiple other species	No	No	No	Yes	No: not present in milk
Ureaplasma diversum	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)
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

Disease agent (disease)	Susceptible species	Present or transmissible in milk	WOAH-listed disease	Present in Australia	Nationally notifiable in Australia	Retained for risk review
Yersinia enterocolitica (Yersiniosis)	Sheep, goats, cattle, pigs, humans	Yes	No	Yes	No	No: present in Australia
Yersinia pestis (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
- lumpy skin disease virus and sheeppox virus and goatpox virus
- peste des petits ruminants virus
- scrapie protease-resistant prion protein
- 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:

- bovine leukemia virus
- *Brucella* spp.
- *Chlamydia (chlamydophilia) abortus*
- *Ehrlichia ruminantium*
- jaagsiekte sheep retrovirus
- Jembrana disease virus
- louping ill 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 (FMD) virus (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 FMD virus 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 WOAH as FMD-free, either with or without vaccination (Alexandersen et al. 2003; WOAH 2021a). Traditional grazing methods, movement of livestock and circulating virus in wildlife and feral species are the main causes of FMD virus 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; WOAH 2021d). Other species in which experimental infection with high titres of FMD virus 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 FMD virus is a WOAH-listed disease of multiple species (WOAH 2022d). The WOAH 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 WOAH as FMD-free where vaccination is not practised (WOAH 2022t). In Australia, infection with FMD virus is nationally notifiable and FMD has not occurred since 1872 (AHA 2021a; DAWE 2020).

3.1.2 Technical information

Agent properties

FMD virus 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). FMD virus is pH-labile and is rapidly inactivated below pH 6.0 and above pH 9.0 (Bachrach et al. 1957). FMD virus is progressively inactivated at temperatures above 50°C and is inactivated at 70°C for 30 minutes; however, FMD virus survives freezing and drying (WOAH 2021d).

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 WOAH reports that excretion of FMD virus begins up to 4 days before the onset of clinical signs of disease (AHA 2014; WOAH 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).

FMD virus 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) (AHA 2014). 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 (Tomasula & Konstance 2004) (Pharo 2002).

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; WOAH 2021d). Susceptibility of several Australian wildlife species to FMD virus has been demonstrated in experimental studies, and FMD virus has been reported as the cause of severe disease and death in eastern grey kangaroos (*Macropus giganteus*), residing in a zoo located in a FMD-prevalent area of India (AHA 2014; Bhattacharya et al. 2003).

FMD virus 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 FMD virus during outbreaks, particularly through feeding raw milk from infected animals to pigs (Donaldson 1997). Infectious FMD virus has been isolated from the milk of clinically normal cows (Donaldson 1997; Pharo 2002; Spickler & Roth 2012). FMD virus has also been isolated from milk of other ruminants, including sheep and goats (Aly & Gaber 2007; Spickler & Roth 2012).

FMD virus is excreted in milk during the incubation period, between 1 and 4 days after infection, and continues to be excreted post-viraemia (Ahmed et al. 2017; Reid et al. 2006; Spickler & Roth 2012; Tomasula & Konstance 2004). Excretion of FMD virus in cow's milk has been demonstrated for 3 weeks after the resolution of viraemia (Reid et al. 2006).

The interpretation of inactivation data for FMD virus in dairy products is complicated by the protective effect that milk provides the virus. Virus that is shed from the mammary gland is incorporated into the casein micelles and fat globules, which provide the virus protection from

inactivation (Spickler & Roth 2012; Tomasula & Konstance 2004). Due to the protective effect of fat in milk, data obtained from studies for one type of dairy product may not be applicable to another due to differing fat compositions. For example, studies have demonstrated that FMD virus is more readily inactivated in skim milk compared to whole milk, and dairy products with high fat content such as cream or butter require more severe heat treatment to inactivate FMD virus (Blackwell & Hyde 1976; Spickler & Roth 2012).

Inactivation of FMD virus in whole and skim milk has repeatedly failed using parameters equal to or exceeding HTST and batch pasteurisation (Bohm 1982; de Leeuw & van Bekkum 1979; Dhennin & Labie 1976; El-Alfy 1998; Spickler & Roth 2012; Tomasula et al. 2007). However, a 1979 study achieved inactivation of FMD virus when whole milk was heated at 100°C for 27 minutes (de Leeuw & van Bekkum 1979). Another study conducted in 1984 reported similar results (Walker et al. 1984).

Successful inactivation of FMD virus as determined by inoculation into steers has been consistently demonstrated in milk when treated at a temperature of 148°C for at least 3 seconds, but not at 138°C for 3 seconds (Cunliffe et al. 1979; Walker et al. 1984).

Acidification alone is not consistently effective for inactivation of FMD virus in milk. Alteration in pH can precipitate milk components into an insoluble form that protect the virus instead of facilitating inactivation (Spickler & Roth 2012). FMD virus infectivity can remain in milk following 6 hours at pH 1.97 (Sonder et al. 1990). Inactivation of infectious FMD virus 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 FMD virus. This has been demonstrated in cheese manufactured using milk subjected to a thermal treatment insufficient to inactivate FMD virus; 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).

Cheeses made from raw milk require prolonged periods of ripening to inactivate FMD virus. FMD virus was shown to survive ripening in cheddar cheese made from raw milk at a temperature of 2°C for 60 days, but not 120 days (Blackwell 1976).

Double pasteurisation has been shown to provide adequate risk mitigation for FMD virus in milk; however, it may be difficult to implement commercially (Alexandersen 2005; Danish Veterinary Service 1982; Donaldson 1997) (Aly & Gaber 2007).

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

FMD virus has also been shown to survive evaporation and the drying process used to make dehydrated dairy products (Blackwell & Hyde 1976; Cottral 1969; Spickler & Roth 2012).

Pathogenesis
The most common portal of entry of FMD virus 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 2021d).

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 FMD virus. 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 FMD virus (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 FMD virus.

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 FMD virus, and the products have been processed to ensure the destruction of FMD virus in accordance with one of the following procedures for the inactivation of FMD virus 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 WOAH-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 FMD virus 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 WOAH as FMD-free, either with or without vaccination.
- FMD virus 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 FMD virus begins up to 4 days before the onset of clinical signs of disease. FMD virus is excreted in milk for up to 23 days post-infection.
- Fat globules and casein micelles in milk provide protection for FMD virus against inactivation.
- The presence of FMD virus in dairy products imported for human consumption depends on the type of dairy product and processing parameters applied to the product. However, residual FMD virus 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 FMD 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 FMD virus 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 FMD virus in dairy products imported for human consumption.

- All domestic and wild cloven-hoofed ungulates, and over 70 species of wildlife, are susceptible to FMD.
- FMD virus 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 distributer/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 FMD 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 FMD virus
- 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 FMD virus.

Conclusion: Based on these considerations, the likelihood of susceptible animals being exposed to FMD virus 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 FMD 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 FMD 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 and territories.

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

- FMD is highly contagious. FMD virus 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. 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 FMD virus in dairy products sourced from sheep or goats.
- Pigs are highly susceptible to infection with FMD virus 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 FMD 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 FMD virus 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 FMD virus 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 FMD virus 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 FMD virus 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 FMD virus 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 FMD virus was estimated to be **high**.

Conclusion

The unrestricted risk of FMD virus 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 FMD virus in milk. Additionally, based on the findings of the literature review, the UHT treatment recommended by the Terrestrial Code may not reliably inactivate FMD virus.

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

To manage the risk of FMD virus 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.

Alternatively, to manage the risk of FMD virus 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.

To manage the risk of FMD virus 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 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 FMD virus.

Additional risk management measures for FMD virus 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. This applies to dairy products manufactured using dairy ingredients sourced from any country/zone.

Additional risk management measures for FMD virus 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.

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 FMD 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.

3.2 Lumpy skin disease virus and sheeppox virus and goatpox virus

3.2.1 Background

Lumpy skin disease (LSD) virus (species *Lumpy skin disease virus*; genus *Capripoxvirus*; family *Poxviridae*) causes a pox disease in cattle and buffalo (CFSPH 2017a). 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 2017a, b).

LSD virus strains of capripoxviruses are antigenically indistinguishable from strains of sheeppox and goatpox viruses (EFSA 2006). Although LSD virus naturally causes disease in only cattle and buffalo, it has been demonstrated experimentally that some LSD virus strains can cause clinical disease in sheep (Kukushkina et al. 2016; Namazi & Tafti 2021). Strains of sheeppox and goatpox viruses generally express host preferences for either sheep or goats; however, there are some isolates that infect both sheep and goats equally. 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 LSD virus strain was detected in cattle in Russia, where only the sheeppox virus vaccine is used. This was following the initiation of vaccination campaigns using LSD virus 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).

LSD virus 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 South Eastern Europe and Asia that were previously free from the disease. LSD was reported in Cyprus in 2014, Greece in 2015 and Albania, Bulgaria, Montenegro, Serbia and the former Yugoslav Republic of Macedonia in 2016 (Tuppurainen 2018b). LSD was reported in Bangladesh, China and India in 2019; Bhutan, Hong Kong, Myanmar, Nepal, Sri Lanka, Taiwan and Vietnam in 2020; Cambodia, Malaysia and Thailand in 2021; and Indonesia, Pakistan and Singapore in 2022 (WOAH 2022aa). 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).

Sheeppox and goatpox viruses are prevalent in Bangladesh, India, the Near and 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 2022aa). 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).

Cattle and buffalo are susceptible to LSD (Davies 1982; WOAH 2017). Certain wild ruminants, including African buffalo (*Syncerus caffer*), giraffes, impala and springbok, may also be susceptible to LSD, although the role of wildlife in transmission and/or maintenance of LSD virus is unknown (CFSPH 2017a). Morbidity and mortality can vary considerably depending on the breed of cattle (Gari et al. 2011).

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; WOAH 2013). There is no evidence of sheeppox and goatpox viruses in wildlife, although it cannot be excluded that wild sheep and wild goats can be infected (EFSA Panel on Animal Health and Welfare 2014).

Infection with LSD virus is a WOAH-listed disease of cattle, and sheep pox and goat pox is a WOAH-listed disease of sheep and goats (WOAH 2022d). In Australia, infection with LSD virus and infection with sheeppox virus or goatpox virus are nationally notifiable (DAWE 2020). LSD and sheep pox and goat pox have never occurred in Australia (AHA 2021a).

3.2.2 Technical information

Agent properties

LSD virus and sheeppox and goatpox viruses can remain viable for many months in the environment, especially in dark environmental conditions such as contaminated animal sheds. Sheeppox and goatpox viruses can remain viable in wool for up to 3 months (WOAH 2013). LSD virus can survive in necrotic skin nodules for longer than 33 days, desiccated crusts for up to 35 days and air-dried hides for at least 18 days (WOAH 2017).

The WOAH states that the thermal susceptibility of LSD virus and sheeppox and goatpox viruses is 55°C for 2 hours or 65°C for 30 minutes, and 56°C for 2 hours or 65°C for 30 minutes, respectively (WOAH 2013, 2017). 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).

Sensitivity of sheeppox and goatpox viruses to heat may differ among strains. Heat treatment of 55°C for 1 hour successfully inactivated a Turkish strain of sheeppox virus but not a Jaipur isolate. A Samalpur isolate of goatpox virus was inactivated by heating to 60°C for 30 minutes; however, heating to 56°C for 1 hour failed to significantly reduce viral titre of Iranian and Egyptian strains of goatpox virus (Rao & Bandyopadhyay 2000).

A 2020 study reported that an LSD virus field strain, LSD virus vaccine strain, goatpox virus field strain, and sheeppox virus vaccine strain were all 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).

LSD virus is most stable between pH 6.6 and 8.6 and there is no reduction in viral titre after 5 days at 37°C within that pH range (Weiss 1968; WOAH 2017).

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).

Epidemiology

The incubation period of LSD ranges from 1 to 4 weeks and can be as early as 4 days in experimentally infected animals (CFSPH 2017a). 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 LSD and sheep pox and goat pox in the Terrestrial Code is 28 days and 21 days, respectively (WOAH 2021c, 2022x).

LSD is a highly infectious transboundary disease. The primary mode of transmission of LSD virus is mechanical through biting arthropod vectors such as mosquitoes *Aedes aegypti*, *Anopheles stephensi* and *Culex quinquefasciatus*, the stable fly *Stomoxys calcitrans* and the biting midge *Culicoides nubeculosus*. The virus does not replicate in these arthropods (Klement 2018; Tuppurainen et al. 2013b). Frequency of disease is higher in warm and humid weather conditions when there are high population densities of biting arthropods (Machado et al. 2019).

Ticks are also competent vectors of LSD virus and may act as reservoirs. Transstadial and mechanical transmission have been demonstrated in several species of ticks including *Amblyomma hebraeum* and *Rhipicephalus appendiculatus*, and transovarial transmission has been shown in *R. decoloratus* ticks (Lubinga et al. 2015; Lubinga et al. 2013; Tuppurainen et al. 2013b; Tuppurainen et al. 2013a). However, an understanding of the role of ticks in transmission of the virus requires further investigation (Klement 2018).

Transmission of LSD virus through direct or indirect contact in the absence of vectors is relatively ineffective (Carn & Kitching 1995; Klement 2018; Weiss 1968). Deliberate attempts to infect susceptible animals through direct contact have failed (Carn & Kitching 1995). Indirect transmission is possible, as infected cattle excrete low levels of the virus in saliva and nasal discharge (Babiuk et al. 2008), which may contaminate common feeding or watering sites. In one study, transmission between animals in an insect proof pen was only successful when animals were given a shared drinking trough (Haig 1957), as cited in (Weiss 1968). Results from a 2020 study suggest that recombination of LSD virus could be producing new strains that are more capable of transmission in the absence of vectors (Kononov et al. 2020).

Skin lesions on animals affected by LSD may also shed crusts, which contain virus, into the environment (Tuppurainen 2017). Only 50% of infected animals are likely to develop clinical signs of disease although all animals become viraemic (Tuppurainen et al. 2017). Movement of subclinical viraemic animals into free countries or regions is the main pathway for long-distance dispersal of virus (Sprygin et al 2019).

Movement of infected animals and then direct contact with susceptible animals is the main method 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 (*S. 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

The presence of LSD virus in milk and colostrum from cattle is likely (Davies 1991; EFSA 2006; Scott Williams Consulting Pty Ltd 2017). Although there are no studies which investigate the presence of LSD virus in milk from naturally infected cattle, detection of LSD viral nucleic acid was demonstrated by PCR in 5 out of 10 milk samples collected from diseased buffalo in Egypt. The presence of virus was also detected by PCR in 2 out of 10 samples collected from the bulk milk tanks on the same farms as the diseased buffalo (Sharawi & Abd El-Rahim 2011). The lower number of positive samples in bulk milk tanks compared to samples taken directly from diseased cattle could be due to a decrease in viral titre due to the dilution occurring during milk collection. Cattle suffer from larger numbers of skin nodules than buffalo, which could make contamination of milk from cattle more likely (Sharawi & Abd El-Rahim 2011). This also suggests that the presence of LSD virus in milk from buffaloes is more likely to be due to excretion of virus into milk rather than contamination of milk from skin nodules.

A study investigating the possibility of viral shedding in milk after preventative vaccination in Croatia detected LSD viral genome in the milk of 5 out of 120 cattle (Bedekovic et al. 2018).

There is no experimental evidence that sheeppox and goatpox viruses are present in milk. However, it is generally agreed in the literature that they are present in milk (Bhanuprakash et al. 2006; CFSPH 2017b; Rao & Bandyopadhyay 2000). 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. Infection by ingestion is not regarded as a significant route of transmission for LSD virus or sheeppox and goatpox viruses (EFSA 2006). 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).

Colostrum from cattle vaccinated against LSD virus contains neutralising antibodies, which may reduce the amount of viable virus that is simultaneously present in the colostrum (Agianniotaki et al. 2018). However, there is no experimental evidence that this reduction would be sufficient to prevent LSD infection. In a challenge trial, all lambs that received colostrum from ewes vaccinated with a live attenuated Romanian sheep pox vaccine in Turkey were protected against challenge for the first month of life (Gulyaz 1999).

There are currently no studies available that directly investigate inactivation of capripoxviruses in milk.

Pathogenesis

After biting insects have transmitted LSD virus to the susceptible host, replication occurs in the blood and skin cells. Viraemia is usually detectable after 6 days and lasts for approximately 9 days. LSD virus continues to be shed from nasal, oral and conjunctival secretions for at least a week post viraemia (Babiuk 2018). LSD virus genome has been detected up to 42 days from skin lesions in infected cattle and viral isolation was successful up to 15 days post infection (Babiuk et al. 2008).

Following experimental intradermal infection of sheeppox and goatpox virus in sheep and goats, respectively, 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 of between 1% and 5%, and morbidity rates of between 10% and 20% are expected for LSD in cattle (WOAH 2017). The disease can cause permanent loss of milk production, infertility problems and permanent damage to hides (Leliso, Bari & Chibssa 2021). 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).

A high proportion of animals infected with LSD virus (up to 50%) have subclinical or mild infection but are still viraemic and capable of transmitting the disease via vectors (Osuagwuh et al. 2007; Tuppurainen, Venter & Coetzer 2005; Tuppurainen et al. 2017). Subclinical infections can occur in animals affected by sheeppox and goatpox virus (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 detection of antibodies against LSD virus in milk is possible using commercially available ELISA tests. A commercially available ELISA test for serum and plasma was able to detect antibodies in individual milk and bulk milk from recently vaccinated animals. Of 154 individual milk samples, 38 returned positive results. Antibodies were also detectable through ELISA testing in bulk milk samples; however, sensitivity of the test was reduced compared to the individual milk samples. Sensitivity of

the ELISA test was increased when prevalence of vaccinated cattle was increased in the bulk milk sample (Milovanović et al. 2020).

The use of ELISA tests for serological diagnosis has been validated by the WOAH for LSD virus but not for sheeppox and goatpox viruses (WOAH 2022r, y). 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. 2017; WOAH 2022r, y).

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

Control
Vaccines are commercially available for LSD. Vaccination may be used for outbreak control or as a preventative. Vaccination against LSD virus is also used in many countries where the disease is endemic to control the overall disease burden (Tuppurainen et al. 2017). Vaccinated animals can sometimes show clinical signs that resemble mild LSD and vaccine-like LSDV strains have been demonstrated as the cause of an LSD outbreak in Russia (Sprygin et al. ; Tuppurainen et al. 2021). Serological detection of infected animals in control programs is difficult as the antibody response elicited by vaccines cannot be distinguished from natural infection (Tuppurainen et al. 2017).

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. An annual booster of vaccination is recommended by vaccine manufacturers, as the maximum duration of protection is thought to be 22 months (Tuppurainen et al. 2017).

In countries where sheeppox and goatpox viruses are endemic, vaccination is commonly used for disease control. 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 (Madhaven & Kumar 2016).

3.2.3 Current biosecurity measures

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 WOAH requirements for freedom from LSD. 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 LSD and 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; dairy ingredients may only be sourced from, and products containing dairy ingredients manufactured and exported from, countries/zones on the department's LSD-Free Country List (dairy ingredients sourced from bovines) and the department's Sheep Pox and Goat Pox-Free Country List (dairy ingredients sourced from ovines and/or caprines).

The Terrestrial Code recommends risk management for LSD for importation of milk and milk products intended for human consumption (Article 11.9.11.) (WOAH 2021c). These recommendations are that the milk or milk products have been derived from animals in a country/zone free from LSD, 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.

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 2022x).

3.2.4 Conclusion

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

Australia's current import conditions for dairy products for human consumption for LSD are more stringent than the recommendations in the Terrestrial Code. The Terrestrial Code does not include recommendations for dairy products for sheep pox and goat pox. 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 LSD virus and sheeppox and goatpox viruses being present in dairy products imported for human consumption.

- LSD is a highly infectious transboundary disease. It is spread via insect vectors and the movement of infected livestock.
- The prevalence of LSD in affected countries depends on the presence and movement of arthropods, which is affected by synoptic systems, geography and climate. 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.
- The geographic distribution of sheep pox and goat pox has remained relatively stable but is widespread and prevalent in countries where the agent occurs.
- Capripoxviruses may be present in milk and colostrum of cattle, buffalo, sheep and goats following natural infection or vaccination.
- After infection, capripoxviruses may be shed from skin lesions for long periods of time – up to 42 days for LSD virus and 64 days for sheeppox and goatpox virus. 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 these animals will be undetected while shedding virus into milk.
- Heat treatments, using parameters equivalent to batch pasteurisation and UHT, have demonstrated they are likely to inactivate capripoxviruses in milk. However, there is no

experimental evidence that heat treatment equivalent to HTST pasteurisation will inactivate capripoxviruses 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 LSD virus entering Australia in bovine dairy products imported for human consumption from a country/zone where the disease agent is present was estimated to be **low**. 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 LSD were domestic and feral cattle and water buffalo.

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 LSD virus and sheeppox and goatpox viruses in dairy products imported for human consumption.

- LSD primarily affects cattle and buffalo. Sheep pox and goat pox 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. Capripoxviruses 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. This is unlikely to result in exposure of susceptible animals to capripoxviruses
  - 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 capripoxviruses
  - product was fed directly to animals, such as feeding milk powder to hand-reared animals. This could result in exposure of susceptible animals to capripoxviruses.

Conclusion: Based on these considerations, the likelihood of susceptible animals being exposed to LSD virus in bovine dairy products imported for human consumption was estimated to be **low**. 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 LSD virus was estimated to be low. The likelihood of exposure of LSD virus was estimated to be low. Using Figure 2, the likelihood of entry and exposure for LSD virus was estimated to be **very low**.

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 LSD virus and 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 capripoxviruses would be present in sufficient amounts in contaminated milk to cause infection.
- Transmission of LSD virus is primarily via biting arthropod vectors. Spread of disease is usually influenced by synoptic systems, geography and climate. The virus could spread quickly and be difficult to control in a country or region that has an abundance of competent vectors and favourable conditions for vector survival, such as Australia.
- 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 LSD and 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 LSD virus associated with the identified outbreak scenario was estimated to be **moderate**; and 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 LSD virus and 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 1% and 5% are expected for LSD.
- 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 introduced and younger animals.
- Animals affected by LSD may have permanent loss of milk production, infertility problems and permanent damage to hides.

- 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:

- LSD and 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 LSD was identified in Australia, the response strategy as outlined in the AUSVETPLAN disease strategy manual for LSD 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, control of vectors, tracing and surveillance, zoning and/or compartmentalisation, vaccination if available, and an awareness campaign (AHA 2022).
- LSD 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).
- 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 LSD or 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 LSD and 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 LSD or 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.
- Under WOAH, freedom for LSD can only be claimed after a minimum of 14 months following the stamping out of the last vaccinated or infected animal (WOAH 2021c).
- In 2021, Australian beef and sheepmeat exports were valued at $9.2 billion and $4 billion respectively (MLA 2022).
- Over the 2020-21 financial year, Australian dairy product exports was valued at $3.3 billion and Australian wool exports were valued at $3.6 billion (Dairy Australia 2021; DAFF 2022).
- If LSD or 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 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 LSD or 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 LSD 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.

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

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

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 LSD virus 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.

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

At the time of this draft review studies regarding the effectiveness of HTST pasteurisation at inactivating LSD virus in milk are being undertaken. The results of these studies will potentially affect the proposed risk management measures for LSD virus.

This section describes the various risk management options for LSD virus and 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 LSD virus and 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 bovine origin or 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 LSD-Free Country List and the department's Sheep Pox and Goat Pox-Free Country List, respectively.

Alternatively, to manage the risk of LSD virus and sheeppox and goatpox viruses associated with the importation of dairy products (except for cheese) using dairy ingredients sourced from animals in countries/zones not on the department's LSD-Free Country List (dairy ingredients of bovine origin) and not on the department's Sheep Pox and Goat Pox-Free Country List (for dairy ingredients of ovine and/or caprine origin), 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 LSD virus and sheeppox and goatpox viruses associated with the importation of dairy products (except for cheese) manufactured in and/or exported from countries/zones not on the department's LSD-Free Country List (dairy products of bovine origin) and not on the department's Sheep Pox and Goat Pox-Free Country List (dairy products of ovine and/or caprine origin), 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 LSD virus and sheeppox and goatpox viruses associated with the importation of dairy products (except for cheese) that have been stored or transhipped via countries/zones not on the department's LSD-Free Country List or the department's Sheep Pox and Goat Pox-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 LSD-Free Country List (dairy products of bovine origin) and on the department's Sheep Pox and Goat Pox-Free Country List (dairy products of ovine and/or caprine origin), 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 LSD-Free Country List (dairy products of bovine origin) and not on the department's Sheep Pox and Goat Pox-Free Country List (dairy products of ovine and/or caprine origin) 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 LSD virus and 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 LSD virus and 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.

3.3 Peste des petits ruminants virus

3.3.1 Background

Peste des petits ruminants virus (species *Small ruminant morbillivirus*; genus *Morbillivirus*; family *Paramyxoviridae*) is the cause of peste des petitis 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 WOAH-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 WOAH as the next target for global eradication by 2030 (Clarke et al. 2018; WOAH 2022u).

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 WOAH 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 WOAH-listed disease of sheep and goats (WOAH 2022d). The WOAH maintains a list of member countries/zones that are officially recognised as free from PPR. Australia is officially recognised by the WOAH as free from PPR (WOAH 2022q). In Australia, infection with PPR virus is nationally notifiable (DAWE 2020). PPR has never occurred in Australia (AHA 2021a).

3.3.2 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; WOAH 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 10^5 reduction within seconds at 70°C, and around a 10^6 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 2022p). 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).

3.3.3 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 WOAH 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 2022o) 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 WOAH for the inactivation of FMD virus 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.).

3.3.4 Conclusion

PPR is not present in Australia and is a nationally notifiable and WOAH-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.

3.3.5 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.

3.3.6 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.

3.4 Scrapie protease-resistant prion protein

3.4.1 Background

Scrapie protease-resistant prion protein (PrP^{Sc})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; WOAH 2022w). PrP^{Sc} is a misfolded isoform of the cellular prion protein (PrP^{c}) 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 WOAH-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 2022v). 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 (Detwiler & Baylis 2003) (CABI 2019b). 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 WOAH-listed disease of sheep and goats (WOAH 2022d). In Australia, scrapie is nationally notifiable and classical scrapie has not occurred since 1952 (AHA 2019a; DAWE 2020).

3.4.2 Technical information

Agent properties

PrP^{Sc} 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^{Sc} 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^{Sc} 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 2022v).

The long incubation period between exposure and clinical disease may allow infected animals to shed PrP^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} in milk at least 20 months before showing clinical signs of disease (Maddison et al. 2009). PrP^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} (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 2022w). 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^{Sc} in fluids, including milk. In this test, PrP^{C} is added to the substrate, which can convert and amplify minute amounts of PrP^{Sc} 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^{Sc} 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 2022w).

Failure to detect PrP^{Sc} 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^{Sc} (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^{Sc} 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).

3.4.3 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 scrapie for importation of milk and milk products of sheep or goat origin from countries/zones not considered free from scrapie intended for use in feeding of sheep and goats (Article 14.8.10.) (WOAH 2022v).These recommendations are that the milk and milk products come from scrapie-free establishments (as described in Article 14.8.5.).

3.4.4 Conclusion

Scrapie is not present in Australia and is a nationally notifiable and WOAH-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^{Sc} can be present in milk of infected animals and may be transmissible in dairy products. 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 PrP^{Sc} 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^{Sc} 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^{Sc} in milk and colostrum would not be inactivated by HTST pasteurisation or any other milk processing technique.
- PrP^{Sc} is highly stable outside of the host. If present in dairy products, PrP^{Sc} would be expected to survive storage and transport.

Conclusion: Based on these considerations, the likelihood of PrP^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} is highly stable outside of the host. PrP^{Sc} 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 distributer/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^{Sc}
- 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^{Sc}
- 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^{Sc}.

Conclusion: Based on these considerations, the likelihood of susceptible animals being exposed to PrP^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} 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^{Sc}.
- 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^{Sc} long before clinical signs of disease occur, and clinical signs of scrapie may not be evident until several years after infection.
- Transmission of PrP^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} 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 WOAH 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^{Sc} 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^{Sc} 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^{Sc} 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^{Sc} was estimated to be **low**.

Conclusion

The unrestricted risk of PrP^{Sc} 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^{Sc} 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.

3.4.6 Risk management measures

This section describes risk management for PrP^{Sc} 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^{Sc} , risk management measures are required to reduce the likelihood of young sheep and goats being exposed to PrP^{Sc} 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^{Sc} in milk. Ingestion of only a small volume of colostrum may result in infection. As such, the risk of PrP^{Sc} 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^{Sc}, 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.

3.5 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'Anunciação 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 et al. 2017a). 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 WOAH-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 et al. 2009b; 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'Anunciação 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 et al. 2009a; D'Anunciação 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 (10^7 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 et al. 2017b). 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 et al. 2009b). 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 et al. 2009b; D'Anunciação et al. 2012).

Presence in milk

First reported in 2009, the presence of vaccinia virus in milk has been confirmed by multiple studies (Abrahão et al. 2009a). Vaccinia virus DNA has been detected in milk collected from teats absent of lesions as well as from animals with no clinical signs (Rehfeld et al. 2017b). 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 et al. 2017a).

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 et al. 2017a).

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 et al. 2017b; 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 WOAH 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 WOAH-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 distributer/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 perifocal 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 WOAH-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 for imported dairy products

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 apply to all imported dairy products including to ensure food safety and compliance with the dairy standard. These risk management measures include:

- milk is sourced only from healthy animals
- documented food safety programs for dairy primary production, collection, transportation and processing are implemented
- all the facilities involved in manufacture have current approval for the relevant operations from the competent authority of the country where manufacture occurred.

For all dairy products (except for cheese), one of the following options for heat treatment must be 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 FMD virus, which requires additional risk management measures to achieve Australia's ALOP.

4.2 Disease agent-specific animal biosecurity measures

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

4.2.1 Foot-and-mouth disease virus

Animal biosecurity measures for FMD virus 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 transhipment 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 transhipment and storage.

4.2.2 Lumpy skin disease virus

Animal biosecurity measures for LSD virus apply only to dairy products (except for cheese) containing dairy ingredients of bovine origin.

Country/zone of origin
Either the country/zone is on the department's LSD-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 LSD-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 transhipment en route to Australia
Either the country/zone is on the department's LSD-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 transhipment and storage.

Specific requirements for lumpy skin disease 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 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 transhipment 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 transhipment 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.

4.2.4 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 transhipment 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 transhipment 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 and the department's LSD-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 of the facilities involved in manufacture have current approval for the relevant operations from the competent authority of the country/zone where manufacture occurred.
- 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.

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:

- α-lactalbumin
- β-lactoglobulin
- bovine immunoglobulins
- bovine serum albumin
- glycomacropeptide
- lactoferrin
- lactoperoxidase.

A risk assessment was conducted for whey protein fractions (Appendix B). 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 and the department's LSD-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 20, 21 and 22 of the food standards code set out the maximum residue limits and extraneous residue limits for agricultural and veterinary chemicals that are permitted in foods for sale, including imported food.

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 2022s) 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 2022z).

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; WOAH 2022f).

The disease appears to be widespread globally (CABI 2019a). A small number of countries, particularly in Western Europe, are free from disease (EFSA 2015; WOAH 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 WOAH-listed disease of cattle (WOAH 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; WOAH 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* (WOAH 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 (WOAH 2022c).

Brucellosis is prevalent in China, India, the Mediterranean region, Mexico, the Middle East, Peru and Sub-Saharan Africa (WOAH 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 (DoHAC 2022).

Infection with *B. abortus*, *B. melitensis* and *B. suis* is a WOAH-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 WOAH 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; WOAH 2022aa).

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 2022l).

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 (DoHAC 2022).

Enzootic abortion of ewes or ovine chlamydiosis is a WOAH-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; WOAH 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 WOAH-listed disease of multiple species (WOAH 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; WOAH 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 WOAH-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 WOAH-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.

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; WOAH 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 (WOAH 2022aa). 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 (DoHAC 2022).

Infection with *Mycobacterium tuberculosis* complex is a WOAH-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 WOAH 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 WOAH-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 WOAH 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 WOAH-listed disease of multiple species (WOAH 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 WOAH-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 WOAH 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.

FMD virus 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 FMD virus.

For each type of relevant goods, if the restricted risk of FMD virus 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 β lactoglobulin (50 to 55%), α-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. β-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 2021).

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 (α-lactalbumin, β-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 2021). 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 α-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 α-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 FMD virus. In a 1978 study, α-lactalbumin and β-lactoglobulin extracted from infectious sweet whey did not contain viable FMD virus, even by inoculation into steers. In this study, the sweet whey was obtained as a by-product from the manufacture of cheese using pasteurised milk collected from cows inoculated with FMD virus. Membrane separation processes were not used to produce α lactalbumin and β-lactoglobulin, rather separation was performed through precipitation using hydrochloric acid and then solubilized with ammonium hydroxide solution. The authors postulated that FMD virus was successfully inactivated due to the final product containing negligible fat and casein, which, if present, protect the virus from inactivation. It was also thought that the use of continuous heating, precipitation and solubilisation at pH extremes facilitated FMD virus inactivation (Blackwell 1978).

Risk assessment and risk management

If FMD virus 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. FMD virus 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 FMD virus and likelihood of susceptible animals being exposed to and consuming an infectious dose of FMD virus. This is due to the processing involved in the manufacture of these products.

The likelihood of FMD virus entering Australia in imported whey protein fractions for human consumption was estimated to be very low. The likelihood of susceptible animals being exposed to FMD virus, 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 counties that are recognised by the department as free from FMD, this would further reduce the likelihood of entry of FMD virus and likelihood of susceptible animals being exposed to and consuming an infectious dose of FMD virus, due to the lower proportion of whey protein fractions per unit volume entering and potentially being consumed by susceptible animals.

The likelihood of FMD virus entering Australia in such goods was estimated to be extremely low. The likelihood of susceptible animals being exposed to FMD virus, 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:

- α-lactalbumin
- β-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 (*Bos taurus*) and domestic water buffalo (*Bubalus bubalis*)
BSE	Bovine spongiform encephalopathy
Caprine	Ungulate of the genus Capra. For the purpose of this review limited to domestic goats (*Capra hircus*)
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.
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
EADRA	Emergency Animal Disease Response Agreement
ELISA	Enzyme-linked immunosorbent assay

Term	Definition
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 Ovis. For the purpose of this review limited to domestic sheep (*Ovis aries*).
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).
PPR	Peste des petits ruminants
PrP	Prion protein
PrP^{C}	Normal prion protein
PrP^{Sc}	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.
SPS Agreement	World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

Term	Definition
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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AQIS
Protecting our way of life!

Importation of dairy products into Australia for human consumption

Import Risk Analysis

November 1999

Australian Quarantine and Inspection Service
GPO Box 858
Canberra ACT 2601
AUSTRALIA

Table of contents:

Executive Summary

Under current animal quarantine policy, AQIS permits the importation of dairy products for human consumption under specified conditions. AQIS has reviewed these conditions to ensure that they are consistent with current scientific and technical knowledge.

This import risk analysis (IRA) generally follows the OIE format. AQIS has evaluated potential disease risks and identified risk management strategies appropriate to the sourcing of product from any country.

AQIS has considered all relevant disease agents and has concentrated on those that have the potential to cause serious harm and those for which the risk of transmission via dairy products may be significant. The proposed new import conditions include risk management measures for:

foot and mouth disease
rinderpest
peste des petits ruminants
lumpy skin disease
sheep pox/goat pox
camel pox
buffalo pox
Brucella abortus infection
Brucella melitensis infection
Mycobacterium bovis infection
maedi-visna
Jembrana
contagious caprine pleuropneumonia
contagious agalactia

AQIS proposes to permit the importation of dairy products from OIE recognised FMD-free countries/zones (vaccinating or non-vaccinating), and countries/zones that are free from lumpy skin disease (LSD), sheep pox (SP), goat pox (GP), buffalo pox and camel pox. Moreover, AQIS proposes to permit importation from countries/zones in which FMD and/or these poxviruses are present, subject to individual assessment. Such importations would be permitted provided that the dairy products were manufactured (under specified controls) from raw materials obtained in a country/zone that is free from these viruses, or if they were processed in a manner that would be expected to inactivate them.

In the IRA AQIS has not considered public health issues. Applicants for import permits should ascertain that the imported product would meet Australian food standards under the *Imported Food Control Act (1992)* set out in the *Food Standards Code*.

The final section of the report contains proposed new quarantine conditions for the importation into Australia of dairy products for human consumption.

Abbreviations and Acronyms

AHV	Alcelaphine herpesvirus
ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine and Inspection Service
BT	bluetongue
BTEC	Brucellosis and Tuberculosis Eradication Campaign
CBPP	contagious bovine pleuropneumonia
CCPP	contagious caprine pleuropneumonia
CFR	Code of Federal Regulations
CPE	cytopathic effects
FMD	foot and mouth disease
FMDV	foot and mouth disease virus
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GP	goat pox
HTST	high-temperature short-time pasteurisation
ID_{50}	dose required to infect half the animals in a group
IgG	immunoglobulin G
IRA	Import Risk Analysis
LSD	lumpy skin disease
MV	maedi-visna
NZ	New Zealand
OHV	ovine herpesvirus
OIE	Office International des Epizooties
pH	measure of acidity or alkalinity of a solution
PPR	peste des petits ruminants
RVF	Rift Valley fever
SP	sheep pox
SPS	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
TB	tuberculosis
TBE	tick-borne encephalitis
$TCID_{50}$	median tissue culture infective dose
TFAP	Tuberculosis Freedom Assurance Program
UHT	ultra-high temperature treatment
UK	United Kingdom
USA	United States of America
USDA	United States Department of Agriculture
VS	vesicular stomatitis
WTO	World Trade Organization

Definitions

"Colostrum"	the milk secreted by the udder immediately after parturition and for the following 3-4 days.
"Dairy products"	means milk and milk products.
"Free zone"	means a clearly defined territory within a country in which no case of a disease has been reported during the period stated for such a disease in the OIE Animal Health Code (the Code).
"List A"	means the OIE List of transmissible diseases which have the potential for very serious and rapid spread, irrespective of national borders, which are of serious socio-economic or public health consequence.
"List B"	means the OIE List of transmissible diseases which are considered to be of socio-economic and/or public health importance within countries and which are significant in the international trade of animals and animal products.
"Official Veterinarian"	means a civil service veterinarian or a specially appointed veterinarian, as authorised by the Veterinary Administration of the country.
"Pasteurisation"	- a thermal treatment of milk at: a) 63°C for 30 minutes (holder method), or b)72°C for 15 seconds (high-temperature-short-time or HTST)
"Thermisation"	- heat treatment of milk to 62°C for 15 seconds.
"UHT"	- sterilisation of milk by heating to not less than 135°C for no less than one second.
"Veterinary Administration"	means the Central Veterinary Service having authority in a zone or country for ensuring or supervising the execution of animal health measures.

1. Introduction

This import risk analysis (IRA) concerns the importation of dairy products for human consumption. It does not consider the importation of dairy products for stockfeed or for use as laboratory reagents. For the purpose of this IRA, dairy products are products manufactured from milk obtained from cattle, buffalo, sheep, goats or camels.

1.1 Background

Under existing animal quarantine requirements, imported dairy products must be made from pasteurised milk, or subjected to equivalent heat treatment, to inactivate animal disease agents such as *Brucella abortus* and *Mycobacterium bovis.* Additionally, the conditions are primarily designed to deal with dairy products of bovine origin. Dairy products of ovine and caprine origin are becoming more popular. Additionally, some countries have sought AQIS approval for export to Australia of dairy products manufactured from unpasteurised milk. In November 1997 AQIS commenced a review of quarantine conditions to consider the importation of dairy products not previously permitted for importation.

1.1.1 Legislative requirements

The *Quarantine Act* (1908) provides for the Governor-General to prohibit, by proclamation, the importation of goods, if the importation of those goods into Australia is likely to introduce any pest or disease.

Prior to 1994, the importation of dairy products (except cheese and casein) into Australia was prohibited under Proclamation 88A unless the products were imported from approved countries, i.e. countries that were free from foot and mouth disease (FMD) at the time of introduction of the legislation. To give effect to any changes to the list of approved countries required amendment of the proclamation.

AQIS permitted the importation of cheese and casein from any country provided certain processing requirements were met.

In 1991, AQIS produced a position paper on THE IMPORTATION OF MILK AND MILK PRODUCTS (EXCLUDING CHEESE) FROM COUNTRIES NOT FREE FROM FOOT AND MOUTH DISEASE (FMD). AQIS recommended that, for the export of dairy products to Australia, countries be grouped as follows: FMD-free without vaccination, FMD-free with vaccination, and countries not free from FMD. The importation of dairy products from FMD-affected countries was not approved at that time on the basis of concern at the risk of introducing FMD. AQIS required that dairy products be manufactured from pasteurised milk as viruses and bacteria other than FMD virus had been shown to be inactivated by pasteurisation regimes.

In July 1994 Proclamation 88A was replaced by Proclamation 153A. Under Proclamation 153A, the importation of dairy products required a permit, except for specified exemptions.

AQIS introduced the QUARANTINE REQUIREMENTS FOR THE IMPORTATION OF DAIRY PRODUCTS in August 1994. Under these requirements, AQIS placed countries in one of three categories according to their FMD status and established criteria for the provision of an import permit.

In July 1998 Proclamation 153A was replaced by Quarantine Proclamation 1998, but the conditions under which importation of dairy products was permitted were not changed. Relevant sections of Proclamation 1998 are at appendix IV.

Public health standards are separate from animal quarantine requirements. Under the *Imported Food Control Act* (1992), AQIS is responsible for ensuring that imported foods comply with domestic public health standards, as set out in the *Food Standards Code*.

1.1.2 The international trade framework

As a Member of the World Trade Organization (WTO), Australia has certain rights and obligations under the General Agreement on Tariffs and Trade 1994 (GATT 1994) and the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). Further information on the rights and obligations arising from the SPS Agreement may be found in the publication 'The AQIS Import Risk Analysis Process: A Handbook'**.**

The SPS Agreement identifies the Office International des Epizooties (OIE) as the international organisation responsible for establishing animal health standards, guidelines and recommendations relevant to international trade in animals and their products. Australia is a member of OIE and actively contributes to the process of standards development. The OIE publication relevant to this IRA is the 'International Animal Health Code 1997' (hereinafter referred to as 'the Code'). The principal aim of the Code and its companion volume, the Diagnostic Manual for Animal Diseases and Vaccines, is to facilitate safe international trade in animals and their products. The Code provides detailed definitions of minimum health guarantees to be required of trading partners, in order to minimise the risk of transmission of animal diseases through international trade.

1.2 Description of commercial dairy products

The full range of commercial dairy products marketed may be divided into groups based on the nature of their manufacturing process. A description of the product groups and the more common processing methods is at Appendix I.

1.3 Factors in the establishment of disease

In order to evaluate the quarantine risks potentially associated with an importation, key factors include the probability that viable infectious disease agents will be present in dairy products and the probability that susceptible animals will be exposed to the agent in sufficient amount to establish infection. The following factors are relevant to the probability of infection occurring:

1. Presence of the disease agent in the milk/dairy product relates to:

- presence of the disease agent in the country of origin
- excretion of the disease agent in milk (the disease must be present at a sufficiently high prevalence and/or the agent must be excreted at a sufficiently high level in milk, so that the milk contains a significant amount of the disease agent, relative to the amount of the product that could reasonably be consumed by a susceptible animal).

2. Resistance of the disease agent to processing, and whether the agent will persist and/or multiply in the raw milk or processed dairy product;

    - In this regard, raw milk presents a higher risk than milk that has been thermally treated or treated with a combination of heat and acidulation, depending on the processing temperature/pH attained.

3. Post processing contamination with raw milk or other contaminants could introduce viable disease organisms to manufactured product.

4. The disease organism must be transmissible to susceptible animals per os. In some cases, evidence for the transmission of disease via the ingestion of infected milk may be limited to experimental or anecdotal information while the significance of this route under field conditions remains unclear. In this situation a conservative approach is taken in this IRA.

5. The infected dairy product must be consumed by susceptible animals in Australia. Potential pathways for exposure of domestic animals to imported dairy products include:

    - *Product imported for stock feed*. AQIS does not permit the importation of dairy products for stockfeed from countries other than New Zealand. While such product could be imported illegally, this is unlikely to occur on a commercial scale.
    - *Product enters human food chain, is found to be unfit for human consumption and downgraded to stockfeed.* This contravenes current quarantine legislation. Current import permits for dairy products prohibit their use in stockfeed.
    - *Product imported for human consumption is fed to susceptible animals.* The feeding of unprocessed swill is illegal in Australia. However, household scraps are commonly fed to back yard poultry and in rural areas such material could be accessible to other animals, such as hand-reared piglets and calves. Similarly, imported milk powder could be fed to hand-reared animals.
    - *Product imported for human consumption is disposed of under conditions that make it accessible to free-ranging animals such as wild pigs*. While the management of waste disposal in urban areas is strictly controlled for reasons of environmental and public health, disposal arrangements in rural areas may be relatively poorly controlled. The probability of exposure of free-ranging animals to imported dairy products is probably small, but cannot be dismissed.

Some dairy products are more likely to be consumed by susceptible animals (ie ruminants, pigs) because of physical factors such as form and palatability (eg. calves

are more likely to be fed milk powder than cheese). The dairy products more likely to be incorporated into stock feed include powdered milk, casein, and dairy products imported in bulk and found unfit for human consumption.

AQIS considers that cheese, butter and butter oil are very unlikely to be used to feed ruminants and camelids. Although pigs might find such products palatable, state legislation prohibiting the feeding of unprocessed swill and the relatively high level of awareness of disease risks associated with such practice would greatly reduce the possibility of exposure by this route.

1.4 Country factors

In this context, the country of origin is the country where the animals that produced the milk were domiciled at the time of milk production.

AQIS receives applications to import dairy product from countries affected by FMD. Current conditions preclude the approval of these applications. In some cases, the product subject of the application was manufactured from milk that originated in an FMD-free country.

AQIS has received applications to import dairy product from Malaysia, Hong Kong, Taiwan (dairy based drinks), Middle Eastern countries (butter/ghee), Brazil and Taiwan (bakery products containing milk powder and cheese), Turkey, China, South Africa, and others for approval to import dairy products made from local raw materials and/or milk from Australia, New Zealand and other FMD-free countries. Such applications are evaluated individually. To date only one such product has been approved for importation, ie Thai condensed milk manufactured from milk powder sourced in Australia or New Zealand, at a single approved factory.

1.5 Notes on scientific data

The information considered in the IRA was sourced from available literature or personal communications. In many cases, available data do not relate to organisms in naturally infected, commercially processed milk. For example, heat inactivation data determined using pure, cell-culture derived virus suspended in a buffer may be different from the heat treatment that would inactivate field virus in naturally infected body fluids or tissues. The thermostability of cell-free and cell-bound virus may vary substantially[22,218].

In some cases, data have been derived from review articles and text books, and the original work could not be verified. In other cases the only available information has been for a closely related disease agent. AQIS has treated such data in an appropriately conservative manner.

Units quoted throughout are those used by the original author and, for some foreign language articles, the units are presented as in the original article.

1.6 Public health

The scope of the IRA does not include public health issues. The Australia New Zealand Food Authority has statutory responsibility for the risk categorisation of

imported foods, and for establishing food standards for application within Australia.. Applicants for import permits should ascertain that the imported product would meet Australian public health standards as set out in the *Food Standards Code* and conform with the *Imported Food Control Act* (1992).

2. Hazard Identification

In this IRA AQIS considers the disease agents on OIE lists A and B that affect ruminant animals and other disease agents excreted or likely to occur as a contaminant in milk. Of these disease agents, AQIS has excluded from further consideration:

. agents that are endemic in Australia and not the subject of official control

. those not transmitted via milk

Criteria for hazard identification.

Table 1. Organisms considered to be a quarantine hazard in dairy products.

Disease agent	Susceptible species	Route of transmission	Australia's Status
List A diseases of ruminants			
Foot and mouth disease virus.	Cattle, pigs, sheep, goats.	Direct contact, aerosols, fomites, raw milk. Excretion in milk well documented.	Free
Rinderpest virus	Cattle, pigs; to a lesser extent, sheep and goats	Direct contact with sick animals. High level of viraemia, virus detectable in all body secretions.	Free
Peste des petits ruminants virus	Sheep, goats	Close contact with animals, inhalation of aerosols. High level of viraemia, virus in most body secretions.	Free
Lumpy skin disease virus	Cattle, sheep can be infected experimentally	Insects, mechanical spread by instruments. High level of viraemia, virus in most body secretions.	Free
Sheep pox and goat pox viruses	Sheep, goats	Infection mainly through aerosols and skin abrasions. Possibly also mechanical transmission by arthropods. High level of viraemia, virus in most body secretions.	Free
List B Diseases - cattle			
Brucella abortus	Cattle, man, pigs	Transmitted via ingestion, skin, conjunctiva, the source of infection being uterine discharges, placenta and milk or colostrum.	Free
Mycobacterium bovis.	Cattle, deer, camels, man, pigs; to a lesser extent, dogs, cats, sheep, goats, fauna.	Transmitted chiefly by inhalation. Ingestion of contaminated milk is the source of infection in calves, pigs and humans.	Free

Disease agent	Susceptible species	Route of transmission	Australia's Status
List B diseases - sheep and goats			
Brucella melitensis	Sheep, goats, man, camels and occasionally cattle.	Placental contamination of pasture, milk, intrauterine.	Free
Mycoplasma agalactiae and other *Mycoplasma* spp. associated with contagious agalactia.	Goats, sheep	Milk, urine, lacrimal secretions are all sources of the organism.	Free
Maedi-visna virus	Sheep, goats	Mostly via colostrum and milk, also respiratory route.	Free
Mycoplasma mycoides subsp. *mycoides* associated with contagious caprine pleuropneumonia.	Goats	Transmission via respiratory route.	Free
Diseases not listed by the OIE the agents of which may be excreted in milk			
Buffalo pox	Water buffalo and cattle	Pustular lesions occur on teats and udders of milking buffaloes. Virus present in scab material. Occasionally causes severe systemic disease.	Free
Camel pox	Camelids	Transmission by contact. Virus present in scab material. Also frequently shed in lacrimal secretions and via the respiratory and digestive route. Young camels may develop generalised disease. Scabs may contaminate milk.	Free
Jembrana virus	Cattle	Possibly mechanical transmission by arthropods. Close contact between cattle appears necessary for spread. Excretion in milk has been demonstrated	Free

Table 2. Organisms that are not considered to be a quarantine hazard in dairy products.

List A diseases of ruminants			
Vesicular stomatitis virus[1]	Cattle, pigs, horses, some deer.	Insects, mechanical transmission through milking machines. Some textbooks refer to excretion in milk.	Free
Mycoplasma mycoides subsp. *mycoides* (cattle strain)[2]	Cattle	Spread by inhalation of droplets from infected, coughing animals. Fomite transmission possible.	Free

[1] Whilst Blaha (1988) and Hanson (1988) referred to the possibility of virus being excreted in milk, an extensive search of the literature revealed no original account of this or of transmission through milk. In 1990 a review attributed to Hanson and McMillan did not give milk as a means of transmission of VSV.[74,76,190,268,269,270]

[2] Infection is normally via the inhalation of infected droplets; deliberate attempts to infect cattle per os have failed.[23,72,183,190,208,242]

Disease agent	Susceptible species	Route of transmission	Australia's Status
Rift Valley fever virus[3]	Multiple species, including humans	Insect spread. Humans may contract disease from handling infectious tissues. Some reports of excretion in milk.	Free
Bluetongue virus	Clinical in sheep, cattle have non-clinical infections	Insect spread. Not contagious.	Clinical BT in sheep not present.
List B Diseases			
Bacillus anthracis	Multiple species, including humans	Ingestion, inhalation of spores from the environment. Not known to be transmitted by dairy products.	Present in Australia, official control program in all states, but does not include controls on dairy products
Aujeszky's disease virus	Pigs are the main host, cattle secondary host.	Transmission via the milk of ruminant animals has not been put forward as a normal means of transmission(169).Infected pigs are the most important source of infection.	Free
Echinococcus spp.	Sheep, goats, cattle, horses (dogs are primary hosts)	Animals are infected by ingestion from pastures contaminated by infected dogs. Not infectious.	Present in Australia, official control program in some states.
Leptospira interrogans serovar. *canicola*[4]	Chiefly infects dogs, rodents and man.	Infection via skin or ingestion. Source of organisms, water contaminated with the urine of infected animals. May be transmitted through semen. Ruminants are not considered to be an important source of infection.	Free from *L. i. canicola*
Coxiella burnetti	Sheep, goats, cattle, humans	Transmitted by ticks. Also transmitted to people through handling tissue of infected animals, or milk.	Endemic. Control programs in high risk occupations for humans only.
Rabies virus	Multiple species, zoonosis.	Transmitted through the saliva of infected animals entering breaks in the skin of susceptible animals/people. Reports of milk borne transmission are rare and anecdotal.	Free
Mycobacterium paratuberculosis[5]	Cattle, sheep, goats, camelids, camels, suspect zoonosis.	Ingestion of faecal material, intrauterine transmission, milk or colostrum are all means of transmission.	Present in Australia, official control programs in all states.
Cowdria ruminantium	Cattle, sheep, goats	Tick-borne rickettsia, not naturally transmitted via milk.	Free

[3] A literature search has revealed one case of circumstantial evidence suggesting transmission to humans through milk. Milk is not considered to be a means of transmission of RVF virus.(23,72,76,277,280,283)

[4] The dog is considered to be the main vector of *L. i. canicola*. Ruminants are not considered to be an important source of this organism. (271)

[5] Whilst some States in Australia claim freedom from paratuberculosis, there are no restrictions on the interstate movement of dairy products for the control of this agent.

Disease agent	Susceptible species	Route of transmission	Australia's Status
Chrysomyia bezziana and *Callitroga hominivorax (Cochliomyia)*	Multiple species	Deposition of eggs by adult fly. Not infectious.	Free
Campylobacter foetus	Cattle	Transmitted venereally, not through milk.	Endemic.
Enzootic bovine leucosis virus	Cattle	Transmitted from dam to young through milk, colostrum, placenta	Endemic[181]. No restrictions on the interstate movement of dairy products within Australia for the control of enzootic bovine leucosis virus.
Infectious bovine rhinotracheitis - infectious pustular vulvovaginitis virus	Cattle, goats, pigs, buffalo.	Aerosol spread, associated with herding cattle together.	Endemic, no controls in dairy products for this agent within Australia
Trichomonas foetus	Cattle	Venereally spread.	Endemic, no controls in dairy products within Australia for this agent.
T. brucei, *T. vivax* and *T. congolense* in Africa, *T. cruzi* in the Americas.	Many species, including cattle, sheep, goats, man.	Spread by insects. Parasites must undergo a part of their life cycle in biting flies.	Free
Anaplasma spp.	Cattle. *A. marginale* is the most pathogenic	Protozoan blood parasite. Spread by ticks, parasite undergoing part of its life cycle in the tick.	Present in Australia.
Babesia bigemina and *B. bovis*	Cattle	Protozoan blood parasite. Spread by ticks, parasite undergoing part of its life cycle in the tick.	Present in Australia.
Cysticercus bovis	Life cycle through cattle and man	Spread to cattle grazing pastures contaminated with human faeces. Not transmitted through milk.	Present in Australia.
Dermatophilus congolensis	Multiple species	Spread by contact of organism with broken skin.	Endemic
T. parva parva	Protozoan blood parasite of cattle	Spread by ticks, undergoes part of life cycle in ticks.	Free
Pasteurella multocida (Asian strain, serotype B and African form serotype E.[6]	Clinical syndrome is haemorrhagic septicaemia, seen in cattle	Intranasal route believed to be normal mode of transmission.	Free

[6] Shedding of bacteria in the milk is said to occur in the terminal stages of the disease, while other authors do not mention milk as a means of transmission. The agent is unlikely to be in the milk of animals producing milk for human consumption.[23,72,76, 249]

Disease agent	Susceptible species	Route of transmission	Australia's Status
Malignant catarrhal fever virus (two forms of herpesvirus, AHV-1 derived from wildebeest and OHV-2 derived from sheep)	Cattle and wildebeest	Close contact, respiratory route. the literature does not suggest that the virus is transmitted through milk.	Present in Australia.
Bovine spongiform encephalopathy agent[7]	Cattle	Believed to be transmitted by ingestion of feedstuffs containing tissues from diseased animals. Milk is not believed to transmit the infectious agent.	Free
Caprine arthritis and encephalitis virus	Goats	Colostrum, milk, respiratory routes of transmission	Endemic, no interstate controls on dairy products for this virus.
Brucella ovis	Sheep	Mostly venereal transmission.	Endemic
Chlamydia psittaci associated with enzootic abortion of ewes.[8]	Sheep, occasionally cattle and other species, humans susceptible.	Ingestion of pasture contaminated with faeces, urine and uterine secretions. Some references mention milk as a source of infection.	Free
Nairobi sheep disease virus.	Sheep, goats	Ticks are believed to be the sole means of transmission(23)	Free
Salmonella abortusovis	Sheep, goats	Excreted in faeces, infection via oral route, often predisposed by stress(285,286,287,288).	One human case reported in Australia. No reports from livestock.
Jaagsiekte virus, agent of pulmonary adenomatosis[9]	Sheep	Close contact between live animals.	Free
Scrapie agent	Sheep, goats	Close contact between live animals, possibly also transplacental transmission.	Free
Diseases not listed by the OIE whose agents may be excreted in milk			
Bovine immunodeficiency virus[10]	Cattle	Colostrum and milk .	Endemic

[7] A review of literature by the OIE (1998) concluded that BSE and Scrapie are not transmitted via milk.(220,292)

[8] Some references mention milk as a source of infection, but experimental transmission through milk has not been demonstrated.(76,180,202,205)

[9] Several retroviruses are excreted in milk, however JSRV has not been shown to be excreted in milk.(232,243,250,251)

[10] Endemic in Australia, no restrictions on dairy products in Australia for the control of this disease.

Disease agent	Susceptible species	Route of transmission	Australia's Status
Louping ill virus[11]	Sheep, less frequently cattle, other species and man	Mainly by tick (*Ixodes ricinus)* also excretion and transmission via milk has been demonstrated.	Free
Tick-borne encephalitis virus[12]	Multiple species	Outbreaks generally associated with tick infestations. Transmission via milk to humans is known to occur.	Free
Bovine virus diarrhoea/ mucosal disease virus[13]	Cattle, (border disease in sheep)	The presence of persistently infected carriers is commonly accepted as the main source of infection. Vertical and horizontal transmission occur. Vaccines made using contaminated foetal calf serum may be a source of infection. Secretion in the milk has been demonstrated.	Endemic, with the exception of one virulent strain.
Wesselsbron virus	Sheep, man	Spread by mosquitos	Free

[11] Virus has been found in the milk of experimentally infected goats and sheep. (206,207). Louping ill is said by to be transmitted by *Ixodes ricinus* only, which is not present in Australia(216,289,290). Not considered to be a risk with the importation of dairy products.

[12] TBE appears to be more pathogenic to humans than to animals. Domestic animals are referred to as indicator hosts, tend to have short term viraemias and are not maintenance hosts for TBE virus. Cases of TBE in humans have been associated with the consumption of raw milk, although some evidence is circumstantial. Ticks are the main source of infection.(72,214) (215,219,247). TBE is not considered to be a hazard with the importation of dairy products.

[13] The virus is excreted in all body secretions, including milk, however this is not considered to be an established mode of transmission(76, 291). Direct contact between persistently viraemic animals and susceptible animals, or transplacental transmission are the most common means of spread of the virus(76, 291). About 1% of cows in a herd are persistently infected, and the virus excreted in their milk, when pooled with milk from the remainder of the herd could be neutralised by antibody produced by her herdmates.(282, 284) Imported dairy product is more likely to be fed to calves than pregnant animals. Infection in calves would be self limiting. (23,76,158,224,225,282) Control programs centre around the detection and removal of persistently infected animals.(281)

3. Risk Assessment

3.1 Foot and mouth disease virus

Foot and mouth disease (FMD) is caused by a virus of the genus *Aphthovirus* within the family Picornaviridae. Seven serotypes have been identified. Antigenic variation occurs within a type as a continuous process of antigenic drift without clear-cut demarcations between subtypes.

FMD occurs in most countries of Asia (excluding the Republic of Korea, Japan and Indonesia), some parts of Eastern Europe, Russia and the former soviet republics, the Middle East, Africa, and parts of Central and South America.

The last occurrence of FMD in Australia was in 1872.

Cattle (including buffalo) and pigs are the most susceptible species. Deer, sheep and goats are also susceptible. FMD virus is perpetuated by ruminants, mainly cattle and sheep, but pigs act as amplifiers because they are easily infected by the oral route and excrete high levels of virus in the aerosols of expired air[1,21,252].

a) Transmission of the disease agent and its potential to be present in milk

FMDV is known to be excreted in the milk, and this may occur before clinical signs of disease[42]. High titres of virus have been detected in milk from dairies before the disease was suspected or diagnosed [4]. Virus may appear in the milk on the fourth day following exposure and excretion of virus may continue for a further four days before clinical signs of the disease appear[5].

Milk has been associated with the spread of FMD. The feeding of raw infected milk to susceptible animals is a recognised means of transmission.[3,14,15]

The species and route of entry of the virus markedly influence the infectious dose required to produce the disease. For example, the lowest infectious dose for cattle by the intranasal route is taken to be $10^{1.0}$ ID_{50}, and the infectious dose by the oral route for cattle is of the order of 10^6 ID_{50}, and for pigs of the order of $10^4 ID_{50}$, the latter using a pig adapted strain[6].

Vaccination does not prevent infection, but in vaccinated animals the course of the disease is mild, if not sub-clinical, and the infected animals are less likely to excrete infectious amounts of virus[253,254,258,260,263]. De Leeuw[173] demonstrated that milk from vaccinated cows that had been challenged with virulent FMDV failed to infect pigs (oral administration) or steers (injected). In a 1981 review, Wegen[256] suggested that regularly vaccinated cattle are unlikely to excrete FMD virus in milk, and if the virus did get into the milk, it would be in small quantities that would probably be destroyed by ordinary pasteurisation. There is also evidence to suggest that antibodies in milk from vaccinated cows have the effect of inactivating FMD virus, and that bulk milk from regularly vaccinated animals is highly unlikely to contain live virus[257].

b) Survivability/inactivation of the agent in dairy products.

FMDV has been shown to survive in whole milk heated at 72°C for 5 minutes[11,17], but to be inactivated when held at 148°C for 2-3 seconds or longer[12, 13]. FMDV is inactivated more rapidly at pH 6.7 than at pH 7.6 [16]. Milk from an infected cow would have a pH above 7, and this factor would contribute to virus stability during pasteurisation. The actual pH of milk at the time of pasteurisation at the processing plant however, would depend on the dilution factor that comes from the pooling of milk from other farms.

It has been shown that FMDV is rapidly inactivated at pH 4 or less.[16] Few dairy products attain a pH less than 4.6.

Research has shown that the virus receives some protection from milk fat, and it survives up to 93°C for 15 seconds in cream, and in buttermilk and butter derived from cream thus treated[8,11,35,46]. FMDV has been shown to survive in whole milk evaporated by a process of first heating at 72°C for 3 minutes, then evaporating to 50% of its original volume at 65°C under 60 cm mercury vacuum for 1 hour[11]. When skim milk was subjected to the same process, the virus was inactivated[11].

Although it has been frequently stated that FMDV can live for many months (years) in powdered milk, this statement appears to stem from work published by Nikitin[174] in 1965 in which unpasteurised milk from infected cows was used. The drying process used in these trials is not clear from the paper but did not appear to be modelled on any commercial drying process. We were unable to find any accounts of more recent research on the stability of FMD virus in powdered milk, however experiments have been conducted on dried casein and sodium caseinate[7,36]. It is likely that pasteurisation followed by the high heat of the modern spray drying process would inactivate FMDV.

Blackwell, heating milk at 67°C for 1 minute, 15 seconds and 10 seconds, prior to making cheddar cheese showed that cattle could not be infected by the cheese once the cheese is 30 days of age. In Camembert cheese (pasteurisation at 72°C for 16 secs) the virus survived 21 but not for 35 days. In Mozzarella cheese (pasteurisation at 72°C for 16 secs, followed by a further heat treatment during manufacture up to 85° C), the virus could not be detected[18]. FMDV in cheddar cheese made from unpasteurised milk did not survive longer than 4 months. [58,18].

Detection of virus in the studies by Blackwell, Cunliffe, Bohm and their co-workers was by means of multiple intradermal tongue inoculations into cattle. It has been postulated that the procedure may have detected naked RNA rather than intact virions[17]. Feeding trials were not conducted.

Donaldson[14], having regard to the degree of reduction in infectivity by pasteurisation and the dilution effect from non-infected animals/herds, examined the risk of spreading FMD through milk if animals were exposed to raw or treated milk. He examined the likelihood of infective doses being present in pooled, pasteurised milk. He concluded that the greatest hazard is likely to be in the early stages of an outbreak, before disease control measures have been implemented; that infective raw milk can play an important part in the spread of FMD during outbreaks; and that the risk of spread by pasteurised milk or dairy products made from pasteurised milk is very low.

The Danish experience during the 1982 outbreak of FMD showed that milk from infected areas could safely be fed to animals after it had been treated by heating the

raw milk (72°C for 15 sec), processing (production of whey etc), a further heat treatment (80°C for 3 sec) and acidification to pH below 4.5. No outbreak was related to the feeding of animals with milk treated in this way, and it was estimated that some 18 million kilos of milk were fed to domestic animals on the Island of Funen during the epizootic[15].

c) Likelihood of introduction of disease agent with imported dairy product

Milk from infected animals not heat treated in a manner to destroy the virus poses a risk of introduction of the disease agent. If the milk is heat treated in a manner to destroy the virus, and post processing contamination does not occur, the risk is minimised.

Milk from countries that are free from FMD presents a negligible risk of introducing FMDV.

d) Likelihood of disease establishment in Australia following introduction of agent

Susceptible animals are present in a wide range of Australian habitats. Farming enterprises vary from extensive grazing situations to high density grazing enterprises such as dairy farming, and concentrations of animals in feed lots and piggeries.

Feral pigs, cattle, buffalo and goats are well established in parts of Australia. The spread of an outbreak into these populations would have most serious consequences because of the difficulty in detecting and eliminating foci of infection[1].

The pathways by which these animals may be exposed to imported dairy product are discussed in Section 1.3

The highly infectious nature of FMD makes it likely that if one susceptible animal became infected, the disease would spread rapidly to others.

e) Consequences of agent introduction and disease establishment in Australia.

The economic effects of an outbreak of foot and mouth disease in Australia, even on a small scale, would be enormous to individuals, the farming industry as a whole and subsidiary and support industries. The potential cost has been estimated at 3.5% of GDP and 0.6% in aggregate employment for the first year, equating to a one percentage point increase in unemployment[1]. The loss of export earnings in the first year was estimated in 1991 at $2000 million. Markets would be closed to Australian exports for cloven-hoofed animals and their products. The export of grain and other feedstuffs would also be affected[1].

f) Conclusions

Any incursion of FMD in Australia would be likely to have serious and extensive consequences that would impact widely throughout the economy.

FMD virus is excreted in milk of infected animals. Excretion in milk occurs during the prodromal period, i.e. before the development of vesicles.

The risk of FMD virus being present in the milk of cows in a country free from FMD with vaccination is no greater than the risk of virus being present in the milk of cows from a country that is FMD free without vaccination.

FMD virus can be transmitted by ingestion and it is known that the infectious dose by the respiratory route is lower than by the oral route. The infectious dose by mouth is lower for pigs than for cattle.

Normal pasteurisation cannot be relied on to completely inactivate FMD virus.

Heating to 138°C for a minimum of 1 second will inactivate FMD virus in milk. Double pasteurisation, as recommended by the OIE, and required by the EU, are accepted methods of inactivation of FMD virus. Pasteurisation followed by a second equivalent heat treatment and acidulation[15] will inactivate FMD virus.

Cheese making that employs pasteurisation of the milk, followed by acidulation to a pH below 6 and a minimum of 30 days maturing period will inactivate FMDV, and cheese making that employs unpasteurised milk, if it attains a pH of below 6 and is stored at a temperature not less than 2°C for a minimum of 120 days will inactivate FMD virus.

3.2 Rinderpest and peste des petits ruminants viruses

Rinderpest in cattle, and peste des petits ruminants (PPR) in sheep and goats, are diseases caused by a virus of the genus *Morbillivirus* of the family Paramyxoviridae. They are acute, highly contagious diseases characterised by high fever, necrotic stomatitis, diarrhoea and a high mortality[76].

Rinderpest is present in Africa (eastern countries), the Middle East, and South Asia. There has been a single reported outbreak in Australia in 1923[72]. PPR is present in West Africa, the Arabian Peninsula and may also be present in other Middle Eastern countries and India. It has never been reported in Australia.

Rinderpest virus and PPR virus are very closely related genetically, clinically and epidemiologically. They are considered here together to avoid unnecessary duplication of data.

a) Transmission of the disease agent and its potential to be present in milk

Rinderpest.

The ease with which rinderpest spreads naturally varies considerably with the strain of the virus[22]. Cattle and buffalo are especially susceptible, with sheep, goats and pigs less susceptible[23]. Reports of the disease in camels are rare[55]. Experimental studies have induced only subclinical infection in sheep and goats[23].

Following natural exposure, viraemia takes 8-13 days to develop, preceding pyrexia by at least one day[60]. Virus is usually present in the blood 1-2 days before the onset of fever[22]. The prodromal phase, i.e. the time between the onset of pyrexia and the first appearance of mucosal lesions is about 3 days[22]. Virus is present in all secretions, nasal, urine, faeces, vaginal discharges and milk. In recovered animals, virus is said to persist for up to 45 days in milk.[22]. In spite of this, the epidemiological literature reviewed does not point to milk as a likely means of transmission.

Peste des petits ruminants.

The pathogenesis of PPR is similar to that of rinderpest.

Field experiences are that only sheep and goats are susceptible to PPR[23]. Transmission of PPR is predominantly by the inhalation of aerosols derived from nearby animals, or by licking infected animals[23]. The literature reviewed does not point to milk as a likely means of transmission of the virus.

b) Survivability/inactivation of the agent in dairy products

Some information is available on the stability and inactivation of rinderpest and PPR viruses generally, but details specific to dairy products do not appear to be available[176].

Diluted, cultured rinderpest virus has a half life of 3.68 days in a buffer at pH 7.2 at 4°C; the addition of serum increased the half life to 11.5 days[22]. This illustrates the need for caution in extrapolating lability/stability data obtained in one medium to the behaviour of a virus in another medium, e.g. milk.

While rinderpest virus is considered to be easily inactivated, small fractions of tissue culture virus have survived heating to 56°C for 50-60 minutes and 60°C for 30 minutes[22]. Rinderpest virus, in the form of tissue culture supernatant fluid, at pH 7.3 had a greater than 6 $\log_{10}$ reduction within seconds at 70°C, and around a 5 $\log_{10}$ reduction in 30 minutes at 60°C. Virus suspended in tissue culture supernatant fluid was inactivated so rapidly at 75°C that samples taken at zero time produced no cytopathic changes[122].

The virus has been shown to have a half life at 37°C of 3.3 hours[23], at 50°C of 30 minutes[24], and at 56°C of 2.2 minutes. It is considered from this that rinderpest and PPR viruses in milk would be inactivated by pasteurisation.

Dried virus is much more heat resistant than hydrated virus, and the method of drying influences the virus's ability to survive the dehydration process[175].

Both viruses are probably relatively stable at the pH of most common dairy products. High-passage rinderpest virus is relatively stable between pH 4 and 10, but is inactivated within minutes at pH of 2 or 12[122]. Inactivation is exponential. The virulent RGK/1 isolate was more sensitive to low pH, and other isolates have demonstrated varying sensitivity to pH[22]. Peste des petits ruminants virus is sensitive to lipid solvents and low pH. Scott[175] gives the optimal pH for virus survival as 7. PPR virus is stable between pH 5.8 and 9.5, but rapidly inactivated below pH 4.0 or above pH 11.0[23].

The virus can only survive a short period of time in the environment, and restocking of depopulated premises may occur after 30 days[1].

c) Likelihood of introduction of disease agent with imported dairy product

The high level of viraemia in rinderpest and PPR, and the presence of the virus in all body secretions leads to the conclusion that milk from infected animals would likely be contaminated with the virus, either by secretion or external contamination.

AUSVETPLAN considers the introduction of rinderpest virus in animal products unlikely because it survives poorly outside the host[1]. Thus, while contamination of milk in an endemic area may occur, survival of the virus in milk is less likely.

d) Likelihood of disease establishment in Australia following introduction of agent

Spread of rinderpest is almost exclusively by contact between infected and susceptible animals[23]. Infection takes place readily via the upper respiratory tract[22]. Attempts to infect cattle by the oral route have frequently failed, however pigs can easily be infected by the oral route, and it is suggested that the 1923 outbreak in Western Australia may have been transferred to cattle via infected offals fed to pigs.[22].

Rinderpest is considered to be relatively easy to control, and the stamping out policy has been successful in Europe and South Africa[1]. An outbreak in an area where controlling the movement of susceptible animals and products was easy would probably be rapidly arrested. However, AUSVETPLAN does not discount the possibility of the disease becoming endemic if there was an extensive outbreak in the more remote areas of the country.

Vaccination as a means of control would only be considered if the outbreak outstripped the resources available to eradicate it.

e) Consequences of agent introduction and disease establishment in Australia.

In an uncontrolled outbreak of rinderpest in a naive population, mortalities of the order of 90% can be expected. Serious mortality and high morbidity rates could be expected in an outbreak in Australia. The resulting financial losses both at the local level and the loss of export markets would have a serious effect throughout the country. Job losses both on farms and in support industries would occur during a prolonged outbreak. A large outbreak in a dairy area would affect the viability of dairy factories and may result in temporary domestic shortages. Beef exports to the United States and other countries might be lost for an indefinite period. If rinderpest became endemic, permanent loss of some markets could be expected[1].

Peste des petits ruminants would cause high mortalities if an outbreak occurred. An uncontrolled outbreak of PPR would cause serious stock and financial losses in the goat and sheep industries and local communities. In 1993, the value of exports to the Australian sheep industry was $3,837 million. These markets would be affected, the live sheep and goat export markets would be lost, with markets for these animal products also affected. Eradication by stamping out would involve waiting for a six month period after the last case before Australia would be considered free from the disease[1].

f) Conclusions

An outbreak of rinderpest or PPR in this country could have a devastating effect.

Although transmission of rinderpest by the oral route to cattle is unlikely, transmission by this route to pigs occurs readily. For this reason AQIS proposes to impose quarantine restrictions on all dairy products on account of rinderpest.

The host range for PPR is more restricted, pigs not being susceptible to natural infections. Quarantine restrictions for this disease agent will be limited to dairy products that might possibly be fed to sheep or goats.

Pasteurisation would be an appropriate risk management measure for both diseases.

3.3 *Mycoplasma mycoides* subsp. *mycoides* infections of cattle and goats

Mycoplasma mycoides subsp. *mycoides* SC is the strain that causes contagious bovine pleuropneumonia (CBPP)[72], where "SC" stands for "small colony". "LC" which stands for "large colony" is used to describe one of the caprine strains.

In goats, the classical pathology of contagious caprine pleuropneumonia (CCPP) is most likely caused by *Mycoplasma mycoides* strain F-38[23,147,185,259]. However, Geering[72] gives *Mycoplasma capricolum* subsp. *capripneumoniae* as the current name for this agent. The organisms mentioned below are quoted using the name used by the authors. In Coetzer[23] *Mycoplasma mycoides* is still considered as a possible causative agent of CCPP[147] along with F-38. Diagnosis of CCPP is made more difficult because closely related strains of *Mycoplasma* cross react and also cause pleuropneumonia. *Mycoplasma mycoides* strain F-38 causes a disease that is readily contagious to susceptible goats, does not affect sheep or cattle, and has histopathological changes that distinguish it from other *Mycoplasma mycoides* subspecies.

The close relationship of the agents and the clinical and epidemiological similarities of CBPP and CCPP justifies them being considered together.

CBPP was introduced into Australia in 1858, and within forty years had spread throughout the country. Eradication of CBPP from southern Australia had occurred by the 1930s, but it remained endemic in the north, and took until 1973 for Australia to be able to declare itself free from the disease. Since then Australia has remained free from CBPP. North America, South Africa and most of Europe are free from CBPP.

CCPP has never been recorded in Australia. CCPP has not been recorded in North America. South Africa and Western Europe also claim freedom from the disease. It occurs in other parts of Africa, the Middle East, Eastern Europe, Russia and Asia[23]. Economically, it is one of the most important diseases of goats in North Africa[257].

a) Transmission of the disease agent and its potential to be present in milk

The three factors that are of greatest significance in the rate of spread of CBPP are closeness of contact, intensity of infection and the number of susceptible animals[23, 72,183]. Infection is normally via the inhalation of infected droplets[72,183]. Chronic carriers are an important reservoir for infection; when these animals are stressed, localised lesions are reactivated leading to spread of the organisms, however re-activating may not always occur[72,184].

A number of species of mycoplasma are associated with mastitis in cattle and goats, and are excreted in the milk. *M. mycoides* subsp. *mycoides* belonging to the small colony (SC) type has been isolated from the milk of sheep and goats[187,188,189], and Cottew[197] implicates *M. mycoides* subsp. *mycoides* LC in arthritis, mastitis and pneumonia. It is possible that acutely infected lactating animals could excrete infectious organisms in their milk. Despite this, Schneider in Coetzer[23] said that direct contact of susceptible with diseased animals appeared to be essential for transmission. Schneider stated that "*neither ingestion of infected fodder nor direct exposure to diseased organs of animals suffering from CBPP will cause transmission*". This would lead to the conclusion that any transmission of CBPP other than by direct contact would be a rare event.

It is believed that camels play no part in transmission of the *Mycoplasma mycoides* infections.[195].

b) Survivability/inactivation of the agent in dairy products

Mycoplasmas are generally very susceptible to heat and drying, and are killed in a few minutes at 60°C[23,58,78]. The mycoplasmas associated with subclinical mastitis in cows could not survive pasteurisation or the yoghurt manufacturing process[192]. *M. agalactiae* is inactivated by heating of milk at 56°C for 30 minutes[194]. This heat treatment is less than the 63°C for 30 minutes or the equivalent in HTST that is normally used for pasteurisation of milk.

c) Likelihood of introduction of disease agent with imported dairy product

Milk has not played a part in the spread of CBPP. The literature searched did not refer to excretion of *M. mycoides* subsp. *mycoides* SC in milk. There appears to be little risk of introduction of *M. mycoides* subsp. *mycoides* SC in milk.

Whilst the likelihood of transmission of CBPP via dairy products seems remote, the case of CCPP needs to be considered a little more carefully. A number of mycoplasmas closely related to the causal agent have been isolated from the milk of goats, and the risk of transmission of this agent via milk may be greater than the risk of transmitting CBPP via milk (see also the section on contagious agalactia).

d) Likelihood of disease establishment in Australia following introduction of agent

Deliberate attempts to transmit *M. mycoides* subsp. *mycoides* SC to cattle by the oral route have failed, so introduction and establishment of CBPP as a result of importation of dairy products from endemic countries is unlikely to occur.

e) Consequences of agent introduction and disease establishment in Australia.

Very high mortalities have resulted from the initial introduction of CBPP into a number of countries. For example, the 1969 outbreak in Zambia resulted in a 75% morbidity rate and 68% mortality rate in some affected herds[23].

Acute and chronic forms exist, and mortality rates are up to 50% for CBPP and up to 90% for CCPP. Recovered animals are weak, emaciated and chronic carriers of the causal organism[72].

f) Conclusions

There appears to be little risk of transmission of CBPP via milk, and risk management is not warranted for dairy products of bovine, ovine or camel origin for this agent. However, the actual identity of the causative organism(s) of CCPP is still being debated. Some *Mycoplasma mycoides* species have been isolated from milk in goats[187,188,189, 197]. There was no definitive information available on oral transmission of this organism, thus AQIS considers CCPP as an agent of potential quarantine concern.
AQIS proposes to impose quarantine requirements for the importation of ovine/caprine products in relation to CCPP.

3.4 Poxviridae

Lumpy skin disease (LSD), sheep pox and goat pox are caused by viruses of the genus *Capripoxvirus*, whereas camel pox and buffalo pox are caused by viruses of the genus *Orthopoxvirus* [295]. LSD, sheep pox and goat pox viruses are closely related [169]. The host specificity of sheep and goat pox strains is lost when sheep and goats are herded together[169] and cross immunity between sheep and goat pox viruses exists[199].

In Africa, some surveys of buffalo have returned high positive titres to LSD virus, whilst others have shown no evidence of the disease. Domestic buffalo seem to be more susceptible than wild buffalo[51].

Lumpy skin disease (LSD) occurs chiefly in sub-Saharan Africa, and has now spread to Egypt and Madagascar[23,222]. In sub-Saharan Africa it has proved impossible to eradicate[222]. There was an outbreak in Israel in 1989[164]. It has never been recorded in Australia.

Sheep and goat pox viruses are prevalent in the Near and Middle East, India, Bangladesh and North and Central Africa, with occasional incursions into Eastern and Southern European Countries[51, 52]. They have never been recorded in Australia, and the Americas are free.

Buffalo pox virus is seen in India, Egypt, Indonesia [169,293] and Pakistan [23]. It is regarded as the most important viral disease of buffaloes in India[293]. Camel pox is found in Africa and south-western Asia[169]

a) Transmission of the disease agent and its potential to be present in milk

For lumpy skin disease, the incubation period is 4-12 days, followed by pyrexia and anorexia. There are increased secretions from the eyes and nasopharyngeal regions. Lesions develop on the muzzle, larynx and trachea giving rise to persistent dribbling of infected saliva[172]. Lesions also develop on the skin of the body, udder and teats providing a high level of contamination to the environment[178]. Teat lesions suggest the possibility of contamination of milk with LSD virus. LSD virus has been shown to be present in nasal and lacrimal secretions, semen and milk of infected animals[76,178]. Available evidence suggests that LSD may be transmissible to suckling calves through infected milk (Prozesky *pers. comm.*[296]). Despite this, ingestion has not been shown to be a common route of infection.

Insects play a significant role in the spread of lumpy skin disease. Wind borne *Stomoxys calcitrans* have been implicated in transporting the virus over distances greater than 85 Km[164]. Seasonal cycles and periodic epizootics linked to rainfall patterns (and therefore insect activity) are also characteristics of the disease[48,178, 196, 221].

The transmission of sheep pox and goat pox has been demonstrated by aerosol and contact[48,126]. Aerosol transmission requires close contact between a susceptible and infected animal[51]. Infection may take place through skin abrasions[23]. Ingestion is not a common route of infection, although the virus has been shown to be present in nasal and lacrimal secretions, and semen and in milk of infected animals[76,178]. Biting flies, viz. *Stomoxys calcitrans*, have been shown experimentally to transmit capripoxvirus, probably by mechanical transmission, although insects do not seem to

be important epizootically[51,178,186]. *S. calcitrans* remained infective for 3-4 days after feeding on infected material[186].

Epidemics occur as incursions from endemic areas into disease free areas, or as a resurgence of the disease following a period of quiescence and the build up of a susceptible population[196]. Outbreaks of lumpy skin disease are linked to rainfall patterns, heavy rains often being associated with epizootics[221]. Movement of cattle is also associated with spread of the disease[221]. Woods[221] said the spread of the disease outside Africa was possible, but that it is unlikely to be spread by meat or products. However, Davies[222] said that restrictions on cattle movements have not prevented the spread of LSD within affected countries.

Sheep pox lesions are best seen on the bare skin such as under the tail, udder, groin etc. [47,50]. Physical contamination of milk during the milking process is therefore possible, if sick animals were to continue to be milked. In spite of this, infection via milk is of minor importance[23]. and infection per os is not regarded as the normal route of infection in countries where capripoxviruses are endemic.

Camel pox virus has a very restricted host range. Experimental transmission to cattle, buffalo, sheep and goats was unsuccessful[211]. However, camel pox virus is believed to be transmissible to South American camelids.

Buffalo pox virus causes disease in water buffaloes [23,169]. It has also been shown to occur in cattle [294]. Buffalo pox virus causes typical pox lesions on the teats and udders of milking buffaloes and occasionally causes severe systemic disease, particularly in calves [169, 293, 295].

b) Survivability/inactivation of the agent in dairy products

Lumpy skin disease virus is stable in the environment, and can retain infectivity for up to 33 days in dried skin lesions[166]. It is stable between pH 6.6 and 8.6, and shows no significant reduction in titre after 5 days at 37°C within the pH range mentioned[23,166]. It is readily inactivated by the detergent sodium-dodecyl-sulphate, and is chloroform and ether sensitive[166].

Ferreira[165], using sheep pox virus suspended in a buffer with an initial concentration of 8 $\log_{10}$ TCID50/ml, found that at 45°C there was a reduction of 2.3 $\log_{10}$ in two hours. At 50°C there was a 4 $\log_{10}$ reduction in 30 minutes and a 6 $\log_{10}$ reduction in 1 hour. At 55°C, the reduction after 30 minutes was 4.6 $\log_{10}$ TCID50/ml, and virus was not detectable after 1 hour. At 60°C the reduction was 5.6 $\log_{10}$ in 30 minutes, and undetectable in a hour. At 65°C there was a 5 $\log_{10}$ reduction in the first 5 minutes, and after 30 minutes the virus was undetectable.

Pandey[213] used sheep and goat pox viruses of scab origin. He found the loss of infectivity at 50°C after 60 minutes exposure to be of the order of $10^{4.03}$ and $10^{3.97}$ $TCID_{50}$ respectively. Datta[152] achieved a 5 $\log_{10}$ drop in infectivity of goat pox virus held at 56°C for 30 minutes, and it was completely inactivated in 3 minutes at 60°C. Das[154] demonstrated substantial variability between strains of sheep pox virus in the response to heating to 50°C for 60 minutes.

Mahnel showed that cell free vaccinia and monkey pox virus underwent a 5 $\log_{10}$ reduction when heated at 56°C for 15 minutes, whilst cell bound virus underwent a

one $\log_{10}$ reduction in the same time[218]. Andrewes[167], discussing orthopoxviruses in general, quoted virus inactivation in 10 minutes at 60°C, but that dried virus could withstand 100°C for 10 minutes. Kaplan observed that vaccinia virus was heterogeneous in its heat sensitivity between 50°C and 60°C[59]. Fresh suspensions of vaccinia virus were completely inactivated in less than 1 hour at 55°C. Virus stored at 4°C for one week prior to heating showed a 6 $\log_{10}$ reduction in 120 minutes at 55°C.

While there is some evidence for heat inactivation of capripoxviruses at 62°C for 30 minutes[152], which is considered to be equivalent to the low temperature/long time pasteurisation method, no data is available on the behaviour of the virus at 72°C. It is also recognised that heat inactivation of viruses occurs exponentially and complete inactivation of all live virus cannot be assured, even after boiling (Kitching *pers.comm.*[297]*)*. Furthermore, virus would be protected by the protein and fat in milk and, consequently, inactivated at a substantially slower rate when compared to inactivation rates in a laboratory buffer (Boyle *pers.comm.*[298]*)*.

At pH 3 the loss of CPE was 4.7 $\log_{10}$ in 30 minutes, and total loss in 2 hours. At pH 11 a loss of CPE of 3.4 $\log_{10}$ was achieved in 30 minutes and total loss in 2 hours[165]. Datta[152] obtained a 3 $\log_{10}$ drop in infectivity when goat pox virus was exposed to pH 5 for 1 hour. The virus is less sensitive to alkali than to acid. Datta[152] obtained only a 1 $\log_{10}$ reduction at pH 8 in the same experiment using goat pox virus.

It would appear that the low pH of cheese alone may be insufficient to inactivate capripoxviruses.

c) Likelihood of introduction of disease agent with imported dairy product

Poxviruses are present in the exudate and scabs from skin lesions that occur on the udder and other parts of the body. The virus survives well in the environment. It is concluded that it is possible for poxviruses to contaminate raw milk either as a secretion or an external contaminant.

Although high temperature/short time pasteurisation is likely to substantially reduce poxvirus numbers, there is no evidence available to demonstrate either its efficiency or the degree of inactivation. Milk fat, milk protein and scab contaminants may also protect virus from inactivation.

Available information therefore suggests that there may be a risk of introduction of poxviruses in milk and milk products derived from pasteurised milk.

d) Likelihood of disease establishment in Australia following introduction of agent

The scientific data available suggests that poxviruses may be infectious by mouth. However, neither infected milk, nor the oral route of infection, is considered to be a likely means of transmission of poxviruses.

Australia has, for about twenty years permitted the importation of cheeses that met the requirements for inactivation of FMDV from countries in the south eastern corner of Europe that have had periodic incursions of sheep or goat pox. This trade was permitted on the basis that a process which inactivated FMDV could be assumed to be sufficient to inactivate other animal pathogens of concern. During the period these cheeses have been imported there have been no outbreaks of capripox infection in

Australian livestock populations.

AUSVETPLAN considers that rapid spread of an infection of lumpy skin disease could occur if conditions favourable to vectors were prevalent[1]. The longevity of the agent in the environment, and the potential for spread by insects would both make eradication difficult. Biting flies of the species present in Australia have been shown to be capable of mechanically transmitting the virus up to 4 days after feeding on infected material.

Recovered animals act as a source of infection to susceptible animals with which they come in contact, and, together with the long survivability of the virus outside the host, ensures the disease cycle is maintained[170].

e) Consequences of agent introduction and disease establishment in Australia.

Capripoxviruses cause the most severe pox diseases of animals[51]. In capripox enzootic countries the disease reduces the productive potential and limits intensive systems. In a country previously free from the disease the consequences would be much more severe[212].

Lumpy skin disease only naturally affects cattle, although experimental transmission to sheep has been recorded[196]. In endemic areas the morbidity is variable, but rates of 80% have been seen in South Africa[178]. An outbreak in a previously free country such as Australia could be expected to result in a high morbidity rate. The slaughter of infected and in-contact animals would impose severe hardship on the rural sector. Permanent loss of some markets could be expected with associated downturn in the rural economy[1]. An eradication programme in Australia would involve the destruction and disposal of all infected and in contact animals, and the destruction of all milk and other products from susceptible animals at the premises under control. Milk that left affected premises within 28 days before the diagnosis would be traced, if possible, and destroyed[1].

The LSD panzootic in South Africa that lasted from 1945 to 1949 affected some eight million cattle, and incurred enormous economic losses[222,235]. Eradication of LSD in Africa has not been achieved. Israel did manage to eradicate an outbreak that occurred in 1989.

An uncontrolled outbreak of sheep pox or goat pox in Australia would cause serious stock losses in the goat and sheep industries. The resulting financial losses would have a serious effect on the local economy in the area of the outbreak. If the disease became endemic, continuing economic loss would occur due to loss of animals and the cost of vaccination. Permanent loss of some export markets would also be expected with associated downturn in the rural economy and possibly increased rural unemployment. In the worst case scenario, our major wool markets will be lost. This may be assuaged if zoning is accepted[1].

In the event of an outbreak of sheep pox/goat pox in Australia, infected animals would be destroyed. Milk that left affected premises within the 21-day period prior to the diagnosis of the disease would be traced and destroyed. Milk from suspect animals under observation would be destroyed [1]. Although goat and sheep meat and milk supplies in the area near the outbreak of sheep pox/goat pox would be disrupted, consumers would continue to get adequate supplies of cows milk and beef[1].

f) Conclusions

It is noted that the EU, the USA and New Zealand do not impose restrictions related to capripoxviruses on dairy products. Ingestion of infected milk is not the normal route of transmission in countries where capripoxviruses, camel pox and buffalo pox are endemic. Nevertheless, milk from infected animals could be contaminated with poxviruses, and oral transmission is thought to be possible. There is insufficient evidence to conclude that pasteurisation inactivates poxviruses to an extent that removes the risk of entry of these viruses into Australia. Therefore, on balance, there is an unacceptable risk of importing sheep and goat milk from countries in which sheep and goat pox occur, cow and buffalo milk from countries where lumpy skin disease and buffalo pox are found, or camel milk from camel pox affected countries.

3.5 *Brucella abortus* and *Br. melitensis*

Brucella abortus infection is primarily a disease of cattle, and *Br. melitensis* is primarily a disease associated with sheep and goats. However, there are records of *Br. melitensis* infecting cattle,[25,64] *Br. abortus* infecting goats and sheep,[23] and camels are shown to be susceptible to both [26,27,54]. Both are major zoonoses.

Br. abortus has worldwide distribution with a few countries now claiming successful eradication. These include Australia, Canada, New Zealand and some countries of Europe[72].

Br. melitensis has never been reported in livestock in Australia. Its international distribution is more restricted than *Br. abortus,* but it is widespread in southern Europe, west and central Asia, Mexico, South America and Africa. It would have a significant economic impact if introduced.

a) Transmission of the disease agent and its potential to be present in milk

For both *Brucella* species the most common form of transmission between adult animals is via infected foetal membranes and vaginal discharges, which may be licked or ingested directly, or via contaminated feed or water supplies. *Brucellae* are excreted in the milk and may act as a source of infection for calves, lambs and kids[23,25,29,41]. One in ten infected cows are infected in the udder and shed *Brucellae* at least intermittently[114].

The number of *Br. abortus* organisms excreted in the milk of an infected cow may vary from a few to 10^6 per ml, the number being greatest in the colostrum[45]. Calves may acquire infection *in utero* or by the oral route and bulls and cows retain the infection into adult life[23].

Humans are highly susceptible to infection and may be infected from handling infective material or from the consumption of milk and cheese made from unpasteurised milk[23,28,30].

b) Survivability/inactivation of the agent in dairy products

Because of the zoonotic importance of *Br. abortus* and *Br. melitensis*, much research is available dealing with the stability of these organisms in dairy products and their sensitivity to pasteurisation and similar heat treatments[45,73].

There is substantial evidence that pasteurisation inactivates *Brucellae* in milk, for example, the decline of human brucellosis in Malta was attributed to the pasteurisation of goats' milk[67,73].

By lowering the pH of milk or skimmed milk (at temperature 5°C), *Br abortus* could be destroyed in 78 hours at pH 3, but at pH 4, the organism survived for 8 days[45]. Few dairy products reach a pH of less than 4.6. el Daher[44] showed *Br. melitensis* could survive for four weeks in broth at a pH of 5.5 or greater, but was inhibited in less than three weeks at pH 5, and in one day at pH 4.

There are numerous reports of human infection with *Br. melitensis* believed to result from eating cheese made from unpasteurised goat or sheep milk. There are a number of published studies on the survivability of *Brucella* organisms in cheese[41, 53,68,123]. Fabian[66], having regard for a number of pathogenic organisms, including *Brucellae* and *Mycobacterium*, suggested that 90 days should be a minimum ripening period, with 120 days preferred. He recommended a combination of pasteurisation and a 90-day holding period as a more ideal way to remove a number of human pathogens from cheese[66].

The current heat treatment usually employed to "thermise" milk for cheese production is 62°C for 15 seconds. This heat treatment is insufficient to destroy *Brucella* organisms[86].

c) Likelihood of introduction of disease agent with imported dairy product

Except in countries where *Br. abortus* and/or *Br melitensis* have been eradicated, or where infected herds are quarantined, raw milk could be expected to contain some infectious agents. Depending on the nature of processing, which is discussed under risk management, organisms in contaminated raw milk may or may not be destroyed.

Raw milk cheeses are very popular in some parts of the world, and some of these cheeses have been imported into Australia for around 20 years provided they complied with criteria known to inactivate FMDV. Cheese is unlikely to be fed to ruminants, so the quarantine risks are considered to be extremely low.

d) Likelihood of disease establishment in Australia following introduction of agent

Establishment of infection depends on the dose of organisms consumed and the age, sex and reproductive status of the recipient animal. Clinical manifestations in young animals may be unapparent and infections may spontaneously resolve[23].

Bovine brucellosis was introduced into Australia, probably with the earliest introductions of livestock and was eradicated through the efforts of industry and government. Re-establishment of infection could occur. Once detected, stamping out would be undertaken.

Br. melitensis infection of livestock has never occurred in Australia. If introduced and established, stamping out would be undertaken.

e) Consequences of agent introduction and disease establishment in Australia.

Australia has been free from bovine brucellosis (*Brucella abortus)* since 1989[80]. The eradication program that began in the 1970s was necessary to maintain our beef markets, for human health reasons and because of the loss in productivity in infected

herds. The cost of the Brucellosis and Tuberculosis Eradication Campaign (BTEC) between 1970 and 1997 was $840 million[79]. The re-introduction of either of these diseases would put at risk the enormous investment and effort that has been expended on the eradication programme that took 27 years to conclude.

Bovine brucellosis is still a disease of major economic importance in many parts of the world. Losses are from lowered milk production and poor fertility which seriously interferes with breeding programs. There is a high incidence of temporary infertility in females and permanent infertility in bulls[76].

As a zoonotic disease transmitted via milk and cheese, *Br. melitensis* is the more serious of the two agents discussed here[64,66,150]. As the most pathogenic of the *Brucella* spp. it is likely to have a significant socio-economic effect if it were to enter Australia. Because it is highly pathogenic to man, some restrictions on the slaughter of sheep from affected herds could be expected, as would the sale of sheep and goat dairy products.

f) Conclusions

Br. abortus and *Br. melitensis* could be imported into Australia in dairy products made from unpasteurised milk. This risk would be virtually eliminated if the product were made from pasteurised milk, or if the country of origin of the milk was free from *Br. abortus* in the case of bovine product, or *Br. melitensis* in the case of ovine/caprine product.

AQIS proposes to adopt quarantine restrictions on imported dairy products for these two agents.

3.6 *Mycobacterium bovis*

The term *Mycobacterium bovis* is commonly used to distinguish the bovine species of the tubercle bacillus from the human species. In older literature, *M. tuberculosis* is used to describe organisms of bovine or human origin, however the foundation for differentiation into human and bovine types was laid down as early as the 1890s[73]. Early references to *M. tuberculosis* in cows' milk are presumed to refer to the organism now known as *M. bovis*. It is necessary to quote some of these older works in this discussion.

Bovine tuberculosis has worldwide distribution, Australia being one of the few countries to have achieved eradication.

a) Transmission of the disease agent and its potential to be present in milk

Mycobacterium bovis occurs chiefly in cattle. Other species affected to a lesser extent include pigs, goats, camels and deer[23,55,75,76]. The incidence in pigs is generally related to the incidence in dairy cattle in the area, while goats are quite susceptible if they are maintained in association with infected cattle herds[76]. In New Zealand, tuberculosis in sheep is believed to be related to the prevalence in local populations of cattle and possums[76].

The disease is rare in horses[76]. Dogs are susceptible to both human and bovine infections, while cats are less susceptible to the human but quite susceptible to the bovine bacillus[78].

The chief methods of transmission between animals are by inhalation and ingestion of bacilli[23,76,115]. Stagnant drinking water may remain infectious for up to 18 days, and faeces for 6-8 weeks[76].

Infected animals may excrete bacilli for many months in milk. Drinking infected milk is a common method of spread of the disease to young animals[76]. Excretion of tubercule bacilli in milk is intermittent,[73] however, because of the low infectious dose associated with tubercule bacilli[56], and the large number of organisms excreted in the milk, it is possible for the milk of one cow to contaminate the milk of as many as 100 uninfected cows when the milk is pooled for transportation[23,77,81]. In the 1940's tuberculosis was looked upon as the most serious milk-borne disease of humans [62,149].

Lesions of the udder commonly result in milk containing *M. tuberculosis* organisms, while some tuberculous cows without infected udders may also give milk containing *M. tuberculosis*[73].

b) Survivability/inactivation of the agent in dairy products

Tubercle bacilli are destroyed by heating at 63.5°C for 20 minutes[43] and by boiling for 2 minutes[57]. Pasteurisation of milk was first recommended as a means of reducing human tuberculosis contracted from infected milk[62,63]. In the 1940s, it was shown that tubercule bacilli and a heat resistant *Bact. coli* (presumably *E. coli*) were completely destroyed by the High Temperature Short Time (HTST) pasteurisation method[65,71].

The pH levels achieved in sour milk are not sufficient to destroy tubercle bacilli[69,133]. Human tubercule bacilli were also able to survive four hours exposure to normal caustic soda[130].

Research on the viability of *M. tuberculosis* in cheese dates back to the late 1880's. Milk containing live tubercule bacilli* was used to make a variety of cheeses. The survival times were 5-30 days for the hard, 305 days for the semi-soft, and 47 days for Camembert style soft cheese. Kästli concluded that hard cheese ripened for several months would not pose a quarantine risk[61]. (*Whether spiked or naturally infected milk was used, it is fairly certain that in this experiment the cheeses were not made from pasteurised milk.)

c) Likelihood of introduction of disease agent with imported dairy product

Except in countries where *M. bovis* is absent, or where milk production from infected herds is subject to official control, raw milk could be expected to contain some bacteria. Dairy products made from unpasteurised milk sourced in countries affected by *M. bovis* could introduce the organism into Australia.

d) Likelihood of disease establishment in Australia following introduction of agent

Calves, lambs and kids would be more likely to be fed milk-based feeds than adult animals. In pigs, however, animals of any age could be fed milk-based feeds. While pigs are susceptible to infection, they do not play a role in the perpetuation of the disease.

Tuberculosis may have a long incubation period and slow development of clinical disease. Once established, a focus of infection may become extensive before it is detected.

e) Consequences of agent introduction and disease establishment in Australia.

Bovine tuberculosis probably entered Australia with early cattle importations, and was eventually found in herds in all regions. Impetus for the Brucellosis and Tuberculosis Eradication Campaign (BTEC) stemmed from human health concerns, and threats to our beef export industry that supplied, in the main, countries also engaged in eradication programs. The Australia-wide campaign for eradication of bovine TB and brucellosis commenced in 1970 and concluded on 31 December, 1997, when Australia was declared free from the disease. A Tuberculosis Freedom Assurance Program (TFAP) has replaced BTEC, and provides continuing surveillance.

The cost of BTEC over that period was $840 million. Re-establishment of either disease in Australia would be considered very serious.

f) Conclusions

M. bovis could be introduced in raw milk products sourced from countries not free from bovine tuberculosis.

The risk of establishment and spread of *M. bovis* through the importation of cheese is considered to be negligible because of the extremely low risk of cheese finding its way into the ruminant feed chain.

AQIS proposes to adopt quarantine restrictions in relation to dairy products other than cheese.

3.7 Contagious agalactia

Contagious agalactia primarily affects goats, and also sheep. Some texts give the causative agent as *Mycoplasma agalactiae*, while Radostits lists *M. agalactiae*, *M. mycoides* var. *mycoides*, *M. arginini*, *M. capricolum* and *M. putrefaciens* as possible causative agents[76]. Levisohn[236] recognised *M. agalactiae* as the causal agent, but said that *M. mycoides* var. *mycoides* (LC) and *M. capricolum* caused the same clinical signs.

Contagious agalactia is characterised by acute mastitis, keratoconjunctivitis and arthritis[76,190]. Animals may suffer protracted illness from which they do not recover and loss of milk production can be high[237]. One report of outbreaks spanning 11 years said that *M. agalactiae* was isolated from both sheep and goats, but that *M. mycoides* subsp. *mycoides* was isolated only from goats[226].

Contagious agalactia is endemic in Mediterranean countries[180,227,228], and Central and Northern Europe. America and Australia are free from the disease[190].

a) Transmission of the disease agent and its potential to be present in milk.

The incubation period is 1-9 weeks. The disease is initially septicaemic and may be fatal in this phase[180]. The disease may be spread from acutely infected animals in milk, urine, nasal and lacrimal secretions. Chronically diseased animals may also be a source of infection[190]. Organisms are excreted in the milk for many months in animals that recover from the initial disease[180]. Subclinical mastitis may occur prior to parturition which may proceed to clinical mastitis after parturition or remain subclinical but with the milk positive for *M. agalactiae*[241].

Lambert[266] said that transmission by the digestive route is important, and young animals are directly infected by suckling. Mechanical transmission by milkers hands and via bedding is possible. He also said the spread of the disease from infected locations could be extremely haphazard.

b) Survivability/inactivation of the agent in dairy products

Mycoplasmas are generally very susceptible to heat and drying, and are killed in a few minutes at 60°C[23,58,78]. They remain viable for long periods in frozen tissue[78].

c) Likelihood of introduction of disease agent with imported dairy product

Woodhead[267], commenting on the risk of introduction of contagious agalactia to the UK, said that heat treated milk would be unlikely to contain mycoplasmas, but that raw milk could pose a risk. He considered that the processing methods for yoghurt and cheese production would kill any mycoplasmas present.

d) Likelihood of disease establishment in Australia following introduction of agent

This disease is caused by a number of putative agents, and a definitive diagnosis of an outbreak in Australia may not be easy.

The likelihood of establishment would depend on the speed with which an outbreak was recognised coupled with the measures that the affected State may put into effect.

e) Consequences of agent introduction and disease establishment in Australia.

The morbidity of contagious agalactia can be up to 50% if unchecked, but mortality is generally low[190]. The disease is of greater economic importance in countries that consume a significant amount of sheep and goats' milk and milk products[190]. The disease affects efficiency of milk production and herd replacement costs[248].

The UK, which is free from contagious agalactia imposes strict quarantine requirements on the importation of live sheep and goats for this disease[267]. Some restrictions on live sheep/goat exports may be imposed on Australia in the event of an outbreak.

f) Conclusions

Raw sheep and goats' milk/milk products sourced in countries affected by contagious agalactia could be contaminated by these disease agents. AQIS proposes to adopt quarantine measures for these agents.

3.8 Maedi-visna

Maedi-visna (also known as ovine progressive pneumonia) is caused by a *Lentivirus* of the family Retroviridae. Maedi-visna occurs as two distinct syndromes. The pneumonic form (maedi) is the more common; emaciation, dyspnoea, non-suppurative mastitis and paralysis (visna) may be exhibited to varying degrees. Sheep are most commonly affected, and goats are also susceptible.

Few countries in the world are free from this disease. However, Australia, New Zealand and Finland are reported to be free, and it has been eradicated from Iceland by a stamping out programme over a 20 year period[105].

a) Transmission of the disease agent and its potential to be present in milk.

The incubation period is long, several years in most cases. Udder lesions appear to be widespread in MV-infected flocks in Holland, and even in some flocks where classical maedi is not recognised, indurative mastitis has retarded growth rates in lambs[107,239].

Sheep and goats are both said to be susceptible[179], but the classical descriptions of the disease all involve sheep.

Transmission of the agent is primarily from ewe to lamb via colostrum and milk, while intrauterine transmission is thought to be rare[23,105,106,107]. Mononuclear cells in the colostrum and milk are infected with the virus, and probably pass through the intestinal epithelium of the neonate[179]. Production of infected cells begins 10 days before parturition and persists for up to two months[238].

Contact transmission also occurs when animals are housed together[179]. Removing lambs at birth and rearing them on bovine colostrum and milk, has been shown to be an effective control measure[105,106,107].

b) Survivability/inactivation of the agent in dairy products

Thormar[108], using isolates from maedi and visna cases diluted in medium 199 containing 1% sheep serum (pH 7.3-7.5), showed that 90% of infectivity (1 $\log_{10}$) was lost after 10 minutes at 50°C. A 5 $\log_{10}$ reduction took place at 56°C for 10 mins. This suggests that pasteurisation at normal commercial times and temperatures would be effective at inactivating Maedi-visna virus. However, when excreted in colostrum and milk, the virus is present in monocyte/macrophage cells, and as such is in a more protected environment than naked virus in solution. Caution should be used in extrapolating the above data to naturally infected milk. Retroviruses as a group are taken as being inactivated by heating to 56°C for 30 minutes[169].

Data could not be located which showed the effects of HTST pasteurisation on milk infected with maedi-visna virus. However, the pasteurisation of goat milk at 56°C for 1 hour has been an effective measure in the control of the closely related virus, caprine arthritis-encephalitis virus[161].

Thormar[108] also tested the effect of pH on maedi and visna viruses, using virus suspended in buffers that were maintained at 19-21°C. There was a 1 $\log_{10}$ reduction in infectivity at the following pH levels:

at pH 9.4	1 $\log_{10}$ reduction	4 days
at pH 7.7	1 $\log_{10}$ reduction	7 day
at pH 5.1	1 $\log_{10}$ reduction	1 day
at pH 4.2	1 $\log_{10}$ reduction	1.5 hours (maedi) and 1 hr (visna)
at pH 3.2	4 $\log_{10}$ reduction	30 mins (visna)
at pH 3.2	5.5 $\log_{10}$ reduction	30 mins (maedi)

Figure 5
Effect of pH on isolates from maedi and visna viruses at 19-21°C

From the above data, it would seem likely that pH in the range attained by most cheeses would inactivate maedi-visna virus.

c) Likelihood of introduction of disease agent with imported dairy product

Sheep/goat milk sourced from countries affected by maedi-visna could contain maedi-visna virus.

d) Likelihood of disease establishment in Australia following introduction of agent

If susceptible animals were infected with maedi-visna virus it is likely that the infection would not be detected for a substantial period of time. During this time, the disease may become established in Australia.

e) Consequences of agent introduction and disease establishment in Australia.

The economic consequences of maedi or visna forms of the infection vary, depending on factors including strain of virus, breed of host and husbandry procedures. Iceland reported annual losses of up to 30% per flock following the introduction of a maedi-visna carrier. One report from the USA was that subclinical ovine progressive pneumonia did not influence wool or lamb production. Generally the condition will lead to an increased culling rate such as pneumonia, mastitis and poor condition[105].

Iceland is the only country in the world that has successfully eradicated this virus, which suggests that a disease incursion in Australia may be difficult to eradicate. A South African study is being conducted to ascertain the feasibility of eradication by means of frequent serological surveys and selective elimination[201]. Norway introduced a control program in 1973, forbidding the sale or exhibition of animals from infected flocks[146], and now reports only an occasional occurrence of the disease.

f) Conclusions

The potential for maedi-visna virus to be present in raw milk from sheep and goats in many countries is significant. AQIS proposes to adopt quarantine measures in relation to this disease agent.

3.9 Jembrana disease

Clinically, Jembrana disease resembles rinderpest, but it is caused by a virus of the family Retroviridae that is related to, but clinically distinct from, bovine immunodeficiency virus[72,159,177]. It is atypical of retroviruses in that it has an incubation period of a few days[159]. The disease is believed to be milder (and possibly undetectable) in *Bos taurus* cattle than in *Bos javanicus* cattle in which it is severe and may have a case fatality rate of about 20%[160]. The known distribution of Jembrana is currently limited to Indonesia[72].

a) Transmission of the disease agent and its potential to be present in milk.

The major pathological changes are in the lymphoid tissue[177]. Close contact appears necessary for natural spread of the disease, although the virus has been detected in saliva and milk during the febrile stage of the disease, and test animals could be infected with milk containing the virus. The conjunctival, intranasal and oral routes have been successfully used to infect animals experimentally[138]. It is postulated that arthropods spread the infection mechanically[138].

Data on this organism is limited. It is not known for how long the virus is excreted in milk, or whether it is present in colostrum.

b) Survivability/inactivation of the agent in dairy products

Generally retroviruses are heat sensitive and should be inactivated by thermal treatment equivalent to pasteurisation.

c) Likelihood of introduction of disease agent with imported dairy product

The literature refers to virus isolation from febrile animals only. However, subclinical infections occur in cattle other than Bali cattle. There are no data on whether virus is excreted in the milk of these animals and it is difficult to conclude if Jembrana virus could be introduced in dairy products.

d) Likelihood of disease establishment in Australia following introduction of agent

Currently it is believed that Bali cattle (*Bos javanicus*) are more susceptible to Jembrana disease than other types of cattle and buffalo. The quarantine risk associated with the introduction of the virus is unclear.

e) Consequences of agent introduction and disease establishment in Australia.

If Jembrana disease were to become established, the clinical similarity to rinderpest could cause major disruption to trade at least until the outbreak was diagnosed.

Outbreaks are associated with a high morbidity and high mortality rate, whereas the disease is characterised by lower morbidity and mortality rates in areas where infection is endemic. Recovered cattle may be persistently viraemic, but their role in transmission of the disease is unknown[72].

f) Conclusions

There are gaps in the information needed to make a full risk assessment of this agent. It is exotic and has the potential to cause severe disease in susceptible cattle.

Transmission via milk has been demonstrated. AQIS proposes to adopt quarantine restrictions on dairy products for this disease.

4. Risk management

4.1 Risk management measures - general

Quarantine risk may be managed by:

. sourcing product from countries or zones that are free from the diseases of concern ('exporting country factors')

. sourcing product from animals free from clinical signs of disease

. subjecting the product to a process that would inactivate disease organisms of concern ('commodity factors')

. controlling of the use of imported product to prevent exposure of susceptible animals ('importing country factors').

In relation to the first three measures, it is necessary for an importing country to seek confirmation regarding the status of the country/zone, the health status of animals from which the milk was obtained and that the specified processing has been conducted. This is normally provided by the Veterinary Authority of the exporting country.

4.1.1 Exporting country factors

a) Assessment of veterinary services

AQIS follows OIE guidelines for the evaluation of veterinary services and will take into account all available information, including the results of formal and informal assessments undertaken by other governments and organisations such as the OIE. AQIS may make visits and discuss matters/conduct inspections in the countries subject of assessment.

In some cases, AQIS may base its decisions on information acquired in previous dealings or provided by other countries. While not automatically accepting the results of assessments conducted by other parties, AQIS would take into account the extent to which such assessments provide answers to relevant questions. AQIS may conduct any inspections deemed necessary to investigate the animal health situation in a country proposing or approved to export dairy products to Australia.

b) Animal health status of countries/zones

Where the OIE has a standard for recognition of disease freedom, AQIS will normally accept this. On valid animal health grounds, AQIS may decide to seek additional assurances.

In order to confirm a country's claim to a particular animal health status AQIS may evaluate the basis for such claim, including by an assessment of the veterinary services of that country. AQIS's assessment would be based on relevant OIE recommendations and may include examination of the country's quarantine security, and its capability to detect and respond to a disease incursion, as well as its record in notifying disease incursions.

c) Regionalisation

Australia, as a Member of the WTO, agrees under Article 6 of the AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES to ensure that sanitary or phytosanitary measures are adapted to the area from which the product originated and to which the product is destined. In particular, Australia has committed to accept the concept of pest- or disease-free areas and manage quarantine risk accordingly. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance and the effectiveness of sanitary or phytosanitary controls.

Where international standards for disease-free zones have not been agreed, the definition of such zones will be decided on the basis of bilateral negotiations. This will take into account the geographical isolation of the zone from the remainder of the country, the quarantine controls on the entry of animals and products into that zone, the disease surveillance within the zone, the size and nature of buffer zones, the promptness of disease reporting by the Official Veterinary Service and the competence of veterinary services in the country.

d) Identifying the country of origin of raw materials

In dealing with import applications for a dairy product manufactured in one country from raw materials sourced in one or several countries, it may be difficult ensure that raw materials from the nominated country of origin are not mixed or substituted with raw materials from another source. Where ingredients or finished product are traded and/ or moved across national borders, it may be difficult to confirm the source of raw materials. Country of origin certification may be difficult to obtain. Nevertheless, AQIS requires, as a minimum safeguard, accurate certification from a responsible Veterinary Authority. AQIS may refuse to issue an import permit under circumstances of significant uncertainty, for example, where the origin of raw materials cannot be determined with confidence, or relevant veterinary certification cannot be obtained.

e) Certifying authorities

Declarations of disease-freedom of a country or part of a country must be based on official certification by the responsible Veterinary Authority. In the case of dairy product that is sourced in one country and exported from another, the Veterinary Authority of the exporting country must certify to the country of origin of the milk or that the country of origin of the milk has an animal health status no less favourable than that of the country of manufacture/export.

If Veterinary Authorities are unable to certify as to the country of origin of the milk from which the dairy product was manufactured, AQIS may refuse to permit the importation.

Veterinary authorities may be reluctant to sign certificates that attest to the processing of product within a factory if they do not have direct control over the factory's operations. Under existing policy AQIS has accepted certification of processing details provided by the manufacturer and endorsed by the Veterinary Authority in the country of export. AQIS will continue to accept these officially endorsed manufacturer's certificates in relation to the processing of product.

4.1.2 Commodity factors

Where a disease of quarantine concern occurs in a country/zone, for the purpose of risk management AQIS may require that dairy products be processed to inactivate specified disease agents prior to importation.

In addition to requiring official certification as to processing, as outlined above, AQIS may conduct individual inspections of premises including processing plants and export facilities. The purpose of such inspection is to confirm that the standards of operations and regulatory controls meet Australian animal quarantine requirements.

Particular attention would be paid to the effectiveness of measures (based on company control, quality assurance or official requirements) intended to prevent post-processing contamination of product.

In determining the minimum processing requirements for dairy products, AQIS takes into consideration normal commercial practice and established inactivation data for particular disease agents (or closely related organisms).

Where AQIS's risk management is based on the attainment of a specified pH, e.g. in the case of certain cheeses, imported product will be randomly sampled on arrival in Australia and the pH checked, prior to release from quarantine.

AQIS proposes that any heat treatment which forms part of a risk management measure is applied to the milk before any other processing takes place. For example, if the product is made from cream, the heat treatment will refer to the whole milk prior to separation of the cream, or if the product is made from a curd which is subsequently cooked, the specified heat treatment will be applied to the milk before the setting of the curd. This simplifies quarantine requirements and is consistent with commercial practice.

Where a dairy product is made from milk from more than one species of animal, the most stringent risk management measure (of the individual measures required, as appropriate to the type of milk) would apply.

4.1.3 Restricting the final use of imported product.

Once food has been released from quarantine, AQIS has no further regulatory control, eg over the use of imported product. Accordingly, restrictions on the end use of imported product are not part of AQIS's approach to risk management.

The physical nature of cheese and butter does not lend these products to incorporation in stock feed. However pigs find most human foods palatable. Disease agents that might occur in butter and cheese and infect pigs are of quarantine concern. Other non-ruminant domestic animals including poultry are not likely to act as vectors for any ruminant disease agent likely to occur in dairy products.

AQIS notes that the USDA, in 9 CFR 94.16, exempts cheese, butter and butter oil (ghee) from the application of management measures to address risks associated with FMD. Butter oil is produced by a high heat treatment (see appendix I). AQIS proposes to exempt butter oil, but not butter, from quarantine restrictions.

4.1.4 Colostrum

Colostrum is used primarily as a feed supplement for newborn animals and for the production of specific immunoglobulins for human therapeutics. It is being used increasingly in the health food industry.

Some disease agents, including *Mycobacteria*, *Brucellae* and *Retroviruses*, are excreted in as high, if not higher concentrations in colostrum than in milk.

Immunoglobulins confer passive immunity to the newborn. They are damaged at pasteurisation temperatures, but the level of destruction by thermisation is far less[272,99,112]. Preservation of colostrum is by freezing or drying. Spray drying is the most economical, whilst freeze drying utilises the lowest temperatures[273]. Significant numbers of bacteria survived both processes[273],and it could be assumed that viral pathogens would also survive. A number of colostral products are available commercially[273,274].

Having consideration for the deleterious effects of heating on the immunoglobulins in colostrum, it is likely that colostrum could not be heat treated to destroy all pathogens without also destroying the immunoglobulins. Claims by manufacturers that colostrum products had been fully pasteurised and retained their immunoglobulin activity may not be accurate. AQIS therefore believes the risk of misrepresentation in this respect is higher for colostrum than for other dairy products.

Considering also, the attractiveness of this product as a food for newborn animals, AQIS will adopt a policy of not issuing import permits for colostrum other than for human therapeutic use.

4.2 Risk management - specific disease agents

AQIS proposes to adopt risk management measures for the following diseases/disease agents:

Foot and mouth disease
Rinderpest
Peste des petits ruminants
Contagious caprine pleuropneumonia
Lumpy skin disease

Sheep pox
Goat pox
buffalo pox
camel pox
Brucella abortus
Brucella melitensis
Mycobacterium bovis
Contagious agalactia
Maedi-visna
Jembrana disease

4.2.1 Risk management in relation to FMD.

An incursion of FMD would have very serious consequences for Australia, hence AQIS will continue to take an extremely conservative approach to the management of quarantine risk for this agent.

AQIS proposes to permit the importation of dairy products from FMD-free countries/zones and the importation of specified cheeses from FMD-affected countries/zones. Moreover, AQIS proposes to permit the importation of dairy products other than specified cheeses from FMD-affected countries/zones, subject to individual assessment. Such importations would be permitted provided that the dairy products were manufactured (under specified controls) from raw materials obtained in an FMD-free country/zone or if they were processed in a manner that would be expected to inactivate FMD virus. Approval for such an import would be preceded by assessment of the manufacturing plant and the veterinary and/or export certifying authority. Permits would then be issued if AQIS was satisfied that the above conditions would be met.

In the Code (Article 2.1.1.19[ϕ]), for the purpose of importation of milk and milk products from FMD-free countries or zones the OIE does not distinguish between countries that do or do not vaccinate. For countries that vaccinate, the OIE requires a period of two years disease freedom before the country will be recognised as FMD-free. A disease-free period of 12 months applies in the case of non-vaccinating countries. Having regard for this and for the conclusion of Heng and Wilson[(2)], AQIS proposes that countries or zones that are recognised by the OIE as FMD-free whether vaccinating or non-vaccinating, be approved for the export of dairy products to Australia.

AQIS acknowledges that importation from FMD-free countries poses some, albeit small, risk in that milk could be collected in the period immediately after an FMD incursion and prior to detection/official notification. Milk produced during the prodromal period can contain FMDV. To manage this risk, AQIS recommends that for all dairy products the milk should be pasteurised or the imported milk/milk products should not be released from quarantine control until at least 30 days from the date of manufacture.

[ϕ] See appendix II

The following processes used in the manufacture of cheese have been shown to be effective in inactivating FMDV. Thus AQIS proposes to permit the importation of cheese from countries/zones affected by FMD provided that:

- the milk from which the cheese was manufactured was pasteurised at a minimum of 72°C for 15 seconds or the equivalent, in terms of phosphatase destruction, and
- the cheese attained a pH of less than 6 and
- the cheese is stamped with the date of manufacture and
- the cheese is at least 30 days old before release from quarantine.

OR

- the cheese attained a pH of less than 6 and
- the cheese is stamped with the date of manufacture and
- the cheese is stored for a period of 120 days at a temperature at or above 2°C before release from quarantine.

In addition, AQIS will continue to permit the importation of dairy products from countries/zones affected by FMD in the case of samples for scientific analysis; and will ease the restrictions on infant formula to enable travellers accompanied by an infant to bring with them sufficient for the child's needs. AQIS is also considering a request to permit the importation of powdered, composite, milk based beverages in personal baggage by persons entering Australia.

AQIS receives numerous applications for import permits for dairy products or products containing dairy ingredients from countries that are not approved to export dairy products to Australia. Currently these are rejected. However, there are cases where such products may pose little quarantine risk. AQIS proposes to conduct a formal assessment on applications if they fall into one of the following categories:

. the processing of the product includes a heat treatment that would be expected to destroy FMDV or

. the milk ingredients are sourced from a country/zone free from FMD.

Such an assessment would include inspection of the manufacturing plant to confirm that AQIS requirements (including the prevention of post processing contamination) can be satisfied and an evaluation of the responsible veterinary authority to confirm its ability to provide valid export certification. AQIS proposes to permit the importation of dairy products in these categories on the basis of a formal assessment and the determination of specific conditions appropriate to the product and manufacturing plant subject of the application.

4.2.2 Risk management in relation to rinderpest

The pertinent points to consider in determining risk management measures for rinderpest are:

- cattle are highly susceptible to the disease; pigs and other ruminants are also susceptible
- virus is likely to be in the milk of viraemic animals,
- the virus would be expected to be inactivated by pasteurisation,
- rinderpest virus has not been shown to be transmitted by mouth to cattle,
- transmission of rinderpest virus by mouth to pigs is relatively easy and
- if given the opportunity, pigs would be expected to eat any/all dairy products.

AQIS proposes to permit the importation of dairy product, including cheese and butter, of bovine, ovine/caprine or camel origin from rinderpest-free countries/zones . Importation would be permitted from rinderpest-affected countries/zones provided that the milk from which the dairy products are manufactured is pasteurised prior to processing.

4.2.3 Risk Management in relation to Poxviridae

The pertinent points to consider in determining risk management measures for poxviruses are:

- capripoxvirus could be present in raw milk due to either contamination from skin lesions or secreted directly into the milk,
- there is evidence that pasteurisation at 60°C for 30 minutes is effective in inactivating the virus, but the effect of high temperature/short time pasteurisation has not been studied. Further, the presence of milk fat, milk protein and scab material may protect virus from inactivation,
- available evidence suggests that capripoxvirus may be transmitted orally, though this route of infection is not considered important where these diseases are endemic,
- LSD can be transmitted only to cattle and buffalo,
- SP and GP can be transmitted to sheep and goats but not to other animals,
- an incursion of LSD, SP or GP would have serious consequences for Australia,
- camel pox is restricted to camelids,
- buffalo pox is restricted to water buffalo and, less commonly, cattle,
- cheese and butter are unlikely to be fed to ruminant animals,
- the importation of sheep and goat cheeses from SP and GP affected countries has been permitted for more than 20 years without incident.

AQIS proposes to permit the importation of dairy product, including cheese and butter, of bovine, ovine/caprine or camel origin from Poxviridae-free countries/zones. Importation of butter and cheese alone would be permitted from Poxviridae-affected countries/zones.

For dairy products other than butter and cheese, whether or not made from pasteurised milk, importation will not be permitted in the case of product of bovine origin from LSD or buffalo pox affected countries; in the case of product of ovine or caprine origin from SP/GP affected countries; and in the case of product of camel origin from camel pox affected countries.

4.2.4 Risk management in relation to other diseases

Cheese and butter

AQIS proposes to adopt no risk management measures in relation to the importation of cheese and butter other than as described above for FMD, rinderpest and Poxviridae. In making this recommendation, primary considerations include: that there is a low probability of exposure of ruminants to significant quantities of imported cheese and butter and that pigs are of negligible significance in the transmission of other diseases of quarantine concern.

Dairy products other than cheese and butter

AQIS proposes to permit the importation of products made from unpasteurised milk from countries free from FMD and rinderpest, and free from poxviruses relevant to the species from which the product was derived (LSD and buffalo pox for cows milk, SP and GP for sheep and goat milk, and camel pox for camel milk), provided those countries are free from the diseases listed below. Products other than cheese and butter will not be permitted from countries in which FMD or the above poxviruses relevant to the species in question are present.

AQIS further proposes to permit such importations from countries affected by one or more of the listed diseases provided the dairy product is manufactured from milk that is pasteurised prior to processing:

Dairy product of bovine origin

- Brucella abortus
- Brucella melitensis
- Mycobacterium bovis
- Jembrana disease

Dairy product of ovine origin

- Peste des petits ruminants
- Brucella abortus
- Brucella melitensis
- Contagious agalactia
- Maedi-visna

Dairy product of caprine origin

- Peste des petits ruminants
- Contagious caprine pleuropneumonia
- Brucella abortus
- Brucella melitensis
- Contagious agalactia
- Maedi-visna

Dairy products of camel origin

- Brucella abortus
- Brucella melitensis
- Mycobacterium bovis

5. Requirements for the importation of dairy products into Australia.

5.1 Eligibility:

A country must be approved by AQIS as a whole, or a zone of a country must be approved by AQIS for the purpose of exporting dairy products other than cheese to Australia. AQIS is developing Guidelines for the approval of countries to export animals and animal products to Australia and this will be used as the basis for this approval.

Furthermore, AQIS may require inspection and approval of individual manufacturing plants prior to issuing an import permit.

5.2 Quarantine requirements for the importation of dairy products from approved countries

5.2.1 Under Proclamation 1998 the importation of dairy products is prohibited unless an import permit has been obtained to import those goods. This proclamation has provided for certain defined exemptions. Proclamation 1998 was amended in May 1999 such that all of the following may be imported without the requirement of in import permit.

. a dairy product imported directly from New Zealand that is comprised only of:

- milk produced in New Zealand or
- dairy products made in New Zealand from milk that did not originate in or transit a country other than New Zealand or Australia;

. goods in relation to which each individually packaged unit contains less than 10% by weight (other than added water) of a dairy product;

. commercially packaged chocolate

. lactose and its derivatives

. commercially prepared and packaged clarified butter oil.

. infant food, being imported by a person accompanied by the infant for whom the food is intended.

5.2.2 As a matter of policy, AQIS will not issue import permits for colostrum except where the product is for human therapeutic purposes.

5.2.3 Some of the following import requirements are species-specific. For product made from the milk of more than one ruminant species, health certification includes requirements relevant to all species from which the product is derived.

I. DOCUMENTATION

With the exception of goods exempt under Quarantine Proclamation 1998, each consignment of dairy products must be accompanied by:

(i) a *Permit to Import* obtained prior to export from the Australian Quarantine and Inspection Service (AQIS) and

(ii) a *Sanitary Certificate*, conforming to the relevant example certificate attached and signed by an *Official Veterinarian* of the exporting country, which will form part of the *Permit to Import* and

(iii) a *Manufacturer's Certificate*, conforming to the relevant example certificate attached, signed by a responsible employee of the manufacturer and endorsed by the *Official Veterinarian* of the exporting country.

(iv) A Quarantine Entry is required.

II. REQUIREMENTS

1. DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER) OF BOVINE ORIGIN FROM APPROVED COUNTRIES

1.1 The milk or the milk from which the dairy product is made must originate from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

1.2 The milk or the milk from which the dairy product is made must originate from a country/zone which meets OIE requirements for freedom from lumpy skin disease, and which is free from buffalo pox.

1.3 The animals must be clinically healthy at the time the milk was obtained.

1.4 The products must be processed in a foot and mouth disease-free country/zone.

1.5 EITHER

(a) the milk or the milk from which the dairy product was made must originate from a country/zone which meets OIE requirements for freedom from:

rinderpest (Code Article 2.1.4.2) and
bovine brucellosis (Code Article 3.2. 1.1) and
bovine tuberculosis (Code Article 3.2.3.1) and
which is free from Jembrana.

OR

(b) the milk or the milk from which the dairy product was made must be subjected to one of the following heat treatments:

pasteurisation at 72°C for a minimum of 15 seconds or an equivalent treatment, in terms of phosphatase destruction or

a UHT treatment of 135°C for a minimum of 1 second.

1.6 The packaging or immediate container must be stamped with the date of manufacture of the products.

1.7 Dairy products imported under condition 2.1.5(a) shall not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture.

2. DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER) OF OVINE/CAPRINE ORIGIN FROM APPROVED COUNTRIES

2.1 The milk or the milk from which the dairy product is made must originate from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

2.2 The milk or the milk from which the dairy product is made must originate from a country/zone which meets OIE requirements for freedom from sheep pox and goat pox.

2.3 The animals must be clinically healthy at the time the milk was obtained.

2.4 The products must be processed in a foot and mouth disease-free country/zone.

2.5 EITHER

(a) the milk or the milk from which the dairy product was made originated in a country/zone which meets OIE requirements for freedom from:

rinderpest (Code Article 2.1.4.2) and
peste des petits ruminants (Code Article 2.1.5.2) and
ovine brucellosis (*Brucella melitensis*) (Code Article 3.3.2.1) and
maedi-visna (Code Article 3.3.5.1) and
contagious agalactia (Code Article 3.3.3.1) and
contagious caprine pleuropneumonia (Code Article 3.3.6.2) [caprine products only].

OR

(b) The milk or the milk from which the dairy product was made must be subjected to one of the following heat treatments:

pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of phosphatase destruction or

a UHT treatment of 135°C for a minimum of 1 second.

2.6 The packaging or immediate container of products must be stamped with the date of manufacture.

2.7 Dairy products imported under condition 2.2.5(a) will not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture.

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3 DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER) OF CAMEL ORIGIN FROM APPROVED COUNTRIES

3.1 The milk or the milk from which the dairy product is made must originate from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

3.2 The milk or the milk from which the dairy product is made must originate from a country/zone which is free from camel pox.

3.3 The animals must be clinically healthy at the time the milk was obtained.

3.4 The products must be processed in a foot and mouth disease-free country/zone.

3.5 EITHER

(a) the milk or the milk from which the dairy product was made must originate from a country/zone which meets OIE requirements for freedom from:

rinderpest (Code Article 2.1.4.2) and
ovine brucellosis (*Brucella melitensis*) (Code Article 3.3.2.1) and
bovine brucellosis (Code Article 3.2. 1.1) and
bovine tuberculosis (Code Article 3.2.3.1)

OR

(b) The milk or the milk from which the dairy product was made must be subjected to one of the following heat treatments

pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of phosphatase destruction or

a UHT treatment of 135°C for a minimum of 1 second.

3.6 The packaging or immediate container must be stamped with the date of manufacture of the products.

3.7 Dairy products imported under condition 2.3.4(a) will not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture.

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4. CHEESE AND BUTTER FROM APPROVED COUNTRIES WHICH ARE FREE OF FOOT AND MOUTH DISEASE

4.1 The milk or the milk from which the cheese or butter is made must originate from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

4.2 The animals must be clinically healthy at the time the milk was obtained.

4.3 The products must be processed in a foot and mouth disease-free country/zone.

4.4 EITHER:

(a) The milk or the milk from which the cheese or butter was made must be subjected to one of the following heat treatments:

pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of phosphatase destruction or

a UHT treatment of 135°C for a minimum of 1 second.

OR

(b) The milk from which the cheese or butter was made was not heat treated as above and the milk or the milk from which the cheese or butter was made must originate from a country/zone which meets the OIE requirements for freedom from rinderpest in accordance with Code Article 2.1.4.2.

4.5 The packaging or immediate container must be stamped with the date of manufacture of the products.

4.6 Cheese or butter not heat treated in accordance with requirement 2.4.4(a) will not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture*.

*[Note: For cheese the date of manufacture is the date the curd was set.]

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5. CHEESE FROM APPROVED COUNTRIES AFFECTED BY FOOT AND MOUTH DISEASE

5.1 The milk or the milk from which the cheese is made must originate from a country/zone approved by AQIS for the export of dairy products to Australia.

5.2 The animals must be clinically healthy at the time the milk was obtained.

5.3 EITHER

(a) the milk from which the cheese was made was

pasteurised at a minimum of 72°C for 15 seconds or equivalent treatment, in terms of phosphatase destruction and
the cheese has attained a pH of less than 6 and the cheese has aged for 30 days or more.

OR

(b) the cheese has attained a pH of less than 6 and has aged for 120 days or more at a temperature not less than 2°C.

5.4 The packaging or immediate container must be stamped with the date of manufacture of the products.

5.5 Cheese made according to requirement 2.5.3(a) above will not be released from quarantine until a minimum of 30 days after the date of manufacture. Sampling of cheeses prior to release from quarantine to ensure the pH is not above 6 may be required by the Director of Quarantine.

5.6 Cheese made according to requirement 2.5.3(b) above shall not be released from quarantine until a minimum period of 120 days storage at a temperature not less than 2°C after the date of manufacture. Sampling of cheeses prior to release from quarantine to ensure the pH is not above 6 may be required by the Director of Quarantine.

*[Note: For cheese the date of manufacture is the date the curd was set.]

III. AGENTS/IMPORTERS RESPONSIBILITIES

Importers must ensure that they obtain any required clearance from Customs and comply with other relevant legislation, including the *Imported Food Control Act* (1992).

IV. POST ARRIVAL QUARANTINE

Dairy products imported under this protocol shall not to be used for stockfeed.

V. REVIEW

The Director may review the conditions or revoke them, or any permit, if there is a change in the disease status of the country/zone from which the milk or dairy product from which the milk was made was sourced or exported or in response to any other information likely to significantly change the quarantine risk presented by the importation.

Signed

DAVID BANKS
A/g Assistant Director
Animal Quarantine Policy Branch

5.3 Model sanitary certificates to accompany dairy products exported to Australia.

SANITARY CERTIFICATE FOR DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER), OF BOVINE ORIGIN FROM APPROVED COUNTRIES

Exporting country:.....

Ministry of:.....

Province, district etc:.....

I. Identification of consignment

Name and address of manufacturing establishment:.....

.....

.....

Registration Number of manufacturing establishment:.....

Type of product:.....

Type of package:.....

Number of packages:.....

Net weight:.....

II. Origin of the milk contained in the dairy product to which this certification applies.

The milk or the milk from which this dairy product is made originated in:

..... (country/zone)

The milk or the dairy product was processed and packaged in:

..... (country/zone)

III. Destination of the dairy product

The dairy product is being sent from:

.....

to: .....

Nature and identification of means of transport:

.....

Name and address of exporter:

.....

.....

.....

Name and address of consignee:

.....

.....

.....

IV. Attestation of Animal Health

Note: It is essential that either Part A or Part B be signed by the *Official Veterinarian*. An endorsed manufacturer's statement must be attached.

A. Product not heat treated.

The undersigned *Official Veterinarian* certifies that:

(i) The milk or the milk from which the dairy product was made originated from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free (with or without vaccination).

(ii) The milk or the milk from which the dairy product was made originated from a country/zone which meets OIE requirements for freedom from lumpy skin disease, and which is free from buffalo pox.

(iii) The animals were clinically healthy at the time the milk was obtained.

(iv) The products were processed in a foot and mouth disease free country/zone.

(v) The milk or the milk from which the dairy product was made originated from a country/zone which meets OIE requirements for freedom from:

rinderpest (Code Article 2.1.4.2), and
bovine brucellosis (Code Article 3.2. 1. 1.), and
bovine tuberculosis (Code Article 3.2.3. 1.), and
which is free from Jembrana.

(vi) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(vii) The packaging or immediate container of products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... on .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

Note: Product carrying Attestation Part A must be accompanied by a manufacturer's certificate that must include either *III Treatments (a)* or *(b)* of the attached format:

B. Product heat treated.

The undersigned *Official Veterinarian* certifies that:

(i) The milk or the milk from which the dairy product was made originated from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free (with or without vaccination).

(ii) The milk or the milk from which the dairy product was made originated from a country/zone which meets OIE requirements for freedom from lumpy skin disease, and which is free from buffalo pox.

(iii) The animals were clinically healthy at the time the milk was obtained.

(iv) The products were processed in a foot and mouth disease free country/zone.

(v) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(vi) The packaging or immediate container of products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... on .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

Note: Product carrying Attestation Part B must be accompanied by a manufacturer's certificate that includes the heat treatment described in *III Treatments (a)* of the attached format:

MANUFACTURER'S CERTIFICATE -for dairy products (other than cheese and butter) of bovine origin from approved countries

I Manufacturer details

Name and address of manufacturing establishment:
.....

.....

Registration Number of manufacturing establishment: .....

II Product

Description of product:.....

Origin of raw materials:.....

Date of manufacture as appears on the packaging or immediate container of the product:
.....

III Treatments*

EITHER

The milk or the milk from which the dairy product was made was heated to one of the following minimum temperature/times:

(a) 72°C for a minimum of 15 seconds, or the equivalent in terms of phosphatase destruction; or

135°C for a minimum of 1 second.

OR

(b) The milk or the milk from which the dairy product was made was not heat treated as above.

* [Delete either (a) or (b)]

Signed:.....
Date:.....

Position within Company: .....

Name and address of Company employee:

.....

.....

[**Note**: The Official Seal or Trademark of the Manufacturing Company must appear on each page.]

Company seal or trademark:

Signature of Official Veterinarian: .....

Date: .....

Printed name of Official Veterinarian: .....

Official stamp:

SANITARY CERTIFICATE FOR DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER), OF OVINE/CAPRINE ORIGIN FROM APPROVED COUNTRIES

Exporting country: .....

Ministry of: .....

Province, district etc: .....

I. Identification of consignment

Name and address of manufacturing establishment:

.....

.....

Registration Number of manufacturing establishment: .....

Type of product: .....

Type of package: .....

Number of packages: .....

Net weight: .....

II. Origin of the milk contained in the dairy product to which this certification applies.

The milk or the milk from which this dairy product is made originated in:

..... (country/zone)

The milk or the dairy product was processed and packaged in:

..... (country/zone)

III. Destination of the dairy product

The dairy product is being sent from:

.....

to .....

Nature and identification of means of transport:

.....

Name and address of exporter:

.....

.....

Name and address of consignee:

.....

.....

.....

IV. Attestation of Animal Health

Note: It is essential that either Part A or Part B be signed by the *Official Veterinarian*. An endorsed manufacturer's statement must be attached.

A. Product not heat treated.

The undersigned *Official Veterinarian* certifies that:

(i) The milk or the milk from which the dairy product was made originated from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free (with or without vaccination).

(ii) The milk or the milk from which the dairy product was made originated from a country/zone which meets OIE requirements for freedom from sheep pox and goat pox.

(iii) The animals were clinically healthy at the time the milk was obtained.

(iv) The products were processed in a foot and mouth disease free country/zone.

(v) the milk or the milk from which the dairy product was made originated from a country/zone which meets OIE requirements for freedom from:

rinderpest (Code Article 2.1.4.2),
peste des petits ruminants (Code Article 2.1.5.2.),
ovine brucellosis (Code Article 3.3.2. I.);
maedi-visna (Code Article 3.3.5. I.);
contagious agalactia (Code Article 3.3.3. I.), and
contagious caprine pleuropneumonia (Code Article 3.3.6.2.), [caprine products only].

(vi) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(vii) The packaging or immediate container of products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... *on* .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

Note: Product carrying Attestation Part A must be accompanied by a manufacturer's certificate that must include either *III Treatments (a)* or *(b)* of the attached format:

B. Product heat treated.

The undersigned *Official Veterinarian* certifies that:

(i) The milk or the milk from which the dairy product was made originated from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free (with or without vaccination).

(ii) The milk or the milk from which the dairy product was made originated from a country/zone which meets OIE requirements for freedom from sheep pox and goat pox.

(iii) The animals were clinically healthy at the time the milk was obtained.

(iv) The products were processed in a foot and mouth disease free country/zone.

(v) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(vi) The packaging or immediate container of products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... on .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

Note: Product carrying Attestation Part B must be accompanied by a manufacturer's certificate that includes the heat treatment described in *III Treatments (a)* of the attached format:

MANUFACTURER'S CERTIFICATE *-for dairy products (other than cheese and butter) of ovine/caprine origin from approved countries*

I Manufacturer details

Name and address of manufacturing establishment:

.....

.....

Registration Number of manufacturing establishment: .....

II Product

Description of product: .....

Origin of raw materials: .....

Date of manufacture as appears on the packaging or immediate container of the product: .....

III Treatments*

EITHER

The milk or the milk from which the dairy product was made was heated to one of the following minimum temperature/times:

(a) 72°C for a minimum of 15 seconds, or the equivalent in terms of phosphatase destruction; or

135°C for a minimum of 1 second.

OR

(b) The milk or the milk from which the dairy product was made was not heat treated as above.

* [Delete either (a) or (b)]

Signed:..... Date: .....

Position within Company:.....

Name and address of Company employee:

.....

.....

[Note: The Official Seal or Trademark of the Manufacturing Company must appear on each page.]

Company seal or trademark:

Signature of Official Veterinarian: .....

Date: .....

Printed name of Official Veterinarian: .....

Official stamp:

SANITARY CERTIFICATE FOR DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER), OF CAMEL ORIGIN FROM APPROVED COUNTRIES

Exporting country: .....

Ministry of: .....

Province, district etc: .....

I. Identification of consignment

Name and address of manufacturing establishment:

.....

.....

Registration Number of manufacturing establishment: .....

Type of product: .....

Type of package: .....

Number of packages: .....

Net weight: .....

II. Origin of the milk contained in the dairy product to which this certification applies.

The milk or the milk from which this dairy product is made originated in:

..... (country/zone)

The milk or the dairy product was processed and packaged in:

..... (country/zone)

III. Destination of the dairy product

The dairy product is being sent from:

.....

to:.....

Nature and identification of means of transport:

.....

Name and address of exporter:

.....

.....

Name and address of consignee:

.....

.....

IV. Attestation of Animal Health

Note: It is essential that either Part A or Part B be signed by the *Official Veterinarian*. An endorsed manufacturer's statement must be attached.

A. Product not heat treated.

The undersigned *Official Veterinarian* certifies that:

(i) The milk or the milk from which the dairy product was made originated from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free (with or without vaccination).

(ii) The milk or milk from which the dairy product was made originated from a country/zone which is free from camel pox.

(iii) The animals were clinically healthy at the time the milk was obtained.

(iv) The products were processed in a foot and mouth disease free country/zone.

(v) the milk or the milk from which the dairy product was made originate from a country/zone which meets OIE requirements for freedom from:

rinderpest (Code Article 2.1.4.2), and
ovine brucellosis (*Brucella melitensis*)(Code Article 3.3.2. 1), and
bovine brucellosis (Code Article 3.2.1.1), and
bovine tuberculosis (Code Article 3.2.3.1)

(vi) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(vii) The packaging or immediate container of products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... on .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

Note: Product carrying Attestation Part A must be accompanied by a manufacturer's certificate that must include either *III Treatments (a)* or *(b)* of the attached format:

B. Product heat treated.

The undersigned *Official Veterinarian* certifies that:

(i) The milk or the milk from which the dairy product was made originated from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free (with or without vaccination).

(ii) The milk or milk from which the dairy product was made originated from a country/zone which is free from camel pox.

(iii) The animals were clinically healthy at the time the milk was obtained.

(iv) The products were processed in a foot and mouth disease free country/zone.

(v) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(vi) The packaging or immediate container of products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... on .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

Note: Product carrying Attestation Part B must be accompanied by a manufacturer's certificate that includes the heat treatment described in *III Treatments (a)* of the attached format:

MANUFACTURER'S CERTIFICATE - for dairy products (other than cheese and butter) of camel origin from approved countries

I Manufacturer details

Name and address of manufacturing establishment:

.....

.....

Registration Number of manufacturing establishment: .....

II Product

Description of product: .....

Origin of raw materials: .....

Date of manufacture as appears on the packaging or immediate container of the product:

.....

III Treatments*

EITHER

The milk or the milk from which the dairy product was made was heated to one of the following minimum temperature/times:

(a) 72°C for a minimum of 15 seconds, or the equivalent in terms of phosphatase destruction; or

135°C for a minimum of 1 second.

OR

(b) The milk or the milk from which the dairy product was made was not heat treated as above.

* [Delete either (a) or (b)]

Signed:..... Date: .....

Position within Company:.....

Name and address of Company employee:

.....

.....

[Note: The Official Seal or Trademark of the Manufacturing Company must appear on each page.]

Company seal or trademark:

Signature of Official Veterinarian: .....

Date: .....

Printed name of Official Veterinarian: .....

Official stamp:

SANITARY CERTIFICATE FOR CHEESE AND BUTTER FROM APPROVED COUNTRIES WHICH ARE FREE FROM FOOT AND MOUTH DISEASE

Exporting country:.....

Ministry of:.....

Province, district etc:.....

I. Identification of consignment

Name and address of manufacturing establishment:

.....

.....

Registration Number of manufacturing establishment:.....

Type of product: .....

Type of package: .....

Number of packages: .....

Net weight: .....

II. Origin of the milk contained in the dairy product to which this certification applies.

The milk or the milk from which this dairy product is made originated in:

..... (country/zone)

The cheese or butter was processed and packaged in:

..... (country/zone)

III. Destination of the cheese or butter

The cheese or butter is being sent from:

.....

to:

.....

Nature and identification of means of transport:

.....

Name and address of exporter:

.....

.....

Name and address of consignee:

.....

.....

IV. Attestation of Animal Health

Note: It is essential that either Part A or Part B be signed by the *Official Veterinarian*. An endorsed manufacturer's statement must be attached.

A. Product not heat treated.

The undersigned *Official Veterinarian* certifies that:

(i) The milk or the milk from which the cheese or butter was made originated from a country/zone recognised by Office International des Epizooties (OIE) as foot and mouth disease-free (with or without vaccination).

(ii) The milk or the milk from which the cheese or butter was made originated from a country which meets the OIE requirements for freedom from rinderpest in accordance with Code Article 2.1.4.2.

(iii) The animals were clinically healthy at the time the milk was obtained.

(iv) The products were processed in a foot and mouth disease free country/zone.

(v) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(vi) The packaging or immediate container of products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... on .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

Note: Product carrying Attestation Part A must be accompanied by a manufacturer's certificate that must include either *III Treatments (a)* or *(b)* of the attached format:

B. Product heat treated.

The undersigned Official Veterinarian certifies that:

(i) The milk or the milk from which the cheese or butter was made originated from a country/zone recognised by the Office International des Epizooties (OIE) as foot and mouth disease-free (with or without vaccination).

(ii) The animals were clinically healthy at the time the milk was obtained.

(ii) The products were processed in a foot and mouth disease free country/zone.

(iv) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(v) The packaging or immediate container of products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... on .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

Note: Product carrying Attestation Part B must be accompanied by a manufacturer's certificate that includes the heat treatment described in *III Treatments (a)* of the attached format:

MANUFACTURER'S CERTIFICATE - for cheese and butter from approved countries which are free from foot and mouth disease.

I Manufacturer details

Name and address of manufacturing establishment:

.....

.....

Registration Number of manufacturing establishment: .....

II Product

Description of product:.....

Origin of raw materials:.....

Date of manufacture as appears on the packaging or immediate container of the product: .....

III Treatments *

EITHER

The milk or the milk from which the cheese or butter was made was heated to one of the following minimum temperature/times:

(a) 72°C for a minimum of 15 seconds, or the equivalent in terms of phosphatase destruction; or 135°C for a minimum of 1 second.

OR

(b) The milk or the milk from which the cheese or butter was made was not heat treated as above.

* [Delete either (a) or (b)]

Signed:.....

Name and address of Company employee:

.....

.....

Position within Company:.....

Date:.....

[Note: The Official Seal or Trademark of the Manufacturing Company must appear on each page.]

Company seal or trademark:

Signature of Official Veterinarian:
.....

Date: .....

Printed name of Official Veterinarian: .....

Official stamp:

SANITARY CERTIFICATE FOR CHEESE FROM APPROVED COUNTRIES NOT FREE FROM FOOT AND MOUTH DISEASE.

Exporting country:.....

Ministry of:.....

Province, district etc:.....

I. Identification of consignment

Name and address of manufacturing establishment:

.....

.....

Registration Number of manufacturing establishment:.....

Type of product: .....

Type of package: .....

Number of packages: .....

Net weight: .....

II. Origin of the milk contained in the cheese to which this certification applies.

The milk or the milk from which this cheese is made originated in:

..... (country/zone)

The milk cheese was processed and packaged in:

..... (country/zone)

III. Destination of the cheese

The cheese is being sent from:

.....

to:

.....

Nature and identification of means of transport:

.....

Name and address of exporter:

.....

.....

Name and address of consignee:

.....

.....

IV. Attestation of Animal Health

Note: It is essential that an endorsed manufacturer's statement that conforms to the attached format be attached to the Sanitary Certificate.

The undersigned Official Veterinarian certifies that:

(i) The animals were clinically healthy at the time the milk was obtained.

(ii) I have read and endorsed the attached manufacturer's statement and have no reason to doubt the truth of the statement.

(iii) The packaging or immediate container of the products were stamped with the date of manufacture.

Official Stamp:

Issued at: ..... on .....

Name and address of Veterinarian

.....

.....

.....

Signature .....

MANUFACTURER'S CERTIFICATE *- cheese from approved countries not free from foot and mouth disease.*

I Manufacturer details

Name and address of manufacturing establishment:

.....

.....

Registration Number of manufacturing establishment: .....

II Product

Description of product: .....

Origin of raw materials: .....

Date of manufacture as appears on the packaging or immediate container of the product: .....

III Treatments *

EITHER

(a) the milk from which the cheese was made was pasteurised at a minimum of 72°C for 15 seconds, or the equivalent in terms of phosphatase destruction and has attained a pH less than 6,

OR

(b) the cheese has attained a pH of less than 6 and has been maintained since manufacture at a temperature not less than 2°C.

* [Delete either (a) or (b)]

Signed:.....

Name and address of Company employee:

.....

.....

Position within Company:.....

Date:.....

[Note: The Official Seal or Trademark of the Manufacturing Company must appear on each page.]

Company seal or trademark:

Signature of Official Veterinarian:
.....

Date: .....

Printed name of Official Veterinarian: .....

Official stamp:

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Appendix I

Common processes used in dairy product manufacture.

The main groups of dairy products are described below. The description is largely based on information in "Milk and Dairy Product Technology"[36]

Market milk, milk drinks and cream products

. Market milk/industrial milk. Usually this milk is subjected to some form of heat treatment to destroy pathogens and enhance keeping qualities. Such treatments include pasteurisation and ultra-high temperature treatment (UHT). In some developing countries, milk is sold for human consumption without prior treatment.

. Milk drinks comprise milk of variable fat content, including various ingredients such as sweeteners, flavourings, colourings, hydrocolloids or fruit.

. Cream is made by the separation of the cream from whole milk. The fat content varies from 10% for light cream to 45% for double cream.

. Sour cream is made using an active bacterial culture, followed by heat treatment. In some cases, the milk is pasteurised before souring.

. Dairy desserts comprise mixtures of dairy products with other ingredients, such as. chocolate or fruit. The milk is usually subjected to initial pasteurisation, sometimes followed by further thermal processing .

. Reconstituted milk is made by the rehydration of dried or concentrated milk. It may then be pasteurised or UHT processed and packed like fresh milk. Recombination is used in the manufacture of dairy products with a significantly modified composition.

Butter

. Butter is a water in fat emulsion, normally comprising 80-90% milk fat. Butter may be made from soured cream or non-acidified cream. The pH may range from <5.1 to >6.4. Cream for butter manufacture is normally heated to >85°C.

. Ghee is the clarified oil of butter produced by subjecting butter to an additional thermal treatment.

Cheese

. Cheese is manufactured by precipitating the protein in milk and pressing and draining away the whey fraction. Cream or buttermilk may be added. Solids may be precipitated using enzymes derived from microorganisms or by acidification. Cheese may be manufactured from raw, thermised or pasteurised

milk, depending on the type of cheese and the public health requirements of the country in which the cheese is manufactured.

. There are three major groups of cheeses: (a) rennet or natural cheese, manufactured using proteolytic enzymes and acid. Hard and semi-hard cheese is in this group. (b) Fresh, non-ripened cheese made similarly to rennet cheese, that has high acidity and is not subjected to a proteolytic ripening process. Quarg (a soft cheese used fresh in desserts) is an example of this group. (c) Long-life cheese or processed cheese, which is textured by thermal treatment and does not require refrigeration.

Acidified milk products

. These products are manufactured by acidification of milk or cream using lactic acid bacteria. Included in this group are yoghurt, kefir, buttermilk and sour milk.

Casein and whey

. Casein is precipitated from skim milk by the addition of acid and heating. The pH is reduced to 4.2-4.6.

. Whey is the aqueous fraction that remains after coagulation of cheese or casein. Sweet whey is produced during enzymatic (rennet) coagulation, while acid whey is the product of acid coagulation (casein manufacture).

Filtration.

Milk is filtered or strained on farms and in dairy plants. The only real value is an aesthetic one, it has no effect on bacteria in milk.

Clarification is another process for the removal of sediment. It is more effective than filtration in removing "sludge"[1].

Ultrafiltration concentrates milk in the manufacture of cheese and other products requiring concentration of solids. It used particularly in the manufacture of soft cheeses, and also in preparing milk for spray drying[9].

Microfiltration is a process of selectively removing from skim milk, particles including fat particles and bacterial cells.

Bactofugation is a centrifugal treatment that removes bacteria, especially spores that are not destroyed by pasteurisation, however it cannot be used to replace pasteurisation[8,20].

Homogenisation may also break up clumps of bacteria. Homogenised market milk is pasteurised.. Milk may be pasteurised both before and after homogenisation, but from the bacteriological standpoint pasteurisation following homogenisation is preferable since it tends to control contamination from the homogeniser.

Pasteurisation. This is the heat treatment of milk to reduce the bacterial load and increase shelf life. Low-temperature long-time (LTLT), applies to a now largely superseded method of heating milk in vats at about 63°C for 30 minutes[16]. The most common method of pasteurisation raises the milk to a higher temperature for a shorter time. The OIE International Animal Health Code accepts 72°C for 15 seconds as a standard for high temperature-short time (HTST) pasteurisation, though this may differ from other standards.

Pasteurised milk must be phosphatase negative.

"UHT" -ultra high temperature (UHT) is the sterilisation of milk by very high heat for a very short time. The standard for UHT milk laid down the OIE International Animal Health Code is 132°C for at least 1 second.

Thermization (thermalising) is a pre treatment of 62-63°C for a few seconds followed by rapid cooling to below 6°C. It has been demonstrated to reduce total plate counts for raw milk, but the reduction is significantly less than the reduction due to the process of pasteurisation[8]. It must be phosphatase negative following heat treatment. It extends storage time of milk, and the process is usually followed by pasteurisation or cheesemaking[12,14,16,26].

Double heat treatments Although milk, in applying thermization and subsequently pasteurisation is twice increased in temperature, the influence of thermization is so slight that such a treatment cannot be considered as a double heat treatment in the sense that it is used in the OIE Animal Health Code.

Phosphatase test is used to detect improperly pasteurised milk. Most enzymes that occur in raw milk can be inactivated by pasteurisation conditions[16]. Because of its close relationship with the destruction curve for *M. tuberculosis*, phosphatase is used as an index of efficient pasteurisation of milk[6].

Peroxidase is an enzyme, the destruction of which is used as an indicator for high temperature (>85°C) heating.

Nisin addition. The natural antibiotic nisin, derived from food grade organisms, is a very effective inhibitor of spoilage of pasteurised product. It works specifically against Gram positive organisms, so gram negative organisms must be removed first[8].

Butter is made from cream, the whole milk may be pasteurised first, or the cream may be pasteurised following separation. The pasteurisation temperature of cream whether for sale as such or for butter making is higher than milk pasteurisation temperatures. Butter may be made from ripened cream or sweet cream, the former has a pH of less than or equal to 5, the latter has a pH of more than or equal to 6.2[4]. "Farm butter" is the term used for butter made from unpasteurised cream[3].

Ghee, Butter oil, Clarified butter, anyhdrous milk fat. This is made by heating butter or cream to separate the oil from the aqueous material. Temperatures of 110°C to

180°C may be used for about five minutes, and the clarified oil is filtered off. Heat treatments of 85°C for 45 minutes and 90°C for 30 minutes may also be used. The product is shelf stable at ambient temperatures for several months[8, 10,11, 13].

Dried milk powder Milk contains about 87% water, and dehydration is practiced for long term storage and convenience of packaging and transport. Milk is heated at temperatures from 90°C to >100°C. It is concentrated to about 45% moisture before being spray dried. Pasteurisation or thermisation prior to concentration and drying is commonplace[21].

Cultured milks (e.g. yoghurt, kefir, cultured buttermilk) are made from skim milk, partially skimmed milk, or whole milk. Nonfat dry milk is commonly added to milk used for making yoghurt. The type of milk chosen, with or without added nonfat dry milk, is commonly heated at 82-84°C for 20 minutes to pasteurise the milk and to insure that the desired body will develop in the fermented product.

Casein is coagulated milk protein. The process involves the acidification of skim milk at a pH of 4.6 - 4.7. The solid coagulated phase is washed and dried. Casein is generally downgraded to “industrial” grade because of an unsatisfactory microbiological content. This could be a reflection of poor or no pasteurisation, or post processing contamination.

Whey is the liquid product of protein coagulation. Sweet whey is a by-product of cheese manufacture, acid whey is a by product of casein manufacture[2].

Cheese Traditionally cheeses were fermented products which underwent digestion by enzymes attendant with odours[5].

Milk protein is coagulated by the addition of rennet or a similar enzyme for protein coagulation. The pH drops to 5.2-5.5 during the first 24 hours[2,15].

Colostrum

Colostrum is used primarily as a feed supplement for newborn animals and for the production of specific immunoglobulins for human therapeutics. Immunoglobulin IgG confers passive immunity to the newborn. It is damaged at pasteurisation temperatures, but the level of destruction by thermisation is far less[17,22,19]. Preservation of colostrum is by freezing or drying, spray drying is the most economical, whilst freeze drying utilises the lowest temperatures[24]. Significant numbers of bacteria survived both processes[24], so it could be assumed that pathogens would survive the process. A number of colostral products are available commercially[24,23].

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Appendix II

International Animal Health Code

Standards for the importation of dairy products into countries free from foot and mouth disease.

Article 2.1.1.19

When importing dairy products from an FMD free country or zone (where vaccination either is or is not practiced), Veterinary Administrations will require:

for milk products destined for human consumption and for products of animal origin (from FMD susceptible animals) destined for use in animal feeding or for industrial use

the presentation of an international sanitary certificate attesting that these products come from animals which have been kept in the country or zone since birth, or which have been imported from an FMD free country or zone (where vaccination either is or is not practiced).

Article 2.1.1.20

When importing from FMD infected countries or zones, Veterinary Administrations will require:

for milk and cream

the presentation of an international sanitary certificate attesting that:

(1) these products originate from herds or flocks which were not subjected to any restrictions due to FMD at the time of milk collection;

(2) the products have been processed to ensure the destruction of the FMD virus according to the procedures in Appendix 4.3.2.3;

(3) necessary precautions were taken after processing to avoid contact of the product with any potential source of FMD virus;

for milk powder and milk products

the presentation of an international sanitary certificate stating that:

(1) these products are derived from milk complying with the above requirements;

(2) necessary precautions were taken after processing to avoid contact of the milk powder or the milk products with any potential source of FMD virus.

Article 4.3.2.3

Milk and Cream

For the inactivation of viruses present in milk and cream, one of the following procedures should be used:

1. Milk or cream for human consumption

(a) Ultra-high temperature (UHT = minimum temperature of 132°C for at least 1 second).

(b) If the milk has a pH of less than 7.0, simple high temperature - short time pasteurisation (HTST).

(c) If the milk has a pH of 7.0 or over, double HTST.

2. Milk for animal consumption

(a) Double HTST (72°C for at least 15 seconds).

(b) HTST combined with another physical treatment, e.g. maintaining a pH < 6 for at least one hour or additional heating to at least 72°C combined with desiccation.

(c) UHT combined with another physical treatment referred to in (b) above.

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Appendix III

Quarantine Proclamation 1998
Animal Quarantine Part 6
Importation of animals, animal parts and animal products into Australia, Division 2
Section 40 [current on 06/05/99]

40 Importation of milk and dairy products

(1) In this section:

dairy product means:

(a) milk (including condensed, concentrated, dried and powdered milk); or

(b) goods produced from milk (including butter, cheese, casein, cream, ghee, whey, ice cream, milk albumin and yoghurt).

(2) The importation into Australia of a dairy product (whether for human consumption or not) is prohibited.

(3) However, subsection (2) is not taken to prohibit the importation of the following dairy products (if not intended to be used for stockfood):

(a) a dairy product imported directly from New Zealand that is, or whose dairy product ingredients consist only of:

(i) milk produced in New Zealand; or

(ii) dairy products made in New Zealand from milk that did not originate in, or pass through, a country other than New Zealand or Australia;

(b) goods of which each individually packaged unit contains less than 10% by weight (other than any added water) of a dairy product;

(c) commercially prepared and packaged chocolate;

(d) lactose, and its derivatives;

(e) commercially prepared and packaged clarified butter oil.

(4) Also, subsection (2) is not taken to prohibit the importation by a person of a thing if a Director of Quarantine has granted the person a permit to import the thing into Australia.

Note For what a Director of Quarantine must consider when deciding whether to grant such a permit, see Part 8.

(5) Also, if a person entering Australia has the care of, and is accompanied by, 1 or more infants, subsection (2) is not taken to prohibit the importation by the person of a commercially prepared dairy product that is an infant food.

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Australian Government
Department of Agriculture, Water and the Environment

I accept the recommended conclusions of this risk assessment in relation to the level of biosecurity risk associated with bringing or importing this class of goods into Australian territory, and the conditions that are necessary to reduce the level of biosecurity risk to very low, in accordance with the ALOP for Australia

s. 47F(1)

(signature)

Risk Assessment for Animal Material and Goods Containing or Made of Animal Material Class of Goods

(12 March 2021)

Preamble

1) This risk assessment has been completed to inform the making of a determination under s 174(1) of the Biosecurity Act (the '**Act**').

2) Whilst completed for this purpose, the risk assessment has been conducted in addition to the previous risk assessments carried out to determine the level of biosecurity risk and conditions necessary to ensure Australia's appropriate level of protection (ALOP). These assessments are set out in the following documents, at **Annexure A**:

   a) biosecurity import risk assessments (BIRAs);

   b) import risk assessments (IRAs, both current and draft);

   c) import policy reviews; and

   d) pest risk assessments (PRAs).

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

4) Risk analyses may take the form of a regulated biosecurity import risk analysis (BIRA) or a non-regulated risk analysis (such as scientific review of existing policy and import conditions, or scientific advice). Australia's biosecurity framework is provided in the Biosecurity import risk analysis guidelines 2016.

5) Because plant and animal risk analyses are covered by two different international standards (International Plant Protection Convention and World Organisation for Animal Health (OIE) respectively), the specific methodology and terminology used to conduct a risk analysis vary between plants and animals. Details are contained in individual reports and are appropriate to the circumstances, as required by the SPS Agreement.

6) The components of risk analysis for animal pests and diseases as described in Chapter 2.1 of the OIE Code are:

   a) hazard identification

   b) risk assessment (entry assessment, exposure assessment, consequence assessment and risk estimation)

   c) risk management

   d) risk communication.

7) In accordance with the OIE Code, the entry assessment describes the likelihood of entry of each of the potential hazards (pests and diseases) under each specified set of conditions and how these might change as a result of various actions, events or measures. The exposure assessment describes the biological pathways necessary for exposure to the hazards from a given risk source and estimates the likelihood of the exposures occurring. The consequence assessment describes the potential consequences of a given exposure and estimates the likelihood of them occurring. The risk assessment for an identified hazard concludes with risk estimation - the combination of the results from the entry assessment, exposure assessment and consequence assessment to determine the unrestricted risk estimate in accordance with the following matrix.

Likelihood of entry and exposure	Negligible	Very low	Low	Moderate	High	Extreme
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

Likely consequences of establishment and/or spread

8) For the purposes of this risk assessment, the likelihood of entry and exposure is combined with the effects of the establishment and/or spread of relevant pests and diseases for the most likely outbreak scenario. This can be considered equivalent to the likelihood of entry, establishment and/or spread, the terms referenced in the Act and existing underlying risk assessments.

9) As part of conducting this risk assessment the documents referred to at paragraph **Error! Reference source not found.** above have been reviewed, in order to ensure that estimates of the risks expressed in those other documents are consistent with the estimates provided in this risk assessment and that the ALOP has been applied. The consistency of the risk estimates serves to confirm the estimate of the overall unrestricted risk of the entire class arrived at in this risk assessment.

10) For the purposes of determining the biosecurity risk associated with animals material and goods containing animal material:

   i) the disease or pest is considered to be present in overseas countries, and not present in Australia, or present in Australia but under official control

   ii) no risk management measures were considered in the estimation of the likelihood of entry

   iii) no consideration was given to Australia's current risk management measures for animal material.

11) The likelihood of entry and exposure as it relates to the likely outbreak scenarios for establishment and spread in Australia will vary depending on a number of factors relating to particular pests or diseases, including the susceptible species, whether the pests and diseases

are present in the imported animal material and whether establishment and/or spread is by direct contact, vectors or fomites.

12) The consequences of the establishment and/or spread are assessed by considering the potential harm to animal, plant and human health, the environment (including loss of biodiversity), and potential economic (including socioeconomic) effects of the establishment and/or spread of the pest or diseases.

13) The estimate of the likelihood of entry and exposure is combined with consequence of establishment and spread using the matrix above to determine the unrestricted risk, which is the estimate of the biosecurity risk in the absence of risk mitigation measures.

14) The unrestricted risk for the entire class is the likelihood that the importation of any good in the class could have one or more of a number of pests or diseases and the potential consequences of the establishment and/or spread of those pests and diseases.

15) In this risk assessment specific diseases and pests are identified and assessed. Whilst other pests and diseases affecting the class have not been separately assessed, those pests and diseases are assumed to present a similar biosecurity risk because of the relevant biological similarities of all goods in the class.

16) If the estimated unrestricted risk does not achieve Australia's ALOP, sanitary measures will be considered to mitigate the risk. These measures will be required through the imposition of conditions for the goods brought into or imported into Australia.

Scope of risk assessment: class of goods

17) This risk assessment applies to the "Animal materials and goods containing, or made of, animal material" class of goods. This class includes meat, dairy, oil, roe or caviar, hides and skins, and any other parts of an animal – including materials such as blood products, foetal serum and organs. It also includes goods that contain or are derived from material of animal origin including various foods, human and veterinary therapeutics and testing materials, hunting trophies, and also household goods (e.g. musical or sporting equipment made from animal hides). Animals are all taxa of the Kingdom Animalia including, but not limited to, cats, dogs, horses, cattle, sheep, pigs, goats, reptiles, fish, molluscs, crustaceans, amphibians, birds and bees.

Risk assessment for the class

18) Animal goods may contain and transmit a number of pests and diseases. The pests and diseases will vary depending on the type of biological product (e.g. meat, dairy, roe or skins and hides), species of origin, and the country of origin, manufacture and/or export, and a variety of other variables.

19) Pests and diseases, as defined in section 9 of the Act, which are likely to enter, establish or spread through the bringing in or import of the class include:

a) Pests and diseases of potential biosecurity risk for Australia, as determined in import risk analyses and import policy reviews (see **Annexure A**)

b) Emergency Animal Diseases, as listed in Schedule 3 of the Emergency Animal Disease Response Agreement and identified in AQUAVETPLAN Disease Strategy Manuals

c) National list of notifiable diseases of terrestrial animals

d) National list of notifiable diseases of bees

e) Australia's national list of reportable diseases of aquatic animals

f) National Environmental Exotic Priority Pests and Disease List (interim)

g) OIE-listed diseases, infections and infestations.

h) Aquatic Animal Diseases Significant to Australia: Identification Field Guide 5th Edition

Likelihood

20) The potential for a pest or disease to be introduced in animal materials imported into Australia together with the risk of exposing susceptible animal species in Australia to the pest or disease, is considered a likely outcome without risk management measures in place. Disease agents may persist in animal materials for significant periods of time – for example, foot- and- mouth disease (FMD) virus has been found to persist in dried hams for 168 days (Mebus et al 1993) while African swine fever virus, another significant animal disease, has been found to survive between 291 and 399 days in dried hams (McKercher et al 1987). Lumpy skin disease (LSD) virus has been found to persist in dried hides for 18 days, and for six months in refrigerated tissue culture fluid (Spickler 2008). Infectious hypodermal and haematopoietic necrosis virus (IHHNV) remains infectious for up to 10 years in crustaceans under certain environmental conditions. Some animal materials may also carry plant material or pests and pathogens of plants, for example unscoured wool could contain weed seeds or insects that may harm plants.

21) Imported animal material may introduce pests and diseases as many of these materials have a direct pathway into live animals – for examples, as ingredients used to make veterinary therapeutics and vaccines which are then directly administered to animals, or materials fed to aquatic animals as bait or berley. In addition, animal products may be deliberately or inadvertently fed to animals as swill even where specifically prohibited – for example, waste may be sent to rubbish tips where it may be scavenged by wildlife or feral animals, such as pigs. Aquatic animal material can also be exposed to live animals through the regular discharge of untreated waste from a fish processing plant into the aquatic environment.

22) The likelihood of entry and exposure for pests and diseases in imported animal material and goods containing, or made of, animal material is estimated as **moderate**.

Consequences

23) The introduction of pests and diseases through animal material has the potential to cause harm to human, animal or plant health, the environment (including loss of biodiversity) and potential economic (including socioeconomic) effects.

24) The consequences associated with several example pests and diseases listed by the World Organisation for Animal Health (OIE), and for which the OIE Terrestrial Animal Health Code or OIE Aquatic Animal Health Code recommends measures to manage the risk associated with trade in biological material derived from susceptible species, follow.

25) Taken together, the following specific pests and diseases have wide applicability across the class: foot-and-mouth disease virus (FMDV), *Trichinella spiralis* (trichinellosis), capripoxviruses, highly pathogenic avian influenza virus (HPAIV), viral haemorrhagic septicaemia virus (VHSV), *Perkinsus marinus*, *Aphanomyces astaci*, White spot syndrome virus (WSSV) and the Ranavirus, Frog Virus 3 (FV3).

26) Some examples of specific consequences, including estimates of the financial impact, if these pests and diseases were to enter, become established and/or spread in the Australian territory are indicated in the table below.

Disease / disease agent	**Consequence / Estimate of financial impact**
FMDV	Foot-and-mouth disease virus (FMDV) is the most serious pest or disease affecting cloven hoofed animals such as cattle, sheep, goats, pigs, buffalo, camels and deer and is considered the greatest biosecurity threat of any disease to Australia's livestock

	industries. FMDV would have consequences for animal health and significant economic impacts. A 2013 report by the Australian Bureau of Agricultural and Resource Economics and Sciences estimated that the direct impact of a large multi-state FMD outbreak in Australia would result in an economic cost of up to approximately $50 billion over 10 years. The *2004 Generic import risk analysis for pig meat* (pig meat IRA) assessed a number of outbreak scenarios for the entry of FMDV into Australia and determined the overall likely consequences as being extreme.
Trichinella spiralis	Trichinellosis is a parasitic zoonotic disease caused by infection with *Trichinella spiralis*. Most mammals are considered susceptible and infection has been documented in pigs and horses, amongst other species. Humans are also susceptible, with ingestion of infected pig meat typically the most important source of human infection. The pig meat IRA noted the likely consequences of an incursion of *Trichinella spiralis* via pig meat would likely be low. The OIE Terrestrial Animal Health Code recommends the application of risk management measures for *T. spiralis* in the international trade of meat from pigs and horses.
Capripoxviruses	Capripoxviruses, including sheep pox (SPP) and goat pox (GTP) and lumpy skin disease (LSD) affect cattle, sheep and goats. Capripoxviruses are typically stable for long periods of time in the environment and in animal products - for example LSD has been found to survive in dried hides for up to 18 days (Spickler 2008, EFSA 2015). LSD, SPP and GTP are categorized by the OIE as notifiable diseases due to their potential for rapid spread and substantial economic impact (Tuppurainen et al 2017). Geering (1990) previously suggested that "introduction of sheep pox into Australia would have very serious socio-economic consequences, which may even approach or be on a par with those of FMD". The OIE Terrestrial Animal Health Code recommends the application of risk management measures for these diseases for biological materials such as dairy and hides and skins.
HPAIV	Highly pathogenic avian influenza (HPAI), caused by influenza A viruses, can infect a wide range of domestic and wild bird species as well as mammals, including humans and would have consequences for animal and human health, the environment, and economic impacts. The most devastating clinical, social, economic and trade effects occur with outbreaks of HPAI in commercial poultry flocks. In commercial poultry, mortality may approach 100% with any remaining birds euthanised through stamping out procedures. Past outbreaks of HPAI in Australia have been extremely costly to industry and the affected communities. A 2013 outbreak of HPAI in laying chickens in New South Wales resulted in the destruction of over 400,000 chickens and cost the government and industry $5 million. A 2020 outbreak in Victoria resulted in the destruction of over 300,000

	chickens; the final cost of this outbreak has not yet been calculated.
VHSV	Viral haemorrhagic septicaemia virus (VHSV) causes acute to chronic disease in salmonid and non-salmonid finfish in marine and freshwater environments. The *Aquatic animal diseases significant to Australia: identification field guide* provides information about VHSV including signs of infection and epidemiology. VHSV infection is characterised by haemorrhaging under the skin and swelling of the abdomen. Mortality rates can range from 10% to 80% depending on temperature, age, species, route of exposure and presence of additional stressors. Rainbow trout is the species most susceptible to infection with freshwater strains of VHSV. The consequences of the establishment and/or spread of freshwater European strains of VHSV in Australia was assessed in the *Import risk analysis on non-viable salmonids and non-salmonid marine finfish* as moderate, due primarily to effects on commercial and recreational trout stocks in Australia.
Perkinsus marinus	*Perkinsus marinus* is a protist and the causative agent of Perkinsosis (or dermo disease) in oysters. The *Aquatic animal diseases significant to Australia: identification field guide* provides information about infection with *P. marinus* including signs of infection and epidemiology. Clinical signs of dermo disease in oysters include gaping, poor condition or emaciation, shrinkage of mantle and retarded growth. Infection with *P. marinus* is usually fatal depending on the host and environmental conditions. Cumulative American oyster mortalities of up to 95% have been observed following transfer of naive stock to an area where the disease is known to be present. Outbreaks of *P. marinus* have also impacted the natural ecology of aquatic habitats in the U.S due to the elimination of oyster bed habitats, the alteration of food webs and removal of filter feeders (Gottlieb & Schweighofer, 1996). Species susceptible to infection with *P. marinus* include the Pacific oyster (*Crassostrea gigas*) which is one of the main species of oyster commercially grown and harvested in Australia. The consequences of the establishment and/or spread of *P. marinus* in Australia would be high, primarily due to the impacts on the oyster industry and the natural ecology of aquatic habitats in Australia.
Aphanomyces astaci	Crayfish plague is caused by infection with the oomycete *Aphanomyces astaci*. Oomycota are considered protists and are classified with diatoms and brown algae. The *Aquatic animal diseases significant to Australia: identification field guide* provides information about infection with *A. astaci.* Crayfish plague is a highly infectious disease of freshwater crayfish that has the potential to cause 100% mortality in farmed and wild crayfish in Australia. The disease would devastate the natural ecology of freshwater habitats in affected areas of Australia because populations of native species of freshwater crayfish are likely to become seriously depleted. The freshwater crayfish

	aquaculture industry would also be seriously affected by the loss of overseas markets and increased costs from the implementation of extra disease control measures. The likely consequences of the establishment and/or spread of an outbreak of crayfish plague in Australia were assessed as extreme in the *Risk assessment for Aphanomyces astaci in Chinese mitten crabs* for susceptible species, primarily due to the effect on the crayfish industry and the devastation of the natural ecology of freshwater habitats due to loss of native species of freshwater crayfish.
WSSV	White spot syndrome virus (WSSV) is the aetiological agent of white spot disease (WSD) The *Aquatic animal diseases significant to Australia: identification field guide* and *Review of the biosecurity risks of prawns imported from all countries for human consumption* provide information about infection with WSSV including signs of infection, epidemiology and geographical distribution. A wide range of decapod crustaceans, including penaeid and caridean prawns, crayfish and lobsters are susceptible to infection with WSSV. Signs of WSD can include lethargy, cessation of feeding and rapid onset of mass mortality (usually near 100%) in farmed penaeid prawns. WSSV is now considered established in populations of wild crustacean within the Queensland movement regulated area (MRA). This decision was based on surveillance and genetic evidence accumulated since 2017. A national surveillance program for WSSV has demonstrated that all areas of Australia outside of the MRA are considered free from WSSV. The outbreak of WSSV in south east Queensland has caused serious losses to prawn farms and prawn fishers in the MRA. The likely consequences of an outbreak of WSSV in Australia were assessed in the *Review of the biosecurity risks of prawns imported from all countries for human consumption* and found to be high for farmed, hatchery and wild crustacean exposure groups.
Ranaviruses (other than Bohle iridovirus).	Ranaviruses are a group of pathogens that predominantly cause systemic clinical or subclinical infections in amphibians but can also infect reptiles and fish. There are many species of *Ranavirus*, including some tentative species (OIE,2019). The risk review *Importation of freshwater ornamental fish: review of biosecurity risks associated with gourami iridovirus and related viruses* provides information about Ranaviruses including geographical distribution and epidemiology. Frog virus 3 (FV3) is a *Ranavirus* both exotic and of concern to Australia. Clinical signs of infection with FV3 include multifocal multi-organ haemorrhaging and necrosis. Mortality and morbidity as a result of infection with a *Ranavirus* varies from (0–100%). The risk review of the *Importation of freshwater ornamental fish: review of biosecurity risks associated with gourami iridovirus and related viruses* (the review) found that the establishment and/or

	spread of FV3 would have an impact on native Australian populations of amphibians and fish, as well as alter the biodiversity of local aquatic environments. The likely consequences of the establishment and/or spread of FV3 in Australia were assessed in the review as moderate for the ornamental fish industry in Australia.

27) In addition, animal materials may carry plant material or pests that that can harm plants and cause significant consequences. Examples of the harm to plant health that can be caused by these pests can be found in the risk assessment for the live plants class of goods.

28) The consequences to animal and human health, the environment, and economic impacts of the establishment and/or spread of pests and diseases, including but not limited to those examples provided above, and included in animal import risk analyses for animal products (see **Annexure A**) are considered **high** (and for some pests and diseases extreme).

Unrestricted risk

29) For the likelihood of entry and exposure of **moderate** for animal material and goods made from animal material, consequences of establishment and/or spread of **high** will result in an overall unrestricted risk of **high** which does not achieve Australia's ALOP.

30) As the importation of animal material and goods containing, or made of, animal material poses a **high** unrestricted risk for the introduction of pests and diseases into Australia, measures to manage the associated biosecurity risks are required to reduce the risk to achieve Australia's ALOP. It is therefore appropriate that goods within this class are conditionally non-prohibited imports and must not be brought into or imported into Australia without complying with specified conditions.

31) However, for a small number of animal materials of animal origin the biosecurity risk has been separately assessed as achieving Australia's ALOP.

a) These goods are:

i) biological additives in unused blood collection tubes;

ii) a dye or colouring agent of animal origin (other than carminic acid in relation to which alternative conditions are specified in section 39) that is used on, or is an ingredient of, goods included in a class of goods to which this Division applies;

iii) lactose or any derivative of lactose (other than lactose, or a derivative of lactose, that is intended for animal consumption, veterinary therapeutic use or use as fertiliser);

iv) goods sourced from the ocean, or the ocean floor, within the exclusive economic zone of Australia that have not left the exclusive economic zone of Australia before being brought or imported into Australian territory.

Managing the biosecurity risk with respect to this class

32) A sanitary measure that can mitigate the biosecurity risk for the entire class is requiring an import permit. Under Chapter 3, Part 3, Division 3 of the Act, assessment during the application for and granting of an import permit will allow the department to assess the level of biosecurity risk associated with the animal material and goods made from animal material proposed for import, and consider applying import conditions as part of issuing the relevant import permit to reduce the level of risk to achieve Australia's ALOP.

33) The granting of an import permit involves an individual assessment of the goods and their associated biosecurity risk. Where risk management measures exist that can sufficiently reduce the risk to achieve Australia's ALOP, an import permit containing those conditions may be

granted. Where risk management measures (or combination of measures) that reduce the biosecurity risk to achieve Australia's ALOP have not been identified, then an import permit cannot be granted, and import cannot occur.

34) The conditions that may be listed in the Goods Determination 2021 and imposed without requiring an import permit include one or more of the conditions known as alternative conditions, discussed below. Due to the variety of treatments and processing options available and evolution of trade processes and practices, additional risk mitigation measures may also be applied for the purposes of issuing an import permit.

Alternative conditions for specific pests and diseases affecting animal material and goods containing, or made of animal material

35) The identification of pest or disease specific risks for specific goods identified in column 1 of the table below enables the identification of specific measures to reduce the level of biosecurity risk associated with the relevant class of goods to achieve Australia's ALOP. These specific measures can also be called 'alternative conditions' because they are an alternative to the generic condition of obtaining an import permit. The specific measures can be implemented through the imposition of the alternative conditions on the bringing in or importation of goods in the relevant class to Australia.

36) To achieve Australia's ALOP, a number of risk management options, including a combination of options, can be applied to manage the level of biosecurity risks of specific pests and diseases associated with the importation of animal material and goods containing animal material.

a) Restricting imports from specified country: For goods that are sourced from, manufactured in and/or exported from a country (or zone) or countries that are free from pests and diseases, the likelihood of entry is reduced. In some cases, additional assurance about a country's animal disease status, or ability to meet Australia's import conditions, may be provided by performing an assessment of information available about the country of sourcing/manufacture/export. Imports can then be restricted to a list of countries that are deemed to have an acceptable disease status (for example, listed countries for natural casings derived from bovine, caprine, ovine or porcine animals) or a list of countries that have been assessed as being able to meet Australia's import conditions. This reduces the likelihood of entry of pests and diseases.

   Allowing restricted movement of specified goods imported from Papua New Guinea into the Torres Strait Protected Zone, due to close geographical proximity, manages the likelihood of entry and exposure of pests and diseases. Limiting the goods to personal quantities or personal belongings carried only by specific people, reduces the likelihood of entry and exposure of pests and diseases.

b) Restricting imports to a specific species: Certain pests and diseases can only infect specific species of animals. Restricting imports of goods to those only sourced from specific animal species that cannot contain pests and diseases, or excluding animal species that can contain pests and diseases, may significantly reduce the likelihood of entry of certain pests and diseases. This may also affect the pathways of exposure for certain goods – for example, herbivorous animals are less likely to eat meat and therefore reduce the likelihood of exposure. Restriction of materials of microbial origin to pure cultures or derivatives of a particular genus/species that is not a pest or disease agent reduces the likelihood of entry.

c) Inactivation of infectious agents and microorganisms: Complete or partial inactivation of pests and diseases associated with imported goods reduces the likelihood of entry. These include thermal treatments, irradiation, adjusting the pH of the goods, aging for specified timeframes at specific temperatures, or other preservation and treatments including those set by international standards. Specific examples include :

i) Retorting: retorting of goods in accordance with recognised international standards is considered to effectively inactivate all pests and diseases of animal biosecurity concern, with the exception of prions (e.g. bovine spongiform encephalopathy or scrapie). This reduces the likelihood of entry of pests and diseases.

ii) Irradiation: irradiation of goods by specific types of radiation and at specified doses, can inactivate many pests and diseases. This reduces the likelihood of entry of pests and diseases. This measure cannot be applied to certain goods, such as goods for human consumption.

iii) Embedded in non-biological material or preserved: the process of embedding biological material in other non-biological materials (e.g. resin) or preserving in non-biological material (e.g. taxidermy, or applying formaldehyde) can inactivate some pests and diseases of biological concern and reduce the likelihood of entry of specific pests and diseases. Additionally, the resulting goods may be in a form that is less likely to be exposed to a susceptible species – e.g. due to forming a physical barrier, or changes that mean the product is not able to be ingested. This reduces the likelihood of exposure of pests and diseases.

iv) Ageing: ageing of goods allows time for the natural deterioration of pests and diseases to occur, reducing the likelihood of entry. The additional time also increases the likelihood of the country of origin retrospectively detecting an outbreak of a pest or disease that may not have been apparent at the time of processing of the goods, as a disease outbreak is more likely to be detected as time passes and more animals become infected. Therefore, potentially infected or contaminated goods will be identified and withdrawn prior to being exported to Australia. This reduces the likelihood of entry and exposure of pests and diseases.

v) Highly processed or purified goods: for certain goods the normal production processes include treatments or combinations of treatment such as heating/cooking, pH changes, and removal of extraneous material. These measures contribute to the inactivation of contaminating infectious agents or microorganisms, which may reduce the likelihood of entry of pests and diseases. In addition, the resulting product may also be less suitable for certain uses - for example, highly refined chemicals or enzymes derived from animal tissue are much less likely to be fed to animals than the meat or tissue from which they were derived. This reduces the likelihood of exposure of pests and diseases.

vi) Compliance with international standards: manufacturing processes that comply with international standards such as the United States Pharmacopeia, European Pharmacopoeia, British Pharmacopoeia or USP Food Chemicals Codex are highly regulated, and compliance provides assurance that the goods are highly processed and purified and have minimal likelihood of contamination with extraneous infectious agents or microorganisms. Processes compliant with these standards are designed to protect public health. This reduces the likelihood of entry and exposure of pests and diseases.

vii) Thermal treatments such as 'cooking' reduce the likelihood of entry of hazards as it reduces the viability of the pathogens present in imported goods. Thermal treatments can also reduce the likelihood of exposure of hazards as cooked aquatic animal products are less likely be fed to aquatic animals or used as bait compared to goods which have not been cooked.

d) Restricting high risk material: Limiting imports to only allow import of a specific component, or components, of animal biological material, or goods which have been inspected (including the source of the biological material within the goods) to ensure risk material has been removed, may reduce the likelihood of entry of the pest or disease. Pests and diseases

may be more likely to be found in particular tissues of an animal carcass. These tissues represent a higher biosecurity risk as opposed to other tissues of an animal carcass and can be removed. For example, specific pests and diseases are more likely to be found in the head, gills and viscera of some fish and the removal of these tissues through de-heading, de-gilling or evisceration reduces the likelihood of entry of pests and diseases. Pests and disease may also be evident on visual inspection and so can be removed from a good. This also reduces the likelihood of entry of pests and diseases.

e) Restricting imports for specific uses: Restricting imports to only allow goods that will be used for specific purposes within Australia, will reduce the likelihood of exposure to susceptible species within Australia. For example, by restricting import of certain goods to specific classes of laboratories, or to Approved Arrangements which have been assessed by the department, it reduces the likelihood that material containing pests and diseases will be exposed to susceptible Australian animals. These facilities may also have measures in place to control exposure of staff to material being used in research, reducing the likelihood of exposure of people to zoonotic agents. In addition, prohibiting isolation of infectious agents from the imported goods provides assurance that any contaminating infectious agents will not be further amplified, which reduces the likelihood of exposure of Australian animals to pests and diseases. Specifically excluding animal consumption or bioremediation purposes from the allowed end use reduces the likelihood of exposure as it disables the direct pathway into an Australian animal. The addition of ingredients that are likely to decrease the diversion of specific goods to other uses (e.g. the inclusion of tea or coffee in dairy products) also reduces the likelihood of exposure of pests and diseases.

f) Verification measures: By applying measures to ensure imported goods are compliant with risk mitigation measures (e.g. adequately heat-treated material) the likelihood of entry can be reduced. For example, after having undergone retorting, the treated goods will be stable when stored at room temperature. Goods that are found not to be shelf-stable cannot have met retorting requirements. The shelf stability of the goods can be checked at the point of entry, providing assurance that the goods have met the retorting requirements (and therefore goods that are not shelf-stable, and have not met the retorting requirements, can be rejected). Appropriate labelling with information relevant to the goods (such as information about the manufacturing facility or the inclusion/exclusion of animal-derived ingredients), or provision of appropriate documentation such as manufacturer's declarations, or government certification attesting to certain conditions, identifies goods that do not comply with other applicable risk mitigation measures, and allows exclusion of those goods. This reduces the likelihood of entry of pests and diseases. For Australian goods that have been exported and are being re-imported, ensuring that any Australian government container seals or that commercial packaging remains intact provides assurance that the goods are of Australian origin and have not been manipulated, substituted or contaminated with pests and diseases. This reduces the likelihood of entry of pests and diseases. Other measures assist in verifying the intended use of the goods. For example, infant formula being brought in by a traveller accompanied by an infant is likely to be used as intended and not diverted to other uses such as being fed to animals, reducing the likelihood of exposure to susceptible species.

g) Quantity restriction: Limitations on the quantity of a good allowed for import may reduce the biosecurity risk associated with a number of pests and diseases. By restricting imports to specific quantities, only allowing import of goods containing low proportions of risk material, or products commercially packaged and ready for retail sale, there is a reduced likelihood of entry and exposure of pests and diseases. Additionally, goods imported in restricted quantities (and/or commercially packed) are less likely to be diverted and fed to animals (due to the nature of the material being unsuited for animal feed or due to lower

commercial incentive when smaller volumes are involved) and are less likely to expire before being eaten/used and discarded or fed to animals. This reduces the likelihood of exposure of pests and diseases.

h) Source material hazard requirements: Requiring that goods are sourced from animals that were not showing signs of disease and/or have not been exposed to animals with infectious disease reduces the likelihood that the goods will contain pests and diseases. This may occur by restricting sourcing to herds free from certain pests and diseases, or requiring inspection of source material (e.g. animals pre and post slaughter) to ensure there is no evidence of pests and diseases being present. This reduces the likelihood of entry and exposure of pests and diseases.

   Removing biosecurity risk material from goods offshore additionally avoids the generation of large volumes of waste containing high biosecurity risk material onshore. The repeated high-level exposure of susceptible species to a significant titre of a pest or disease from the regular discharge of untreated effluent from a processing plant is more likely to result in infection, rather than sporadic or isolated entries of a pest or disease into the aquatic environment. Therefore restricting imports to goods that are 'ready for retail sale without any further processing' reduces the likelihood of exposure of certain pests and diseases by stopping waste streams being established on shore.

i) Cleaning and decontamination: Requiring goods to be clean and free from additional materials reduces the likelihood that contaminating material may be present, which may include pests and disease. For example, this includes requirements that a specific biological material must be part of fully manufactured goods (where the material would have undergone processing/cleaning as part of the manufacturing process), requiring that goods are manufactured in accordance with certain commercial standards or levels of purity, requiring that goods are not exposed to contamination, or requiring that clean and new packaging is used. Specific catch methods for aquatic animals can also reduce the likelihood of contamination with higher biosecurity risk material. For example, squid jigging is a highly selective method for catching cephalopods compared to trawl net or purse seine fishing which inadvertently captures other biological material as by-catch. Restricting the import of cephalopods to goods that have been jig-caught minimises the risk of contamination. This reduces the likelihood of entry and exposure of pests and diseases. Following cleaning and decontamination, it may also be important to prevent further contamination. Measures to prevent this include restricting transport to vessels that are not grain- or animal-based carriers, and prohibiting stockpiling of goods in an open environment.

j) Import permits: For goods where management of the biosecurity risk is deemed too complex or variable to enable the use of alternative conditions, the risk management measures can be applied as conditions on an import permit. This may involve a case-by-case assessment of the goods and their associated biosecurity risk. Where risk management measures (or a combination of measures) are unable to reduce the biosecurity risk to achieve Australia's ALOP, then an import permit cannot be granted, and import cannot occur.

37) The application of specific risk management measures as detailed in the draft Goods Determination 2021 as requirements for importation into Australia for the following goods, would sufficiently reduce the likelihood of entry and exposure so as to reduce the biosecurity risk to achieve Australia's ALOP:

a) The following goods not for: animal consumption, or use as a bioremedial agent or fertiliser; or growing purposes or veterinary therapeutic use:

   i) Animal skins and hides

ii) Goods made with rawhide

iii) Animal bristles or hair, other than: animal bristles or hair for use in animal husbandry or human or animal grooming; or wool or fibre from sheep, goats or camelids

iv) Animal bristles or hair for use in animal husbandry or human or animal grooming

v) Feathers

vi) Catgut strings derived from animal intestines for use in musical instruments or sporting equipment

vii) Catgut derived from animal intestines

viii) Wool or fibre from sheep, goats or camelids

ix) Eggshells or eggshell ornaments

x) Kopi luwak

xi) Fishing flies

xii) Seashells, other than oyster shells that are not part of manufactured goods

xiii) Natural or cultured pearls for jewellery, personal use, or display purposes

xiv) Dead animals, animal parts, animal secretions or animal tissue, other than goods covered by another item in section 15 of the proposed Goods Determination

xv) Casein glue or gelatine glue

xvi) Untanned and partially processed game trophies, hides or skins that: are not derived from avian animals; and are from New Zealand

xvii) Untanned and partially processed game trophies, hides or skins that: are derived from avian animals; and are from New Zealand

xviii) Animal trophies, artefacts or handicraft items

xix) Bones, horns, antlers, tusks or teeth

xx) Empty giant African snail shells

xxi) Teleost fish, other than fish of the family Salmonidae or Plecoglossidae

xxii) Teleost fish from New Zealand, other than fish of the family Salmonidae or Plecoglossidae

xxiii) Cartilaginous fish (including dried fish), other than fish meal

xxiv) Non-salmonid finfish or finfish product

xxv) Fish and fish products of the family Salmonidae or Plecoglossidae, other than:

(1) roe or caviar; or

(2) salmon oil

xxvi) Roe or caviar of the family Salmonidae or Plecoglossidae

xxvii) Fish oil for human consumption

xxviii) Cnidarians, crustaceans (other than prawns, freshwater crayfish or crustacean meal), echinoderms, molluscs (other than oysters in full or half shell or freshwater snails) poriferans and tunicates

xxix) Freshwater crayfish

xxx) Prawns or prawn products, other than:

(1) dried prawns; or

(2) prawn meal; or

(3) prawn-based food products

xxxi) Prawn-based food products

xxxii) Dried prawns, other than crustacean meal

xxxiii) Oysters in half shell from New Zealand

xxxiv) Meat-based flavouring product

xxxv) Meat or meat products from New Zealand, other than: pork; or avian meat

xxxvi) Pâté (whether or not egg is included as an ingredient) or foie gras

xxxvii) Pork crackling or pork rind

xxxviii) Meat floss

xxxix) Meat jerky or biltong, other than meat jerky or biltong derived from porcine animals

xl) Natural casings derived from bovine, caprine, ovine or porcine animals

xli) Meat or meat products, other than meat or meat products covered by another item in section 17 of the proposed Goods Determination

xlii) Dairy products, other than: infant formula; or dairy products intended for use as stockfeed

xliii) Infant formula

xliv) Commercial dairy products from New Zealand, other than dairy products intended for use as stockfeed

xlv) The following goods: cheesecakes; cooked biscuits, cooked breads, cooked cakes or cooked pastries containing uncooked dairy fillings or toppings

xlvi) Dairy-based beverages

xlvii) Chocolate

xlviii) Clarified butter oil or ghee

xlix) Whole eggs

l) Egg products, goods that include egg as an ingredient, or goods that contain egg

li) Egg waffles

lii) Mooncakes that include egg

b) The following goods for human consumption purposes

i) Biscuits, breads, cakes and pastries; other than goods to which column 1 of item 4 in the table in subsection 18(2) of the proposed Goods Determination applies

ii) Soup

iii) Birds' nests

iv) Noodles or pasta that contain or include as an ingredient: eggs or egg products; or meat-based flavouring products

v) Snails

vi) Protein powders or supplements (which may include enzymes or egg proteins)

a) The following goods

vii) Honey (whether or not containing honeycomb); bee venom; bee wax; honeycomb; propolis; royal jelly

viii) For certain honey and bee products that enter, or are unloaded in, Western Australia:

(1) Honey (whether or not containing honeycomb), other than honey in individually packaged units with a capacity of 150 millilitres or less; or powdered honey in individually packaged units with a capacity of 35 grams or less;

ix) Honeycomb;

x) Propolis, other than: propolis in the form of a liquid tincture, powder, tablet or cream, in individually packaged units with a capacity of 200 millilitres or less; or propolis in a cosmetic in individually packaged units with a capacity of 200 millilitres or less;

xi) Royal jelly, other than royal jelly: in capsules that contain a quantity of royal jelly of 800 milligrams or less; or in individually packaged units with a capacity of 35 grams or less; or in individually packaged units with a capacity of 150 millilitres or less.

c) The following goods for animal consumption:

i) Food for consumption by domestic cats or domestic dogs

ii) Rawhide chews that: are derived from bovine animals; and are for consumption by domestic dogs

iii) Rawhide chews that: are derived from porcine animals; and are for consumption by domestic dogs

iv) Cuttlefish bone

v) Dead teleost fish (other than fish from the family Salmonidae or Plecoglossidae) or cephalopods from New Zealand

vi) Dead cephalopods that were jig caught

vii) Dead cephalopods that were caught using trawl or purse seine fishing methods

viii) Marine molluscs, other than oysters or snails

ix) Food for consumption by pet fish in enclosed aquariums or ponds

x) Food or supplements for animals containing alcohol, citric acid, lactic acid or xanthan gum

xi) Purified vitamin D3 that is a highly processed derivative of wool grease

d) The following goods:

i) Cosmetics containing biological material for human use

ii) Soap

iii) Highly refined organic chemicals and substances for certain purposes

iv) Biological material intended for personal use

v) Fertilisers, soil conditioners and soil growth supplements made of animal material, plant material or biological material

vi) Other biological material for certain purposes

vii) Gelatine intended for: human consumption; or human therapeutic use; or in-vitro purposes; or in-vivo work in laboratory organisms

viii) Gelatine intended for culture media

ix) Gelatine intended for veterinary therapeutic use or use in cosmetics for animals

x) Bioremedial products

xi) Goods to be brought or imported from Papua New Guinea into the protected zone area

xii) Animal products exported from Australian territory

38) The following table summarises the risk management options that are applied to achieve Australia's ALOP for each of the alternative condition for goods in this part of the class.

39) The recommendations contained in this table are based on the professional knowledge, judgement and experience of officers working in Biosecurity Animal Division. In general, the risk mitigation options that are recommended for the good(s) associated with each alternative condition are intended, both individually and in combination, to reduce the likelihood of the relevant pest or disease entering, establishing or spreading in Australia. Each alternative condition comprises sufficient recommended risk mitigation options to reduce the biosecurity risk for the good(s) to the ALOP. Accordingly, more risk mitigation measures have been recommended in respect of those good(s) which present a higher biosecurity risk.

Goods	Risk management measure (may be required alone or in combination)	Restricting imports from a specified country	Restricting imports to a specific species	Source material hazard requirements	Restricting imports for specific uses	Quantity restriction	Excluding ingredients of animal origin	Inactivation of infectious agents and microorganisms	Restricting high risk material	Cleaning and decontamination	Verification measures	Import permits
Animal skins and hides	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are preserved or tanned using a process that the Director of Biosecurity is satisfied is appropriate to manage the biosecurity risks associated with the goods to an acceptable level							X				
Goods made with rawhide	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Not more than 10 of the same kind of goods are brought or imported into Australian territory together;					X						
	The goods have been treated by immersion in a lime solution at a pH of at least 12.5 and are accompanied by a declaration from the manufacturer of the goods stating that fact;							X			X	
	Have been treated with gamma irradiation to a level that achieves a minimum of 50 kGray at a facility that the Director of Biosecurity is satisfied can treat goods made with rawhide so that biosecurity risks associated with the goods are managed to an acceptable level; and							X				
	Are accompanied by written evidence stating the matter in subparagraph										X	
	The goods are treated, while subject to biosecurity control, with gamma irradiation to a level that achieves a minimum of 50 kGray							X				
Animal bristles or hair, other than: (a) animal bristles or hair for use in animal husbandry or human or animal grooming; or (b) wool or fibre from sheep, goats or camelids	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are are clean and free from other animal or plant material and soil; and									X		
	Are not for use in animal foods or fertilisers				X							
nimal bristles or hair for se in animal husbandry or human or animal grooming	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are for personal use					X						
	Are clean and free from other animal or plant material and soil;									X		
	Have been scoured or sterilised to manage biosecurity risks associated with the goods to an acceptable level; and							X				
	Are accompanied by evidence stating that the goods have been scoured or sterilised to manage biosecurity risks associated with the goods to an acceptable level										X	
Feathers	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are clean and free from other animal or plant material and soil,									X		
	The goods are fully contained within a manufactured product				X							
	The goods are accompanied by documentation stating that the goods have been treated with a treatment the Director of Biosecurity is satisfied is appropriate to manage the biosecurity risks associated with the goods to an acceptable level							X			X	
	The goods are to be treated in accordance with an approved arrangement, while subject to biosecurity control, with a treatment the Director of Biosecurity is satisfied is appropriate to manage the biosecurity risks associated with the goods to an acceptable level;							X				

Goods	Risk management measure (may be required alone or in combination)	Restricting imports from a specified country	Restricting imports to a specific species	Source material hazard requirements	Restricting imports for specific uses	Quantity restriction	Excluding ingredients of animal origin	Inactivation of infectious agents and microorganisms	Restricting high risk material	Cleaning and decontamination	Verification measures	Import permits
	The goods are part of one or more manufactured products				X							
	The quantity of the manufactured products is not more than 10					X						
	The goods are for personal use					X						
Catgut strings derived from animal intestines for use in musical instruments or sporting equipment	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods do not require refrigeration or any further processing										X	
Catgut derived from animal intestines	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods were derived from bovine, caprine, ovine or porcine animals only		X									
	The animals from which the goods were derived were free from diseases of biosecurity concern at the time they were slaughtered			X								
	The goods were made from intestinal material only								X			
	The goods are accompanied by a health certificate stating the matters referred to in paragraphs (a), (b) and (c)										X	
Wool or fibre from sheep, goats or camelids	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Are clean and free from other animal or plant material and soil									X		
	Have been commercially prepared, processed and packaged					X						
	Are ready for retail sale				X							
	Have been scoured to manage the biosecurity risks associated with the goods to an acceptable level or treated with a treatment the Director of Biosecurity is satisfied is appropriate to manage the biosecurity risks associated with the goods to an acceptable level;								X			
	If the gross weight of the goods is more than 500 grams—are accompanied by evidence that the condition referred to in subparagraph (i) has been complied with										X	
Eggshells or eggshell ornaments	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are clean and free of adhering materials									X		
Kopi Luwak	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Are completed embedded in resin				X							
	Are intended for display only				X							
Fishing flies	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are not viable and are clean and free from other animal or plant material and soil									X		

Goods	Risk management measure (may be required alone or in combination)	Restricting imports from a specified country	Restricting imports to a specific species	Source material hazard requirements	Restricting imports for specific uses	Quantity restriction	Excluding ingredients of animal origin	Inactivation of infectious agents and microorganisms	Restricting high risk material	Cleaning and decontamination	Verification measures	Import permits
Dead animals, animal parts, animal secretions or animal tissue, other than goods covered by another item in this table	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X				X			
	The goods have been preserved by taxidermy for display				X			X				
	The goods have been cremated							X			X	
	The goods are completely embedded in resin and are intended for display only				X			X				
	The goods are in a sealed container;									X		
	The goods have been preserved in a solution containing 70% alcohol or 10% formalin or a minimum of 2% glutaraldehyde, or the goods have been plastinated using curable polymers							X				
	The goods are accompanied by a certificate from the laboratory or other facility that preserved or plastinated the goods stating that the goods have undergone complete preservation and fixation or the goods have been completely plastinated										X	
	No animal is, or will be, exposed (whether directly or indirectly) to the goods or any derivatives of the goods				X							
	The goods are not intended to be used for isolation or synthesis of viable microorganisms or infectious agents or their homologues				X							
	The goods have been preserved for collection or display				X							
	The goods are not intended to be used for isolation or synthesis of viable microorganisms or infectious agents or their homologues;				X							
	No animal is, or will be, exposed (whether directly or indirectly) to the goods or any derivatives of the good				X							
Casein glue or gelatine glue	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods have been commercially prepared for industrial, commercial or hobby purposes				X						X	
Untanned and partially processed game trophies, hides or skins that: (a) are not derived from avian animals; and (b) are from New Zealand	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X*							
	The goods were derived from animals (other than avian animals) that resided and were slaughtered in New Zealand;	X	X									
	Are accompanied by a health certificate stating the matter referred to in paragraph (a)										X	
Untanned and partially processed game trophies, hides or skins that: (a) are derived from avian animals; and (b) are from New Zealand	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Were derived from avian animals that resided and were slaughtered in New Zealand	X	X									
	Have undergone one of the following processes: treatment with salt or borax; immersion in an acid pickling solution at a pH of not more than 4; immersion in an alcohol solution; and							X				
	Are accompanied by a health certificate stating the matters referred to in paragraphs (a) and (b)										X	

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Animal trophies, artefacts or handicraft items	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are more than 5 years old							X				
	The goods are preserved so that they do not require refrigeration							X			X	
	The goods are intended only for in-vitro use or display by a museum or scientific institute, or in a public exhibition				X							
	The goods, and any derivatives of the goods, must not come into contact with any animal				X							
	The goods must not be used for isolation of microorganisms or infectious agents				X							
	The goods are accompanied by a declaration from the manufacturer or supplier of the goods, stating the matters referred to in paragraphs (a) and (b)										X	
	The goods are accompanied by a declaration from the person bringing in or importing the goods stating all of the following										X	
	The goods are intended only for in-vitro use or display by a museum or scientific institute, or in a public exhibition				X							
	The goods, and any derivatives of the goods, will not come into contact with any animal				X							
	The goods will not be used for isolation of microorganisms or infectious agents				X							
Bones, horns, antlers, tusks or teeth	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are clean and free from other animal or plant material and soil									X		
Empty giant African snail shells	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are not viable							X			X	
	The goods are clean and free from other animal or plant material and soil									X		
Meat-based flavouring product	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.											
	Have been commercially manufactured and packaged					X					X	
	Do not contain any discernible pieces of meat							X			X	
	Are for personal use					X						
Meat or meat products from New Zealand, other than: (a) pork; or (b) avian meat	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Were produced from animals in New Zealand	X										
	Are clearly labelled on the outermost of the largest packaged unit with the date of processing, the name and address of the place of production, and "Product of New Zealand	X									X	
	Are clearly labelled as a product of New Zealand;	X									X	

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	Are for personal use					X						
Pâté (whether or not egg is included as an ingredient) or foie gras	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are shelf-stable										X	
	The goods are for personal use					X						
	The quantity of the goods is not more than 1 kilogram or 1 litre					X						
Pork crackling or pork rind	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Are shelf-stable										X	
	Are for personal use					X						
Meat floss	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Have been commercially prepared											
	Are for personal use											
Meat jerky or biltong, other than meat jerky or biltong derived from porcine animals	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are shelf-stable										X	
	The goods are for personal use					X						
	The quantity of the goods is not more than 1 kilogram					X						
	If the goods are not from avian meat—the goods have been manufactured in an FMD-free country	X										
Natural casings derived from bovine, caprine, ovine or porcine animals	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Were born, raised and slaughtered in one or more countries, each of which is a listed country for natural casings derived from bovine, caprine, ovine or porcine animals	X	X									
	Were found to be free from contagious and infectious disease at ante-mortem and post-mortem veterinary inspections, conducted under official veterinary supervision			X								
	Were slaughtered at least 30 days before the day the goods are brought or imported into Australian territory							X				
	The goods were not exposed to contamination before being exported									X		
	Each package containing the goods states the identification or veterinary control number of the establishment at which the casings were packed										X	
	The goods are accompanied by a health certificate stating the matters referred to in paragraphs (a), (b), and (c)										X	
Meat or meat products, other than meat or meat products covered by another item in this table	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							

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	Have been retorted and the container in which the goods were retorted has not been opened since the goods were retorted							X		X		
	Contain less than 5% by weight of meat					X						
	Are shelf-stable										X	
	Have been commercially manufactured and packaged					X					X	
	Have been retorted and the container in which the goods were retorted has not been opened since the goods were retorted							X		X		
	Are shelf-stable										X	
	Are for personal use					X						
Dairy products, other than: (a) infant formula; or (b) dairy products intended for use as stockfeed	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Have been commercially prepared and packaged					X					X	
	Were manufactured in an FMD-free country	X										
	Are for personal use					X						
	Are shelf-stable										X	
	Are in a quantity of not more than 1 litre or 1 kilogram; and					X						
	If the goods contain one or more packets (for example, a box containing a cake mix)—the total dry weight of the components of the goods (other than added water) contains less than 10% of dairy products					X						
Infant formula	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.		X		X			X	X			
	Have been commercially prepared and packaged					X						
	Were manufactured in FMD-free countries only	X										
	Are for personal use					X						
	The person bringing in the goods is accompanied by one or more infants										X	
	If the goods are not brought in as baggage—the quantity of the goods is not more than 1 kilogram or 1 litre					X						
	If the goods are brought in as baggage—the quantity of the goods is not more than 5 kilograms or 5 litres					X						
	The goods contain less than 10% by dry weight (other than added water) of dairy products					X						
Commercial dairy products from New Zealand, other than dairy products intended for use as stockfeed	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Are brought in or imported directly from New Zealand										X	
	Are made of ingredients that originated in, and were produced, processed and manufactured in, Australian territory or New Zealand only	X										
The following goods: (a) cheesecakes; (b) cooked biscuits, cooked breads, cooked cakes or cooked pastries containing uncooked dairy fillings or toppings	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Were manufactured in an FMD-free country	X										
	Are for personal use					X						

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Dairy-based beverages	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Include tea, coffee or flavouring as an ingredient				X							
	Are shelf-stable										X	
	Are for instant use						X					
	Are for personal use					X						
Chocolate	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods have been commercially prepared and packaged					X					X	
Clarified butter oil or ghee	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods have been commercially prepared and packaged					X					X	
Whole eggs	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods have been retorted and the container in which the goods were retorted has not been opened since the goods were retorted							X		X		
	The goods are shelf-stable										X	
	the quantity of the goods is not more than 1 kilogram or 1 litre					X						
	The goods are for personal use					X						
Egg products, goods that include egg as an ingredient, or goods that contain egg	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Contain less than 10% by weight (other than added water) of egg or egg product					X						
	Do not contain discernible pieces of egg										X	
	Have been processed so that they are not whole eggs							X				
	Are shelf-stable										X	
	Are in a quantity of not more than 1 kilogram or 1 litre					X						
	Are for personal use					X						
Egg waffles	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Are shelf-stable										X	
	Are for personal use					X						
Mooncakes that include egg	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	Do not contain meat as an ingredient						X					
	Are shelf-stable										X	
	Are for personal use					X						

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Soup	For human consumption				X							
	Have been commercially prepared and packaged					X					X	
	Are ready for retail sale				X	X						
Biscuits, breads cakes and pastries; other than goods to which column 1 of item 4 in the table in subsection 18(2) applies	The goods (excluding any fillings or toppings) have been cooked throughout							X				
	If the goods contain any fillings or toppings that are made of ingredients including either or both of the following: (i) 10% or more dairy products; (ii) 10% or more egg products; those fillings or toppings are cooked throughout;							X				
	The goods are shelf-stable										X	
	The goods do not contain meat or meat product						X		X			
	The goods are accompanied by a declaration from the manufacturer of the goods										X	
	The goods are for personal use				X	X						
	The goods do not require refrigeration										X	
Birds' nests	For human consumption				X							
	Have been commercially manufactured					X					X	
	Have been retorted and the container in which the goods were retorted has not been opened since the goods were retorted							X		X		
	Are for personal use					X						
Noodles or pasta that contain or include as an ingredient:(a) eggs or egg products; or (b) meat-based flavouring products	For human consumption				X							
	The goods are shelf-stable										X	
	If the goods contain meat, meat-based flavouring products or discernible pieces of egg—the goods are for instant use				X	X						
	The goods are for personal use					X						
7 Snails	For human consumption				X							
	The goods have been retorted and the container in which the goods were retorted has not been opened since the goods were retorted							X		X		
Protein powders or supplements (which may include enzymes or egg proteins)	For human consumption				X							
	Have been commercially prepared and packaged					X					X	
	Have been manufactured in an FMD-free country	X										
	Are for personal use					X						
The following goods: (a) honey (whether or not containing honeycomb); (b) bee venom; (c) bee wax; (d) honeycomb; (e) propolis; (f) royal jelly***	Does not apply to honey or bee products that are intended for: stock feed, including food for bees; or use as bioremedial agents or fertiliser; or growing purposes				X							
	Are pure and free from extraneous material									X		
	If the goods are an ingredient of other goods—were pure and free from extraneous material before being added to the other goods				X					X		

Goods	Risk management measure (may be required alone or in combination)	Restricting imports from a specified country	Restricting imports to a specific species	Source material hazard requirements	Restricting imports for specific uses	Quantity restriction	Excluding ingredients of animal origin	Inactivation of infectious agents and microorganisms	Restricting high risk material	Cleaning and decontamination	Verification measures	Import permits
The following goods: (a) honey (whether or not containing honeycomb), other than: (i) honey in individually packaged units with a capacity of 150 millilitres or less; or (ii) powdered honey in individually packaged units with a capacity of 35 grams or less; (b) honeycomb; (c) propolis, other than: (i) propolis in the form of a liquid tincture, powder, tablet or cream, in individually packaged units with a capacity of 200 millilitres or less; or (ii) propolis in a cosmetic in individually packaged units with a capacity of 200 millilitres or less; (d) royal jelly, other than royal jelly: (i) in capsules that contain a quantity of royal jelly of 800 milligrams or less; or (ii) in individually packaged units with a capacity of 35 grams or less; or (iii) in individually packaged units with a capacity of 150 millilitres or less.	Does not apply to honey or bee products that are intended for: stock feed, including food for bees; or use as bioremedial agents or fertiliser; or growing purposes										X	
	If the goods enter, or are unloaded in, Western Australia, the goods are accompanied by a certificate, issued by the government of the exporting country, in a form approved by the Director of Biosecurity.										X	
Food for consumption by domestic cats or domestic dogs	Do not contain any ingredients derived from ruminants (other than dairy products)		X									
	Contain ingredients derived from ruminants that originated from Australia or New Zealand only, and the goods were manufactured in, and exported from, New Zealand	X	X									
	The goods have been retorted and the container in which the goods were retorted has not been opened since the goods were retorted							X		X		
	The goods are shelf-stable										X	
	The goods are in a hermetically sealed container that is stamped or embossed in indelible ink with the identification number of the manufacturing facility and the batch number									X	X	
	The goods are accompanied by commercial documentation that lists the trade names of the goods										X	
	The goods are accompanied by an official government veterinary certificate from the country where the goods were manufactured										X	
	If the food contains animal material (other than dairy, avian or fish material or products originating in Australia or New Zealand)—that the animal from which the material was derived was found to be free from contagious and infectious disease in ante-mortem and post-mortem inspections		X	X								
	If the food contains avian material (other than egg or egg products)—that the animal from which the material was derived was found to be free from contagious and infectious disease in any inspections carried out (whether ante-mortem or post-mortem)			X								
	The identification number, or veterinary control number, of the establishment where the goods were manufactured										X	
Rawhide chews that: (a) are derived from bovine animals; and (b) are for	The goods were made using only hide or skin of bovine animals with no other biological materials (for example, cartilage)		X						X			

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consumption by domestic dogs	The hide or skin was soaked in a liming solution of pH 14 for not less than 8 hours							X				
	An official government veterinary certificate from the country in which the goods were manufactured stating the matters referred to in paragraphs (a) and (b										X	
	A declaration by the manufacturer of the goods that has been endorsed by an official government veterinarian stating the matters referred to in paragraphs (a) and (b)										X	
Rawhide chews that: (a) are derived from porcine animals; and (b) are for consumption by domestic dog	The goods were made using only hide or skin of porcine animals with no other biological materials (for example, cartilage)		X						X			
	The hide or skin was soaked in a liming solution of pH 14 for not less than 8 hours							X				
	The animals from which the goods were derived were not slaughtered as part of disease control measures in the country of origin of the animals			X								
	The goods are accompanied by an official government veterinary certificate from the country in which the goods were manufactured stating the matters referred to in paragraphs (a) to (c)										X	
	A declaration by the manufacturer of the goods stating the matters referred to in paragraphs (a) to (c)										X	
	If the goods are accompanied by a declaration referred to in subparagraph (d)(ii)—the goods are treated, while subject to biosecurity control, with gamma irradiation to a level that achieves a minimum of 50 kGray							X				
Food or supplements for animals containing alcohol, citric acid, lactic acid or xanthan gum	The goods are accompanied by documentation stating the ingredients in the product and the highly processed and purified nature of the goods							X			X	
Purified vitamin D3 that is a highly processed derivative of wool grease	The goods are free from extraneous material						X			X		
	The goods have been processed in a way that ensures that biosecurity risks associated with the goods have been managed to an acceptable level							X				
	The goods are accompanied by a declaration by the manufacturer of the goods										X	
	The goods are a highly processed derivative of wool grease						X					
	The only material of terrestrial animal or avian origin used during the manufacture of the goods was wool grease		X							X		
	The goods have been manufactured to be compliant with the relevant monograph from at least one of the following published standards: United States Pharmacopeia, European Pharmacopoeia, British Pharmacopoeia or USP Food Chemicals Codex							X				
	The level of purity of the goods (excluding any non-biological carrier) has been shown to be at least 96%, calculated on a dry weight basis									X		
	The goods are not on a grain or animal-based carrier						X					
	The goods have not been exposed to contamination after processing									X		
	The goods have been packed in clean and new packaging only					X				X		
	The goods were manufactured in a facility that is operated according to standards of quality applicable to the production of stockfeed products, including appropriate standards for prevention of cross-contamination of production cultures or raw materials									X	X	
Cosmetics containing biological material for human use	Have been commercially manufactured, prepared and packaged					X					X	
	Are ready for retail sale without any further processing				X			X			X	
	Are for personal use				X	X						

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	Contain, in total, less than 20% by mass of material of animal origin (other than material of animal origin that is covered by an item in a table in this Division)					X						
Soap	The goods have been commercially prepared					X					X	
	The biological ingredients of the goods have undergone a process of saponification							X				
	After saponification, no material of animal origin has been added (other than material of animal origin that is covered by an item in a table in this Division)						X			X		
Highly refined organic chemicals and substances for certain purposes	Goods are not intended for animal consumption; or				X							
	Goods are not intended for use as bioremedial agents or fertiliser; or				X							
	Goods are not intended for veterinary therapeutic use; and				X							
	The goods are highly processed; and							X				
	The goods are purified substances							X				
Biological material for personal use	The goods are intended for human therapeutic use; and				X							
	The goods do not contain bee pollen; and						X					
	Are for personal use by the person bringing in or importing the goods; or				X							
	Are for use by any spouse, de facto partner, child, parent or sibling of the person bringing in or importing the goods; and				X							
	The goods are in a quantity of not more than 3 months' supply; and					X						
	The goods are accompanied by documentation stating that the goods are in a quantity of not more than 3 months' supply.										X	
Fertilisers, soil conditioners and soil growth supplements made of animal material, plant material or biological material	The only animal materials, plant materials or biological materials used to make the goods are one or more of the following: alcohols, citric acid, cultures of Saccharomyces cerevisiae (for example, Baker's yeast or Brewer's yeast), lactic acid, purified amino acids (other than those derived from neural material), purified vitamins, or xanthan gum						X					
Biological material intended for human consumption, in-vitro purposes or human therapeutic use or contained in cosmetics for human use	The goods are intended for human consumption, in-vitro purposes or human therapeutic use; or				X							
	Are contained in cosmetics for human use; and				X							
	The goods have been commercially prepared and packaged; and					X					X	
	The goods are ready for retail sale without any further processing				X	X						
Biological material intended for veterinary therapeutic use or use as cosmetics for animals	The goods are intended for veterinary therapeutic use or use as cosmetics for animals; and				X							
	The goods have been commercially prepared and packaged; and					X					X	
	The goods are ready for retail sale without any further processing; and				X	X						
	If the goods contain ingredients of animal, plant or microbial origin—those ingredients are biological material specified in the table in subsection 39(4); and						X					
	The goods are accompanied by documentation stating the ingredients contained in the goods; or										X	
	If applicable, a declaration or other documentation from the manufacturer of the goods stating the matter referred to in paragraph (d).										X	

Goods	Risk management measure (may be required alone or in combination)	Restricting imports from a specified country	Restricting imports to a specific species	Source material hazard requirements	Restricting imports for specific uses	Quantity restriction	Excluding ingredients of animal origin	Inactivation of infectious agents and microorganisms	Restricting high risk material	Cleaning and decontamination	Verification measures	Import permits
Gelatine intended for: (a) human consumption; or (b) human therapeutic use; or (c) in-vitro purposes; Or (d) in-vivo work in laboratory organisms	The goods have been commercially prepared										X	
Gelatine intended for culture media	The goods have been commercially prepared and packaged;					X					X	
	If the goods were derived from bovines—the goods were derived from hides and skins only						X		X			
Gelatine intended for veterinary therapeutic use or use in cosmetics for animals	Were not derived from ruminant animals; and						X					
	Do not contain any biological material except gelatine or biological material specified in the table in subsection 39(4); and						X					
	Have been commercially prepared and packaged; and					X					X	
	Are ready for retail sale without any further processing; and				X	X						
	Are accompanied by a declaration or other documentation from the manufacturer of the goods, stating the matters referred to in paragraphs (a) to (d)										X	
Bioremedial products	The goods contain, as the only biological material, any of the following ingredients: alcohols, citric acid, highly processed chemicals derived from wool grease (including cholesterol, cholecalciferol vitamin D3, lanolin and lanolin alcohols), lactic acid, cultures of Saccharomyces cerevisiae (or a derivative or extract of a pure culture of Saccharomyces cerevisiae), purified amino acids (other than those derived from neural material), purified vitamins, xantham gum; and						X					
	Contain no other material of animal, plant or microbial origin; and						X					
	Are packed in clean and new packaging									X		
Goods to be brought or imported from Papua New Guinea into the protected zone area	This section applies to the following classes of goods - fish meat; coconut (processed or without husk); sago; cooked taros, cooked yams and cooked cassava, kundu drums made from any of the following: lizard skin, snake skin, hard treated beeswax, or soft wood; empty sea shells; goods made from: dried pandanus or dried palm leaves or both dried pandanus and dried palm leaves; bows of black palm or bamboo; spears of bamboo, mangrove or wongai wood with a steel prong; beads and jewellery made of seeds; wood carvings; goods made from woven fibres		X				X		X			
	The goods are covered by an import permit;											X
	The goods are on a vessel that would be a protected zone vessel if it entered a part of Australian territory that is in the protected zone area; and				X						X	
	Are owned by, or are under the control of, a traditional inhabitant who is on board that vessel and have been used, are being used or are intended to be used by him or her in connection with the performance of traditional activities in the protected zone area; or				X	X						
	Are the personal belongings of a person referred to in subparagraph (e)(i) or (ii) of the definition of ***protected zone vessel*** in subsection 617(4) of the Act				X	X						
	The goods are for personal use.				X	X						
The following goods: (a) sea shells, other than oyster shells that are not part of manufactured goods; (b) natural or cultured pearls for jewellery, personal use or display purposes	This section does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	the goods are not viable							X			X	
	are clean and free from other animal or plant material and soil									X		

Goods	Risk management measure (may be required alone or in combination)	Restricting imports from a specified country	Restricting imports to a specific species	Source material hazard requirements	Restricting imports for specific uses	Quantity restriction	Excluding ingredients of animal origin	Inactivation of infectious agents and microorganisms	Restricting high risk material	Cleaning and decontamination	Verification measures	Import permits
Teleost fish, other than fish of the family Salmonidae or Plecoglossidae	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	the goods have been processed to the extent needed to manage biosecurity risks associated with the goods to an acceptable level							X				
	are eviscerated or processed further than evisceration							X	X			
	are in a quantity of not more than 5 kilograms					X						
	are brought in as baggage				X	X						
	have been eviscerated and the head and gills have been removed								X			
	are accompanied by a certificate from a body listed in the List of Overseas Authorities—Aquatic Animals for Import stating that the goods have been processed to the extent needed to manage biosecurity risks associated with the goods to an acceptable level											
Teleost fish from New Zealand, other than fish of the family Salmonidae or Plecoglossidae	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	were caught in the exclusive economic zone of New Zealand (as defined in the United Nations Convention on the Law of the Sea), or in international waters adjacent to the exclusive economic zone of New Zealand, by persons who were approved or registered to catch the goods in accordance with controls administered by the government of New Zealand	X										
	are accompanied by a certificate given by an official of the government of New Zealand stating that the goods were caught as described in paragraph (a)										X	
Cartilaginous fish (including dried fish), other than fish meal	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	the goods are clean and free from other animal or plant material and soil									X		
	have been processed to manage biosecurity risks associated with the goods to an acceptable level							X				
	are fit for human consumption										X	
Non-salmonid finfish or finfish product	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	can be stored at room or ambient temperature and do not need to be refrigerated or frozen before being used										X	
	are for personal use				X							
Fish and fish products of the family Salmonidae or Plecoglossidae, other than: (a) roe or caviar; or (b) salmon oil	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	the goods have been retorted and the container in which the goods were retorted has not been opened since the goods were retorted							X		X		
	have been processed to the extent needed to manage biosecurity risks associated with the goods to an acceptable level							X				
	have been commercially prepared and packaged					X						
	if brought in as baggage—are in a quantity of less than 5 kilograms					X						
	if not brought in as baggage—are in a quantity of less than 450 grams					X						
Roe or caviar of the family Salmonidae or Plecoglossidae	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods have been retorted and the container in which the goods were retorted has not been opened since the goods were retorted							X		X		

Goods	Risk management measure (may be required alone or in combination)	Restricting imports from a specified country	Restricting imports to a specific species	Source material hazard requirements	Restricting imports for specific uses	Quantity restriction	Excluding ingredients of animal origin	Inactivation of infectious agents and microorganisms	Restricting high risk material	Cleaning and decontamination	Verification measures	Import permits
Fish oil for human consumption	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	are in a quantity of not more than 25 kilograms, or 25 litres, for each packaged unit					X						
	are accompanied by a declaration by the manufacturer of the goods stating that the condition in paragraph (a) has been complied with										X	
Cnidarians, crustaceans (other than prawns, freshwater crayfish or crustacean meal), echinoderms, molluscs (other than oysters in full or half shell or freshwater snails) poriferans and tunicates	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are clean and free from other animal or plant material and soil									X		
Freshwater crayfish	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are cooked to the extent needed to manage biosecurity risks associated with the goods to an acceptable level							X				
Prawns or prawn products, other than: (a) dried prawns; or (b) prawn meal; or (c) prawn-based food products	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	the goods have been cooked in premises in the exporting country that are approved by, and under the control of, a body listed in the List of Overseas Authorities—Aquatic Animals for Import;	X						X				
	as a result of the cooking process, all the protein in the prawn meat has coagulated and no raw prawn meat remains										X	
	the goods are accompanied by a certificate from the body referred to in paragraph (a) stating that the conditions in paragraphs (a) and (b) have been met										X	
Prawn-based food products	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are shelf-stable							X			X	
Dried prawns, other than crustacean meal	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	The goods are clean and free from other animal or plant material and soil									X		
Oysters in half shell from New Zealand	Does not apply to dead animals, animal parts or related goods that are intended for animal consumption; or use as a bioremedial agent or fertiliser; or growing purposes; or veterinary therapeutic use.				X							
	have been produced or cultivated in New Zealand	X										
	are clean and free from other animal or plant material and soil									X		
Cuttlefish bone	are cuttlefish bone only		X						X			
	are accompanied by a declaration by the manufacturer of the goods stating that the goods are cuttlefish bone only;										X	
	if the goods contain ingredients other than cuttlefish bone—the goods are accompanied by a declaration by the manufacturer of the goods stating those ingredients and that any conditions specified in this Division for those ingredients have been complied with										X	
Dead teleost fish (other than fish from the family Salmonidae or Plecoglossidae) or cephalopods from New Zealand	were caught in the exclusive economic zone of New Zealand (as defined in the United Nations Convention on the Law of the Sea), or in international waters adjacent to the exclusive economic zone of New Zealand, by persons who were approved or registered to catch the goods in accordance with controls administered by the government of New Zealand	X									X	
	are accompanied by a certificate given by an official of the government of New Zealand stating that the goods were caught as described in paragraph (a)										X	

Goods	Risk management measure (may be required alone or in combination)	Restricting imports from a specified country	Restricting imports to a specific species	Source material hazard requirements	Restricting imports for specific uses	Quantity restriction	Excluding ingredients of animal origin	Inactivation of infectious agents and microorganisms	Restricting high risk material	Cleaning and decontamination	Verification measures	Import permits
Dead cephalopods that were jig caught	were jig caught			X				X				
	are in clean and new packaging					X				X		
	are accompanied by an official health certificate issued by the government of the exporting country stating that the cephalopods were jig caught										X	
Dead cephalopods that were caught using trawl or purse seine fishing methods	were caught using trawl or purse seine fishing methods			X				X				
	contain no other ingredients									X		
	are in clean and new packaging					X				X		
Marine molluscs, other than oysters or snails												
	The goods are treated in Australian territory with gamma irradiation to a level that achieves a minimum of 50 kGray							X				
Food for consumption by pet fish in enclosed aquariums or ponds	the goods do not contain materials originating from terrestrial or avian animals, fish of the family *Salmonidae*, microalgae or macroalgae		X									
	the goods do not contain whole seeds or viable plant materials								X			
	the goods have been processed to the extent needed to manage biosecurity risks associated with the goods to an acceptable level							X				
	the goods are packed in individual containers of not more than 5 kilograms					X						
	the goods have been commercially prepared and packaged					X					X	
	the goods are ready for retail sale without any further processing										X	
	the goods are accompanied by a declaration by the manufacturer of the goods, stating the matters referred to in paragraphs (a), (b) and (c)										X	
	The goods were commercially manufactured in Australian territory	X									X	
	The goods were packaged in Australian territory by the manufacturer	X								X		
	The packaging indicates that the goods are a product of Australia										X	
	The packaging has not been opened and is not broken									X	X	
Animal products exported from Australian territory	The goods are for personal use					X						
	The goods have not been unloaded from the shipping container in which they were exported from Australian territory										X	
	The Australian government container seal that was applied to the shipping container before the goods were exported is intact when the goods arrive at a landing place or port in Australian territory										X	
	If the goods, or any ingredients in the goods, had previously been imported into Australian territory—those goods or ingredients were released from biosecurity control under paragraph 162(1)(a), (b) or (c) of the Act before they were exported									X	X	

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Australian Government
Department of Agriculture

TO: Carol Sheridan, Assistant Secretary A/g, Biological Import Operations
CC: s. 22(1)(a)(ii) Director A/g, Biological Imports Program (BIP)
s. 22(1)(a)(ii) Director A/g, Ruminant Section, Animal Biosecurity
s. 22(1)(a)(ii) Director, Non-Ruminant Section, Animal Biosecurity
FROM: Andrew Cupit, Assistant Secretary, Animal Biosecurity
DATE: 5 May 2014 **FILE:** 2013/14053 **MN #:** R277
SUBJECT: Conditions for the Use of Downgraded Imported Dairy Products for Stockfeed

PURPOSE

To provide conditions allowing the use of downgraded imported dairy products (other than colostrum) for stockfeed.

Note: Throughout this minute 'downgrading' refers to product originally intended for human consumption which has been downgraded for use as stockfeed.

RECOMMENDATIONS

That BIP notes the following:

1. Animal Biosecurity (AB) considers the potential animal biosecurity risks of downgrading imported dairy products (other than colostrum) for stockfeed use to be acceptably low, provided the conditions in Attachment A are met.

2. These conditions should not be extrapolated for dairy products, or compound products containing dairy ingredients, which are specifically manufactured and imported for stockfeed use. These products have a greater potential to be contaminated with high risk animal material such as meat and bone meal which may be used at animal feed manufacturing facilities. If required, conditions for the importation of products manufactured specifically for stockfeed use could be considered at a later date, subject to prioritisation on Animal Biosecurity's work program.

3. In providing this advice, AB does not intend to consider this issue further during the forthcoming review of dairy products as requested (most recently) by BIP minute of 21 February 2014. However, if issues arise during the implementation of this advice AB will assist as required.

ISSUES

As a matter of policy, the department has long restricted the importation of stockfeed derived from animal material, other than fish meal, to products of New Zealand origin exported directly to Australia. This allowed the importation of both meat-and-bone meal and dairy products of New Zealand origin for stockfeed use, subject to an import permit being granted.

In late 2013, allegations were brought to the department claiming that downgrading of imported dairy products for stockfeed use was common practice amongst Australian dairy manufacturers; that the dairy products were sourced from, processed in and exported from foot-and-mouth disease (FMD) free countries other than New Zealand; and that this practice was occurring without approval by the department.

Representatives from the s. 47G(1)(a) advised the department that products manufactured using imported dairy ingredients will be downgraded by the Australian manufacturer if the product fails to meet the specification required for a particular client. Downgrading product for stockfeed use is considered a last resort because it sells for about 25% of the value it would otherwise sell for in the human consumption market. Manufacturers try to avoid wastage and will only downgrade if that product cannot be reprocessed for another use in the human consumption market.

Animal Biosecurity was asked to consider the biosecurity risk of downgrading dairy products for stockfeed use and, if appropriate, recommend risk-management measures which would reduce the biosecurity risk to an acceptably low level.

With a few exceptions (eg. lactose, ripened cheeses) most dairy products for human consumption can only be imported from countries on the department's 'FMD-Free Approved Country List'. In addition to FMD, the department's conditions for dairy products for human consumption include risk-management measures for pox viruses (lumpy skin disease, sheep pox and goat pox), bovine tuberculosis, bovine and ovine brucellosis, Jembrana, peste des petits ruminants, maedi-visna, contagious agalactia and contagious caprine pleuropneumonia.

The 1999 *Dairy IRA* considered it likely that dairy products imported for human consumption could be consumed by animals, but it did not recommend post-border controls to prevent potential diversion of products imported for human consumption. Therefore, the risk-management measures established by the *Dairy IRA* for human consumption addressed animal pathogens of concern which are known to be transmissible through milk because of the potential for diversion of product for consumption by animals.

Because of this, Animal Biosecurity considers the potential animal biosecurity risk of downgrading imported dairy products for stockfeed use is largely managed by the existing conditions for human consumption. However, because stockfeed provides a direct pathway for the introduction of exotic animal pathogens to susceptible species, not all dairy products which can be imported for human consumption should be approved by the department for downgrading to stockfeed. Therefore, the following restrictions should be applied in addition to the product being imported in accordance with the existing requirements for dairy products for human consumption:

- only dairy products sourced from, processed in and exported from countries on the department's 'FMD-Free Approved Country List' and meeting the OIE requirements for declaring freedom from lumpy skin disease should be permitted;
- only dairy products derived from bovine milk (eg. cow's milk) should be permitted;
- only products containing or derived from pasteurised milk should be permitted;
- colostrum or products containing colostrum should not be permitted.

Because of the direct pathway for the introduction of pathogens of concern presented by stockfeed, restricting approvals to pasteurised dairy products which are sourced from, processed in and

exported from 'FMD-Free Approved Countries' provides an additional level of assurance that the potential biosecurity risk of feeding these products to animals has been addressed.

Additionally, restricting these conditions to 'human grade' product imported with the primary intention of human consumption means the dairy (and other) ingredients must have been manufactured in accordance with human food safety and other related standards in the country of manufacture/origin. It is also highly unlikely that a facility manufacturing for human consumption would house meat-and-bone meal or other specified risk material presenting an unacceptable TSE risk.

With colostrum there are a range of biosecurity risks including the potential for disease agents of concern, including mycobacteria, brucellae and retroviruses, to be excreted in high, if not higher, concentrations in colostrum than in milk. Considering the destructive effects of heating on the immunoglobulins in colostrum, it is unlikely that colostrum could be heat treated to destroy all pathogens of concern without also destroying the immunoglobulins. Animal Biosecurity therefore considers both the biosecurity risk and the risk of misrepresentation regarding the heat treatment applied to colostrum to be higher than for other dairy products. Additionally, the department has existing biosecurity restrictions[1] prohibiting the use of colostrum in veterinary therapeutics and other products destined for use in animals which are susceptible to transmissible spongiform encephalopathies (TSEs) eg. bovine spongiform encephalopathy (BSE) and scrapie. Because of this, imported colostrum and products containing imported colostrum should not be approved for downgrading for stockfeed use.

Bovine milk is considered unlikely to present a risk of BSE transmission and the 2013 World Organisation for Animal Health (OIE) Terrestrial Animal Health Code does not recommend any BSE-related conditions for milk and milk products, regardless of the BSE status of the cattle population from which they're collected. The European Medicines Agency considers that bovine milk and bovine milk derivatives are unlikely to present a risk of BSE transmission provided that the milk is sourced from healthy animals and in the same conditions as milk collected for human consumption.[2]

However, classical scrapie can be transmitted in sheep's milk and colostrum to scrapie-susceptible animals. Therefore, imported dairy products containing milk from sheep or goats should not be approved for downgrading to stockfeed use.

Any downgraded dairy products containing non-dairy ingredients of biosecurity concern must be assessed against the department's existing requirements for these ingredients. If conditions exist that would allow the ingredients to be imported for stockfeed use, downgrading can be approved.

Importers should also be made aware that they must comply with any state or territory legislation relating to the 'ruminant feed ban' or swill feeding. The department should also encourage importers to inform purchasers of downgraded product of the need to comply with this legislation.

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[1] *Guidelines for managing the risk of transmitting transmissible spongiform encephalopathies (TSEs) via veterinary vaccines and other in vivo veterinary products* – October 2012, Department of Agriculture.

[2] European Medicines Agency (2011) Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/02 Rev. 3 - July 2011) adopted by the Committee for Proprietary Medicinal Products (CPMP) and by the Committee for Veterinary Medicinal products (CVMP). *Official Journal of the European Union* 73: 1-18.

BACKGROUND

s. 47G(1)(a)

s. 47G(1)(a)

The department was also contacted by representatives of the s. 47G(1)(a) regarding the broader issue of downgrading imported dairy products for stockfeed use. Representatives from s. 47G(1)(a), s. 47G(1)(a) and the s. 47G(1)(a) Inc. met with Deputy Secretary Mellor and Acting First Assistant Secretary Jenny Cupit regarding this issue and the department assured the representatives that it would take a 'measured approach' and not immediately ban all imports or make significant changes to import requirements without understanding the implications of any such decision.

The department was provided with data from the s. 47G(1)(a) of the types of dairy products and associated ingredients which were already being downgraded for stockfeed use or had the potential to be downgraded. Attachment B provides a summary of that data.

CONSULTATION

- Teleconference between the department (including AB and BIP) and s. 47G(1)(a) – 12 September 2013.
- Email from BIP (s. 22(1)(a)(ii)) to AB (s. 22(1)(a)(ii)) requesting advice about s. 47G(1)(a) wishing to downgrade dairy ingredients imported for human consumption to stockfeed use – 17 September 2013.
- Meeting between the department (Deputy Secretary Mellor, Acting First Assistant Secretary Jenny Cupit) and representatives from the s. 47G(1)(a) (s. 47G(1)(a) – s. 47F(1) s. 47G(1)(a), s. 47G(1)(a) – s. 47F(1) s. 47G(1)(a) s. 47G(1)(a) – s. 47F(1) – 26 September 2013.
- Comments on draft AB Minute **R276** received from AB and BIP – 3 - 4 October 2013.
- Meeting between the department (AB and BIP) and representatives from the s. 47G(1)(a) s. 47G(1)(a) (s. 47F(1) s. 47F(1) s. 47F(1) s. 47F(1)) – 14 October 2013.
- AB Minute **R276** – s. 47G(1)(a) *'On Hold Product' – Dairy from France & Finland for Stockfeed Use* – 15 October 2013
- Teleconference between the department (AB and BIP) and representatives from the s. 47G(1)(a) (s. 47F(1) s. 47F(1) s. 47F(1) – 6 December 2013.
- Teleconference between the department (AB and BIP) and representatives from the s. 47G(1)(a) (s. 47F(1) s. 47F(1), s. 47F(1) s. 47F(1) – 13 February 2014.
- Information paper and proposed conditions provided by BIP to representatives from the s. 47G(1)(a) for consultation with their members – 20 February 2014.

- Minute from BIP to AB – *Request for a review of policies related to the importation of dairy products* – 21 February 2014.
- s. 47G(1)(a) provided feedback to BIP about the issues raised by their members about the proposal. The issues were 'operational' in nature, eg. Cost of the import permits. No objection to the conditions themselves was presented – 4 April 2014.
- BIP responded to issues raised by the dairy industry representatives – 15 April 2014.
- BIP advised AB that it had responded to the issues raised by the s. 47G(1)(a) representatives and requested finalisation of the minute supporting the proposed, now accepted, conditions – 16 April 2014.

s. 47F(1)

Andrew Cupit
Assistant Secretary
Animal Biosecurity Branch

ATTACHMENT A

BIOSECURITY REQUIREMENTS FOR THE USE OF DOWNGRADED IMPORTED DAIRY PRODUCTS (OTHER THAN COLOSTRUM) AS STOCKFEED

The potential animal biosecurity risk associated with the use of downgraded imported dairy products for stockfeed can be addressed through the application of the following conditions.

1. The dairy product was imported in accordance with Australia's requirements for dairy products imported for human consumption; including:

    a. The dairy product, or the milk from which the product was derived, was sourced from, processed in and exported from countries approved by the department for the export of products to Australia where freedom from FMD is required; and

    b. The dairy product, or the milk from which the product was derived, was sourced from, processed in and exported from countries meeting the World Organisation for Animal Health (OIE) requirements for declaring freedom from lumpy skin disease; and

    c. The dairy product is derived only from bovine milk (eg. cow's milk); and

    d. The dairy product, or the milk from which the product was derived, was subjected to one of the following heat treatments:

        i. pasteurisation at 72°C for a minimum of 15 seconds or an equivalent treatment, in terms of phosphatase destruction; or

        ii. UHT treatment of 135°C for a minimum of 1 second; and

    e. The dairy product is not/does not contain colostrum.

2. The dairy product was imported for human consumption and subsequently downgraded in Australia for stockfeed use;

3. The importer must obtain an import permit from the Department of Agriculture allowing the use of the imported dairy product and any imported 'non-dairy' ingredients in the downgraded product for stockfeed use;

4. All other imported ingredients in the downgraded product must be approved by the department for stockfeed use in accordance with existing policy requirements. Eg. Plant oils, fish oils, amino acids, vitamins and vitamin premixes.

The department shall also make importers aware that they must comply with any state or territory legislation relating to the 'ruminant feed ban' or swill feeding. The department shall also recommend that importers inform purchasers of downgraded product of the need to comply with the legislation.

ATTACHMENT B

Summary of data provided by industry:

Table 1: Imported Dairy Ingredients used in Finished Products Downgraded for Stockfeed Use

Anhydrous Milk Fat (AMF – 'butter oil')	Butter Flavour	Demineralised Whey Powder (DWP)	Flavoured premixes containing milk protein
Lactoferrin	Lactose	Milk Ceramide	Milk Permeate Powder
Milk Phospholipids	Skim Milk Powder (SMP)	Sodium Caseinate	Whey Protein Concentrate (WPC)
Whey Protein Isolate (WPI)	Whole Milk Powder (WMP)		

Table 2: Countries of Origin of the Dairy Ingredients used in Finished Products Downgraded for Stockfeed Use

Australia	Austria	Denmark	European Union
Finland	France	Germany	Ireland
Netherlands	New Zealand	Switzerland	United States of America

Table 3: Imported Ingredients of Animal/Microbial Origin (excluding Dairy) used in Finished Products Downgraded for Stockfeed Use

Ingredient	Species of Origin	Country of Origin
Lactococcus spp Culture on dairy carrier	Microbial / Bovine milk carrier	Denmark
Rennet	Bovine	New Zealand
Rennet	Microbial (fermentation derived)	Denmark
Lipase	Bovine / Ovine / Caprine	New Zealand

Ingredient	Species of Origin	Country of Origin
Vitamins on dairy carrier	Bovine milk carrier	Germany United States of America
Vitamin premixes	Sheep – Wool Grease	New Zealand Singapore
	Bovine milk carrier	Germany New Zealand United States of America
Honey	Bees	Argentina
Fish Oil	Tuna	American Samoa Japan Switzerland
Cochineal Colouring	Insect	South America
Chondroitin Sulphate Sodium	Shark	China

Table 4: Imported Ingredients from FMD-affected Countries used in Finished Products Downgraded for Stockfeed Use

Ingredient	Species of Origin	Country of Origin
Plant oils	Canola Maize Palm	Argentina Brazil Malaysia
Fish oil	Tuna	American Samoa
Cochineal Colouring	Insect	South America
Chondroitin Sulphate Sodium	Shark	China