



## **Importation of dairy products into Australia for human consumption**

*Import Risk Analysis*



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AUSTRALIA



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## 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 <sub>50</sub>	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 <sub>50</sub>	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

<i>“Colostrum”</i>	the milk secreted by the udder immediately after parturition and for the following 3-4 days.
<i>“Dairy products”</i>	means milk and milk products.
<i>“Free zone”</i>	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).
<i>“List A”</i>	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.
<i>“List B”</i>	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.
<i>“Official Veterinarian”</i>	means a civil service veterinarian or a specially appointed veterinarian, as authorised by the Veterinary Administration of the country.
<i>“Pasteurisation”</i>	- 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)
<i>“Thermisation”</i>	- heat treatment of milk to 62°C for 15 seconds.
<i>“UHT”</i>	- sterilisation of milk by heating to not less than 135°C for no less than one second.
<i>“Veterinary Administration”</i>	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<sup>(22,218)</sup>.

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
<b>List A diseases of ruminants</b>			
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
<b>List B Diseases - cattle</b>			
<i>Brucella abortus</i>	Cattle, man, pigs	Transmitted via ingestion, skin, conjunctiva, the source of infection being uterine discharges, placenta and milk or colostrum.	Free
<i>Mycobacterium bovis.</i>	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
<b>List B diseases - sheep and goats</b>			
<i>Brucella melitensis</i>	Sheep, goats, man, camels and occasionally cattle.	Placental contamination of pasture, milk, intrauterine.	Free
<i>Mycoplasma agalactiae</i> and other <i>Mycoplasma</i> 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
<i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> associated with contagious caprine pleuropneumonia.	Goats	Transmission via respiratory route.	Free
<b>Diseases not listed by the OIE the agents of which may be excreted in milk</b>			
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.

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

<sup>1</sup> 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)

<sup>2</sup> 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 <sup>3</sup>	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.
<b>List B Diseases</b>			
<i>Bacillus anthracis</i>	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 <sup>(169)</sup> . Infected pigs are the most important source of infection.	Free
<i>Echinococcus</i> 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.
<i>Leptospira interrogans</i> serovar. <i>canicola</i> <sup>4</sup>	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 <i>L. i. canicola</i>
<i>Coxiella burnetti</i>	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
<i>Mycobacterium paratuberculosis</i> <sup>5</sup>	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.
<i>Cowdria ruminantium</i>	Cattle, sheep, goats	Tick-borne rickettsia, not naturally transmitted via milk.	Free

<sup>3</sup> 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. <sup>(23,72,76,277,280,283)</sup>

<sup>4</sup> 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. <sup>(271)</sup>

<sup>5</sup> 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
<i>Chrysomya bezziana</i> and <i>Callitroga hominivorax</i> ( <i>Cochliomyia</i> )	Multiple species	Deposition of eggs by adult fly. Not infectious.	Free
<i>Campylobacter foetus</i>	Cattle	Transmitted venereally, not through milk.	Endemic.
Enzootic bovine leucosis virus	Cattle	Transmitted from dam to young through milk, colostrum, placenta	Endemic <sup>(181)</sup> . 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
<i>Trichomonas foetus</i>	Cattle	Venereally spread.	Endemic, no controls in dairy products within Australia for this agent.
<i>T. brucei</i> , <i>T. vivax</i> and <i>T. congolense</i> in Africa, <i>T. cruzi</i> 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
<i>Anaplasma</i> spp.	Cattle. <i>A. marginale</i> is the most pathogenic	Protozoan blood parasite. Spread by ticks, parasite undergoing part of its life cycle in the tick.	Present in Australia.
<i>Babesia bigemina</i> and <i>B. bovis</i>	Cattle	Protozoan blood parasite. Spread by ticks, parasite undergoing part of its life cycle in the tick.	Present in Australia.
<i>Cysticercus bovis</i>	Life cycle through cattle and man	Spread to cattle grazing pastures contaminated with human faeces. Not transmitted through milk.	Present in Australia.
<i>Dermatophilus congolensis</i>	Multiple species	Spread by contact of organism with broken skin.	Endemic
<i>T. parva parva</i>	Protozoan blood parasite of cattle	Spread by ticks, undergoes part of life cycle in ticks.	Free
<i>Pasteurella multocida</i> (Asian strain, serotype B and African form serotype E. <sup>6</sup>	Clinical syndrome is haemorrhagic septicaemia, seen in cattle	Intranasal route believed to be normal mode of transmission.	Free

<sup>6</sup> 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.<sup>(23,72,76, 249)</sup>

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 <sup>7</sup>	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.
<i>Brucella ovis</i>	Sheep	Mostly venereal transmission.	Endemic
<i>Chlamydia psittaci</i> associated with enzootic abortion of ewes. <sup>8</sup>	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 <sup>(23)</sup>	Free
<i>Salmonella abortusovis</i>	Sheep, goats	Excreted in faeces, infection via oral route, often predisposed by stress <sup>(285,286,287,288)</sup> .	One human case reported in Australia. No reports from livestock.
Jaagsiekte virus, agent of pulmonary adenomatosis <sup>9</sup>	Sheep	Close contact between live animals.	Free
Scrapie agent	Sheep, goats	Close contact between live animals, possibly also transplacental transmission.	Free
<b>Diseases not listed by the OIE whose agents may be excreted in milk</b>			
Bovine immunodeficiency virus <sup>10</sup>	Cattle	Colostrum and milk .	Endemic

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

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

<sup>9</sup> Several retroviruses are excreted in milk, however JSRV has not been shown to be excreted in milk. <sup>(232,243,250,251)</sup>

<sup>10</sup> 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 <sup>11</sup>	Sheep, less frequently cattle, other species and man	Mainly by tick ( <i>Ixodes ricinus</i> ) also excretion and transmission via milk has been demonstrated.	Free
Tick-borne encephalitis virus <sup>12</sup>	Multiple species	Outbreaks generally associated with tick infestations. Transmission via milk to humans is known to occur.	Free
Bovine virus diarrhoea/ mucosal disease virus <sup>13</sup>	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

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

<sup>12</sup> 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.<sup>(72,214) (215,219,247)</sup>. TBE is not considered to be a hazard with the importation of dairy products.

<sup>13</sup> The virus is excreted in all body secretions, including milk, however this is not considered to be an established mode of transmission<sup>(76, 291)</sup>. Direct contact between persistently viraemic animals and susceptible animals, or transplacental transmission are the most common means of spread of the virus<sup>(76, 291)</sup>. 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.<sup>(282, 284)</sup> Imported dairy product is more likely to be fed to calves than pregnant animals. Infection in calves would be self limiting.<sup>(23,76,158,224,225,282)</sup> Control programs centre around the detection and removal of persistently infected animals.<sup>(281)</sup>

## 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<sup>(1,21,252)</sup>.

#### *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<sup>(42)</sup>. High titres of virus have been detected in milk from dairies before the disease was suspected or diagnosed<sup>(4)</sup>. 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<sup>(5)</sup>.

Milk has been associated with the spread of FMD. The feeding of raw infected milk to susceptible animals is a recognised means of transmission.<sup>(3,14,15)</sup>

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<sub>50</sub>, and the infectious dose by the oral route for cattle is of the order of  $10^6$  ID<sub>50</sub>, and for pigs of the order of  $10^4$  ID<sub>50</sub>, the latter using a pig adapted strain<sup>(6)</sup>.

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<sup>(253,254,258,260,263)</sup>. De Leeuw<sup>(173)</sup> 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<sup>(256)</sup> 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<sup>(257)</sup>.

***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<sup>(11,17)</sup>, but to be inactivated when held at 148°C for 2-3 seconds or longer<sup>(12, 13)</sup>. FMDV is inactivated more rapidly at pH 6.7 than at pH 7.6<sup>(16)</sup>. 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.<sup>(16)</sup> 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<sup>(8,11,35,46)</sup>. 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<sup>(11)</sup>. When skim milk was subjected to the same process, the virus was inactivated<sup>(11)</sup>.

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<sup>(174)</sup> 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<sup>(7,36)</sup>. 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<sup>(18)</sup>. FMDV in cheddar cheese made from unpasteurised milk did not survive longer than 4 months.<sup>(58,18)</sup>

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<sup>(17)</sup>. Feeding trials were not conducted.

Donaldson<sup>(14)</sup>, 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<sup>(15)</sup>.

***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<sup>(1)</sup>.

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<sup>(1)</sup>. 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<sup>(1)</sup>.

***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<sup>(15)</sup> 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<sup>(76)</sup>.

Rinderpest is present in Africa (eastern countries), the Middle East, and South Asia. There has been a single reported outbreak in Australia in 1923<sup>(72)</sup>. 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<sup>(22)</sup>. Cattle and buffalo are especially susceptible, with sheep, goats and pigs less susceptible<sup>(23)</sup>. Reports of the disease in camels are rare<sup>(55)</sup>. Experimental studies have induced only subclinical infection in sheep and goats<sup>(23)</sup>.

Following natural exposure, viraemia takes 8-13 days to develop, preceding pyrexia by at least one day<sup>(60)</sup>. Virus is usually present in the blood 1-2 days before the onset of fever<sup>(22)</sup>. The prodromal phase, i.e. the time between the onset of pyrexia and the first appearance of mucosal lesions is about 3 days<sup>(22)</sup>. 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.<sup>(22)</sup> 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<sup>(23)</sup>. Transmission of PPR is predominantly by the inhalation of aerosols derived from nearby animals, or by licking infected animals<sup>(23)</sup>. 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<sup>(176)</sup>.

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<sup>(22)</sup>. 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<sup>(22)</sup>. Rinderpest virus, in the form of tissue culture supernatant fluid, at pH 7.3 had a greater than 6 log<sub>10</sub> reduction within seconds at 70°C, and around a 5 log<sub>10</sub> 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<sup>(122)</sup>.

The virus has been shown to have a half life at 37°C of 3.3 hours<sup>(23)</sup>, at 50°C of 30 minutes<sup>(24)</sup>, 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<sup>(175)</sup>.

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<sup>(122)</sup>. Inactivation is exponential. The virulent RGK/1 isolate was more sensitive to low pH, and other isolates have demonstrated varying sensitivity to pH<sup>(22)</sup>. Peste des petits ruminants virus is sensitive to lipid solvents and low pH. Scott<sup>(175)</sup> 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<sup>(23)</sup>.

The virus can only survive a short period of time in the environment, and restocking of depopulated premises may occur after 30 days<sup>(1)</sup>.

### ***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<sup>(1)</sup>. 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<sup>(23)</sup>. Infection takes place readily via the upper respiratory tract<sup>(22)</sup>. 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.<sup>(22)</sup>

Rinderpest is considered to be relatively easy to control, and the stamping out policy has been successful in Europe and South Africa<sup>(1)</sup>. 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<sup>(1)</sup>.

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<sup>(1)</sup>.

***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)<sup>(72)</sup>, 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<sup>(23,147,185,259)</sup>. However, Geering<sup>(72)</sup> 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<sup>(23)</sup> *Mycoplasma mycoides* is still considered as a possible causative agent of CCPP<sup>(147)</sup> 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<sup>(23)</sup>. Economically, it is one of the most important diseases of goats in North Africa<sup>(257)</sup>.

#### ***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<sup>(23,72,183)</sup>. Infection is normally via the inhalation of infected droplets<sup>(72,183)</sup>. 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<sup>(72,184)</sup>.

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<sup>(187,188,189)</sup>, and Cottew<sup>(197)</sup> 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<sup>(23)</sup> 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.<sup>(195)</sup>

**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<sup>(23,58,78)</sup>. The mycoplasmas associated with subclinical mastitis in cows could not survive pasteurisation or the yoghurt manufacturing process<sup>(192)</sup>. *M. agalactiae* is inactivated by heating of milk at 56°C for 30 minutes<sup>(194)</sup>. 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<sup>(23)</sup>.

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<sup>(72)</sup>.

**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<sup>(187,188,189,197)</sup>. 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*<sup>(295)</sup>. LSD, sheep pox and goat pox viruses are closely related<sup>(169)</sup>. The host specificity of sheep and goat pox strains is lost when sheep and goats are herded together<sup>(169)</sup> and cross immunity between sheep and goat pox viruses exists<sup>(199)</sup>.

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<sup>(51)</sup>.

Lumpy skin disease (LSD) occurs chiefly in sub-Saharan Africa, and has now spread to Egypt and Madagascar<sup>(23,222)</sup>. In sub-Saharan Africa it has proved impossible to eradicate<sup>(222)</sup>. There was an outbreak in Israel in 1989<sup>(164)</sup>. 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<sup>(51, 52)</sup>. They have never been recorded in Australia, and the Americas are free.

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

#### ***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<sup>(172)</sup>. Lesions also develop on the skin of the body, udder and teats providing a high level of contamination to the environment<sup>(178)</sup>. 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<sup>(76,178)</sup>. Available evidence suggests that LSD may be transmissible to suckling calves through infected milk (Prozesky *pers. comm.*<sup>296</sup>). 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<sup>(164)</sup>. Seasonal cycles and periodic epizootics linked to rainfall patterns (and therefore insect activity) are also characteristics of the disease<sup>(48,178, 196, 221)</sup>.

The transmission of sheep pox and goat pox has been demonstrated by aerosol and contact<sup>(48,126)</sup>. Aerosol transmission requires close contact between a susceptible and infected animal<sup>(51)</sup>. Infection may take place through skin abrasions<sup>(23)</sup>. 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<sup>(76,178)</sup>. 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<sup>(51,178,186)</sup>. *S. calcitrans* remained infective for 3-4 days after feeding on infected material<sup>(186)</sup>.

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<sup>(196)</sup>. Outbreaks of lumpy skin disease are linked to rainfall patterns, heavy rains often being associated with epizootics<sup>(221)</sup>. Movement of cattle is also associated with spread of the disease<sup>(221)</sup>. Woods<sup>(221)</sup> said the spread of the disease outside Africa was possible, but that it is unlikely to be spread by meat or products. However, Davies<sup>(222)</sup> 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.<sup>(47,50)</sup>. 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<sup>(23)</sup> 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<sup>(211)</sup>. However, camel pox virus is believed to be transmissible to South American camelids.

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

#### ***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<sup>(166)</sup>. 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<sup>(23,166)</sup>. It is readily inactivated by the detergent sodium-dodecyl-sulphate, and is chloroform and ether sensitive<sup>(166)</sup>.

Ferreira<sup>(165)</sup>, using sheep pox virus suspended in a buffer with an initial concentration of 8 log<sub>10</sub> TCID<sub>50</sub>/ml, found that at 45°C there was a reduction of 2.3 log<sub>10</sub> in two hours. At 50°C there was a 4 log<sub>10</sub> reduction in 30 minutes and a 6 log<sub>10</sub> reduction in 1 hour. At 55°C, the reduction after 30 minutes was 4.6 log<sub>10</sub> TCID<sub>50</sub>/ml, and virus was not detectable after 1 hour. At 60°C the reduction was 5.6 log<sub>10</sub> in 30 minutes, and undetectable in a hour. At 65°C there was a 5 log<sub>10</sub> reduction in the first 5 minutes, and after 30 minutes the virus was undetectable.

Pandey<sup>(213)</sup> 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<sup>4.03</sup> and 10<sup>3.97</sup> TCID<sub>50</sub> respectively. Datta<sup>(152)</sup> achieved a 5 log<sub>10</sub> 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<sup>(154)</sup> 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<sub>10</sub> reduction when heated at 56°C for 15 minutes, whilst cell bound virus underwent a

one log<sub>10</sub> reduction in the same time<sup>(218)</sup>. Andrewes<sup>(167)</sup>, 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<sup>(59)</sup>. 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<sub>10</sub> reduction in 120 minutes at 55°C.

While there is some evidence for heat inactivation of capripoxviruses at 62°C for 30 minutes<sup>(152)</sup>, 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.*<sup>(297)</sup>). 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.*<sup>(298)</sup>).

At pH 3 the loss of CPE was 4.7 log<sub>10</sub> in 30 minutes, and total loss in 2 hours. At pH 11 a loss of CPE of 3.4 log<sub>10</sub> was achieved in 30 minutes and total loss in 2 hours<sup>(165)</sup>. Datta<sup>(152)</sup> obtained a 3 log<sub>10</sub> 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<sup>(152)</sup> obtained only a 1 log<sub>10</sub> 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<sup>(1)</sup>. 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<sup>(170)</sup>.

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

Capripoxviruses cause the most severe pox diseases of animals<sup>(51)</sup>. 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<sup>(212)</sup>.

Lumpy skin disease only naturally affects cattle, although experimental transmission to sheep has been recorded<sup>(196)</sup>. In endemic areas the morbidity is variable, but rates of 80% have been seen in South Africa<sup>(178)</sup>. 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<sup>(1)</sup>. 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<sup>(1)</sup>.

The LSD panzootic in South Africa that lasted from 1945 to 1949 affected some eight million cattle, and incurred enormous economic losses<sup>(222,235)</sup>. 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<sup>(1)</sup>.

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<sup>(1)</sup>. 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<sup>(1)</sup>.

## ***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,<sup>(25,64)</sup> *Br. abortus* infecting goats and sheep,<sup>(23)</sup> and camels are shown to be susceptible to both<sup>(26,27,54)</sup>. 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<sup>(72)</sup>.

*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<sup>(23,25,29,41)</sup>. One in ten infected cows are infected in the udder and shed *Brucellae* at least intermittently<sup>(114)</sup>.

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

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<sup>(23,28,30)</sup>.

#### ***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<sup>(45,73)</sup>.

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<sup>(67,73)</sup>.

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<sup>(45)</sup>. Few dairy products reach a pH of less than 4.6. el Daher<sup>(44)</sup> 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<sup>(41, 53,68,123)</sup>. Fabian<sup>(66)</sup>, 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<sup>(66)</sup>.

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<sup>(86)</sup>.

#### ***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<sup>(23)</sup>.

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<sup>(80)</sup>. 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<sup>(79)</sup>. 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<sup>(76)</sup>.

As a zoonotic disease transmitted via milk and cheese, *Br. melitensis* is the more serious of the two agents discussed here<sup>(64,66,150)</sup>. 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<sup>(73)</sup>. 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<sup>(23,55,75,76)</sup>. 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<sup>(76)</sup>. In New Zealand, tuberculosis in sheep is believed to be related to the prevalence in local populations of cattle and possums<sup>(76)</sup>.

The disease is rare in horses<sup>(76)</sup>. Dogs are susceptible to both human and bovine infections, while cats are less susceptible to the human but quite susceptible to the bovine bacillus<sup>(78)</sup>.

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

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<sup>(76)</sup>. Excretion of tubercle bacilli in milk is intermittent,<sup>(73)</sup> however, because of the low infectious dose associated with tubercle bacilli<sup>(56)</sup>, 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<sup>(23,77,81)</sup>. In the 1940's tuberculosis was looked upon as the most serious milk-borne disease of humans<sup>(62,149)</sup>.

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*<sup>(73)</sup>.

#### ***b) Survivability/inactivation of the agent in dairy products***

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

The pH levels achieved in sour milk are not sufficient to destroy tubercle bacilli<sup>(69,133)</sup>. Human tubercle bacilli were also able to survive four hours exposure to normal caustic soda<sup>(130)</sup>.

Research on the viability of *M. tuberculosis* in cheese dates back to the late 1880's. Milk containing live tubercle 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<sup>(61)</sup>. (\*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<sup>(76)</sup>. Levisohn<sup>(236)</sup> 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<sup>(76,190)</sup>. Animals may suffer protracted illness from which they do not recover and loss of milk production can be high<sup>(237)</sup>. 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<sup>(226)</sup>.

Contagious agalactia is endemic in Mediterranean countries<sup>(180,227,228)</sup>, and Central and Northern Europe. America and Australia are free from the disease<sup>(190)</sup>.

**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<sup>(180)</sup>. 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<sup>(190)</sup>. Organisms are excreted in the milk for many months in animals that recover from the initial disease<sup>(180)</sup>. 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*<sup>(241)</sup>.

Lambert<sup>(266)</sup> 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<sup>(23,58,78)</sup>. They remain viable for long periods in frozen tissue<sup>(78)</sup>.

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

Woodhead<sup>(267)</sup>, 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<sup>(190)</sup>. The disease is of greater economic importance in countries that consume a significant amount of sheep and goats' milk and milk products<sup>(190)</sup>. The disease affects efficiency of milk production and herd replacement costs<sup>(248)</sup>.

The UK, which is free from contagious agalactia imposes strict quarantine requirements on the importation of live sheep and goats for this disease<sup>(267)</sup>. 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<sup>(105)</sup>.

***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<sup>(107,239)</sup>.

Sheep and goats are both said to be susceptible<sup>(179)</sup>, 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<sup>(23,105,106,107)</sup>. Mononuclear cells in the colostrum and milk are infected with the virus, and probably pass through the intestinal epithelium of the neonate<sup>(179)</sup>. Production of infected cells begins 10 days before parturition and persists for up to two months<sup>(238)</sup>.

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

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

Thormar<sup>(108)</sup>, 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<sub>10</sub>) was lost after 10 minutes at 50°C. A 5 log<sub>10</sub> 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<sup>(169)</sup>.

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<sup>(161)</sup>.

Thormar<sup>(108)</sup> 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<sub>10</sub> reduction in infectivity at the following pH levels:

at pH 9.4	1 log <sub>10</sub> reduction	4 days
at pH 7.7	1 log <sub>10</sub> reduction	7 day
at pH 5.1	1 log <sub>10</sub> reduction	1 day
at pH 4.2	1 log <sub>10</sub> reduction	1.5 hours (maedi) and 1 hr (visna)
at pH 3.2	4 log <sub>10</sub> reduction	30 mins (visna)
at pH 3.2	5.5 log <sub>10</sub> 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<sup>(105)</sup>.

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<sup>(201)</sup>. Norway introduced a control program in 1973, forbidding the sale or exhibition of animals from infected flocks<sup>(146)</sup>, 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<sup>(72,159,177)</sup>. It is atypical of retroviruses in that it has an incubation period of a few days<sup>(159)</sup>. 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%<sup>(160)</sup>. The known distribution of Jembrana is currently limited to Indonesia<sup>(72)</sup>.

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

The major pathological changes are in the lymphoid tissue<sup>(177)</sup>. 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<sup>(138)</sup>. It is postulated that arthropods spread the infection mechanically<sup>(138)</sup>.

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<sup>(72)</sup>.

#### ***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<sup>(272,99,112)</sup>. Preservation of colostrum is by freezing or drying. Spray drying is the most economical, whilst freeze drying utilises the lowest temperatures<sup>(273)</sup>. Significant numbers of bacteria survived both processes<sup>(273)</sup>, and it could be assumed that viral pathogens would also survive. A number of colostrum products are available commercially<sup>(273,274)</sup>.

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<sup>φ</sup>), 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<sup>(2)</sup>, 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.

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<sup>φ</sup> 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 an 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.]

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## 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:

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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:

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**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:

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.....

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”<sup>(36)</sup>

#### 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”<sup>(1)</sup>.

Ultrafiltration concentrates milk in the manufacture of cheese and other products requiring concentration of solids. It is used particularly in the manufacture of soft cheeses, and also in preparing milk for spray drying<sup>(9)</sup>.

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<sup>(8,20)</sup>.

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<sup>(16)</sup>. 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<sup>(8)</sup>. It must be phosphatase negative following heat treatment. It extends storage time of milk, and the process is usually followed by pasteurisation or cheesemaking<sup>(12,14,16,26)</sup>.

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<sup>16</sup>. Because of its close relationship with the destruction curve for *M. tuberculosis*, phosphatase is used as an index of efficient pasteurisation of milk<sup>(6)</sup>.

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<sup>(8)</sup>.

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<sup>(4)</sup>. “Farm butter” is the term used for butter made from unpasteurised cream<sup>(3)</sup>.

Ghee, Butter oil, Clarified butter, anhydrous 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<sup>(8, 10, 11, 13)</sup>.

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<sup>(21)</sup>.

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<sup>(2)</sup>.

Cheese Traditionally cheeses were fermented products which underwent digestion by enzymes attendant with odours<sup>(5)</sup>.

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<sup>(2,15)</sup>.

### 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<sup>(17,22,19)</sup>. Preservation of colostrum is by freezing or drying, spray drying is the most economical, whilst freeze drying utilises the lowest temperatures<sup>(24)</sup>. Significant numbers of bacteria survived both processes<sup>(24)</sup>, so it could be assumed that pathogens would survive the process. A number of colostrum products are available commercially<sup>(24,23)</sup>.

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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.*

## 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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