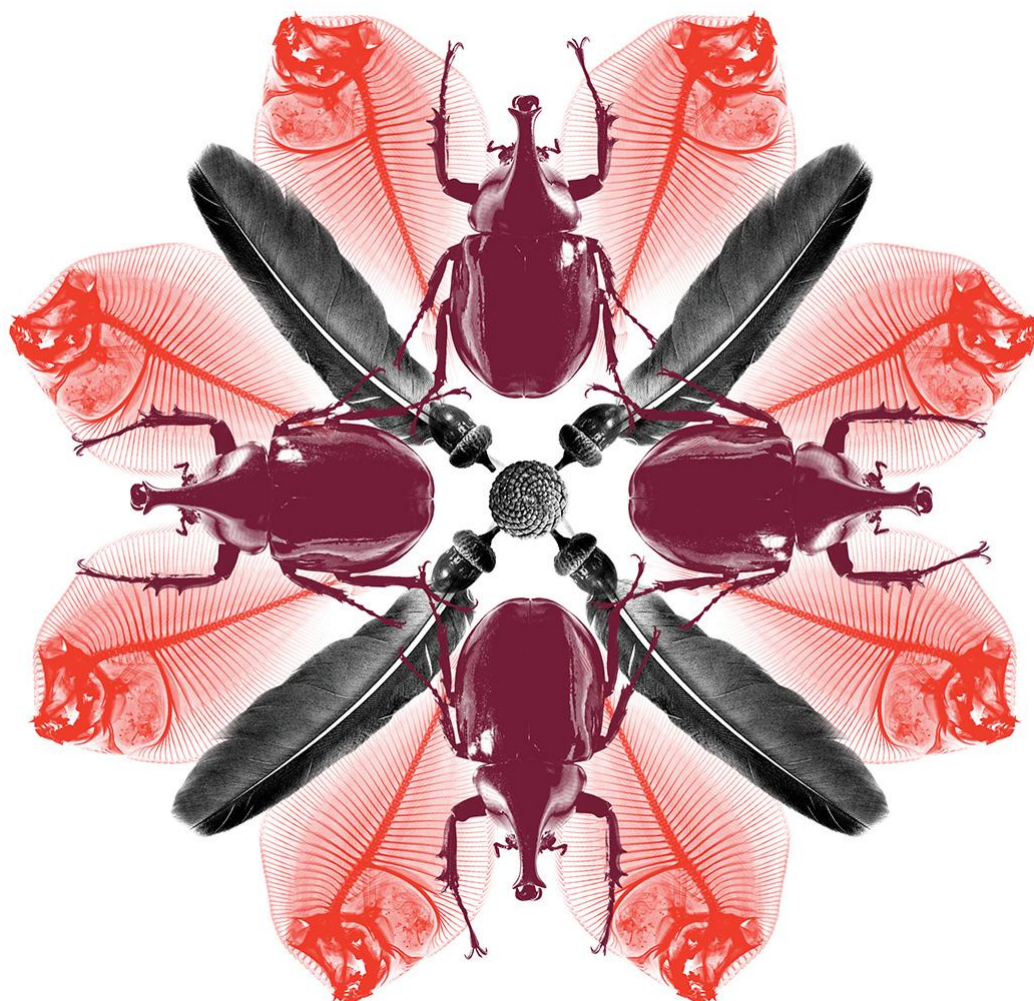




Australian Government
Department of Agriculture
and Water Resources

Fresh (chilled or frozen) beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu – draft review

December 2016



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Stakeholder submissions on draft reports

This draft report has been issued to give all interested parties an opportunity to comment on relevant technical biosecurity issues, with supporting rationale. A final report will then be produced taking into consideration any comments received.

Submissions should be sent to the Australian Government Department of Agriculture and Water Resources following the conditions specified within the related Biosecurity Advice, which is available at: agriculture.gov.au/biosecurity/risk-analysis/memos

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Acronyms and abbreviations

Term or abbreviation	Definition
Ab-ELISA	absorbed-enzyme-linked immunosorbent assay
ACSSuT	ampicillin, chloramphenicol, streptomycin, sulphonamides and tetracycline resistance
ACSuT	ampicillin, chloramphenicol, sulphonamides and tetracycline resistance
ADV	Aujesky's disease virus
AHA	Animal Health Australia
ALOP	appropriate level of protection
APHIS	USDA Animal and Plant Health Inspection Service
AUSEVETPLAN	Australian Veterinary Emergency Plan
BA	Biosecurity Advice
bovine TB	bovine tuberculosis
BSE	bovine spongiform encephalopathy
BTEC	Brucellosis and Tuberculosis Eradication Campaign
BVDV	bovine viral diarrhoea virus
CA	competent authority
CBPP	contagious bovine pleuropneumonia
CCFH	Codex Committee on Food Hygiene
CCHF	Crimean-Congo haemorrhagic fever
CDC	Centre for Disease Control
CFR	Code of Federal Regulations
CFSPH	Centre for Food Security and Public Health
CFT	complement fixation test
CMI	cell-mediated immune response
CP	cytopathic
DAID	Domestic Animal Infectious Disease
DoH	Department of Health
DT104	<i>Salmonella enterica</i> serotype Typhimurium definitive type 104
EAD	emergency animal disease
EADRA	Emergency Animal Disease Response Agreement
EFSA	European Food and Safety Authority
ELISA	enzyme-linked immunosorbent assay
ESAM	<i>Escherichia coli</i> and <i>Salmonella</i> monitoring programme

Term or abbreviation	Definition
ESR	Institute of Environmental Science and Research
EZ	Ministry of Economic Affairs (the Netherlands)
FAO	Food and Agriculture Organization of the United Nations
FMD	foot and mouth disease
FSANZ	Food Safety Australia New Zealand
FSIS	USDA Food Safety Inspection Service
HACCP	Hazard Analysis Critical Control Point
HS	haemorrhagic septicaemia
IPP	Intensive Paratuberculosis Programme
LHSC	Livestock Hygiene Service Centre
LSD	lumpy skin disease
MAFF	Ministry of Agriculture, Forestry and Fisheries
MARAN	Monitoring of Antimicrobial Resistance and Antibiotic Usage in Animals in the Netherlands
MBM	meat and bone meal
MHLW	Ministry of Health, Labour and Welfare
MLVA	multiple-locus variable-number tandem repeat analysis
MPI	Ministry for Primary Industries (New Zealand)
MQAP	Milk Quality Assurance Programme
NAHMS	National Animal Health Monitoring Systems
NCP	non-cytopathic
NID	notifiable infectious diseases other than domestic animal infectious diseases
NLRAD	National List of Reportable Animal Diseases
NMD	National Microbiological Database
NZ	New Zealand
NVBJCP	National Voluntary Bovine Johne's Control Program
NVMA	The Netherlands Food and Consumer Product Safety Authority
OIE	World Organisation for Animal Health
OIE Code	OIE Terrestrial Animal Health Code
OIE Manual	OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
OIE WAHIS	OIE World Animal Health Information System
PCR	polymerase chain reaction
PFGE	pulsed-field gel electrophoresis

Term or abbreviation	Definition
PI	persistently infected
PR	pathogen reduction
PRV	Pseudorabies virus
RIVM	National Institute of Public Health and the Environment (the Netherlands)
RT-PCR	reverse transcriptase polymerase chain reaction
RVF	Rift Valley fever
SC	Small-colony type (for <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i>)
SCAHAW	Scientific Committee on Animal Health and Animal Welfare
SHV-1	<i>Suid herpesvirus 1</i>
SGI1	<i>Salmonella</i> genomic island 1
spp.	species
SPS Agreement	WTO agreement on the Application of Sanitary and Phytosanitary Measures
subsp.	subspecies
TB	tuberculosis
TFAP	Tuberculosis Freedom Assurance Program
US	United States
USDA	United States Department of Agriculture
VS	vesicular stomatitis
WAHID	World Animal Health Information Database
WB	Wesslesbron disease
WTO	World Trade Organization

Summary

A number of Australia's trading partners have formally approached the Australian government for market access for fresh (chilled or frozen) beef and beef products for human consumption. In this document the term 'fresh' implies chilled or frozen product. Unless otherwise stated, it is assumed that any biosecurity risk applicable to fresh beef product is equivalent to or less than that applicable to fresh beef.

In line with Australia's international trade obligations, the Australian Government Department of Agriculture and Water Resources committed to undertaking a review of the import conditions for fresh beef and beef products from specified countries. In this review, specified countries are referred to as applicant countries.

To access the Australian market for fresh beef and beef products, applicant countries undergo a two-part review process that identifies food safety and biosecurity risks, and applies conditions that exporting countries must meet. The first part of the review is undertaken by Food Standards Australia New Zealand (FSANZ), an independent statutory agency within the Australian Government's Health portfolio with responsibility for food safety. The FSANZ review assesses the level of risk posed by bovine spongiform encephalopathy (BSE) to the health of Australian consumers. A favourable FSANZ BSE assessment allows access for heat-treated shelf-stable beef products into Australia, subject to compliance with existing biosecurity requirements and finalisation of agreed health certificates for importation. The second part of the review is undertaken by the Department of Agriculture and Water Resources and evaluates animal biosecurity risks associated with fresh beef and beef products access to mainland Australia. The Australian External Territories are not considered in this review.

This biosecurity review considered importation of fresh beef and beef products from applicant countries that have a favourable BSE assessment by FSANZ, and have also formally applied to the department for access for fresh beef and beef products. To ensure consistency with existing import policy, New Zealand and Vanuatu were included as applicant countries in this review as both are FSANZ assessed and approved countries with long-standing access for fresh beef and beef products.

Applicant countries considered in this review were:

- Japan
- The Netherlands
- New Zealand
- United States
- Vanuatu

Beef and beef products included in this review were meat, bone and offal from domesticated American bison (*Bison bison*), buffalo (*Bubalus bubalis*—water buffalo or domestic Asian water buffalo), or cattle (*Bos taurus* and *Bos indicus*), as fresh (chilled or frozen) beef and beef products derived from fresh beef. For the purpose of this review, offal was considered the heart, oesophagus, organs of the abdominal cavity (other than reproductive organs), the muscular tissues of the head, tissues of the diaphragm, the tail, and tendons.

The review specifically excluded:

- brain, all pulmonary and reproductive organs, including udders (and associated lymph nodes)
- milk and dairy products
- gelatine and collagen derived from bovine skins and hides (including casings produced from this type of material)
- edible bovine fats or bovine tallows included as a minor ingredient of a processed product
- natural casings, heat-processed meat-based flavours and retorted beef and beef products for human consumption, because separate import requirements apply to these products
- blood and blood products excepting that which is naturally contained in meat flesh after slaughter and bleeding.

The department adopted the following standards as the benchmark for the assessment of the unrestricted risk estimate associated with imported fresh beef and beef products from the applicant countries:

- *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (2007)* (Australian Meat Standard) (FRSC 2007).
- *Bovine spongiform encephalopathy (BSE): requirements for the importation of beef and beef products for human consumption – effective 1 March 2010* (Australian BSE requirements) (FSANZ 2010).
- *Imported Food Control Act 1992* which requires imported food to comply with the *Australia New Zealand Food Standards Code*.

The Department of Agriculture and Water Resources assessed the animal biosecurity risks (excluding BSE which is covered by FSANZ) associated with the proposed importation of fresh beef and beef products from the applicant countries in this draft review. Human health concerns are the responsibility of the Australian Government Department of Health (DoH). The Department of Agriculture and Water Resources consulted with DoH in the development of this draft review. For those diseases of human health significance, DoH is currently undertaking an assessment of the human health risk and, if required, will recommend appropriate risk management measures. Where DoH assesses that the risk to human health was higher than Australia's appropriate level of protection (ALOP), the recommended risk management measures will be incorporated into the final risk review.

The review took into account new and relevant peer-reviewed scientific information, advice from scientific experts, and relevant changes in industry practices and operational practicalities. The department recognises that there might be new scientific information and technologies, or other combinations of measures that may provide an equivalent level of biosecurity for the disease agents identified as requiring risk management. Submissions supporting equivalent measures will be considered on a case-by-case basis.

Hazard identification identified several significant bovine diseases which are currently exotic to all the applicant countries and Australia. These diseases are:

- contagious bovine pleuropneumonia
- Crimean-Congo haemorrhagic fever
- foot-and-mouth disease
- haemorrhagic septicaemia.

- lumpy skin disease
- surra
- Rift Valley fever
- theileriosis
- trypanosomiasis
- Wesselsbron disease

Country freedom from these diseases is an appropriate risk management for imports from these countries and risk management will be covered under a country freedom clause in the required certification. No risk management was required for rinderpest as the disease was declared globally eradicated in 2011 (OIE 2013a). Information validating this approach for the applicant countries is summarised in Chapter 6 (Hazard Identification).

The following diseases were identified in the hazard identification stage as requiring risk assessment:

- anthrax
- Aujeszky's disease
- bovine brucellosis
- bovine tuberculosis
- bovine viral diarrhoea virus
- *Cysticercus bovis*
- echinococcosis
- paratuberculosis
- *Salmonella enterica* serotype Typhimurium DT104
- vesicular stomatitis

The conclusions of risk assessment for each of these diseases in terms of estimated risk from the importation of beef and beef products and, if required, the proposed risk management measures to achieve Australia's ALOP are summarised below.

Anthrax (*Bacillus anthracis*)

The animal biosecurity risk from *Bacillus anthracis* associated with importation of fresh beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and achieves Australia's ALOP.

Additional risk management for *B. anthracis* is therefore not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Aujeszky's disease (*Suid herpesvirus 1*)

The risk from Aujeszky's disease (SHV-1) associated with importation of fresh beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and achieves Australia's ALOP.

Risk management for this disease/disease agent is therefore not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Bovine brucellosis (*Brucella abortus*, *B. melitensis*, *B. suis*)

B. melitensis is not present in Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Given that reproductive organs, udders and products from non-domesticated bison, buffalo and cattle are excluded from importation under the scope of this review, the risk from *B. abortus* or *B. suis* associated with importation of fresh beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and achieves Australia's ALOP with respect to animal biosecurity risks.

Additional risk management for *B. abortus* and *B. suis* is not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu. Certification of country freedom from brucellosis caused by *B. melitensis* is therefore considered sufficient, reasonable and practical to address the unrestricted risk of importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Bovine tuberculosis (*Mycobacterium bovis*)

The risk from bovine tuberculosis associated with the importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and therefore achieves Australia's ALOP with respect to animal biosecurity risks.

Additional risk management for bovine tuberculosis is therefore not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Bovine viral diarrhoea virus (BVDV)

The risk from BVDV associated with importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and achieves Australia's ALOP.

Additional risk management for BVDV is therefore not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Cysticercus bovis

The risk from *C. bovis* associated with importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and achieves Australia's ALOP.

Additional risk management for *C. bovis* is therefore not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Echinococcosis

The risk from echinococcosis associated with importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and achieves Australia's ALOP.

Additional risk management for Echinococcosis is therefore not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Paratuberculosis (*Mycobacterium avium* subspecies *paratuberculosis*)

The risk from *M. avium* subspecies *paratuberculosis* associated with importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and therefore achieves Australia's ALOP with respect to animal biosecurity risks.

Additional risk management for *M. avium* subspecies *paratuberculosis* is therefore not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

Salmonella enterica serotype Typhimurium DT104 (DT104)

The risk from DT104 associated with importation of fresh beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and therefore achieves Australia's ALOP with respect to animal biosecurity risks.

Preliminary analysis of the risk to human health associated with imports of beef and beef products from Japan, the Netherlands and the United States has shown that there is an unrestricted risk that needs to be managed. Further analysis is currently being conducted to assess this risk more fully.

The importation of beef and beef products from Japan, the Netherlands and the United States does not achieve Australia's ALOP with respect to human biosecurity and risk management is required to address this risk.

The following risk management options are considered sufficient, reasonable and practical to address the risk of DT104 from the importation of beef and beef product from the applicant countries where it is endemic:

- The country of origin must have a documented, regulated *Salmonella* surveillance and reduction system with specified *Salmonella* performance standards, which is deemed acceptable by the Australian Government through audit and equivalence determinations, in abattoirs processing beef for export to Australia; and
- An agreed pre-export sampling and testing regime for *Salmonella* Typhimurium, with regard to DT104 or an equivalence regime as assessed by the Department of Agriculture and Water Resources.

Vesicular stomatitis

The risk from vesicular stomatitis associated with importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and achieves Australia's ALOP with respect to animal biosecurity risks.

Additional risk management for vesicular stomatitis is therefore not required for importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

1 Introduction

1.1 Australia's biosecurity policy framework

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

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

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

Australia's risk analyses are undertaken by the Australian Government Department of Agriculture and Water Resources using technical and scientific experts in relevant fields, and involve consultation with stakeholders at various stages during the process.

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

Further information about Australia's biosecurity framework is provided in the *Biosecurity Import Risk Analysis Guidelines 2016* (Department of Agriculture and Water Resources 2016a) located on the [Australian Government Department of Agriculture and Water Resources](#) website.

The Department of Agriculture and Water Resources recognises that there might be new scientific information and technologies, or other combinations of measures that may provide an equivalent level of biosecurity protection for the disease agents identified as requiring risk management. Submissions supporting equivalence measures will be considered on a case-by-case basis.

1.2 This policy review

1.2.1 Background

The Department of Agriculture and Water Resources initiated this review in response to market access requests from Japan, the Netherlands and the United States for the importation of fresh (chilled or frozen) beef and beef products for human consumption. Stakeholders were notified of the formal commencement of this review through [Biosecurity Advice 2015/21](#) (Department of Agriculture and Water Resources 2015) on 10 December 2015.

New Zealand and Vanuatu are included in the review as both have long standing access for fresh beef; however, the appropriateness of the conditions under which importation occurs has not been reviewed for some time, and as such a review is warranted.

The Australian Government has policies in place to meet both food safety and animal biosecurity requirements associated with imported foods for human consumption. While the Department of Agriculture and Water Resources manages the potential risks to animal health, the potential risks to human health are the concern of the Department of Health (DoH). The potential food safety risks of imported food for human consumption are addressed by Food Standards Australia New Zealand (FSANZ), an independent statutory body in the Health portfolio. The Director of Human Biosecurity may recommend measures for human biosecurity risks.

Food imported into the Australian mainland, including fresh beef and beef products, must comply with the *Imported Food Control Act 1992*, the *Imported Food Control Regulations 1993* and the Food Standards Code developed under the *Food Standards Australia New Zealand Act 1991*. The Food Standards Code manages the human health risks associated with both domestic and imported meat and meat products for human consumption. Under the *Imported Food Control Act 1992* and its subordinate legislation, the department may inspect and analyse imported beef and beef products to ensure compliance with the requirements of the Food Standards Code. In addition to the inspection activity undertaken at the border, state and territory authorities have responsibility for monitoring all food, including imported food that is available for sale.

The Food Standards Code requires that beef and beef products must only be sourced from animals free from BSE. In addition, Australian BSE requirements only allow importation of beef and beef products from countries that have applied to Australia for a BSE assessment and have been assigned Category 1 or Category 2 status by Australian authorities (FSANZ 2010). FSANZ conducts this BSE food safety risk assessment, which assesses the level of risk posed by BSE to the health of Australian consumers. FSANZ assigns a Category 1 status to countries assessed as meeting the 'negligible BSE risk' requirements defined by the World Organisation for Animal Health (OIE). Category 2 is assigned to those countries assessed as meeting the 'controlled BSE risk' requirements defined by the OIE.

A favourable FSANZ BSE food safety risk assessment (Category 1 or 2) allows access for heat-treated shelf-stable beef products into Australia after finalisation of agreed health certificates for the trade. A biosecurity risk assessment then needs to be undertaken for access for fresh beef and beef products before such trade would be considered.

1.2.2 Scope

The scope of this draft policy review is to consider the biosecurity risk that may be associated with the importation of fresh beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu (hereafter referred to as the applicant countries). This review examines the animal biosecurity risks association with fresh beef and beef products access to mainland Australia and Tasmania. The Australian External Territories are not considered in this review.

Beef and beef products included in this review are meat, bone and offal from American bison (*Bison bison*), buffalo (*Bubalus bubalis*—water buffalo or domestic Asian water buffalo), or cattle

(*Bos taurus* and *Bos indicus*), as fresh (chilled or frozen) beef and beef products derived from fresh beef.

For the purpose of this review, offal means the heart, oesophagus, organs of the abdominal cavity, other than reproductive organs, the muscular tissues of the head, tissues of the diaphragm, the tail and tendons.

The review specifically excludes:

- brain, all pulmonary and reproductive organs, including udders (and associated lymph nodes)
- milk and dairy products
- gelatine and collagen derived from bovine skins and hides (including casings produced from this type of material)
- edible bovine fats or bovine tallow included as a minor ingredient of a processed product
- natural casings, heat-processed meat-based flavours and retorted beef and beef products for human consumption, as separate import requirements apply to these products.

Animal health risks from imported fresh beef and beef products from applicant countries were assessed after application of equivalent standards at slaughter and meat processing facilities. The department adopted the following standards as the benchmark for the assessment of the unrestricted risk estimate:

- *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (2007)* (Australian Meat Standard) (FRSC 2007).
- *Bovine spongiform encephalopathy (BSE): requirements for the importation of beef and beef products for human consumption – effective 1 March 2010* (Australian BSE requirements) (FSANZ 2010).
- *Imported Food Control Act 1992* which requires imported food to comply with the *Australian New Zealand Food Standards Code*.

The department assessed the animal biosecurity risks (excluding BSE which is covered by FSANZ) associated with the proposed importation of fresh beef and beef products from the applicant countries. The department has consulted with DoH in the development of this draft review. For those diseases of human health significance, DoH is currently undertaking an assessment of the human health and, if required, will recommend appropriate risk management measures. If these diseases are assessed as hazards, DoH will recommend risk management measures that will be incorporated into the final risk review.

1.2.3 Existing policy

International policy

Import policy currently exists for fresh beef and beef products from New Zealand and Vanuatu. FSANZ has assessed New Zealand and Vanuatu, and assigned Category 1 BSE status. The [import requirements](#) for this commodity can be found on the department's website.

Under the *Biosecurity (Prohibited and Conditionally Non Prohibited Goods) Determination 2015*, fresh beef and beef products from New Zealand do not require an import permit. However certification attesting to the origin and manufacturer is required. An import permit and accompanying certification is required for beef and beef product from Vanuatu. This certification

includes country freedom from foot-and-mouth disease, rinderpest and BSE; origin of the animals; manufacturer and/or processing plant details; and ante and post mortem veterinary inspection.

The department has considered all the diseases previously identified in the existing policies and where relevant, the information in these assessments has been taken into account in this review of policy.

Domestic arrangements

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

1.2.4 Consultation

The draft policy is released for 60 days public consultation to give stakeholders the opportunity to provide technical comment. Stakeholder submissions will be considered when finalising the review.

1.2.5 Next Steps

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

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

The final policy review will be published on the department's website along with a notice advising stakeholders of the release. The department will also notify the proposers, the registered stakeholders and the World Trade Organisation (WTO) Secretariat about the release of the final report. Publication of the final report represents the end of the process. The conditions recommended in the final report will be the basis of any import permits issued.

2 Method

Australia performs risk reviews referencing the World Organisation for Animal Health (OIE), Terrestrial Animal Health Code (the OIE Code). The OIE code describes 'General obligations related to certification' in Chapter 5.1 (OIE 2016r).

The OIE Code states in Article 5.1.2. that:

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

Article 5.1.2. further states that:

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

The components of risk analysis as described in Chapter 2.1. of the OIE Code are:

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

Hazard identification, risk assessment and risk management are sequential steps within a risk analysis. Risk communication is conducted as an ongoing process, and includes both formal and informal consultation with stakeholders. The outcome is the development of import requirements included in a bilaterally negotiated veterinary certificate, or certificates, for each country intending to export beef or beef products to Australia.

2.1 Risk review

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

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

A risk review may be undertaken in response to a market access request for a commodity where a policy exists for the commodity but from a different country, or where a policy exists for a similar commodity with similar biosecurity concerns. A risk review may also be undertaken where concern is raised that the existing policy may not adequately address the biosecurity risk. This could be due to changes in the nature of the product including production processes, new

or emerging disease concerns, changes in the relevant animal health status and/or controls in exporting country or in Australia.

This policy review has drawn on the following sources of information (this list is not exhaustive):

- the OIE Code (OIE 2016r)
- current requirements for importation of fresh beef and beef products from New Zealand and Vanuatu
- information provided by the applicant countries
- a review of relevant scientific literature.

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

2.2 Hazard identification

In this review, potential hazards were identified using the hazard identification process described in the OIE Code (Article 2.1.2). Hazard identification is a classification step undertaken to identify potential hazards associated with a commodity import.

In the hazard identification step, the department identified bovine diseases primarily affecting animal health and referred to the DoH and FSANZ any additional disease agents that may primarily affect human health. The Director of Human Biosecurity can implement biosecurity measures to manage the risks to human life or health associated with the importation of beef and beef products.

In accordance with the OIE Code, a disease agent was considered a hazard potentially present in fresh beef and beef products if it was assessed to be:

- a disease of cattle (*Bos taurus* and *Bos indicus*) or buffalo (*Bubalus bubalis*) or domesticated American bison (*Bison bison*) and
- an OIE-listed disease, an emerging disease, or a disease capable of producing adverse consequences in Australia.

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

- the disease is exotic to Australia (serotypes or strains considered exotic to Australia may meet this criterion), or if present is a nationally notifiable animal disease (Department of Agriculture and Water Resources 2016c) or subject to official control or eradication, and
- there is scientific evidence that the disease agent is present and potentially transmissible by beef carcasses and carcase parts, and
- the disease agent is present, or may be present, in the country of export (Japan, New Zealand, the Netherlands, the United States or Vanuatu).

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

2.3 Risk assessment

Disease agents retained following the hazard refinement stage were subjected to scientific review. Where the scientific review led to the conclusion that a full risk assessment was required, this was conducted in accordance with Chapter 2.1 of the OIE Code.

Risk assessment is the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country. As described in Chapter 2.1 of the OIE Code, it consists of an entry assessment, exposure assessment, consequence assessment and risk estimation for each hazard.

The unrestricted risk estimate is defined as the level of risk that would be present if there were no safeguards in excess of standard practices. The department adopted the following standards as the benchmark for assessment of the unrestricted risk estimate:

- *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (2007)* (Australian Meat Standard)(FRSC 2007).
- *Bovine spongiform encephalopathy (BSE): requirements for the importation of beef and beef products for human consumption– effective 1 March 2010* (Australian BSE requirements) (FSANZ 2010).
- *Imported Food Control Act 1992* which requires imported food to comply with the *Australia New Zealand Food Standards Code*.

A review of the scientific literature was conducted concerning factors relevant to the entry, exposure and consequence assessment for each hazard retained for risk review.

2.3.1 Risk assessment framework

For each disease identified as requiring risk assessment, the evaluation of disease risk associated with the importation of beef and beef products required evaluation of the following:

- the likelihood of the disease agent entering Australia via imported beef and beef products (entry assessment)
- the likelihood of susceptible animals being exposed to and infected with the disease agent via imported beef and beef products (exposure assessment)
- the likelihood of significant outbreaks occurring due to exposure (part of the consequence assessment)
- the potential impacts of any significant outbreaks (part of the consequence assessment).

In accordance with the OIE Code, if any of the stages of the risk assessment demonstrated no significant risk, the risk assessment did not proceed further.

For the purpose of this review, a significant outbreak was considered to be one where the disease establishes in the directly exposed population, and spreads to other populations, which may include other exposure groups. If not detected and eradicated in a timely manner, the disease has the potential to become endemic.

Based on the risk assessment, a conclusion was reached for each hazard about whether the importation represents an unrestricted biosecurity risk that exceeds Australia's ALOP for that hazard.

Entry, exposure and consequence assessment, applicable to this review, are described further below.

Entry assessment

Entry assessment describes the biological pathways necessary for importation to introduce pathogenic agents into the importing country and estimating the probability of that complete process occurring. It considers biological factors of the pathogen and the species of origin; country factors including prevalence and animal health systems in the country of export; and commodity factors such as the quantity to be imported, testing, treatment and/or processing.

The minimum requirement for the entry assessment was considered to be equivalency to the Australian standards (the Australian Meat Standard, and the Australian BSE food safety requirements) for sourcing of domesticated bison, buffalo or cattle, the production of beef and beef products for human consumption and their storage and transportation.

The entry pathway evaluated the following seven factors affecting the presence of the disease agent:

- the herd of origin of the animal slaughtered
- the animal selected for slaughter
- ante mortem inspection at the abattoir
- dressing of the carcase and carcase parts
- post mortem inspection
- storage and preparation for transport to Australia, and
- clearance at the Australian border for entry into the food chain.

If the entry assessment demonstrated no significant risk, the risk assessment did not proceed further.

Exposure assessment

Exposure assessment describes the biological pathways necessary for exposure of susceptible animals to the hazard from the imported product and estimating the probability of the exposure occurring. It considers biological factors of the pathogen; importing country factors such as the presence of competent vectors, human and animal demographics; geographical and environmental characteristics; and commodity factors such as quantity to be imported, end use and disposal practices.

Exposure assessment estimates the likelihood of susceptible animals in Australia being directly exposed to and infected with the disease agent introduced via contaminated imported beef and beef product.

The assessment took into account the different groups of animals that were susceptible to infection to disease agents in infected beef and beef products, and the pathways by which these animals could be exposed to infection.

The exposure assessment commenced with the clearance of beef and beef products at the border for entry into Australia. For each disease agent, the most relevant pathway(s) of direct exposure were evaluated. Agent survival in these pathways was also discussed for each agent.

Following importation of beef and beef products into Australia, five discrete stages were identified, illustrating the probable sequence of events for exposure of susceptible animals:

- the distribution stage – imported beef and beef products were distributed to wholesalers, beef product manufacturers and then to retailers
- the consumer stage – beef and beef products were sold by retailers to households and by retailers, wholesalers and manufacturers to food service establishments such as restaurants, cafes, take-away fast food outlets and institutions (for example, hospitals, schools)
- the disposal stage – beef and beef products were consumed either as food by humans or discarded. The discarded portion became waste, that is, material deemed to be of no further use to society or a resource for other use
- the management of unconsumed food stage – this included incineration, disposal in landfills, scraps, bait and litter, material recycled or rendered into animal feed or fertiliser
- the exposed animal stage – the exposure of susceptible animals that had direct access to contaminated waste products.

Distribution, consumption and disposal factors determine what proportion of imported product would be considered waste and potentially exposed directly to susceptible animals. Imported beef and beef products is likely to be distributed within Australia similarly to domestically produced beef. Considering the low volume import trade that is anticipated, only a small proportion of domestically sold fresh beef and beef products would consist of imported product. The proportion of this imported beef, distributed within Australia, that would end up as unconsumed food and disposed of as outlined in the sequence above would be similar to the proportion of domestic product in that pathway.

Factors considered in determining whether contaminated imported beef and beef products may cause infection in exposed susceptible animals include:

- the survival of the disease agent in the environment during the period before exposure to susceptible animals
- the waste being accessible to, and located by, a susceptible animal. Material not properly buried is more likely to be located by scavenging animals or waste being fed to susceptible animals for example, in peri-urban areas,
- accessible waste containing the disease agent, being consumed by, and infecting a susceptible animal and
- applicable legislation.

All states and territories have legislation regulating feeding animal-derived material or anything contaminated by animal-derived material and banning swill feeding of pigs. There is also legislation placing the onus on property owners to prevent wildlife or feral animals from accessing waste sites on their property (QLD DAF 2016). Most Australian states and territories now have legislation or codes of practice governing the design, management and security of landfills, which may reduce opportunities for scavenging animals to access community food waste at these sites (EPA Victoria 2015; NSW EPA 2016; QLD DAF 2016).

This risk assessment determined that there were three groups of potentially susceptible animals in Australia. The exposure groups recognised in this risk assessment were:

- domestic ruminant species

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

Each of these groups comprised animals that may be susceptible to infection when directly exposed by consumption of or direct contact with, infected imported beef and beef product wastes.

Waste management practices at the distribution and consumer stages in Australia, and legislative controls aim to significantly reduce the quantity of beef and beef product waste in stockfeed, landfills, litter and rubbish tips (Dept of Environment, 2016).

The major pathways for each identified exposure group were:

- for domestic ruminants, exposure to contaminated scraps, baits and litter
- for domestic non-ruminants, exposure to
 - feed manufactured from meat and bone meal
 - contaminated scraps, baits and litter through illegal swill feeding of pigs and feeding dogs and cats household scraps
- for wild and feral animals, exposure to
 - contaminated scraps, bait and litter
 - waste through scavenging at poorly controlled landfills and rubbish tips in peri-urban and remote regions.

For each hazard requiring a full risk assessment, the potential exposure of each exposure group to contaminated imported beef, leading to infection in exposed animals, was considered.

If the exposure assessment demonstrated no significant risk, the risk assessment did not proceed further.

Consequence assessment

Consequence assessment describes the relationship between above exposures to the identified hazard and the consequences of those exposures. The consequence assessment describes the potential impacts/effects of a given exposure and estimates the likelihood of the spread and establishment of the hazard (that is, the outbreak scenario) which could result in such effects occurring. Typically, the outbreak scenario(s) assessed is plausible and with significant potential to occur with significant consequences at the overall national level.

For each hazard requiring a full risk assessment, the likelihood of significant outbreaks occurring following incident cases was considered. Factors relevant to the establishment and spread of the disease from the initially exposed/infected susceptible animals leading to significant outbreaks were identified. Depending on the hazard, these factors included relevant pathogen factors, exposure group factors, demographic and environmental factors, disease control factors and any other relevant factors.

Consequences attributable to the outbreaks were addressed in terms of direct and indirect effects on human, animal and plant life and health on a national scale, including adverse health, environmental and socioeconomic effects.

The significance of consequences at the overall national level was based on a consideration of adverse effects which were assessed in terms of seven (two direct and five indirect) criteria.

Direct effects:

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

Indirect effects:

- new or modified eradication, control, monitoring or surveillance and compensation strategies or programs for animal disease
- domestic trade or industry, including changes in consumer demand and effects on other industries reliant on directly affected industries
- international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand
- the environment, including biodiversity, endangered species and the integrity of ecosystems
- communities, including reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures.

For each of the above direct and indirect criteria, the significance of the anticipated effect (impact) of outbreaks at the overall national level was considered. The combined significance for each of the seven criteria was considered to estimate the overall effect (ranging from negligible to extreme) of establishment and spread of the disease.

Risk estimation

Risk estimation consists of integrating the results from the entry assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the identified hazards. Thus, risk estimation determines whether the importation represents an unrestricted biosecurity risk that exceeds Australia's ALOP for that hazard.

If any of the likelihoods of entry assessment, exposure assessment or establishment and spread are considered not significant or if the overall consequences of outbreaks are considered negligible, the risk assessment for that hazard was terminated as the overall risk achieves Australia's ALOP.

For each hazard undergoing full risk assessment, the overall likelihood of outbreaks occurring was combined with the impacts of the outbreaks to obtain the unrestricted risk estimation for that hazard. If the unrestricted risk estimate did not achieve Australia's ALOP, specific risk management was considered necessary for the hazard.

2.4 Risk management

Risk evaluation is defined in the OIE Code as the process of comparing the risk estimated in the risk assessment with the reduction in risk expected from the proposed risk management measures.

The conclusions drawn from the risk reviews conducted for each hazard were used as the basis for risk evaluation during this policy review. A judgement was then made to determine whether risk management was warranted to achieve Australia's ALOP.

Option evaluation is defined in the OIE Code as the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences.

In this draft risk review, risk management options for each hazard retained for further review were evaluated and documented in Chapter 3.

Risk management options reduce to an acceptable level the likelihood that imported beef and beef products would result in the entry, exposure, and establishment and spread of disease agents of biosecurity concern in Australia. Risk management options included:

- country/abattoir/processor approval for export of beef and beef products to Australia
- certification of country freedom from disease
- other relevant biosecurity measures relevant to reducing the likelihood of entry and/or exposure to achieve Australia's ALOP.

In general, risk management measures aim to reduce the likelihood of:

- the disease agent entering Australia in imported beef and beef products by imposing risk management measures, such as pre-entry measures, that reduce the likelihood of entry, and
- exposure of susceptible animals in Australia to the disease agent via the imported beef and beef product by imposing post-entry risk management measures that reduce the likelihood of exposure.

If a disease agent is already present in Australia, Article 2.1.2 of the OIE Code states that import measures are not to be more trade restrictive than those applied within the country.

Where risk management is required for export of beef and beef products to Australia, these are discussed in Chapter 5.

2.5 Risk communication

Risk communication is defined in the OIE Code as 'the interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, risk communicators, the general public and other interested parties.'

In conducting biosecurity import risk analyses and policy reviews, the department consults with the Australian Government Department of Health to ensure that public health considerations are included in the development of Australia's animal biosecurity policies. Furthermore, a formal process of consultation with external stakeholders is a standard procedure for all biosecurity import risk analyses and policy reviews to enable stakeholder assessment and feedback on draft conclusions and recommendations about Australia's animal biosecurity policies.

3 Hazard identification

The method of hazard identification and refinement is described in Chapter 2 section 2.2.

The three outcomes of the hazard refinement process were that either:

- the hazard was not retained for further risk review
- the hazard was retained for further risk review, or
- the hazard was referred to the Department of Health (DoH) and/or Food Standards Australia and New Zealand (FSANZ).

The results of the hazard refinement process, including the reason for removal or retention of each identified hazard are summarised in Table 1.

Where the department determined that a potential hazard is not present in the country of export, certification of country freedom from the disease may be required. For country freedom from FMD, Australia refers to the current OIE classification of the country, but also makes its own assessment due to the extreme consequences of an FMD outbreak in Australia. The department maintains an FMD-free approved country list (Department of Agriculture and Water Resources 2016b), which reflects this assessment. For other hazards for which country free status may be appropriate, the department has reviewed the evidence for each hazard and each applicant country. Potential hazards not present in the applicant countries are addressed in Chapter 3 section 3.1.

Table 1 Hazard identification and refinement

Disease <i>Disease agent</i>	Susceptible species	OIE-listed disease?, emerging disease or adverse consequences in Australia	Exotic, nationally notifiable or under official control	Present/transmissible in beef carcass and carcass parts	Present in one or more applicant countries	Outcome
Akabane disease <i>Akabane virus</i>	Cattle, sheep and goats	No	No	No	Yes	Not retained
Anthrax <i>Bacillus anthracis</i>	Cattle, bison, buffalo and multiple other species including humans	Yes	Yes	Yes	Yes	Retained for further review Referred to DoH / FSANZ for assessment of public health risk
Aujeszky's disease (Pseudorabies) <i>Suid herpesvirus 1</i>	Cattle, bison, pigs (main host) and other mammals excluding humans and apes.	Yes	Yes	Yes	Yes	Retained for further review
Bluetongue <i>Bluetongue virus</i>	Cattle, bison, buffalo, sheep, goats and deer	Yes	Yes	No	Yes	Not retained
Bovine anaplasmosis <i>Anaplasma marginale</i>	Cattle	Yes	Yes	No	Yes	Not retained
Bovine babesiosis <i>Babesia bovis</i> <i>Babesia bigemina</i>	Cattle and buffalo	Yes	Yes	No	Yes	Not retained
Bovine brucellosis <i>Brucella abortus</i> <i>Brucella melitensis</i> <i>Brucella suis</i>	Cattle, bison, buffalo, horses, deer, elk, camels, llamas, alpacas and humans	Yes	Yes	Yes	Yes	Retained for further review Referred to DoH / FSANZ for assessment of public health risk
Bovine cysticercosis (<i>Cysticercus bovis</i>) <i>Taenia saginata</i>	Cattle	Yes	Yes	Yes	Yes	Retained for further review
Bovine ephemeral fever <i>Bovine ephemeral fever virus</i>	Cattle and buffalo	Yes	No	No	No	Not retained

Disease <i>Disease agent</i>	Susceptible species	OIE-listed disease?, emerging disease or adverse consequences in Australia	Exotic, nationally notifiable or under official control	Present/transmissible in beef carcase and carcase parts	Present in one or more applicant countries	Outcome
Bovine genital campylobacteriosis <i>Campylobacter fetus</i> subspp. <i>venerealis</i> <i>Campylobacter fetus</i> subspp. <i>fetus</i>	Cattle	Yes	No	No	Yes	Not retained
Bovine immunodeficiency disease <i>Bovine immunodeficiency virus</i>	Cattle	No	No	No	Yes	Not retained
<i>Bovine parvovirus</i>	Cattle	No	No	No	Yes	Not retained
<i>Bovine respiratory syncytial virus</i>	Cattle, sheep and goats	No	No	No	Yes	Not retained
Bovine spongiform encephalopathy (BSE)	Cattle, bison, cats, zoo felidae, antelope and humans	Yes	Yes	Yes	FSANZ category 1 or 2 status	Not retained Applicant countries must have a FSANZ category 1 or 2 BSE status and FSANZ risk management controls.
Bovine tuberculosis <i>Mycobacterium bovis</i> <i>Mycobacterium caprae</i>	Cattle, bison, buffalo and multiple other species including humans	Yes	Yes	Yes	Yes	Retained for further review Referred to DoH / FSANZ for assessment of public health risk
Bovine viral diarrhoea <i>Bovine viral diarrhoea virus</i>	Cattle, sheep, goats, and cervids	Yes	Yes BVDV-2 exotic and nationally notifiable	Yes	Yes	Retained for further review
Cache Valley fever <i>Cache Valley virus</i>	Cattle, deer, sheep (primary), horses and humans	Yes	Yes	No	Yes	Not retained
Campylobacter enteritis <i>Campylobacter jejuni</i> <i>C. coli</i>	Cattle and multiple other species including humans	No	No	Yes	Yes	Not retained Referred to DoH / FSANZ for assessment of public health risk

Disease Disease agent	Susceptible species	OIE-listed disease?, emerging disease or adverse consequences in Australia	Exotic, nationally notifiable or under official control	Present/transmissible in beef carcase and carcase parts	Present in one or more applicant countries	Outcome
Coenurosis <i>Coenurus cerebralis</i> <i>Taenia multiceps</i>	Cattle, sheep (primary), goats, horses, pigs, dogs and cervids	Yes	Yes	No	Yes	Not retained
Contagious bovine pleuropneumonia <i>Mycoplasma mycoides</i> subsp. <i>mycoides SC</i>	Cattle, buffalo, sheep and goats	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.1
Crimean-Congo haemorrhagic fever	Cattle, sheep, goats, hares, dogs, mice, ostriches and humans	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.2
<i>Cryptosporidium parvum</i>	Cattle, sheep and humans	No	No	No	Yes	Not retained
Echinococcosis <i>Echinococcus ortleppi</i> <i>E. granulosus sensu stricto</i> <i>E. multilocularis</i>	Cattle and multiple other species including humans	Yes	Yes	Yes	Yes	Retained for further review
Enzootic bovine leukosis (bovine leukaemia) <i>Bovine leukaemia virus</i>	Cattle and sheep (experimental)	Yes	Yes	No	Yes	Not retained
Epizootic haemorrhagic disease (including Ibaraki disease) <i>Epizootic haemorrhagic disease virus</i>	Cattle and deer	Yes	Yes	No	Yes	Not retained
Foot and mouth disease <i>Foot and mouth disease virus</i>	Cattle and other cloven hoofed animals	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.3

Disease <i>Disease agent</i>	Susceptible species	OIE-listed disease?, emerging disease or adverse consequences in Australia	Exotic, nationally notifiable or under official control	Present/transmissible in beef carcase and carcase parts	Present in one or more applicant countries	Outcome
Haemorrhagic colitis <i>Escherichia coli</i> O157:H7	Cattle and multiple other species including humans	No	Yes	Yes	Yes	Not retained Referred to DoH / FSANZ for assessment of public health risk
Haemorrhagic septicaemia <i>Pasteurella multocida</i> serotypes B:2 & E:2	Cattle, buffalo, sheep, goats, pigs, camels, equids, yaks, deer and other wild ruminants	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.4
Heartwater <i>Cowdria ruminantium</i>	Cattle and multiple other species	Yes	Yes	No	No	Not retained
Infectious bovine rhinotracheitis / infectious pustular vulvovaginitis <i>Bovine herpesvirus 1</i>	Cattle	Yes	No	No	Yes	Not retained
Influenza D <i>Influenzavirus D</i>	Cattle, pigs	Yes	No	No	Yes	Not retained
Jembrana disease <i>Jembrana disease virus</i>	Cattle	No	Yes	Yes	No	Not retained
Leptospirosis <i>Leptospira</i> spp.	Cattle and multiple other species including humans	Yes	Yes	No	Yes	Not retained
Listeriosis <i>Listeria monocytogenes</i>	Cattle and multiple other species including humans	No	Yes	Yes	Yes	Not retained
Louping ill <i>Louping ill virus</i>	Cattle, sheep (primary), goats, horses, cervids, pigs and dogs	Yes	Yes	No	No	Not retained

Disease <i>Disease agent</i>	Susceptible species	OIE-listed disease?, emerging disease or adverse consequences in Australia	Exotic, nationally notifiable or under official control	Present/transmissible in beef carcase and carcase parts	Present in one or more applicant countries	Outcome
Lumpy skin disease <i>Lumpy skin disease virus</i>	Cattle and buffalo	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.5
Malignant catarrhal fever <i>Ovine herpesvirus-2</i> <i>Alcelaphine herpesvirus-1</i>	Cattle, bison, buffalo, sheep, wildebeest and deer	No	Yes	No	Yes	Not retained
Paratuberculosis <i>Mycobacterium avium</i> subsp. <i>paratuberculosis</i> , cattle & sheep strains	Cattle, buffalo, sheep, goats, camelids and cervids	Yes	Yes	Yes	Yes	Retained for further review Referred to DoH / FSANZ for assessment of public health risk
Q-fever <i>Coxiella burnetii</i>	Cattle and multiple other species including humans.	Yes	Yes	No	Yes	Not retained
Rabies <i>Rabies virus</i>	Cattle and other mammals including humans	Yes	Yes	No	Yes	Not retained
Rift Valley fever <i>Rift Valley fever virus</i>	Cattle, buffalo, sheep, goats and camelids	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.6
Rinderpest <i>Rinderpest virus</i>	Cattle and buffalo	Yes	Yes	Yes	No	Not retained Globally eradicated in 2011
<i>Salmonella enterica</i> serotype Typhimurium DT104 and other <i>Salmonella</i> spp.	Cattle and multiple other species including humans	Yes	Yes	Yes	Yes	Retained for further review Referred to DoH / FSANZ for assessment of public health risk
<i>Schmallenberg virus</i>	Cattle, bison, sheep, goats, deer, dogs, alpacas, mouflons and wild boar	Yes	Yes	No	Yes	Not retained

Disease <i>Disease agent</i>	Susceptible species	OIE-listed disease?, emerging disease or adverse consequences in Australia	Exotic, nationally notifiable or under official control	Present/transmissible in beef carcase and carcase parts	Present in one or more applicant countries	Outcome
Screw worm fly <i>Cochliomyia hominivorax</i> <i>Chrysomya bezziana</i>	Cattle and other mammals including humans	Yes	Yes	No	Yes	Not retained
<i>Staphylococcus</i> spp.	Cattle and multiple other species including humans	No	No	Yes	Yes	Retained for further review Referred to DoH / FSANZ for assessment of public health risk
Surra <i>Trypanosoma evansi</i>	Cattle, buffalo, horses, mules, donkeys, camels, llamas, pigs, sheep, goats, dogs and cats	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.7
Theileriosis <i>Theileria annulata</i> <i>Theileria parva</i>	Cattle buffalo, yaks and camels	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.8
<i>Toxoplasmosis gondii</i>	Cattle and multiple other species including humans	No	No	Yes	Yes	Not retained
Trichomoniasis <i>Trichomonas foetus</i>	Cattle	Yes	No	No	Yes	Not retained
Trypanosomiasis <i>Trypanosoma congolense</i> <i>Trypanosoma brucei brucei</i> <i>Trypanosoma vivax</i>	Cattle, sheep, goats, pigs, horses, deer, dogs and camels	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.9
Vesicular stomatitis <i>Vesicular stomatitis virus</i>	Cattle, horses, pigs and humans	Yes	Yes	Yes	Yes	Retained for further review Referred to DoH / FSANZ for assessment of public health risk

Disease <i>Disease agent</i>	Susceptible species	OIE-listed disease?, emerging disease or adverse consequences in Australia	Exotic, nationally notifiable or under official control	Present/transmissible in beef carcass and carcass parts	Present in one or more applicant countries	Outcome
Wesselsbron disease <i>Wesselsbron virus</i>	Cattle, sheep, goats, cats, dogs and humans	Yes	Yes	Yes	No	Not retained as not present in applicant countries Refer to section 3.1.10
West Nile fever <i>West Nile virus</i>	Cattle, birds, sheep and other mammals including humans	Yes	Yes	No	Yes	Not retained

The following diseases were retained for further review on the basis of the information provided in Table 1:

- anthrax
- Aujeszky's disease
- bovine brucellosis
- bovine tuberculosis
- bovine viral diarrhoea virus
- *Cysticercus bovis* infection
- echinococcosis
- paratuberculosis
- *Salmonella enterica* serotype Typhimurium DT104
- vesicular stomatitis.

The following diseases were identified as potential hazards on the basis of the information provided in Table 1, but were not present in the applicant countries, as discussed in Chapter 3 section 3.1.1:

- contagious bovine pleuropneumonia
- Crimean-Congo haemorrhagic fever
- foot and mouth disease
- haemorrhagic septicaemia
- lumpy skin disease
- Rift Valley fever virus
- surra
- theileriosis
- trypanosomiasis
- Wesselsbron disease

The following diseases were identified as being of potential public health concern. These diseases were referred to the DoH and FSANZ to consider potential human health risks:

- anthrax
- antimicrobial resistance (*Haemorrhagic colitis*, *Campylobacter enteritis* and *Staphylococcus* spp.)
- bovine brucellosis
- bovine tuberculosis
- paratuberculosis
- *Salmonella enterica* serotype Typhimurium DT104
- vesicular stomatitis

3.1 Hazards not present in applicant countries

3.1.1 Contagious bovine pleuropneumonia

Contagious bovine pleuropneumonia (CBPP) is an infectious bacterial disease of cattle and occasionally of water buffalo (*Bubalus bubalis*) caused by the bovine biotype of *Mycoplasma mycoides* subsp. *mycoides* small-colony type (SC). The disease can be acute, subacute or chronic, and is characterised by a serofibrinous pleuropneumonia and severe pleural effusion (Coetzer & Tustin 2004).

CBPP is widespread in Africa with endemic infections extending throughout the pastoral herds of much of western, central, and eastern Africa, and in Angola and northern Namibia in southern Africa (OIE 2016d).

CBPP is an OIE-listed disease (OIE 2016p). CBPP is a notifiable disease in Australia (Department of Agriculture and Water Resources 2016c) and has not been reported since 1967 (OIE 2016u). As a result of a successful national eradication campaign which included culling, vaccination and monitoring mainly at abattoirs, Australia declared freedom from the disease in 1972 (Newton 1992; Turner 2011). The OIE recognises Australia as free from CBPP (OIE 2016n).

M. mycoides SC is primarily found in lungs; however, due to bacteraemia it might spread to other organs. The organism can survive for more than ten years in frozen, infected pleural fluid (Thiaucourt, van der Lugt & Provost 2004).

Japan

Information provided by Japan confirms that CBPP is a notifiable disease. CBPP was last reported to the OIE in 1941 and other literature state that eradication occurred in 1932 (OIE 2016u; Provost et al. 1987).

The Netherlands

CBPP is a notifiable disease in the Netherlands and was eradicated in 1887 (European Commission 2012; OIE 2016u; ter Laak 1992).

New Zealand

CBPP is a notifiable disease (MPI 2016a) and was eradicated from New Zealand around 1864-1865 (Fisher 2006; OIE 2016u).

United States

CBPP was last reported in the United States in 1892 (OIE 2009c; Provost et al. 1987). The OIE recognises the United States as free from CBPP (OIE 2016n).

Vanuatu

CBPP is a notifiable disease in Vanuatu (Government of the Republic of Vanuatu 2003). A study of cattle diseases in Vanuatu from 1971 to 1981 found weak serological evidence of CBPP infection but no historical, clinical or post mortem evidence of the disease (Schandevyl & Deleu 1985). It was surmised at the time that the serological evidence may have been non-specific cross-reactivity. There are no reports of the disease subsequent to this (OIE 2016u).

Conclusion

There is scientific evidence that *M. mycoides* SC may be present in beef carcasses or carcase parts. There is no evidence that *M. mycoides* SC is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk

management is necessary. Certification of country freedom from CBPP is considered sufficient, reasonable and practical to address the risk of importation of *M. mycoides* SC in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.2 Crimean-Congo haemorrhagic fever virus

Crimean-Congo haemorrhagic fever (CCHF) is a serious zoonotic viral disease. Infection in humans and rodents results in high mortality rates (Smirnova 1979), whereas infection in other mammalian hosts is subclinical. CCHF is caused by a single stranded RNA virus in the Nairovirus genus in the family Bunyaviridae (Nichol et al. 2005). CCHF virus is predominantly transmitted by ticks; however, direct animal-to-human and human-to-human transmission can also occur.

CCHF virus is widespread in Africa, Asia and the Middle East. It is currently considered endemic in Bulgaria and in recent decades has been recorded in other countries in south-eastern Europe and south-western regions of the Russian Federation (Maltezou et al. 2010). At the time of writing, recent outbreaks of CCHF have occurred in humans in Spain and Pakistan (ProMED Mail 2016a, b).

CCHF is a multiple species OIE-listed disease (OIE 2016p). CCHF has never occurred in Australia (AHA 2016a) and is a nationally notifiable disease (Department of Agriculture and Water Resources 2016c).

CCHF virus is distributed in the blood and tissues of infected animals including cattle (Smirnova 1979). It is readily transmitted to people who come in direct contact with infected blood and tissues (Maltezou et al. 2010; Swanepoel et al. 1985). Consumption of raw meat can be considered as a risk factor associated with CCHF virus infection (Fazlalipour et al. 2016; Sharifi-Mood et al. 2011). The virus is resistant to freezing but is inactivated by UV light, low pH or when cooked for 15 minutes at 60 °C (Hoogstraal 1979).

Japan

In Japan, no cases of CCHF in animals have been reported to the OIE (OIE 2016u) and the disease is not notifiable in animals. CCHF is a human notifiable disease (National Institute of Infectious Diseases 2016b). The National Institute of Infectious Diseases records weekly surveillance data on human infectious diseases. No human cases of CCHF have been recorded since 2012 which is the extent of the archive (National Institute of Infectious Diseases 2016a).

The Netherlands

CCHF has never been reported in the Netherlands (OIE 2016u). It is not a notifiable disease under European legislation in animals or humans (European Commission 2000, 2012).

New Zealand

CCHF is not present in New Zealand (OIE 2016u). It is a notifiable disease (MPI 2016a).

United States

CCHF does not occur and has never been reported in the United States (Ergönül 2006; Hoogstraal 1979; Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "G.Caporale" 2009; OIE 2016u; Watts et al. 1988). The disease is nationally notifiable (USDA:APHIS 2016a).

Vanuatu

There is no documented evidence that CCHF is present in Vanuatu (OIE 2016u). It is a notifiable disease (Government of the Republic of Vanuatu 2003).

Conclusion

There is scientific evidence that CCHF virus may be transmitted via beef carcasses or carcase parts. There is no evidence that CCHF virus is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from CCHF is considered sufficient, reasonable and practical to address the risk of importation of CCHF virus in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.3 Foot-and-mouth disease virus

Foot-and-mouth disease (FMD) is a highly contagious viral disease that primarily affects cloven-hoofed animals. FMD virus belongs to the family *Picornaviridae* and genus *Aphthovirus* (Knowles et al. 2011). FMD is currently endemic in most of Asia, Africa, the Middle East and parts of South America. Much of Europe is free as is all of North America.

FMD is a multiple species OIE-listed disease (OIE 2016p) and nationally notifiable in Australia (Department of Agriculture and Water Resources 2016c). Disease has not been reported in Australia since 1872 when minor outbreaks of possible FMD were reported (Auty 1998; Bunn, Gerner & Cannon 1986). Australia is recognised by the OIE as a country free from FMD without vaccination (OIE 2016g). An AUSVETPLAN disease strategy, maintained by Animal Health Australia, provides a technical response plan to an incursion of FMD into Australia (AHA 2014).

The transmission of FMD virus via meat or meat products is well documented. In Great Britain between 1954 and 1967, before introduction of restrictions on swill-feeding and the mandatory deboning and maturation of imported meat and meat products, at least 54 per cent of 179 primary outbreaks of FMD were traced to imported meat, bones and meat wrappers (Beynon 1968). The source of the FMD outbreak in England in 2001 was illegal swill-feeding of pigs (Valarcher et al. 2008). Valarcher et al. (2008) explain that in Europe, between 1985 and 2006, 37 outbreaks were reported in 14 countries. Although the origin of 22 outbreaks could not be confirmed, most appeared to be due to illegal imports of infected meat and meat products. One was attributed to imported beef certified as deboned but investigations determined it as bone-in. Ingestion of infected meat and meat products by pigs is regarded as the most likely route by which imported beef and beef products can initiate an outbreak.

The OIE Code recommends that fresh meat or meat products be sourced from animals from FMD free countries or zones where vaccination is not practiced (OIE 2016g). For country freedom from FMD, Australia refers to the current OIE classification of the country, but also makes its own assessment due to the extreme consequences of an FMD outbreak in Australia. The department maintains an FMD-free approved country list (Department of Agriculture and Water Resources 2016b), which reflects this assessment.

Japan

Japan is recognised by the OIE and Australia as a country free from FMD without vaccination (Department of Agriculture and Water Resources 2016b; OIE 2016g). FMD was last recorded in Japan in April, 2010 (OIE 2016u). The outbreak was resolved by July 2010 following application of a series of measures including destruction of affected herds, movement controls, screening, disinfection, quarantine and vaccination (followed by euthanasia) (Muroga et al. 2012). The OIE re-instated freedom on 5 February 2011 (MAFF). Subsequent to this in line with our current policy, Australia conducted an independent review, and found Japan to be free. Information provided by Japan declares that FMD is nationally notifiable.

The Netherlands

The Netherlands is recognised by the OIE and Australia as a country free from FMD without vaccination (Department of Agriculture and Water Resources 2016b; OIE 2016g). FMD has not occurred since 2001 (Bouma et al. 2003; OIE 2016u) and is nationally notifiable under European legislation (European Commission 2012).

New Zealand

FMD has never occurred in New Zealand and is nationally notifiable (MPI 2016a; OIE 2016u). The country is recognised by the OIE and Australia as free from FMD without vaccination (Department of Agriculture and Water Resources 2016b; OIE 2016g).

United States

The United States is recognised by the OIE and Australia as a country free from FMD without vaccination (Department of Agriculture and Water Resources 2016b; OIE 2016g) and the disease is nationally notifiable (USDA:APHIS 2016a). The US has been free from FMD since 1929 (OIE 2016u).

Vanuatu

FMD has never occurred in Vanuatu and hence the country is recognised by the OIE and Australia as a country free from FMD without vaccination (Department of Agriculture and Water Resources 2016b; OIE 2016g). It is a notifiable disease (Government of the Republic of Vanuatu 2003).

Conclusion

There is scientific evidence that FMD virus may be transmitted via beef carcasses or carcase parts. There is no evidence that FMD virus is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from FMD is considered sufficient, reasonable and practical to address the risk of importation of FMD virus in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.4 Haemorrhagic septicaemia

Haemorrhagic septicaemia (HS) is a highly fatal disease of predominantly cattle and water buffalo caused by the B:2 and E:2 serotypes of the bacterium *Pasteurella multocida*. Variable clinical signs are associated with HS, ranging from pyrexia, respiratory distress, nasal discharge and dependent oedema in the submandibular or brisket regions to recumbency and sudden death. Outbreaks are associated with high morbidity and mortality rates. Close contact with infected animals or subclinical carriers is required for transmission by ingestion or inhalation of the organism.

HS is an OIE-listed disease (OIE 2016p). HS is endemic in tropical and subtropical regions including South-East Asia, India, the Middle East, regions of Africa, and southern and central Europe (OIE 2016i; Völker et al. 2014).

HS has never been reported in Australia (AHA 2016a), where it is a nationally notifiable disease (Department of Agriculture and Water Resources 2016c).

HS-causing strains of *P. multocida* have been identified in many tissues of clinically affected animals, including the spleen, liver, kidney, skeletal muscle, small intestine and subcutaneous tissue (Annas et al. 2014; Bastianello & Jonker 1981; Khin, Zamri-Saad & Noordin 2010; Lane et

al. 1992). *P. multocida* HS-causing strains have also been detected in the respiratory, gastrointestinal and urinary tracts of carrier animals (Annas et al. 2014). Moist environmental conditions may prolong environmental survival and the bacteria may be able to survive in animal carcasses for a few days (de Alwis 1999).

Japan

HS was last reported in Japan in 1954 (de Alwis 1999). A recent study did not find HS-causing strains in *P. multocida* isolated from both healthy and unhealthy Japanese cattle (Katsuda et al. 2013). No cases have been reported to the OIE (OIE 2016u). Information provided by the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) indicates that HS is a notifiable disease in cattle, sheep, goats, pigs, water buffalo, deer and wild boar.

The Netherlands

HS has never been reported in the Netherlands, where it is a notifiable disease (OIE 2016u).

New Zealand

Only non HS-causing strains of *P. multocida* have been reported in New Zealand (McFadden et al. 2011b). HS has never been reported in the New Zealand (OIE 2016u), where it is a notifiable disease (MPI 2016a).

United States

Rare and sporadic outbreaks of HS have been reported in the United States. Outbreaks of B:2 HS-causing strains occurred in wild bison occurred in 1922 and in beef cattle in 1993 (Rimler & Wilson 1994). Other outbreaks of *P. multocida* in bison and cattle in the United States have been attributed to non HS-causing strains (Rimler & Wilson 1994). There is no evidence of transmission between bison and domestic ruminants. Since 2010 HS is considered absent in the United States by the OIE (OIE 2016u), and is nationally notifiable (USDA:APHIS 2016a).

Vanuatu

HS has never been reported in Vanuatu (OIE 2016u), where it is a notifiable disease (Government of the Republic of Vanuatu 2003).

Conclusion

There is scientific evidence that HS may be present in beef carcasses or carcase parts. There is no evidence that HS is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from HS is considered sufficient, reasonable and practical to address the risk of importation of HS in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.5 Lumpy skin disease virus

Lumpy skin disease (LSD) is an infectious viral disease of cattle characterised by the eruption of nodules in the skin which may cover the whole of the animal's body. LSD virus belongs to the genus *Capripoxvirus* of the family *Poxviridae*, along with sheeppox and goatpox viruses (Skinner et al. 2011). These viruses are morphologically indistinguishable from each other, but are adapted to different host species. The viruses are difficult to distinguish serologically, and cross protection does occur.

In the last decade, outbreaks have occurred in Africa, the Middle East and Europe (Beard 2016).

LSD is an OIE-listed disease (OIE 2016p). LSD is a nationally notifiable disease (Department of Agriculture and Water Resources 2016c). An AUSVETPLAN disease strategy manual, maintained by Animal Health Australia, provides a technical response plan to an incursion of LSD into Australia (AHA 2009c).

LSD virus is transmitted primarily by biting insects. LSD virus is not readily spread by direct contact. However, poxvirus nodules might be present in the muscles of infected animals and the virus is resistant to environmental degradation. In addition, LSD virus persists for a prolonged period within the skin of infected animals (Tuppurainen, Venter & Coetzer 2005). Thus, it is possible that LSD virus may be spread from meat or other carcase parts, particularly skin, due to viral persistence in these tissues.

Japan

LSD does not occur in Japan (OIE 2016u) and information provided by MAFF confirms that it is nationally notifiable.

The Netherlands

LSD does not occur in the Netherlands (OIE 2016u) and is nationally notifiable under European legislation (European Commission 2012).

New Zealand

LSD has never been reported in New Zealand (OIE 2016u). It is a notifiable disease (MPI 2016a).

United States

LSD has never been reported in the United States (OIE 2016u). It is a nationally reportable animal disease (USDA:APHIS 2016a).

Vanuatu

LSD is not present in Vanuatu (OIE 2016u) and is a notifiable disease (Government of the Republic of Vanuatu 2003).

Conclusion

There is scientific evidence that LSD virus may be present and/or transmitted via beef carcasses or carcase parts. There is no evidence that LSD virus is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from LSD is considered sufficient, reasonable and practical to address the risk of importation of LSD virus in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.6 Rift Valley fever virus

Rift Valley fever (RVF) virus is a zoonotic, arthropod-borne virus that causes disease characterised by mortality in young domestic ruminants and abortions in pregnant animals. RVF virus is an RNA virus in the genus *Phlebovirus* of the family *Bunyaviridae* (ARMCANZ 1996; Nichol et al. 2005).

RVF is endemic in Africa south of the Sahara, including Madagascar (Clements et al. 2007; Fontenille, Mathiot & Coulanges 1985). The virus has also occurred in Egypt (Hoogstraal et al. 1979), Saudi Arabia and Yemen (Arishi et al. 2000; Gould & Higgs 2009; OIE 2010c).

RVF is a multiple species OIE-listed disease (OIE 2016p). RVF is a nationally notifiable disease (Department of Agriculture and Water Resources 2016c) and is not present in Australia. Australia has been shown to have competent mosquito vectors for RVF transmission (Turell & Kay 1998). An AUSVETPLAN disease strategy manual, maintained by Animal Health Australia, provides a technical response plan to an incursion of RVF into Australia (AHA 2013).

In humans, RVF virus can be transmitted by handling fresh meat and carcasses, and the disease commonly occurs in occupational groups exposed to these products, for example farmers and abattoir workers (WHO 2010). Virus can also be transmitted via some carcase parts which contain significant quantities of blood or via organs which remain at or above a neutral pH for a prolonged time. Overall the risk of transmission of RVF virus from imported meat and meat products is considered to be very low (ARMCANZ 1996; Swanepoel & Coetzer 2004a). Nevertheless a risk remains for transmission by the beef carcasses or carcase parts.

The OIE code recommends that fresh meat or meat products be sourced from animals from RVF free countries or establishments (OIE 2016m).

Japan

RVF has never been reported in Japan (OIE 2016u) and information provided by MAFF confirms the disease is nationally notifiable.

The Netherlands

RVF has never been reported in the Netherlands (OIE 2016u) and is nationally notifiable under European legislation (European Commission 2012).

New Zealand

RVF has never been reported in New Zealand (OIE 2016u). It is a notifiable disease (MPI 2016a).

United States

RVF has never been reported in the United States (Kasari et al. 2008; OIE 2016u). It is a nationally reportable animal disease (USDA:APHIS 2016a).

Vanuatu

RVF is not present in Vanuatu (OIE 2016u) and is a notifiable disease (Government of the Republic of Vanuatu 2003).

Conclusion

There is scientific evidence that RVF virus may be transmitted via beef carcasses or carcase parts. There is no evidence that RVF virus is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from RVF is considered sufficient, reasonable and practical to address the risk of importation of RVF virus in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.7 Surra

Surra is caused by the blood-borne protozoan parasite *Trypanosoma evansi*, of the family Trypanosomatidae. *T. evansi* is mechanically transmitted by biting insects such as tabanid and stomoxys flies. Transmission by ingestion of tissues of parasitaemic animals, vampire bat saliva and iatrogenesis has also been described. Surra occurs in camels, horses, buffalo, cattle, dogs, pig, sheep, goats and rodents. Acute disease is characterized by fever, emaciation, anaemia, and

death which may occur within 24 h of the onset of clinical signs. Chronic surra can lead to loss of condition and impaired reproductive performance. Subclinical carrier states also exist.

Surra is endemic in Africa, the Middle East, Southeast Asia, Central and South America. In most countries where *T. evansi* is endemic, infection is not considered pathogenic in cattle although they may act as reservoir of infection. Surra in cattle and buffalo is a particular concern in Southeast Asian countries, such as the Philippines (Mekata et al. 2013), where clinical signs of infection in cattle and the resultant economic impacts are more severe. Differences in strain virulence have been reported which may explain geographic variation in host susceptibility (Mekata et al. 2013).

Surra is a multispecies OIE listed disease (OIE 2016p). It is nationally notifiable in Australia (Department of Agriculture and Water Resources 2016c). There is an AUSVETPLAN disease strategy manual for surra, which provides a technical response plan to an incursion of surra into Australia (AHA 2005b). In 1907, surra was diagnosed in a consignment of nine camels imported from India into Port Hedland, which were subsequently destroyed (AHA 2005b). There has been no further evidence of the disease in camels or any other species, in Australia (AHA 2016a).

Oral transmission of *T. evansi* from meat derived from parasitaemic animals has been demonstrated in dogs and mice (Raina et al. 1985). In addition, *T. evansi* is able to remain viable in equine muscle and liver for up to 12 hours at 27-28 °C, and in muscle for up to 66 hours at 6-12 °C (de Jesus 1962).

Japan

Surra has never been reported in Japan (OIE 2016u). MAFF confirmed that infection with *Trypanosoma* spp. such as *T. evansi* are notifiable diseases for cattle, water buffalo and horses.

New Zealand

Infection with *Trypanosoma* spp. is notifiable in New Zealand (MPI 2016a). The New Zealand Ministry for Primary Industries (MPI) confirmed that surra has never been reported in New Zealand and the insect vectors are not present.

The Netherlands

Information provided by the Dutch Ministry of Economic Affairs (EZ) confirmed that surra is a notifiable disease in the Netherlands and has never been reported (OIE 2016u).

United States

The USDA confirmed that infection with *Trypanosoma* spp., including *T. evansi*, has never been reported in the United States (OIE 2016u). Surra is a nationally notifiable disease (USDA:APHIS 2016a).

Vanuatu

Biosecurity Vanuatu confirmed that surra is a notifiable animal disease. No cases of infection with any *Trypanosoma* spp., including *T. evansi*, have been reported in Vanuatu (OIE 2016u).

Conclusion

There is scientific evidence that surra may be transmitted via beef carcasses or carcase parts. There is no evidence that surra is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from surra is considered sufficient,

reasonable and practical to address the risk of importation of surra in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.8 Theileriosis

Theileriosis is a lympho-proliferative tick-borne disease of cattle and other bovids caused by obligate intracellular protozoan parasites *Theileria parva* and *T. annulata*. These two are considered to be the most economically significant of the *Theileria* spp. in cattle (Bishop et al. 2004). Cattle present with a variety of clinical signs including lymphadenopathy, fever, petechial haemorrhages on mucous membranes developing to anorexia, ocular and nasal discharge, dyspnoea and diarrhoea often leading to death. Disease due to *T. annulata* can also cause jaundice and anaemia. *T. parva* and *T. annulata* have not been shown to be hazardous to humans (OIE 2016s).

T. parva occurs in Eastern and Southern Africa while *T. annulata* occurs in tropical regions of North Africa, southern Europe and Asia (OIE 2016o).

Theileriosis caused by *T. parva* or *T. annulata* is an OIE listed cattle disease (OIE 2016p). It has never been reported in Australia (OIE 2016u) and is nationally notifiable (Department of Agriculture and Water Resources 2016c). The key tick vectors have not been identified in Australia (Roberts 1970) however it is uncertain to what extent domestic ticks have been tested for competence (Morrison 2015).

Theileria spp. are transmitted in saliva of certain species of ixodid ticks. Once the protozoa have entered the host, the sporozoites transform and replicate within lymphocytes (*T. parva*) and macrophages/monocytes (*T. annulata*) (Bishop et al. 2004). Parasitised cells are present throughout the lymphoid system and other organs (Morrison 2015). There is no evidence of transmission of theileriosis by the consumption of affected tissues.

Japan

Theileriosis was last reported in Japan in 1993 (OIE 2016u). Information provided by Japan declares that Theileriosis caused by *T. parva* and *T. annulata* in cattle is nationally notifiable (MAFF 1953).

The Netherlands

Theileriosis, caused by *Theileria annulata* or *T. parva* has never been reported in the Netherlands (OIE 2016u). It is not a notifiable disease (European Commission 2012).

New Zealand

Theileriosis, caused by *Theileria annulata* or *T. parva* has never been reported in New Zealand (OIE 2016u). The disease is nationally notifiable (MPI 2016a).

United States

Theileriosis, caused by *Theileria annulata* or *T. parva* has never been reported in the United States (OIE 2016u). It is a nationally reportable animal disease (USDA:APHIS 2016a).

Vanuatu

Theileriosis, caused by *Theileria annulata* or *T. parva*, is a notifiable disease in Vanuatu (Government of the Republic of Vanuatu 2003). There is no evidence of its occurrence in Vanuatu (OIE 2016u).

Conclusion

There is scientific evidence that theileriosis caused by *T. annulata* or *T. parva* may be present in beef carcasses or carcase parts. There is no evidence that *T. annulata* or *T. parva* are present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from theileriosis caused by *T. annulata* or *T. parva* is considered sufficient, reasonable and practical to address the risk of importation of theileriosis caused by *T. annulata* or *T. parva* in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.9 Trypanosomiasis

Trypanosomes are blood-borne protozoan parasites in the family Trypanosomatidae which are transmitted by haematophagous arthropods. The trypanosome species *Trypanosoma vivax* and *T. congolense*, and, to a lesser extent, *T. brucei brucei* cause trypanosomiasis (or trypanosomosis or nagana) in many mammals including cattle. Clinical signs include anaemia, intermittent fever, oedema, loss of body condition, emaciation, abortion and infertility. Trypanosomiasis is biologically transmitted by tsetse flies (*Glossina* spp.), and mechanically by biting flies (tabanids and stomoxys) for *T. vivax*. Iatrogenic spread has been reported.

Disease occurs predominantly in Africa, from the southern edge of the Sahara desert to Zimbabwe, Angola and Mozambique, where tsetse flies are present (OIE 2016t). However *T. vivax* is also found beyond the tsetse belt in Africa, and in Central and South America, where it is transmitted mechanically by biting flies (Cadioli et al. 2012; Mekata et al. 2009; OIE 2016t; Oliveira et al. 2009; Thumbi et al. 2010).

Trypanosomiasis (tsetse-transmitted) is an OIE-listed disease of cattle (OIE 2016p). Trypanosomiasis is a nationally notifiable animal disease (Department of Agriculture and Water Resources 2016c) and has never been recorded in Australia (AHA 2016a). However, non-pathogenic trypanosomes, which are thought to be distributed worldwide, have been reported in livestock in Australia. These include as *T. melophagium* in sheep (Callow 1984) and *T. theileri* in cattle in Queensland (Ward et al. 1984). In addition, native trypanosomes have been isolated from marsupials but to date have not been detected in introduced mammals such as livestock (Thompson, Godfrey & Thompson 2014).

Experimental transmission of *T. brucei brucei* has been demonstrated by feeding infected goat carcasses to cats and dogs (Moloo, Losos & Kutuza 1973). Ingestion and gavaging of blood infected with *T. brucei brucei*, *T. vivax* or *T. congolense* has also been reported to transmit infection to mice (Clarkson & McCabe 1973).

Japan

MAFF confirmed that infection with *Trypanosoma* spp. such as *T. congolense*, *T. vivax* and *T. brucei brucei* are notifiable diseases for cattle, water buffalo and horses. Japan last reported infection with *Trypanosoma* spp. in cattle to the OIE in December 2014 (OIE 2016u). However only non-pathogenic *Trypanosoma* spp. have ever been isolated in cattle, deer and ticks in Japan (Hatama et al. 2007; Rodrigues et al. 2015; Thekisoe et al. 2007). There is no scientific evidence of *T. congolense*, *T. vivax* or *T. brucei brucei* infection in livestock in Japan, which has been confirmed by information provided by MAFF.

New Zealand

Infection with *Trypanosoma* spp. are notifiable in New Zealand (MPI 2016a). MPI confirmed that trypanosomiasis has never been reported in New Zealand.

The Netherlands

Information provided by EZ confirmed that trypanosomiasis is a notifiable disease in the Netherlands and has never been reported (OIE 2016u).

United States

T. congolense, *T. vivax* or *T. brucei brucei* have never been reported in the United States (OIE 2016u), and are all reportable animal diseases (USDA:APHIS 2016a).

Vanuatu

Biosecurity Vanuatu confirmed that trypanosomiasis is a notifiable animal disease. No cases of infection with any *Trypanosoma* spp. have ever been reported in Vanuatu (OIE 2016u).

Conclusion

There is scientific evidence that trypanosomiasis may be transmitted via beef carcasses or carcase parts. There is no evidence that trypanosomiasis is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from trypanosomiasis is considered sufficient, reasonable and practical to address the risk of importation of trypanosomiasis in beef carcase and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

3.1.10 Wesselsbron disease

Wesselsbron disease (WD) is an arthropod-borne virus in the genus *Flavivirus* of the family *Flaviviridae* (Simmonds et al. 2011). The disease mainly affects sheep although clinical disease has been reported in cattle, pigs, horses and goats (Swanepoel & Coetzer 2004b). Disease in adult animals and calves is usually subclinical (Ali et al. 2012). Mortality in new-born lambs and kids is high. Abortion with foetal abnormalities is reported in pregnant ewes and less commonly in goats and cattle (Coetzer, Theodoridis & van Heerden 1978).

Wesselsbron virus has been isolated from arthropods or vertebrates in South Africa, Zimbabwe, Uganda, Kenya, Nigeria, Central African Republic, Senegal, Cameroon, Ivory Coast and Thailand (Swanepoel & Coetzer 2004b). Clinical disease is restricted to sub-Saharan Africa.

WD is not an OIE listed disease. It is however nationally notifiable in Australia (Department of Agriculture and Water Resources 2016c).

Transmission is typically by *Aedes* spp. mosquitoes but the virus has been isolated from other arthropods. WD virus can be transmitted by handling fresh meat and carcasses. Disease in humans is subclinical or mild and may resemble influenza (Swanepoel & Coetzer 2004b). While aerosol transmission is speculated, transmission from animal to animal has not been demonstrated (CFSPH 2007).

Japan

There are no records of WD ever occurring in the Japan. It is not a nationally notifiable animal disease.

The Netherlands

There are no records of WD ever occurring in the Netherlands. It is not a nationally notifiable animal disease.

New Zealand

There are no records of WD ever occurring in the New Zealand. It is not a nationally notifiable animal disease.

United States

There are no records of WD ever occurring in the United States. It is not a nationally reportable animal disease.

Vanuatu

There are no records of WD ever occurring in the Vanuatu. It is not a nationally notifiable animal disease.

Conclusion

There is scientific evidence that Wesselsbron virus may be transmitted via beef carcasses or carcase parts. There is no evidence that Wesselsbron virus is present in Japan, the Netherlands, New Zealand, the United States and Vanuatu. Therefore further risk assessment is not required, however, risk management is necessary. Certification of country freedom from WD is considered sufficient, reasonable and practical to address the risk of importation of Wesselsbron virus in beef carcasses and carcase parts from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

4 Risk assessments

4.1 Anthrax

4.1.1 Background

Anthrax is an infectious bacterial disease of all mammals, including humans, and several species of birds. The causative agent is *Bacillus anthracis* — a large, spore forming, Gram-positive, rod-shaped bacterium. Anthrax is characterised by rapidly fatal septicaemia with widespread oedema, haemorrhage and necrosis. Due to its effect on public health, wildlife and livestock production, and its potential for spread via international trade, anthrax is a multiple species OIE-listed disease (OIE 2016p).

Herbivores, in particular domesticated and wild ruminants, are most susceptible to anthrax. Omnivores, for example, pigs, and carnivores tend to be more resistant to anthrax. Although *B. anthracis* occurs worldwide, outbreaks are most common in countries with poor surveillance and control programs especially in parts of Africa, Asia and the Middle East. Well-established surveillance and control programs reduced the incidence of anthrax to sporadic cases occurring mostly within defined geographical areas in Australia, Europe and the United States (CFSPH 2007).

In Australia, anthrax is uncommon with sporadic outbreaks mostly limited to areas within northern and north-eastern districts of Victoria and central New South Wales (AHA 2015b). Despite the continued occurrence of anthrax outbreaks in the eastern states of the country, work still remains to understand the ecology and distribution of *B. anthracis* in Australia. Efforts to estimate the spatial extent of the disease risk have mostly been limited to a qualitative definition of an anthrax belt extending from southeast Queensland through the centre of New South Wales and into northern Victoria. A recent study has revealed that the niche of *B. anthracis* in Australia is actually characterized by a narrow range of ecological conditions concentrated in two separate corridors. The dominant corridor parallels the Eastern Highlands and runs from northern Victoria through the centre of New South Wales to central eastern Queensland. This study redefines the anthrax belt in eastern Australia and provides insights into the ecological factors that limit the distribution of *B. anthracis* in Australia. The geographic distributions identified can help inform anthrax surveillance strategies by public and veterinary health agencies (Barro et al. 2016).

Anthrax is a nationally notifiable disease in Australia (Department of Agriculture and Water Resources 2016c) and response to cases or outbreaks in animals is guided by the AUSVETPLAN for anthrax (AHA 2015b).

Vaccines are available for protection of animals against anthrax as are antibiotics for the treatment of anthrax. Vaccinated or treated animals should not be slaughtered until the appropriate withholding period has lapsed (FRSC 2007).

Outbreaks are effectively managed by rapid identification of the disease, quarantine and vaccination for prevention, antibiotics for direct treatment, and appropriate disposal of carcasses and disinfection of the premises (AHA 2015b).

Anthrax is a zoonotic disease of significant worldwide public health concern not only because of natural outbreaks but also of its potential as a biological weapon. Humans generally acquire

anthrax through handling infected animals, live or dead, or materials from infected animals such as carcasses, hides or bone. Reducing the occurrence of natural anthrax in humans relies largely on effective veterinary intervention of animal anthrax.

4.1.2 Technical information

Agent properties

B. anthracis occurs in two forms, a vegetative form or as spores. The vegetative form is fragile and easily inactivated by disinfectants and heat (Stein & Rogers 1945; Whitney et al. 2003). It is also inactivated by putrefactive post mortem changes in carcasses although it takes a few days to kill most if not all vegetative *B. anthracis*. Normally it cannot survive in intact carcasses for more than three days at temperatures higher than 25 °C but it can survive for up to four weeks in low temperatures of 5 – 10 °C (Hugh-Jones & de Vos 2002). Exposure to air results in sporulation, important for survival of the bacteria. Controlling anthrax outbreaks requires measures that prevent disruption of carcasses, although some sporulation does occur within the carcass depending on oxygen supply, nutritional stress and carbon dioxide build-up. Under laboratory conditions, sporulation time generally decreases as temperature increases from 15 °C to 37 °C and as humidity increases (Davies 1960).

B. anthracis spores are more resistant to thermal inactivation than the vegetative form, but not as resistant as the spores of *Clostridia* spp. and other *Bacillus* spp. They can remain dormant in the environment for decades. Temperature, pH, moisture, oxygen, carbon dioxide, and certain nutrients such as l-alanine influence the *B. anthracis* spore germination (Shadomy & Smith 2008). Under laboratory conditions, spores germinate at temperatures between 22 °C and 44 °C with germination time increasing below 30 °C and above 39 °C. Germination does not occur unless relative humidity exceeds 80 per cent (Davies 1960).

Under moist heat treatment of 100 °C (i.e. boiling water), spores of *B. anthracis* are inactivated in three to five minutes (Stein & Rogers 1945) although boiling for more than ten minutes is often recommended. To inactivate the spores with dry heat, over 90 minutes at 140 °C is necessary. Inactivation time decreases with an increase in temperature, with only 30 seconds at 200 °C required (Whitney et al. 2003). Gamma irradiation at a dose of 15 kGy effectively inactivates $\geq 10^6$ spores/mL of *B. anthracis* (Horne, Turner & Willis 1959).

Epidemiology

The natural reservoir of *B. anthracis* is soil, particularly in low-lying areas with high moisture and organic content and alkaline pH. *B. anthracis* was thought to germinate and multiply almost exclusively inside the animal, and exist in the environment as dormant spores. However, there is recent experimental evidence of vegetative *B. anthracis* multiplying in soils on or around roots of grass seedlings (Saile & Koehler 2006) and of earthworms and bacterial viruses providing *B. anthracis* with alternatives to sporulation for survival and possibly multiplication in the soil (Schuch & Fischetti 2009). This suggests the life cycle for *B. anthracis* in the soil is possible though complex.

The usual source of infection in animals is the spores. Transmission occurs by ingestion of contaminated soil and/or vegetation, by inhalation of spores or by biting flies that have fed on infected carcasses. Flies and scavengers can also mechanically spread spores further afield. Contaminated bone meal and other feed can also cause anthrax. Some outbreaks are associated

with prolonged dry periods that follow heavy rainfall or flooding (Hugh-Jones & Blackburn 2009).

Evidence for a carrier state in cattle is limited though it has been reported in pigs (FAO, OIE & WHO 2008; Hugh-Jones & Blackburn 2009). *B. anthracis* has also been isolated from the lymph nodes of apparently healthy cattle in endemic areas (de Vos & Turnbull 2004; FAO, OIE & WHO 2008).

All mammals, including humans, and several species of birds can become infected with *B. anthracis* but anthrax is primarily a disease of wild and domesticated herbivores. Anthrax in cattle, goats and sheep is often peracute, with infected animals found dead before any clinical signs are observed (AHA 2015b). Horses are regarded as less susceptible though in some multi-species outbreaks, the infection rate was observed to be higher in horses than in cattle (Fox et al. 1973). Although outbreaks of anthrax in Australia do not appear to involve indigenous animals, anthrax was suspected in dingoes and kangaroos kept in overseas zoos (Hugh-Jones & de Vos 2002).

Age and sex appear to affect susceptibility of animals to anthrax with adult males being most susceptible in many cases. This is believed to be due mainly to different behaviour pattern and feeding habits (Hugh-Jones & de Vos 2002).

Pathogenesis

Infection in animals is usually acquired through ingestion, inhalation of spores or via the skin, involving wounds, abrasions or biting insects. The outcome of infection is influenced by the route of infection, the susceptibility of the host to bacterial infection and the resistance of the host to the anthrax toxins. Cattle are very susceptible to natural infection, usually dying with high levels of bacilli indicating resistance to toxins. Deer, on the other hand, die with low levels of bacteraemia because of high susceptibility to the toxins. Consequently, laboratory confirmation of anthrax in deer is difficult due to low levels of bacilli (Hugh-Jones & Blackburn 2009).

Following infection, spores are taken up by macrophages and then transported to the lymph nodes and spleen. In these lymphatic tissues, spores germinate into vegetative encapsulated bacilli and multiply, eventually rupturing the macrophages and releasing many more bacilli into the bloodstream. Vegetative bacilli have two important virulence factors, the capsule and the toxin.

The capsule of the bacillus is unique –weakly antigenic while inhibiting phagocytosis – thus enabling the bacilli to evade the immune system and rapidly multiply.

The vegetative bacilli produce a toxin of three polypeptide groups: oedema factor, lethal factor and protective antigen. The protective antigen binds the toxin to the host immune cell receptors causing endocytosis of the toxin. Once in the cytoplasm, the oedema factor and protective antigen combine to cause oedema in the tissues surrounding the bacteria and impair host defences. The lethal factor and protective antigen combine to cause hypoxic tissue injury, terminal shock and death.

Diagnosis

Clinical signs

Anthrax occurs in peracute, acute, subacute and chronic forms. The incubation period after exposure to spores under natural conditions generally varies from three to seven days, but can range from one to 20 days (CFSPH 2007).

The peracute and acute forms of anthrax occur mainly in cattle, goats and sheep. In these species the course of disease is very rapid in that the majority of animals are found dead without having shown any clinical signs of infection. Clinical signs include staggering, muscle tremors, and dyspnoea followed by collapse, convulsions and death (de Vos & Turnbull 2004).

In the acute form of anthrax, the course of disease is usually less than 72 hours, although animals generally die within two days of the appearance of clinical signs. The affected animals may show a short period of excitement but usually show severe depression and listlessness. The appetite is suppressed and ruminal stasis is evident. Respiration is rapid and deep with increased heart rate.

The subacute to chronic forms of anthrax are usually observed in omnivores (for example pigs) and carnivores. The most characteristic feature is swelling of the face, throat and neck, which may become so extensive that it interferes with respiration and ingestion of food and water. The course of the disease extends for more than three days before death or complete recovery occurs (de Vos & Turnbull 2004; Stein 1955).

Pathology

If a ruminant carcase is opened, dark unclotted blood and an enlarged spleen are observed. Excessive peritoneal, pleural and pericardial fluid are seen and the mesentery may appear thickened and oedematous. Petechiae and ecchymoses might be visible in the lymph nodes, the serosal surfaces of the abdomen and thorax, and the epicardium and endocardium. The liver, kidney and lymph nodes might also be enlarged and congested. It is important to note that not all the signs appear uniformly in all cases of anthrax (AHA 2015b; CFSPH 2007).

Testing

The history, including clinical presentation, is the first step in the diagnosis of anthrax. Demonstration of *B. anthracis* in blood or tissue smears is confirmatory for anthrax; however, its absence does not exclude the possibility of anthrax (de Vos & Turnbull 2004). Bacterial culture can be used for diagnosis and polymerase chain reaction testing can be used to identify *B. anthracis*, and to detect bacterial toxin and capsule genes. Antibodies develop late in the course of disease, and serology is only useful in retrospective studies. A skin hypersensitivity test is widely used in some countries for the retrospective diagnosis of anthrax in animals and humans (CFSPH 2007). More recently, hand-held immuno-chromatographic assay kits were evaluated and used in Australia to provide a rapid field diagnosis in livestock.

Transmission in carcase and carcase parts

High levels of vegetative *B. anthracis* are typically present in fresh dead carcasses and carcase parts of infected cattle, buffalo and bison. Slaughter and processing of infected animals results in the formation and release of spores via exposed surfaces and discharges. Spores can also be found in the faeces and urine of cattle. Infectious dose varies considerably between animal species and from humans and depends on the route of infection (Coleman et al. 2008).

There is evidence that *B. anthracis* can be transmitted via the beef carcass or carcass parts after ante and post mortem examination.

Ingestion of raw or improperly cooked meat can cause gastrointestinal anthrax in humans (Sirisanthana & Brown 2002). Non-fatal gastrointestinal anthrax was suspected in a family living in Minnesota, US, that had slaughtered a downer cow for personal meat supply (Bales et al. 2002; CDC 2000). Several outbreaks of anthrax in humans following the consumption of infected meat are reported in Promed each year (promedmail.org).

Animals and birds scavenging infected carcasses can become infected with anthrax. Anthrax outbreaks have been documented in zoo carnivores fed fresh meat sourced from local slaughterhouses (Hugh-Jones & de Vos 2002).

Effective cooking of meat reduces the risk of infection by anthrax. An analysis of an anthrax outbreak in Kazakhstan in 1998 showed that slaughtering and butchering infected animals were significant risk factors for anthrax in humans, however eating cooked infected meat was not a significant risk factor (Woods et al. 2004). In 1968, the accidental release of 200kg of infected meat for human consumption in the United States did not result in any human or animal cases of anthrax being reported (Bales et al. 2002).

Carcass and carcass parts from animals that die of anthrax can transmit the disease if there is inadequate heat treatment to inactivate spores or vegetative organisms. In the United Kingdom, *B. anthracis* was detected in eight of 20 consignments of imported bonemeal (Davies & Harvey 1972). Cutaneous anthrax has been reported in workers handling dried cattle bones for gelatine production. Cases of anthrax as a result of ingesting infected meat or handling processed animal products were reported in humans and animals in the United States between 1950 and 2001 (Bales et al. 2002).

There is epidemiological and experimental evidence of oral transmission of *B. anthracis* in animals. The OIE Code recommends risk management measures for *B. anthracis* for international trade in meat and meat products, that is, fresh meat or meat products be sourced from animals that are clinically free of disease and from anthrax free establishments (OIE 2016a).

The Australian Meat Standard also recommends risk management measures for anthrax (FRSC 2007):

Affected animals should not be admitted to an abattoir. When detected at ante mortem, affected animals condemned. Companion animals isolated and withheld from slaughter. When detected at post mortem, affected carcass and all its parts condemned.

4.1.3 Occurrence and control in the applicant countries

Japan

B. anthracis is not present in Japan and has not been reported since August 2000; the last case prior to this was 1991.

Information provided by Japan in April 2016 stated that Anthrax is a notifiable disease in Japan and is designated as a Domestic Animal Infectious Disease (DAID) under the Act on Domestic

Animal Infectious Disease Control. A suspected case of a DAID is required to be immediately reported to the prefectural governor in accordance with Article 13 of the Act. This notification is then immediately reported to the Minister of Agriculture, Forestry and Fisheries.

As a DAID, various controls are in place including notification, surveillance and movement restrictions and culling of animals as guided by the Act.

The Guidelines for Animal Disease Control provides that suspect cases should be confirmed 'appropriately and promptly'. A confirmed case requires prompt preventative measures such as destruction of the animal and contaminated milk with subsequent disinfection of premises.

The Netherlands

Anthrax is a reportable disease, and there have been no reports of *B. anthracis* in the Netherlands since 1994.

This was supported by information provided by the Netherlands in May 2016 which stated that anthrax is a notifiable disease in any species. Control measures include general surveillance, targeted surveillance and stamping out. Vaccination is prohibited.

New Zealand

Anthrax is a reportable disease in New Zealand. *B. anthracis* is not present in New Zealand and it was last reported in 1954.

Information provided by the New Zealand Ministry for Primary Industries in May 2016 stated that anthrax's first occurrence in New Zealand was between 1896 and 1908 and was related to importation of bones for fertiliser. The last diagnosis in New Zealand was in 1954 and New Zealand regularly reports its anthrax status to the OIE. The information also confirmed that anthrax is notifiable and passive surveillance is in place.

United States

Ranchers in high risk endemic areas are encouraged to vaccinate their stock annually. However, because of handling difficulties, it is difficult to vaccinate game animals, especially deer.

Information received from the United States in July 2016 stated that anthrax occurs sporadically. Recent cases have occurred in Colorado, California, Nevada, Louisiana, Texas, and Mississippi. Outbreaks are usually limited to a small number of animals. This information also confirmed that anthrax is reportable to the State Animal Health Official (SAHO) in each of the 50 states.

Federal and state regulations provide for management and control of anthrax on farms, during transport and at slaughterhouses. Information received from the United States in July 2016 stated that the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) regulation in Title 9, Code of Federal Regulations (9 CFR) 309.7 outlines the controls required for anthrax-infected animals at federally inspected slaughter facilities (US Government 2016a). This regulation states that:

Any livestock found on ante mortem inspection to be infected with anthrax shall be identified as U.S. Condemned and disposed of in accordance with (9 CFR) 309.13.

FSIS regulation 9 CFR 309.7 also has requirements to control spread when there is an animal with anthrax. The regulation states:

No other livestock of a lot in which anthrax is found on ante mortem inspection shall be slaughtered and presented for post mortem inspection until it has been determined by a careful ante mortem inspection that no anthrax infected livestock remains in the lot. When livestock are found on ante mortem inspection to be affected with anthrax, all exposed livestock pens and driveways of the official establishment shall be cleaned and disinfected by promptly and thoroughly removing and burning all straw, litter, and manure. This shall be followed immediately by a thorough disinfection of the exposed premises by soaking the ground, fences, gates, and all exposed material with a 5 percent solution of sodium hydroxide or commercial lye prepared as outlined in 310.9(e)(1) of this subchapter, or other disinfectant that may be approved in specific cases by the Administrator specifically for this purpose.

FSIS regulation 9 CFR 309.7 also has provisions for handling animals exposed on-farm to anthrax or vaccines:

Apparently healthy livestock (other than hogs) from a lot in which anthrax is detected, and any apparently healthy livestock which have been treated with anthrax biologicals which do not contain living anthrax organisms, may be slaughtered and presented for post mortem inspection if they have been held not less than 21 days following the last treatment or the last death of any livestock in the lot.

Alternatively, if desired, all apparently healthy livestock of the lot may be segregated and held for treatment by a State licensed veterinarian under supervision of a Program employee or other official designated by the area supervisor. No anthrax vaccine (live organisms) shall be used on the premises of an official establishment.

And

Livestock which have been injected with anthrax vaccines (live organisms) within 6 weeks, and those bearing evidence of reaction to such treatment, such as inflammation, tumefaction, or oedema at the site of the injection, shall be condemned on ante mortem inspection, or such animals may be held under supervision of a Program employee or other official designated by the area supervisor until the expiration of the 6-week period and the disappearance of any evidence of reaction to the treatment.

The CFR also provides minimal requirements for the passive surveillance of anthrax (US Government 2016a).

Veterinarians are required to notify any suspect cases to their local state health department. The receiving diagnostic laboratory must also be notified when specimens are submitted to ensure safe protocols are followed. The Center for Disease Control (CDC) National Center for Emerging and Zoonotic Infectious Diseases is also notified for advice and management of human cases (cdc.gov/ncezid). Human anthrax, indicative of the effectiveness of surveillance and control programs, is now a rare occurrence.

The disease is listed on the U.S. National List of Reportable Animal Diseases (NLRAD) (USDA:APHIS 2016a).

Vanuatu

Vanuatu provided information in July 2016 that no clinical cases of anthrax had ever been reported and it is a notifiable disease.

4.1.4 Current biosecurity measures in Australia

Anthrax is a nationally notifiable disease. Anthrax has a low prevalence in Australia. Occurrences are sporadic; the last confirmed case in Queensland was in 2002, South Australia in 1914, Tasmania in 1933 and Western Australia in 1994. Anthrax has never been recorded in the Northern Territory. In 2015, New South Wales had three anthrax cases while Victoria had one case. All cases, whether suspected or confirmed, are investigated and controlled according to an agreed jurisdictional program.

The Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption: AS 4696:2007 (the Australian standard) Section 6 in Part 3 – Slaughter and Dressing of Animals outlines the requirements for the supply and admission of animals for slaughter. Animals are to be sourced from holdings where the management of animals ensures the wholesomeness of meat and meat products is not jeopardised. The Australian standard requires that animals affected by a disease or other abnormality do not contaminate other animals or jeopardise the wholesomeness of meat and meat products (FRSC 2007).

There are specific requirements for anthrax in Schedule 3 Ante Mortem and Post Mortem dispositions of the Australian standard. It requires that dead animals should be condemned if anthrax is suspected. Additionally, in part 2.1 it states:

Anthrax affected animals should not be admitted to an abattoir. When detected at ante mortem, affected condemned. Companion animals withheld from slaughter. When detected at post mortem, affected carcase and all its parts condemned. (FRSC 2007)

Detection of anthrax at an abattoir will result in a national response as guided by the AUSVETPLAN for anthrax (AHA 2015b).

4.1.5 Risk review

Anthrax has not been reported in Japan for more than 15 years, the Netherlands for 22 years and New Zealand for 62 years; it has never been reported in Vanuatu. The applicant countries are all OIE members and follow the recommended OIE risk management measures for *B. anthracis* for international trade in meat and meat products, that is, fresh meat or meat products be sourced from animals that are clinically free of disease and from anthrax free establishments (OIE 2016a). Anthrax only occurs sporadically in the United States and in Australia and is subject to surveillance and official control programs in both countries.

Based on the prevalence and existing control measures in the applicant countries, the likelihood of entry of *B. anthracis* with imports of beef and beef products derived from domesticated bovines which passed abattoir admissions, ante and post mortem inspection from the applicant countries is considered not significant.

4.1.6 Conclusion

The risk of anthrax associated with importation of these products from the applicant countries is considered negligible and therefore achieves Australia's ALOP with respect to animal biosecurity risks. Therefore a risk assessment for anthrax is not required in relation to beef and beef products imported from the applicant countries in this review of conditions.

4.2 Aujeszky's disease (Pseudorabies)

4.2.1 Background

Suid herpesvirus 1 (SHV-1) causes Aujeszky's disease or pseudorabies, a condition that affects the central nervous and respiratory systems (OIE 2016b). In Japan, SHV-1 can also be referred to as Pseudo Rabies Virus (PRV) (Yamane, Ishizeki & Yamazaki 2015). In Europe the virus may be referred to as Aujeszky's Disease Virus (ADV) (Meier, Ruiz-Fons & Ryser-Degiorgis 2015). Aujeszky's disease is primarily a disease of pigs. Infection with SHV-1 occurs sporadically in other species and Aujeszky's disease was first described in cattle in 1813 (Mettenleiter et al. 2012).

SHV-1 is a member of the *Alphaherpesvirus* subfamily of the family *Herpesviridae* (Davison et al. 2005). There are numerous sub-strains of SHV-1 of differing pathogenicity within a single serogroup (APHIS 2008).

Aujeszky's disease has a wide geographical distribution, including Asia, Europe, Ireland, North Africa, South America and the United States, but is of primary economic importance to pig production (Radostits et al. 2007b).

Aujeszky's disease is a multiple species OIE-listed disease (OIE 2016p). It is not present in Australia and is nationally notifiable (Department of Agriculture and Water Resources 2016c).

4.2.2 Technical information

Agent properties

SHV-1 is labile in the presence of heat, drying and ultra-violet light. It has a half-life of seven hours at 37 °C but can survive for long periods at <4 °C (for example, up to 46 days in contaminated straw and feeding troughs at -20 °C (Schoenbaum, Freund & Beran 1991). It is destroyed by heating at 56 °C within 30 minutes (Maré 1994). The virus is stable between pH 5.0–9.0 but is rapidly inactivated outside this range (Scott Williams Consulting Pty Ltd 2003).

SHV-1 is inactivated by most disinfectants, including sodium hypochlorite 0.5% (within seconds), phenolic derivatives 3% (ten minutes) and formaldehyde 0.6% (within one hour) and by lipid solvents such as acetone, alcohol, chloroform and ethyl ether. It is relatively resistant to sodium hydroxide, surviving exposure to a concentration of 1.6% for at least six hours (Pensaert & Kluge 1989).

The virus is not inactivated in the course of maturation of pig meat held at 4 °C (Weyhe & Benndorf 1970). Virus was inactivated in muscle, lymph node and bone marrow of an artificially infected hindquarter of a pig, following storage at -18 °C for 35 days (Durham, Gow & Poole 1980).

Epidemiology

SHV-1 has a broad mammalian host range, but does not infect higher primates including humans. Infection with SHV-1 has been reported in many domestic and wild animal species

including pigs, bears, cats, dogs, mink, rodents and ruminants (Mettenleiter et al. 2012). In species other than pigs, infection with SHV-1 is almost uniformly fatal within one to three days. A single case has been reported of the survival of a cow infected with SHV-1 (Hagemoser, Hill & Moss 1978). Despite the broad host range of SHV-1, the pig is the only host able to survive a productive infection and serve as a virus reservoir (Mettenleiter 2000). Species other than pigs may occasionally excrete the virus, but do not transmit it to in-contact animals (van Oirschot 2004).

SHV-1 has an almost worldwide distribution although many countries have managed to either eradicate the disease, or are in the process of eradicating it from their domestic pig herd.

Disease control, prevention and eradication have become possible through the development of modified-live vaccines (including gene-deleted vaccines) that significantly reduce viral shedding and the occurrence of clinical disease in pigs exposed to field strains of SHV-1 (APHIS 2008). The development of serological tests that distinguish between vaccinated pigs and those infected with field strains has facilitated eradication.

Vaccination can also provide cattle with protective immunity (van Oirschot, de Leeuw & Tiessink 1985).

SHV-1 is shed in oral and nasal discharges, the virus is in aerosol droplets which move rapidly around the air space of the pens or shed where infected animals are housed. Close contact between animals facilitates spread. Transmission from pigs to other livestock occurs either directly onto mucous membranes or broken skin, leading to neurological disease (Mettenleiter et al. 2012). Ingestion of infected tissues and foetuses may also lead to infection in cats, dogs, pigs and wildlife (Hahn et al. 1997; Maré 1994; Moresco et al. 1997). The virus can also be transmitted transplacentally and via vaginal mucosa, semen and milk (Mettenleiter et al. 2012). Horizontal transmission of SHV-1 between cattle is considered unlikely due to the short incubation period and acute, fatal course of the disease (Crandell, Mesfin & Mock 1982).

In immunologically naïve pig herds the course of an outbreak depends on risk factors that include virus strain, the stages of gestation in the breeding herd, hygiene and the quality of air, water and feed. Introduction of a highly pathogenic viral strain can lead to a mortality of more than 90% of suckling pigs, nursery pigs stunted in growth, febrile respiratory disease in older pigs and abortion in pregnant sows (Mettenleiter et al. 2012).

Persistent, latent infection is a feature of Aujeszky's disease in pigs that survive acute infection (van Oirschot 2004).

Pathogenesis

Pathogenesis is variable depending on viral strain, age of host, size of inoculum and route of infection. Pigs are the only species in which persistent, latent infection is known to occur (Mettenleiter 2000; Mettenleiter et al. 2012).

The portal of entry is typically abraded skin or via intact nasal mucosa. The virus is pantropic and infects tissues derived from all embryonic layers. Primary multiplication of the virus in the respiratory tract is followed by viraemia with localisation of the virus in many organs. Spread to the brain occurs via the olfactory, glossopharyngeal or trigeminal nerves (that is, via autonomic nerves) and is particularly efficient in young piglets. When SHV-1 enters via a skin abrasion, the virus passes quickly through peripheral nerves, damaging nerve cells and results in a localised

pruritis. Virus invasion of the central nervous system leads to encephalomyelitis. In cattle, pruritis of the head and neck is usually associated with respiratory tract infection; perineal pruritis is usually due to vaginal infection (Radostits et al. 2007b).

Infection can also occur via oral inoculation with viral proliferation occurring in the tonsillar mucosa, followed by spread to regional lymph nodes, localisation and invasion of the central nervous system along peripheral and autonomic nerve trunks and fibres (Mettenleiter et al. 2012; Radostits et al. 2007b). Following experimental inoculation, the peripheral blood mononuclear cells, lymph nodes and bone marrow are poor sources of virus and the trigeminal ganglia and olfactory bulb are good sources of virus (Balasch et al. 1998).

The basis for SHV-1 latency in pigs remains unclear. Primary sites for latent virus are the trigeminal ganglion, sacral ganglia and tonsils (Mettenleiter et al. 2012).

The oral infectious dose of SHV-1 in pigs varies with age, with piglets being more susceptible than older pigs; it has been estimated to range between 10^1 to 10^5 TCID₅₀ (tissue culture infectious dose 50) (Wittmann 1991). Cattle appear to require a higher infectious dose than in pigs (Biront et al. 1982; van Oirschot 2004; van Oirschot, de Leeuw & Tiessink 1985).

Diagnosis

Diagnosis relies on either the direct detection of antigen or isolation of virus from infected tissues. Enzyme-linked immunosorbent assays have replaced the virus neutralization test as the reference standard serum antibody assay (Mettenleiter et al. 2012). In pigs, samples of the following tissues are recommended for viral isolation and/or antigen detection — brain, spinal cord, liver, spleen, tonsil, and retropharyngeal lymph node (Balasch et al. 1998; Radostits et al. 2007b). Virus can also be isolated from the skin of affected cattle (Matsuoka et al. 1987).

Clinical signs

The incubation period is short in all susceptible species, typically ranging from 1–8 days (Mettenleiter et al. 2012; Radostits et al. 2007b). In cattle, sudden death may occur without obvious signs of disease. More commonly there is intense local pruritus with violent licking, chewing and rubbing of the affected area. Itching may be localised to any part of the body surface but is most common about the head, the flanks, or the feet. Intense excitement occurs in this phase; convulsions and bellowing may occur. A stage of paralysis follows in which hypersalivation and respiratory distress occur. Illness is usually accompanied by significant pyrexia of 41–42 °C. Final paralysis is followed by death within 6–48 hours following the first appearance of illness. There are no characteristic gross changes found in animals dying of Aujeszky's disease and post mortem diagnosis must rely on ancillary laboratory examinations (Radostits et al. 2007b).

Transmission in carcase and carcase parts

The transmission of SHV-1 to pigs via consumption of tissues from heads of pigs that died acutely from Aujeszky's disease has been documented (Hahn et al. 1997). The study also showed that the consumption of tissues from heads of latently-infected pigs did not result in transmission of the disease. Disease transmission to other species via consumption of pork offal has also been documented (Moresco et al. 1997).

SHV-1 has been isolated from the brain, tonsil and skin of clinically affected cattle (Beasley et al. 1980; Matsuoka et al. 1987). Infection in cattle results in an acute, fatal course of disease.

SHV-1 might be present at the point of slaughter in parts of the carcass of an animal infected with the virus. However, the importation and consumption of beef and beef products from cattle sourced from Aujeszky's disease-endemic areas to countries or regions free of Aujeszky's disease has occurred for many years without evidence of transmission of SHV-1 to susceptible species.

The OIE does not recommend any risk management measures for SHV-1 for international trade in beef or beef products (OIE 2008a).

4.2.3 Occurrence and control in applicant countries

Japan

The Japanese Ministry of Agriculture, Forestry and Fisheries established prevention and control measures against Aujeszky's disease in 1991, with a regional eradication program implemented. Successful eradication of PRV was completed in some areas, but there remained some regions of Japan where PRV was endemic. A new eradication campaign, based on successful eradication strategies conducted by other countries, commenced in 2009. For this campaign, all swine production areas were designated as one of 5 stages: I, preparation; IIa, enforcement of complete vaccination; IIb, transition phase; III, surveillance with serological testing and slaughter of seropositive animals; and IV, eradication completed. By March 2014, 36 of 47 prefectures were classified as stage IV. However, for the remaining 11 prefectures, 320 areas were classified as stage IIa or IIb, and 86 areas were classified as stage III, demonstrating that Aujeszky's disease remained endemic in some areas of Japan (Yamane, Ishizeki & Yamazaki 2015).

According to the OIE WAHIS Country database, Japan's last reported occurrence for Aujeszky's disease in domestic herds was in March 2012 (OIE 2016u).

In Japan, Aujeszky's disease is a notifiable disease in pigs and wild boar but not in cattle.

Aujeszky's disease in cattle has been reported in Japan (Matsuoka et al. 1987).

In 2015 there were 5 cases of Aujeszky's disease in pigs reported by the Japanese Ministry of Agriculture, Forestry and Fisheries.

The Netherlands

Information provided by the Netherlands in May 2016 stated that Aujeszky's disease was last reported in the Netherlands in 2004 (OIE 2016u). Aujeszky's disease is a notifiable disease in the Netherlands. It has never been reported in wildlife; wild boar sera collected between 2008 and 2013 from the Netherlands showed a 0% seroprevalence for ADV (Meier, Ruiz-Fons & Ryser-Degiorgis 2015).

New Zealand

Information provided by New Zealand in March 2016 detailed that Aujeszky's disease was first diagnosed on the North Island of New Zealand in 1976. It has never been reported in the South Island. An industry-funded eradication program was initiated in 1989 to eradicate the disease from the national pig herd. By using a combination of serological surveys, abattoir surveillance, test and slaughter, depopulation, vaccination and movement restrictions, Aujeszky's disease was eradicated by 1997 (Pannett, Motha & MacDiarmid 1999).

Aujeszky's disease is a notifiable disease in New Zealand. The last OIE reported occurrence of Aujeszky's disease in New Zealand was in 1995 (OIE 2016u).

United States

Information provided by the United States in July, 2016 stated the eradication of SHV-1 from domestic pigs in the United States commenced in 1989. The national Aujeszky's disease eradication campaign entailed an integrated strategy of marker vaccination, serosurveillance, selective removal of infected pigs and finally, depopulation of residual infected herds. Cases of Aujeszky's disease have been limited to feral swine since 2003. All domestic pig herds achieved free status by 2004 with eradication formally declared in 2005 (APHIS 2008). Aujeszky's disease is a notifiable disease in the United States.

The OIE's World Animal Health Information System country database states that Aujeszky's disease is limited to feral and/or non-commercial production swine in the United States. Non-commercial swine are defined as swine managed under biosecurity conditions that allow for potential exposure to feral swine that may be infected with swine diseases, such as Aujeszky's disease. There were no commercial production swine herd detections in 2015 (OIE 2016u).

The United States has in place systematic animal disease monitoring and surveillance programs and a history of successful disease eradication campaigns to support their on-going freedom from most major epidemic diseases of livestock. Monitoring and surveillance comprise active and passive programs, collectively managed and operated by Federal agencies, state governments and private industry and underpinned by National Animal Health Laboratory Network laboratories.

The disease is listed on the U.S. National List of Reportable Animal Diseases (NLRAD) (USDA:APHIS 2016a).

Vanuatu

Information supplied by Vanuatu in July 2016 stated that Aujeszky's disease is a notifiable disease and has never been reported in Vanuatu.

4.2.4 Current biosecurity measures in Australia

Infection with Aujeszky's disease virus is nationally notifiable. Detection of Aujeszky's disease will result in a national response as guided by the AUSVETPLAN for Aujeszky's disease (AHA 2015c).

4.2.5 Risk review

Aujeszky's disease is present in the United States and Japan and is not present in Australia, where it is a nationally notifiable disease (Department of Agriculture and Water Resources 2016c).

SHV-1 is primarily a disease of pigs but does infect cattle and other species.

SHV-1 transmission to pigs via consumption of tissues from heads of acutely infected pigs has been documented and the virus has also been isolated from the brain, tonsil and skin of clinically affected cattle. However, there are no reports of SHV-1 being transmitted via the beef carcass or carcass parts after ante and post mortem examination.

SHV-1 is present in the United States and Japan but is not present in Australia. In the United States, the disease is limited to feral and non-commercial pigs.

Japan has not reported Aujeszky's disease from domestic herds since 2015.

The importation of beef (frozen and chilled) and beef products with appropriate veterinary health certification from Japan, the Netherlands, New Zealand, the United States and Vanuatu is unlikely to introduce SHV-1 into Australia.

The OIE Code does not recommend any risk management measures for SHV-1 for international trade in meat and meat products.

Risk management in relation to Aujeszky's disease (SHV-1) is not applicable to imports of beef and beef products from the applicant countries.

4.2.6 Conclusion

The risk from SHV-1 associated with importation of beef and beef products from the applicant countries is considered negligible and achieves Australia's ALOP. Therefore a risk assessment for SHV-1 is not required in this review for imports of beef and beef product from the applicant countries.

4.3 Bovine brucellosis

4.3.1 Background

Brucellosis, an infectious disease characterised by abortion, infertility, decreased milk production and/or lameness, is caused by bacteria of the *Brucella* genus. The genus consists of small, gram-negative, aerobic, intracellular-reproducing coccobacilli and comprises a group of closely related bacteria (Cem Gul & Erdem 2015). Its classification into species is based mainly on the difference in host preference and pathogenicity. Three of six species that infect terrestrial animals can infect cattle, bison and/or buffalo; these are *Brucella abortus*, *B. melitensis* and *B. suis*. *B. abortus* preferentially infects cattle, *B. melitensis* goats and sheep and *B. suis* pigs (Adams 2002).

The most serious significant biological features of brucellosis are the variable incubation period, latency and the inability to identify animals that might become seropositive. About 15 per cent of cattle in herds infected with *B. abortus* abort before seroconversion and about five per cent of progeny of infected dams retain infection and become seropositive only after first parturition (Nicoletti 2010).

Bovine brucellosis caused by *B. abortus*, caprine and ovine brucellosis caused by *B. melitensis* and porcine brucellosis caused by *B. suis* are OIE-listed diseases (OIE 2016p). They generally occur worldwide, although control and eradication, especially of *B. abortus*, has been achieved in several countries. There is less progress with control and eradication of *B. melitensis* and *B. suis*, though several countries are free from disease and have no history of infection (OIE 2016u).

The three forms of brucellosis are nationally notifiable in Australia (Department of Agriculture and Water Resources 2016c). Australia has been free of bovine brucellosis, caused by *B. abortus*, since 1989. This was a result of a national eradication campaign (BTEC – the Brucellosis and Tuberculosis Eradication Campaign), which began in 1970. Australia is also free from brucellosis caused by *B. melitensis* (never reported) but not *B. suis*, which is endemic in feral pigs in

Queensland and also found in the feral pig population of northern NSW (NSW Department of Primary Industries & NSW Health 2015). Spillover of *B. suis* to domestic pigs (Seddon & Albiston 1965), cattle (Cook & Noble 1984) and horses (Cook & Kingston 1988) has occurred. Vaccination, often an effective and practical method of controlling *B. abortus* in cattle, is not permitted in Australia.

Brucellosis is a zoonotic disease of worldwide public health concern. It is a multisystem disease characterised by undulant fever, arthralgia and fatigue in over 75 per cent of cases (Cem Gul & Erdem 2015). Dairy products, especially those from unpasteurised milk, are a common source of human cases (Mailles et al. 2012). Occupational exposure among livestock handlers (Godfroid et al. 2005; Seleem, Boyle & Sriranganathan 2010) and zoonotic transmission of *B. suis* through recreational and occupational exposure to infected feral pigs in Australia has been reported (Irwin et al. 2009).

4.3.2 Technical information

Agent properties

There is little difference between the *Brucella* species with regards to survival in the environment. The three *Brucella* species are divided into biovars on the basis of cultural and serological properties. *B. abortus* consists of seven biovars (1–6, 9), *B. melitensis* three biovars (1–3) and *B. suis* five biovars (1–5) (Godfroid, Nielsen & Saegerman 2010; OIE 2009a). Some biovars show different host specificity, pathogenicity and geographical distribution (CFSPH 2009b).

Brucella spp. are non-spore forming and non-capsulated and are unique in their resistance to adverse environmental conditions. Survival in the environment increases with cold temperatures, especially freezing and moisture. The bacteria can survive for several months in water, aborted fetuses, foetal membranes, faeces, equipment and clothes (Scientific Committee on Animal Health and Animal Welfare (SCAHAW) 2001). *Brucella* spp. can also survive in carcasses and organs for 135 days and in blood at 4 °C for 180 days (Canada 2001). The bacteria can withstand drying in cool shaded areas with soil and pastures remaining contaminated for up to 43 days (Aune, Rhyhan & Roffe 2007). Direct sunlight (4.5 hours at <31 °C) reduces its survival (AHA 2005a).

Brucella spp. are destroyed by pasteurisation or cooking (Juffs & Deeth 2007).

Epidemiology

B. abortus primarily infects cattle but can also infect bison (*Bison* spp.), water buffalo (*Bubalus bubalis*), African buffalo (*Syncerus caffer*), elk (*Cervus canadensis*) (Olsen 2010) and camelids (both *Camelus* and *Llama* species) (Tibary et al. 2006). It has also been reported in horses, goats, sheep, Rocky Mountain bighorn sheep, chamois, pigs, raccoons, opossums, dogs, coyotes, foxes, wolves and other wildlife species (CFSPH 2009a). Generally, infection does not spread in non-bovid species. There may be exceptions, for example an outbreak in an accredited free cattle herd was attributed to an infected dog excreting *B. abortus* in its urine (Bicknell & Bell 1979). The distribution and epidemiological significance of biovars for *B. abortus* is not clear with several countries reporting several biovars in cattle.

B. melitensis infects primarily goats and sheep, the preferred hosts. It can also infect cattle, but is usually not sustainable within this species, tending to occur exclusively when in direct or indirect contact with infected goats and sheep (Mick et al. 2014). However, an outbreak in cattle

with no known contact with goats or sheep has been reported (Álvarez et al. 2011; Mailles et al. 2012). Outbreaks were also reported in alpacas and camels (Wernery & Kaaden 2002). Of the three different biovars, biovar 3 predominates almost exclusively in Mediterranean countries and the Middle East, and biovar 1 in Latin America. Biovars 1 and 2 were also reported in some southern European countries. However, the precise recognition of biovar 3, especially its differentiation from biovar 2, appears equivocal (CFSPH 2009c).

B. suis biovars 1, 2 and 3 cause infection in pigs, with biovar 2 also infecting hares (*Lepus europaeus*). Biovar 4 infects bison, caribou, reindeer, arctic foxes and wolves and biovar 5 was reported only in wild rodents in the former Soviet Union. *B. suis* has been reported in dogs, horses, humans and cattle but is non-contagious in these species (CFSPH 2009d). Reports of infection with *B. suis* in cattle are limited (Cook & Noble 1984; Ewalt et al. 1997; Fretin et al. 2013). However, in Central and South America, *B. suis* biovar 1 has become established in cattle (Corbel 1997). Though there is no evidence that it is sustainable in cattle, it is a serious zoonosis (CFSPH 2009d). *B. suis* biovar 1 is normally isolated from feral pigs in Australia (Cook & Noble 1984). Although *B. suis* biovar 3 was reported from indigenous rodents in North Queensland (Cook, Campbell & Barrow 1966), recent work suggests this bacterium was a different unnamed *Brucella* species (Tiller et al. 2010).

B. abortus, *B. melitensis* and *B. suis* are usually transmitted to susceptible hosts by direct oral contact with infected placenta, foetus, foetal fluids and vaginal discharges or more rarely with fomites, including hay, equipment, water, pastures and feed, contaminated with infected animal discharges. Sometimes, animals become infected by inhalation or through the mucous membranes or broken skin. The infectious dose is very low; consequently infections are an occupational risk for those who handle infected livestock and fresh animal parts.

In the primary hosts, the infected females do not usually become infectious until after abortion or parturition that might result in the birth of weak or dead offspring, retained placenta and infection of the uterus. Infected males might develop infection and swelling of the testicles. After the initial event, for example, abortion, the females often become subclinical carriers, shedding the bacteria in milk and uterine discharges during subsequent post-parturient periods. A feature of *B. abortus* is the large numbers of organisms shed during the first few weeks following abortion or calving of the infected cow and heavy contamination of the environment. The males can also shed *B. abortus* in their semen, usually intermittently, for long periods or over their lifespan (Amin, Harndy & Ibrahim 2001). Some *Brucella* species can also be shed in urine, faeces, fluid from hygromas, saliva and nasal and ocular secretions but these sources seem to be relatively unimportant as a source of infection.

B. abortus is pathogenic and contagious in cattle, bison, elk and buffalo. *B. melitensis* in cattle is an emerging problem in some European countries and the Middle East, with clinical signs not always apparent (Álvarez et al. 2011). A similar but less severe problem is the establishment of subclinical *B. suis* infection in cattle, especially in parts of South America (Corbel 1997).

In unexposed and unvaccinated herds, exposure to *B. abortus* can result in rapid spread with 30–80 per cent of females aborting (Geering, Forman & Nunn 1995). In chronically infected herds, abortions are usually limited to first pregnancies. In developing countries with minimal veterinary infrastructure, most chronically infected herds are vaccinated to minimise calving losses (CFSPH 2009b).

Epidemiological studies suggest *B. suis* in cattle is subclinical, with normal pregnancies and healthy calves and no evidence of abortion or infertility, and is not transmissible from dam to calf. The bacterium mainly localises in the mammary tissue (Ewalt et al. 1997).

Generally, there is little monitoring and surveillance for *B. suis* compared to *B. abortus* and *B. melitensis*.

Pathogenesis

Infection depends mainly on virulence of the bacteria, infective dose, immunity, age, sex and reproductive status of the host animal (Godfroid et al. 2004).

Infection starts when *Brucella* spp. penetrate the mucosa or skin and are ingested by neutrophils and macrophages, which then transport the bacteria to the draining lymph nodes where they multiply. Further spread via blood to other lymph nodes and the reticuloendothelial cells often follows. Bacteraemia might last for several months, resolve or, in a small proportion of animals, recur. During bacteraemia, the bacteria are carried within neutrophils and macrophages or transported free in the plasma to various organs, particularly the endometrium of the gravid uterus, udder and supramammary lymph nodes, and, if pregnant, the foetal membranes. Localisation might also occur in the spleen and synovial structures. In bulls, the bacteria might localise in the testes and male sex glands (Adams 2002).

Diagnosis

Clinical signs

The incubation period depends primarily on species, sexual maturity and stage of pregnancy at the time of infection. In cattle, the incubation period ranges from two weeks to seven months (Ragan 2002). Sexually immature cattle do not usually show any signs of infection, remaining subclinically infected until maturity and pregnancy. The classical clinical sign in female cattle is late-term abortion at 5–7 months pregnancy with up to 80 per cent abortions of pregnant females in fully susceptible herds. This may be accompanied by retained placentae and endometritis. Infected bulls may develop orchitis, with swelling of the testicles and infected bursae, sometimes manifesting as bursal enlargements and lameness. Death of animals except the newborn or foetus is rare (Geering, Forman & Nunn 1995).

Gross pathology

Evidence of brucellosis is rarely apparent during post mortem inspection. Most of the characteristic lesions are within the gravid uterus, which is removed separately to avoid contamination, and not usually opened for examination during post mortem inspection. Mottling of the cotyledons and purulent foetal fluids may be observed. The udders of infected cows do not show any macroscopic lesions, though the supramammary lymph nodes may be slightly enlarged. Mature bulls might show swollen testicles and mature cattle might develop hygromas on the front knees (Godfroid et al. 2004).

Testing

Cultivation, isolation and identification of the *Brucella* bacterium is the gold standard for diagnosis of brucellosis (Godfroid, Nielsen & Saegerman 2010; Moreno 2014; Nicoletti 2010; OIE 2009a).

Serological tests are the preferred diagnostic methods for routine surveillance. There is no single test suitable for all situations. The buffered *Brucella* antigen tests, for example the Rose Bengal test and the buffered plate agglutination test, are popular for initial screening of herds

and individual animals. The indirect enzyme-linked immunosorbent assay (ELISA) and competitive ELISA, both OIE prescribed tests, have high sensitivity and specificity, especially when used in cattle compared to goats and sheep. Nucleic acid detection tests such as the polymerase chain reaction assay, continue to be developed (Leiser et al. 2013; OIE 2009a).

Transmission in carcase and carcase parts

There is no report confirming brucellosis in animals as a result of exposure to meat and meat products. Swill containing offal of hunted hares infected with *B. suis* were suspected to be the cause of outbreaks of porcine brucellosis in domestic pigs in Denmark (EFSA 2009).

Although *Brucella* spp. are most commonly isolated from the udder, the supramammary lymph nodes and the genitalia of their host, the bacteria can also be isolated from numerous sites widely distributed through the carcasses of naturally and experimentally infected cattle, particularly in the lymph nodes (Sadler 1960).

As airborne transmission of *B. suis* was believed to be the cause of an outbreak of brucellosis in workers throughout an abattoir, aerosol contamination of carcasses is possible (Harris et al. 1962).

Most cases of human brucellosis were from drinking unpasteurised milk and milk products (Gwida et al. 2010) or from handling infected animals and animal parts such as placenta. However, brucellosis has been confirmed in people who had consumed improperly cooked meat and meat products, including liver (Chan, Baxter & Wenman 1989; Malik 1997).

The OIE Terrestrial Code does not recommend risk management measures for brucellosis for international trade in meat and meat products (OIE 2016j).

4.3.3 Occurrence and control in the applicant countries

Japan

Bovine brucellosis is present in Japan. The last recorded domestic case occurred in 2010. *B. abortus* in wildlife is listed as unknown (OIE 2016u). *B. suis* has never been reported in Japan while *B. melitensis* was last reported in 1949.

Information provided by Japan in April 2016 stated that bovine brucellosis is a notifiable disease in Japan and is designated as a Domestic Animal Infectious Disease (DAID) under the Act on Domestic Animal Infectious Disease Control. A suspected case of a DAID is required to be reported to the prefectural governor in accordance with the Act. This notification is then immediately reported to the Minister of Agriculture, Forestry and Fisheries.

According to the Act, livestock owners are obliged to comply with Biosecurity Standards prescribed by the Minister of Agriculture, Forestry and Fisheries. This requires everyday monitoring of their animals and at least annual on-farm inspection by Prefectural Animal Health Inspectors.

Brucellosis is managed with a test and cull policy for eradication, developed by the Animal Health Division of the Ministry of Agriculture, Forestry and Fisheries (MAFF) and implemented by Prefectural governments' Livestock Hygiene Service Centres (LHSCs). LHSCs enforce animal health measures at the farm level in collaboration with MAFF.

Animals that test positive to a rapid agglutination test are also tested with a complement fixation test for disease confirmation.

The Act requires that positive animals are placed under immediate quarantine and destroyed within two weeks of confirmation. Additional measures used include surveillance, movement restrictions and culling.

The Netherlands

Bovine brucellosis is a reportable disease in the Netherlands. *B. abortus* is not present in the Netherlands. It was last reported to the OIE in 1996. *B. suis* is only present in wild pigs, with the last report in domestic pigs in 1973 (Godfroid & Kasbohrer 2002; OIE 2016u). *B. melitensis* has never been reported.

The Netherlands, as a European Union (EU) Member State, must satisfy relevant European Commission (EC) Policies, Directives and Commission Decisions in relation to disease detection, monitoring and control. According to European Union (EU) Commission Decision document 2003/467/EC, the Netherlands is officially free of bovine brucellosis. This was declared in August 1999 (Emmerzaal et al. 2002).

The EC Bovine and Swine Diseases Annual Report (2014) states that all 11,989 notified abortions in cattle were investigated for infection with *Brucella*. Thirty nine animals were serologically positive for *B. abortus* but the agent was not isolated in any animal (European Commission: Directorate-General for Health and Food Safety 2014).

The above information was supported by a submission provided by the Netherlands in May 2016. Control measures include precautions at the border, monitoring, general surveillance, targeted surveillance, movement control inside the country and stamping out. Vaccination is prohibited.

New Zealand

Brucellosis is a reportable disease in New Zealand. *B. suis* and *B. melitensis* have never been reported. New Zealand last reported *B. abortus* in wildlife in 1989 (OIE 2016u).

New Zealand provided information in May 2016 stating disease freedom of *B. abortus* was declared in 1996. A compulsory test, slaughter and quarantine program was employed to stamp out the disease. The primary control measure is passive surveillance.

United States

B. abortus is present in the United States (APHIS 2014; Olsen 2010). *B. abortus*, *B. melitensis* and *B. suis* have been listed on the US National List of Reportable Animal Diseases (NLRAD) (USDA:APHIS 2016a). Information received from the United States in May 2016 stated that Federal regulations provide for management, control and eradication of *B. abortus* and *B. suis*. The Brucellosis Eradication: Uniform Measures and Rules (APHIS 2003), adopted by all states, documents the minimum standards required for eradication and continued surveillance. Vaccination forms part of these control measures. Abattoir surveillance for brucellosis, that is, blood testing all cattle over two years old, excluding steers and spayed heifers, will identify cattle infected with *B. abortus* and/or *B. suis*. While this does not result in their removal from the slaughter process, it contributes to surveillance and confidence in the animal health status of the United States. Routine surveillance in abattoirs has identified that bovine brucellosis affects less than 0.001 per cent of all domestic program herds.

B. abortus occurs in free-ranging bison and elk of the Greater Yellowstone Area with sporadic spillover into nearby cattle herds. The national prevalence rate of brucellosis in cattle in 2008 was 0.0003 per cent. In Wyoming, Idaho and Montana there were 22 affected cattle herds in 2002-2013 (Gear 2014). All states meet the Federal Brucellosis Eradication: Uniform Measures and Rules bovine brucellosis Class Free status.

Cattle are tested for bovine brucellosis through the abattoir testing program with either the Buffered Acidified Plate Antigen tests or Rapid Automated Presumptive test. If positive, cattle are retested using the card test, Standard Plate Test, the tube agglutination test or other official tests. All cattle testing positive are reported and traced to the herd of origin.

B. abortus has not occurred in US domestic livestock since November 2014 but is still present in wildlife in one or more zones (OIE 2016u). Sporadic cases of brucellosis among Wyoming cattle herds are expected to occur into the future as long as there is a wildlife reservoir of the disease (Logan 2014).

B. melitensis has rarely occurred in the United States and was last reported to the OIE in 1999 (OIE 2016u).

B. suis is endemic in feral pigs with reported spillover into some cattle herds occurring in Texas and the south eastern US. (Ewalt et al. 1997; Tae et al. 2012). It is listed as being present in domestic pigs in one or more zones (Leiser et al. 2013; OIE 2016u). Infection has also been reported in Alaskan caribou and muskox (Moreno 2014).

Vanuatu

Brucellosis is a reportable disease in Vanuatu (Tukana et al. 2015). Vanuatu self-declared freedom from bovine brucellosis in 2003. An active surveillance program continues to be undertaken.

Vanuatu provided information in July 2016 stating that *B. abortus* is not present with the last reported occurrence in 1992. *B. melitensis* is not present in Vanuatu. *B. suis* is not present in Vanuatu and the date of the last recorded occurrence is unknown (Tukana et al. 2015).

4.3.4 Current biosecurity measures in Australia

B. abortus and *B. melitensis* do not occur in Australia and are nationally notifiable diseases (Department of Agriculture and Water Resources 2016c). An AUSVETPLAN disease strategy manual for bovine brucellosis is available on the Animal Health Australia website (AHA 2005a).

B. suis is endemic in feral pigs in Queensland and also found in the feral pig population of northern NSW (NSW Department of Primary Industries & NSW Health 2015). It is a nationally notifiable disease.

Due to the potential to import bovine brucellosis from semen and embryos, Australia currently has import conditions for these commodities.

4.3.5 Risk Review

B. melitensis is not present in any of the applicant countries (Japan, the Netherlands, New Zealand, the United States and Vanuatu). Australia's animal biosecurity measures will include certification of country freedom from brucellosis caused by *B. melitensis*.

Noting that reproductive organs and udders from all bovines and product from non-domesticated bison, buffalo and cattle are excluded under the scope of this risk assessment:

The likelihood of entry of *B. abortus* or *B. suis* with imports from all applicant countries, including the United States, of beef and beef products derived from domesticated bovines which passed ante and post mortem inspection is considered negligible and achieves Australia's ALOP.

Additional risk management in relation to *Brucella* spp. is therefore not applicable to imports of beef and beef products from the applicant countries provided that ante mortem and post mortem inspection and the other conditions specified for certification have been met.

4.3.6 Conclusion

Based on the preceding information, the likelihood of entry of brucellosis with the importation of beef and beef products from the applicant countries and derived from domesticated bovines which passed ante and post mortem inspection, is considered negligible and achieves Australia's ALOP. A risk assessment for brucellosis is therefore not required.

4.4 Bovine tuberculosis

4.4.1 Background

Bovine tuberculosis (bovine TB) is a chronic infectious bacterial disease affecting mainly cattle. The primary causal organism is *Mycobacterium bovis*, which can be transmitted to all warm-blooded vertebrates including humans (Radostits et al. 2007d). Bovine TB is an OIE-listed disease because of its effect on public health, wildlife and livestock production, and its potential for spread via international trade. The disease is nationally notifiable in Australia (Department of Agriculture and Water Resources 2014).

M. caprae, another member of the *M. tuberculosis* complex, has also been identified as a cause of bovine TB and a zoonosis (OIE 2009b). *M. caprae* infection in cattle is not regarded as significantly different to that caused by *M. bovis* with similar diagnostic tests used. *M. caprae* is isolated to continental Europe. A human case of *M. caprae* has been detected once in Australia in a person of European origin who had migrated to Australia (Sintchenko et al. 2006). For the purpose of this review, characteristics of *M. bovis* and outcomes of the risk assessment are assumed to apply to *M. caprae*.

As a result of a successful national eradication program, the Brucellosis and Tuberculosis Eradication Campaign (BTEC), Australia declared freedom from bovine TB in accordance with the OIE Code in December 1997. The last case of bovine TB in Australia in any animal species (including free-living species) was reported in 2002 (AHA 2015a). Since January 2005, abattoir submission of granulomas identified at post mortem has continued at the discretion of meat inspectors. In 2011, bovine TB was classified as an emergency animal disease in Australia, and included in the Emergency Animal Disease Response Agreement (AHA 2016b).

Direct contact with infected animals is the main route of infection, while animal to human transmission of *M. bovis* and *M. caprae* via unpasteurised milk is of public health importance (Cvetnic et al. 2007; Rodriguez et al. 2009). Human-to-human and human-to-animal transmission of *M. bovis* has occurred but is rare (Ayele et al. 2004b; Fritsche et al. 2004).

4.4.2 Technical information

Agent properties

Mycobacteria are susceptible to alcohols, phenol, iodophors, peroxyacetic acid, hydrogen peroxide, glutaraldehyde and ultraviolet light while being resistant to chlorhexidine and quaternary ammonium disinfectant compounds (McDonnell & Russell 1999; Rutala et al. 1991). Mycobacteria are also susceptible to desiccation from sunlight, heat treatment above 60 °C and pasteurisation (Grant, Ball & Rowe 1996; Humblet, Boschioli & Saegerman 2009; Merkal & Whipple 1980) but survive in frozen tissue (Corner 1994).

Environmental studies of *M. bovis* have shown that survival outside living animals depends on a variety of factors including availability of nutrients, temperature, moisture, exposure to sunlight, pH and natural microflora (Morris, Pfeiffer & Jackson 1994). Under natural weather conditions, across different seasons, small numbers of bacilli have survived up to 12 weeks in a range of substrates such as hay, soil, water and shelled corn with survival inversely related to temperature (Fine et al. 2011; Humblet, Boschioli & Saegerman 2009). Survival times are also extended when the organism resides in shade or darkness (Duffield & Young 1985).

M. bovis has been shown to survive the stresses related to aerosolisation giving credence to its ability to be transmitted via the respiratory route (Gannon, Hayes & Roe 2007).

Epidemiology

All species of warm-blooded vertebrates of all age groups are susceptible to infection by *M. bovis*. *M. caprae* has been isolated from goats, cattle, bison, pigs, sheep, camels, red deer, wild boar and humans (Kubica, Rusch-Gerdes & Niemann 2003; Muñoz Mendoza et al. 2012; Pate et al. 2006; Rodriguez et al. 2011).

Cattle are the main source of infection of bovine TB and several wildlife species are recognised as maintenance hosts and reservoirs for infection in cattle. Examples include badgers (*Meles meles*) in Great Britain, brushtail possums (*Trichosurus vulpecula*) in New Zealand, and mule deer (*Odocoileus hemionus*), white-tailed deer (*O. virginianus*), elk (*Cervus elaphus canadensis*) and bison (*Bison bison*) in North America (Palmer et al. 2012; Radostits et al. 2007d). Disease has rarely been reported in horses (Pavlik et al. 2004).

In wildlife populations where *M. bovis* has become established, there is a history of direct or indirect contact with cattle. Many of these species are reservoirs of infection and act either as maintenance hosts, capable of maintaining and spreading the disease, or spillover hosts, incapable of maintaining the disease in the population (Palmer et al. 2012). Depending on the ecosystems, some species are both (Humblet, Boschioli & Saegerman 2009). For example, in Australia, prior to eradication, infected feral pigs were classified as dead-end hosts. Infection was thought to occur through scavenging of infected carcasses because lung lesions were infrequently detected (Corner et al. 1981). In contrast, studies show that wild boars and pigs under extensive production systems in Spain become infected even in the absence of cattle and are classed as maintenance hosts. Lung lesions are commonly detected suggesting transmission occurs via the respiratory route. These studies have concluded that the high density of wild boars and pigs in Spain favoured the maintenance and transmission of *M. bovis* (Naranjo et al. 2008; Parra et al. 2003).

Bovine TB is contagious and spreads mainly by contact with infected animals. Direct transmission is generally by inhalation of infected aerosols expelled from hosts by coughing

(Cosivi et al. 1995). A single colony forming unit is sufficient to cause disease via the respiratory route (Dean et al. 2005) and disease severity reflects the size of infectious dose received and the immune status of the host (Menzies & Neill 2000; Risco et al. 2014).

Indirect inhalation and oral transmission via contaminated feed, or infected sputum has also been suspected to be the mode of transmission in several cases (Neill et al. 1994; Palmer, Waters & Whipple 2004; Phillips et al. 2003). Oral transmission occurs where young animals become infected by drinking milk from infected animals, but the infectious dose required is high (Menzies & Neill 2000; O'Reilly & Daborn 1995). Oral transmission via infected milk was the primary means of transmission to humans prior to pasteurisation (Thoen, Lobue & de Kantor 2006).

There is epidemiological and experimental evidence of oral transmission of *M. bovis* in adult cattle. In Australia, prior to eradication, the high incidence of abdominal *M. bovis* lesions in Victorian cattle was in contrast to the high incidence of thoracic *M. bovis* lesions in cattle from tropical northern Australia. This was attributed to transmission via contaminated pastures in the southern temperate climate (Lepper & Pearson 1973).

Pathogenesis

Tuberculosis spreads within the body in two stages. The first stage is the formation of primary lesions or tubercles at or near the point of entry or local lymph node as early as 20 days post-infection (Domingo, Vidal & Marco 2014). Infection via inhalation often results in infectious lesions in the cranio-ventral lung region or their regional lymph nodes. The second stage is the dissemination from the primary lesions and the formation of multiple discrete nodules in other organs, sometimes not involving local lymph nodes (Radostits et al. 2007d).

Early immune response is cell-mediated. The cell-mediated immune response provides not only protective responses against the bacteria but also contributes to the formation of characteristic granulomatous lesions (Neill et al. 1994; Thacker, Palmer & Waters 2007). This is followed by a humoral response which has been detected in infected animals from as early as three weeks post inoculation (Waters et al. 2010).

The bacteria can remain latent in the host without causing disease (Pollock & Neill 2002). This is thought to be due to natural or innate immunity, although research into genetic aspects of bovine TB is still relatively new (Humblet, Boschirola & Saegerman 2009; le Roex et al. 2013).

4.4.3 Diagnosis

Clinical signs

Infection in cattle is characterised by a long incubation period with clinical signs taking many years to develop (de la Rua-Domenech et al. 2006). Consequently, infected cattle can display no clinical signs, despite disseminated disease (Menin et al. 2013). Clinical signs are not pathognomonic and generally depend on the route of infection (Domingo, Vidal & Marco 2014). Infection via aerosols produces lesions in the lung and associated lymph nodes and this might eventually lead to associated respiratory signs. Consumption of infected milk, contaminated feed and water or swallowing infected phlegm might produce lesions in the digestive tract and associated lymph nodes, including those of the oropharynx (Menzies & Neill 2000).

Where infection is generalised and progressive in cattle, goats, sheep and horses, a characteristic productive chronic cough indicating extensive pulmonary involvement sometimes develops

after several months or even years. Cattle could also develop progressive emaciation accompanied by capricious appetite, fluctuating temperatures and weakness (Radostits et al. 2007d).

Pathology

Bovine TB lesions vary in size from microscopic to clearly visible granulomas involving entire lymph nodes and other organs. The lesions also vary in consistency (from soft to caseous), calcification, colour (from white to yellowish) and the extent of organ systems involvement (from a primary focus to generalised tuberculosis with diffuse involvement of multiple organ systems) (Domingo, Vidal & Marco 2014).

Lesions can be found in most organs and lymph nodes of the body, however, the most common sites are lymph nodes associated with lungs and in the thoracic cavity (Corner 1994; Menin et al. 2013; Whipple, Bolin & Miller 1996). Corner (1994) found that 56 per cent of lesions in a sample of 374 tuberculous cattle occurred in the thoracic cavity while an additional 29.4 per cent were found in the medial retropharyngeal lymph nodes. These findings are echoed by other studies (Corner et al. 1990; Liebana et al. 2008; Whipple, Bolin & Miller 1996).

Less frequently, tubercles are found in the liver, hepatic lymph nodes and mesenteric lymph nodes (Corner 1994; Corner et al. 1990; Murray 1986; Neill et al. 1994).

Testing

The delayed-type hypersensitivity test, commonly known as the tuberculin test, is the standard ante mortem test for diagnosing bovine TB in live cattle. It involves injecting bovine tuberculin purified protein derivative (PPD) intradermally and measuring the subsequent swelling at the site of injection three days later (OIE 2009b). The comparative cervical tuberculin test incorporates two injections of bovine and avian tuberculin and is used for initial screening and eradication programs of cattle in several countries or to clarify the status of reactors in herds with no history of *M. bovis* or *M. caprae* exposure. The sensitivity of these tests decreases when cell mediated immunity is suppressed, for example by stress (Schiller et al. 2010). The absence of a normal immune response to the tuberculin tests (anergy) has been reported in infected cattle (Lepper et al. 1977).

Other diagnostic blood tests are available, such as the lymphocyte proliferation assay, the gamma-interferon assay, and enzyme-linked immunosorbent assay (OIE 2009b; Schiller et al. 2010). These are typically used as ancillary tests in addition to the tuberculin test due to their greater cost and complexity.

Ante mortem inspection will not identify subclinical cases (de la Rua-Domenech et al. 2006). Cattle with more advanced, generalised disease may be identified at ante mortem and excluded from processing due to obvious signs of morbidity however presentation at this stage is rarely found in countries with ongoing eradication programs (Domingo, Vidal & Marco 2014).

For tuberculosis, typical post mortem inspection procedures require palpation and/or incision of lymph nodes and organs commonly affected with tuberculous lesions with the complete or partial condemnation of affected carcasses (Corner 1994; Corner et al. 1990; Proano-Perez et al. 2011). Gross inspection often cannot distinguish between tuberculous lesions and non-tuberculous granulomas. Thus, laboratory examination is necessary to confirm tuberculosis.

Studies have found that the visible lesion detection rate, i.e., the number of reactor cattle where a tubercle lesion was subsequently detected at post mortem inspection, varied greatly between abattoirs (Corner 1994; Frankena et al. 2007; Garcia-Saenz et al. 2015; More & Good 2006; Olea-Popelka et al. 2012). Factors such as low probability of bovine TB infected animals arriving at an abattoir (as would be the case in low prevalence countries), the ratio of inspectors to volume of throughput and effective chain speed, and the level of experience and training undergone by the inspectors, affect the sensitivity of post mortem identification of suspect lesions in infected animals (Corner 1994; Garcia-Saenz et al. 2015).

Active surveillance programs have reduced disease prevalence and the likelihood of finding tuberculous lesions at post mortem (Corner 1994; Edwards, Johnston & Mead 1997; Schiller et al. 2010). Specific protocols for the management of carcasses that have been tagged as TB reactors or suspect, provide greater opportunity for the detection or elimination of infected carcasses or parts from the food chain (FRSC 2007; MPI 2016b; US Government 2016c).

Transmission in carcase and carcase parts

It is known that oral transmission of mycobacterial disease is possible by the consumption of mycobacteria in contaminated feed, tissues or milk (Menzies & Neill 2000; O'Reilly & Daborn 1995; Palmer, Waters & Whipple 2004; Thoen, Lobue & de Kantor 2006). The ability to transmit tuberculosis via carcase and carcase parts is due to the presence of tuberculous lesions, which can harbour large numbers of bacteria (Liebana et al. 2008) however infective tubercles rarely occur in meat tissue itself (Corner 2006; Domingo, Vidal & Marco 2014; EFSA Panel on Biological Hazards 2013). Studies have concluded that animals can become infected from scavenging infected carcasses (Corner 2006; de Lisle et al. 1990; Lugton, Johnstone & Morris 1995).

There is the risk of carcase contamination from an infected undressed carcase. The sources of contamination could be broken tuberculous granulomas or bacteria in nasal discharges and, less commonly, faeces (Kao et al. 2007; McIlroy, Neill & McCracken 1986; Neill et al. 1988; Phillips et al. 2003). *M. bovis* can survive in tissues in the environment for up to six weeks in cold temperatures (Cousins et al. 2004; Scott Williams Consulting Pty Ltd 2003). The main criticism of traditional meat inspection, in particular incision of lymph nodes, is the potential for cross-contamination of bacterial pathogens (Edwards, Johnston & Mead 1997). Established meat inspection quality assurance plans such as Hazard Analysis Critical Control Point (HACCP) provide methods to manage the risk of cross-contamination (Edwards, Johnston & Mead 1997; EFSA Panel on Biological Hazards 2013; FRSC 2007).

The OIE Code recommends that fresh meat and meat products from countries affected by bovine TB should be sourced from animals which have passed ante mortem and post mortem inspections as described in Chapter 6.2 of the OIE Code (OIE 2016e).

4.4.4 Occurrence and control in the applicant countries

Bovine TB is present in Japan, the Netherlands, New Zealand and the United States. It is not present in Vanuatu with the last reported case in 1993.

Japan

Bovine TB is present in Japan. The Japan Ministry of Agriculture, Forestry and Fisheries (MAFF) advised that the last recorded case in cattle occurred in 2014.

Bovine TB is a notifiable disease and is designated a Domestic Animal Infectious Disease (DAID) under the Act on Domestic Animal Infectious Disease Control. A suspected case of a DAID is required to be reported to the prefectural governor in accordance with the Act. This notification is then immediately reported to the Minister of Agriculture, Forestry and Fisheries. According to the Act, livestock owners are obliged to comply with Biosecurity Standards prescribed by the Minister of Agriculture, Forestry and Fisheries. This requires everyday monitoring of their own animals and at least annual on-farm inspection by Prefectural Animal Health Inspectors.

Bovine TB is managed with a test and cull policy using the tuberculin test. This has been developed by the Animal Health Division, MAFF, and implemented by Prefectural governments' Livestock Hygiene Service Centres (LHSCs). LHSCs enforce animal health measures at the farm level in collaboration with MAFF.

The Act requires that affected cattle are placed under immediate quarantine and destroyed within two weeks of confirmation. Additional measures used include surveillance, movement restrictions and culling.

The Netherlands

Bovine TB is present in the Netherlands. It was last reported to the OIE in 2013 and is currently limited to specific zones within the country.

The Netherlands, as a European Union (EU) Member State, must satisfy relevant European Commission (EC) Policies, Directives and Commission Decisions in relation to disease detection, monitoring and control of bovine TB.

According to European Union (EU) Commission Decision 2003/437/EC (European Commission 2016), the Netherlands is officially tuberculosis-free for bovine herds. To be classified as officially tuberculosis-free a member state must have less than 0.1 per cent of cattle herds infected in the country and have maintained this level or below for a minimum of six years (European Council 2015). The EC Bovine and Swine Diseases Annual Report records that in 2014, four herds were classified as bovine TB infected (0.008 per cent of the national herd) including seven confirmed positive animals (European Commission: Directorate-General for Health and Food Safety 2014).

Control measures include precautions at the border and general surveillance. A survey-based review of bovine TB surveillance in cattle and free-ranging wildlife in EU member states in 2013, noted that the Netherlands carries out bovine TB surveillance exclusively through post mortem examination at abattoirs (Riviere et al. 2014).

In a case study for the risk-based testing of imported cattle into the Netherlands (de Vos et al. 2015) the authors point out that it would be impossible to prevent the introduction of bovine TB into the Netherlands through intra-EU trade of cattle under the existing directive on intra-community trade and disease control. This is because cattle originating from other officially-free countries are examined by clinical examination only prior to export. The claim is supported by surveillance data on bovine TB detections from 1999 to 2013 that could all be traced to imported cattle (23 head in total with the majority being calves). No domestic bovine TB infections were detected in indigenous cattle over the 15 year period of the study.

New Zealand

Bovine TB is present and a reportable disease in New Zealand. It has been reported that the period prevalence of TB, as of June 2015, was 0.16 per cent. A new TB plan is being applied as of June 2016 (OSPRI 2015). Period prevalence is defined as the number of TB-infected herds at the beginning of the year plus the new infected herds that occur during the next 12 months, divided by the average number of herds at risk during that time.

The domestic control program, called the TBfree program, is co-funded by government and industry and aims to control and eventually eradicate bovine TB. The program utilises three main techniques; in-herd disease management, movement control and the control of wild animal vectors. Under the program, the number of infected herds declined from around 275 herds in 2003 to 41 herds by June 2015 (OSPRI 2015).

Most cattle and deer herds are regularly tested and classified with a TB status of infected, suspended or clear. Testing frequency depends on an assessment of TB risk in a particular herd or region. Animals which test positive to the tuberculin test are either slaughtered or undergo further testing (OSPRI 2013).

Control of wild animal vectors, is undertaken through population management of possums using a series of toxins dependent on the specific environment and possum density. This is undertaken under the guidance of New Zealand's National Policy Direction for Pest Management 2015 (MPI 2015a).

United States

M. bovis is present in the United States and is a notifiable disease. According to data provided by USDA, national herd prevalence of bovine TB is currently less than 0.001 per cent. At the time of writing, based on the domestic classification system detailed in the Uniform Methods and Rules for Bovine Tuberculosis Eradication, all states are accredited free of bovine TB except Michigan, although bovine TB has been detected for the first time in wild deer in Indiana which has been officially bovine TB free since 1984. Those states that are accredited free have not recorded a case of bovine TB in the last 5 years or have appropriate plans in place to prevent further spread from any identified cases (APHIS 2005). California received a status as "TB-Free" in August 2016 with its last case detected in February 2013 (California Department of Food and Agriculture 2016).

Various regulatory documents by the USDA Food Safety Inspection Service (FSIS), the USDA Animal and Plant Health Inspection Service (APHIS) and within the Code of Federal Regulations (CFR), describe procedures to be followed for surveillance, epidemiological investigations, management of affected herds including the movement of reactor, suspect and exposed cattle from the herd of origin to the abattoirs, and for ante mortem and post mortem inspection. The regulations also describe requirements for condemnation and disposal of infected animals, carcasses and carcase parts.

All abattoirs approved for export participate in the Federal abattoir surveillance program that includes a granuloma submission program. To meet monitoring requirements for TB classification state regulators must ensure slaughter plants submit suspicious granulomatous lesions for laboratory examination at a rate of at least one for every 2000 adult animals slaughtered annually (APHIS 2005).

4.4.5 Current biosecurity measures in Australia.

In Australia, bovine TB is an exotic disease and nationally notifiable.

In the event of *M. bovis* infection occurring in Australia, eradication would be guided by the *Bovine Tuberculosis Case Response Manual – Managing an Incident of Bovine Tuberculosis* (AHA 2009b).

The *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption: AS 4696:2007* (the Australian Meat Standard) provides guidance for meat inspection as it relates to bovine TB; however, subsequent to eradication and since January 2005 abattoir submission of granulomas identified at post mortem occurs as guided by the post mortem work instructions and the Australian Meat Standard (Department of Agriculture and Water Resources 2013, 2016d; FRSC 2007).

4.4.6 Risk review

The likelihood of entry of *M. bovis* and/or *M. caprae* with imports of beef and beef products is considered not significant on the basis that:

- *M. bovis* and *M. caprae* have rarely been detected in muscle tissue, even in generalised infection
- the most common sites of tuberculous lesions are excluded from this review; in particular lungs and associated lymph nodes
- existing low prevalence and surveillance or eradication controls in applicant countries reduce the likelihood of infected animals and animal product being presented for human consumption
- beef in the applicant countries has been produced under processes equivalent to the Australian Meat Standard including ante and post mortem inspection; and ensures that meat is wholesome and fit for human consumption.

4.4.7 Conclusion

Based on the preceding information, risk assessment is not applicable. However, proposed health certification will include a requirement that veterinary ante and post mortem inspection is undertaken because bovine TB is exotic to Australia.

4.5 Bovine viral diarrhoea virus

4.5.1 Background

Bovine viral diarrhoea virus (BVDV) infects a range of ruminant species. Infection in cattle is associated with variable outcomes, ranging from the common subclinical disease to mild transient diarrhoea with pyrexia, or fatal acute bovine viral diarrhoea. Signs of reproductive failure, respiratory illness and gastrointestinal disease can also occur (Liebler-Tenorio, Ridpath & Neill 2004; Norton, Tranter & Campbell 1989; OIE 2016c; Radostits et al. 2007d; Taylor et al. 1997). BVDV can also result in mucosal disease which may occur in persistently infected (PI) animals.

BVDV is a single-stranded positive-sense RNA pestivirus of the Flaviviridae family (Thiel et al. 2005). Other closely related pestiviruses include Border disease virus, classical swine fever virus and HoBi-like virus (Hamers et al. 2001). BVDV is classified into two antigenically and phylogenetically distinct genotypes, BVDV-1 and BVDV-2 (Ridpath, Bolin & Dubovi 1994), which are now considered separate species (Thiel et al. 2005). Each of these genotypes is further

divided into subgenotypes; currently there are 17 subgenotypes of BVDV-1 and four subgenotypes of BVDV-2 (Giangaspero et al. 2008; Ridpath et al. 2010; Sato et al. 2016; Silveira et al. 2015). Both genotypes of BVDV can be classified into non-cytopathic (NCP) and cytopathic (CP) biotypes. Genetic mutations occur readily in BVDV causing significant genetic, antigenic and pathogenic variation between genotypes and subgenotypes (Luzzago et al. 2014; Ridpath et al. 2010).

BVDV is an OIE-listed disease, and is endemic world-wide (OIE 2009d, 2016c). BVDV is present in Japan, the Netherlands, New Zealand and the United States (Kramps et al. 1999; Mars & Van Maanen 2005; Matsuno et al. 2007; Pérez, Wilks & Rice 1994; Ridpath et al. 2010; Ridpath et al. 2011; Sanhueza, Heuer & West 2013; Yan et al. 2011). Geographic variation in distribution of subgenotypes has been reported. BVDV-1b is the most common isolate in the United States (Ridpath et al. 2010; Ridpath et al. 2011; Yan et al. 2011) and Japan (Matsuno et al. 2007).

In Australia 34–56 per cent of cattle have serological evidence of having been infected with BVDV (Moore et al. 2015; Norton, Tranter & Campbell 1989). One study in Queensland beef and dairy herds found 89 per cent of cattle herds containing at least one seropositive animal (Taylor et al. 2006). BVDV-1c is the most common subgenotype in Australia (Mahony et al. 2005; Ridpath et al. 2010). BVDV-2 subgenotypes have not been reported in Australia (Kirkland & Mackintosh 2006; Mahony et al. 2005) and disease as a result of BVDV-2 infection is nationally notifiable (Department of Agriculture and Water Resources 2016c).

4.5.2 Technical information

Agent properties

BVDV is stable over a broad pH range (Lindenbach, Thiel & Rice 2007). The virus can survive in cattle slurry for four hours at 35 °C, for three days at 20 °C, and for three weeks at 5 °C (Botner & Belsham 2012; Potgieter 2004; Thiel et al. 2005). Survival may be influenced by the concentrations of protein present and the biotype of the virus (Depner, Bauer & Liess 1992). BVDV in whole and ground beef was able to survive ageing at 4 °C for 21 days and freezing at -20 °C, and was only inactivated by cooking to at least 75 °C (Bratcher et al. 2012). BVDV in milk must be heated to 95 °C to inactivate the virus (Marley et al. 2009). BVDV may be inactivated by UV (Azar Daryany et al. 2009), irradiation (Preuss et al. 1997), organic solvents and detergents (Lindenbach, Thiel & Rice 2007).

Epidemiology

The primary host for BVDV are ruminants such as cattle, goats and sheep. BVDV infection has also been reported in camelids such as alpacas (Barnett et al. 2008; Foster et al. 2007; Kim et al. 2009) and llamas (Belknap et al. 2000).

Experimental and natural BVDV infection of pigs has been reported (Fernelius et al. 1973; Terpstra & Wensvoort 1997; Walz et al. 1999; Wieringa-Jelsma, Quak & Loeffen 2006), but the significance of this to the epidemiology of disease is unclear (Radostits et al. 2007d). Infection in swine is usually subclinical (Terpstra & Wensvoort 1997; Wieringa-Jelsma, Quak & Loeffen 2006). A study describing experimental intranasal BVDV inoculation of pigs found that BVDV-2 was less readily able to establish viraemia and infection than BVDV-1 (Walz et al. 1999).

The virus has been isolated in wild ruminants in Europe and North America, including deer (Casaubon et al. 2012; Passler et al. 2008; Pogranichniy et al. 2008; Radostits et al. 2007d; Rodriguez-Prieto et al. 2016), chamois, ibex (Casaubon et al. 2012), bighorn sheep and mountain

goats (Wolff et al. 2016). Transmission of BVDV from wild to domestic ruminants has not been reported to occur naturally (Van Campen 2010). Experimental infection has been demonstrated in rabbits (Grant et al. 2015). However the seroprevalence of wild rabbits in Europe is variable (Frolich & Streich 1998; Grant et al. 2015), hence rabbits are thought unlikely to act as a major reservoir of infection.

There is variable prevalence of BVDV in individual herds and regions in areas where it is endemic, reflecting different cattle population structures, and husbandry and management practices (Damman et al. 2015; Gates et al. 2013; Graham et al. 2015; Houe 1999). Local spread may be more significant in the epidemiology for intensive management production systems (such for dairy and feedlot cattle) where there is a higher frequency of interventions and close contact between animals (Gates et al. 2013).

Close contact is an important means of transmission and is facilitated by viral shedding in nasal discharges, saliva, tears, semen, urine, faeces and milk (Potgieter 2004) (OIE 2016c). Indirect transmission is also possible by unhygienic vaccination procedures, ambient air, environment contamination by virus shedding (Niskanen & Lindberg 2003), or the administration of live or contaminated vaccines (Falcone & Tollis 1999; Palomares et al. 2013). Experimental transmission by blood feeding flies has been reported (Houe 1999). Contact with contaminated foetal material may also transmit BVDV (Lindberg et al. 2004).

Infection of breeding females can result in reproductive and foetal disease, PI animals, or uninfected normal calves depending on the stage of gestation when the dam is infected. Animals which are PI remain immunotolerant to the specific infecting strain of BVDV (OIE 2008b). PI animals are persistently viraemic, and continuously shed large amounts of virus into the environment (OIE 2016c; Potgieter 2004). Consequently PI carriers are a major source of infection for other animals in the herd (Fulton et al. 2005a; Laureyns et al. 2011; Tinsley, Lewis & Brulisauer 2012). Any PI cattle that survive to breeding age will produce PI calves.

Acute infection with BVDV postnatally results in a transient infection. Transiently infected animals are viraemic and shed low levels of virus for only a short period of time (OIE 2016c; Sarrazin et al. 2014). While transiently infected animals can transmit BVDV, this pathway is less significant in the epidemiology than PI animals.

Pathogenesis

Pathogenesis depends on a number of host factors, such as age and immunological status, as well as the specific properties and virulence of the infecting BVDV-isolate (Radostits et al. 2007d; Strong et al. 2015). The immunosuppressive and immunomodulatory effects of BVDV also play a role in pathogenesis (Molina et al. 2014; Palomares, Brock & Walz 2014), and increase host susceptibility to concurrent secondary infections. Thrombocytopenia is associated with more virulent strains of BVDV (Liebler-Tenorio, Ridpath & Neill 2004; Sarrazin et al. 2014).

In acute infection, the virus initially replicates in the tonsils, before being transported to lymphoid tissues and other organs (Liebler-Tenorio, Ridpath & Neill 2004; Pedrera et al. 2012). Infected leukocytes and extracellular virus are systemically distributed via the lymphatics and circulation (Potgieter 2004). Further virus replication occurs in leukocytes of peripheral blood, fixed lymphoid tissues and bone marrow. Acute infection with BVDV can cause leukopenia and impaired immune responses (Molina et al. 2014; Palomares, Brock & Walz 2014). The virus damages the epithelial integrity of the gastrointestinal and integumentary systems, leading to

erosion and ulceration. Seroconversion usually occurs by two to three weeks post infection depending on the virulence of the infecting strain (Ames 1986; Falkenberg et al. 2014; Liebler-Tenorio, Ridpath & Neill 2004; Strong et al. 2015).

In utero infections are most commonly caused by NCP biotypes of BVDV (Potgieter 2004). Early reproductive losses due to ovarian dysfunction, uterine inflammation or damage to the embryo are an important economic outcome of infection (Grooms 2006). Infection can also result in foetal death and resorption or expulsion, abortion, teratogenesis or ill thrift (Potgieter 2004) depending upon the stage of gestation when infected. BVDV induced congenital defects occur as a result of the combination of direct cellular damage and foetal inflammatory responses to infection during organogenesis, and commonly involve the central nervous system (Blanchard et al. 2010; Grooms 2006).

Infection with NCP BVDV before the development of foetal immunocompetence leads to PI animals which are immunotolerant to the specific infecting BVDV strain. BVDV is able to evade the foetal adaptive immune system and impair anti-viral immune responses (Hansen et al. 2010). PI animals have lifelong viraemia, widespread tissue distribution of BVDV, and shed large amounts of virus. BVDV has been isolated from beef derived from asymptomatic PI calves (Bratcher et al. 2012). PI animals typically have reduced growth rates and increased susceptibility to other diseases (Potgieter 2004).

Mucosal disease occurs when a PI animal is infected with a CP BVDV strain that has similar antigenic properties to the initial NCP isolate that infected the animal in utero. This can occur by superinfection with a CP strain, mutation or recombination of the initial NCP PI strain. Mucosal disease is associated with severe pathological lesions (Fritzemeier et al. 1997) due to uncontrolled inflammation, impaired anti-viral defences and enhanced viraemia in affected animals (Lanyon & Reichel 2014). Early and late onset forms exist, and are thought to be related to the pathogenesis of secondary infection with the CP BVDV strain (Fritzemeier et al. 1997).

BVDV has been occasionally reported to persist in sites such as the testicle and ovary following acute infection or vaccination with a modified live virus vaccine (Givens et al. 2007; Grooms, Brock & Ward 1998; Voges et al. 1998). Bulls with a prolonged infection of the testicle can intermittently excrete the virus in their semen (OIE 2016c). BVDV antigen has been detected in ovarian tissue up to 60 days post-acute infection in naïve cows (Grooms, Brock & Ward 1998).

Diagnosis

Clinical signs

BVDV infection can result in a wide range of clinical signs from inapparent disease to death (Sandvik 1999). BVDV has also been implicated in bovine respiratory disease complex (Moore et al. 2015; Ridpath 2010).

Subclinical or mild disease is most common in acute infection of immunocompetent animals (Walz et al. 2010). Following an incubation period of 5–7 days (Grooms, Baker & Ames 2002), transient clinical signs can include lethargy, pyrexia, anorexia, diarrhoea, increased respiratory rate and ocular / nasal discharges (Falkenberg et al. 2014; Hessman et al. 2012). Morbidity may be high but mortality rates are generally low for acute infections (Hessman et al. 2012; Radostits et al. 2007d).

Acute BVDV infection may sometimes present as a more severe enteric form with depression, anorexia, watery diarrhoea, weakness and death. This more severe form is more commonly associated with NCP BVDV-2 isolates (Jenckel et al. 2014) but has also been reported with BVDV-1b infection (Lunardi et al. 2008; Radostits et al. 2007d). Thrombocytopaenia and haemorrhagic syndrome has also been associated with more virulent strains (Falkenberg et al. 2014; Flores et al. 2000; Hamers et al. 2000).

Reproductive losses have been reported as perhaps the most economically important consequence of BVDV infection (Grooms 2006). BVDV infection in susceptible pregnant heifers may lead to infertility and early embryonic death (Grooms 2006). Foetal resorption, mummification, expulsion or congenital defects may occur (Blanchard et al. 2010; Radostits et al. 2007d). Reproductive losses can manifest insidiously or might be seen as large abortion storms (Blanchard et al. 2010).

PI calves may appear normal or have a decreased growth rate, weakness, failure to thrive and increased susceptibility to concurrent infectious diseases (Bachofen et al. 2010; Radostits et al. 2007d). The mortality rate amongst PI calves is high (Booker et al. 2008).

Mucosal disease can present as either early or late onset disease. Early onset mucosal disease is typically associated with sudden onset anorexia, pyrexia, tachycardia, tachypnoea and signs of depression. Profuse watery diarrhoea is usually evident with the faeces containing variable amounts of blood and mucus. Large oral mucosal erosions can develop (Ohmann 1983). Death is typically observed within five to seven days of clinical signs developing (Radostits et al. 2007d).

The incubation period of late onset mucosal disease can be weeks to months (Fritzemeier et al. 1997). Clinical signs of late onset include episodes of diarrhoea, anorexia and bloat, hoof deformities, chronic skin and oral erosions, rough dry hair, progressive loss of body condition, hypersalivation and signs of depression (Deregt & Loewen 1995; Ohmann 1983; Radostits et al. 2007d; Taylor et al. 1997).

Pathology

Acute infection with BVDV causes variable gross lesions on post mortem. Oral and/or oesophageal mucosal erosions are commonly present (Hessman et al. 2012; Lunardi et al. 2008). Acute infection may result in pathological evidence of enteritis, including mucosal and submucosal oedema, and ecchymotic haemorrhages in the distal ileum and proximal colon. BVDV-2 isolates may also produce generalised haemorrhages in a range of tissues (Hamers et al. 2000; Potgieter 2004). However experimental infection with some strains of BVDV-2 have produced little or no obvious gross lesions on post mortem examination (Ellis et al. 1998; Liebler-Tenorio, Ridpath & Neill 2003, 2004).

PI cattle often have no gross lesions but may appear stunted or have pathology consistent with concurrent secondary infections. This is in contrast to animals that develop mucosal disease, where necrotic lesions of the gastrointestinal tract are typically observed (Fritzemeier et al. 1997; Potgieter 2004). Erosions and/or ulcers can be found in the mucosa/epithelia of the skin, oral cavity, oesophagus, forestomach and intestines (Fritzemeier et al. 1997; Grooms, Baker & Ames 2002; Liebler-Tenorio et al. 2000; Potgieter 2004; Taylor et al. 1997). The most obvious erosive mucosal lesions are commonly over Peyer's patches in the small intestine and ileocaecal lymph nodes (Liebler-Tenorio et al. 2000; OIE 2008b). In addition to an ulcerative/erosive enteritis, intestinal lesions might also appear characteristic of a catarrhal, haemorrhagic and/or

fibro-necrotic enteritis. Pathological lesions of other lymphoid tissue might also be evident, for example thymus atrophy and lymphoid depletion (Potgieter 2004; Taylor et al. 1997).

Subtle differences between gross pathological changes in early and late onset mucosal disease have been reported (Liebler-Tenorio et al. 2000). In cases of late onset mucosal disease, animals might be emaciated and upper gastrointestinal tract lesions may be less severe than in early onset (Liebler-Tenorio et al. 2000; Potgieter 2004).

Testing

Diagnostic testing for BVDV is based on demonstrating the presence of the virus or viral components, and/or assessing the immunological status of the animal (Sandvik 2005). However, agent identification by virus isolation is the only test prescribed for international trade (OIE 2016c). Conventional virus isolation may be combined with a final immune-staining or real time reverse transcriptase polymerase chain reaction (RT-PCR) step to screen for BVDV positive samples (OIE 2016c). Other diagnostic tests for BVDV include antigen detection by immunohistochemistry, enzyme linked immunosorbent assay (ELISA) or nucleic acid detection; or detection of an immune response by ELISA or virus neutralisation (OIE 2016c).

Samples that can be used to detect the virus include bulk milk, blood, skin, or parenchymal tissue (for example spleen, lung, kidney, liver) (Sandvik 2005). False seropositive results can occur in neonatal PI animals until maternal antibodies wane (Brock et al. 1998), and in previously vaccinated herds (Duncan, Gunn & Humphry 2016). Antigen detection tests are better suited to identify PI animals, such as immunohistochemistry on ear-notch samples which have been used to detect PI animals in control programs (Graham et al. 2015).

Transmission in carcase and carcase parts

In cattle infected with BVDV, the virus may be widely distributed in carcase and carcase parts. BVDV has been isolated from fresh, aged and frozen beef from subclinical PI cattle (Bratcher et al. 2012), and from many other bovine tissues from acutely infected and PI cattle including the skin, gastrointestinal and respiratory systems, lymphoid tissue, cerebral cortex, some non-lymphoid organs (liver, kidney and lung), and in reproductive and foetal tissue (Ellis et al. 1998; Fredriksen et al. 1999; Marshall, Moxley & Kelling 1996; Ohmann 1983; Radostits et al. 2007d). Viral antigen has also been isolated from nasal discharges, saliva, tears, semen, urine, faeces and milk of infected cattle (OIE 2016c; Potgieter 2004). Wider tissue distribution and longer persistence of BVDV-2 may be associated with more virulent (Liebler-Tenorio, Ridpath & Neill 2003), and PI rather than acutely infected cattle (Liebler-Tenorio, Ridpath & Neill 2004).

BVDV is stable at temperature ranges associated with refrigeration of carcase and carcase parts. Chilling and freezing have no effect on the BVDV levels in whole and ground meat produced from subclinical PI calves (Bratcher et al. 2012). BVDV can be inactivated by heating beef to 75 °C (Bratcher et al. 2012) and milk to 95 °C (Marley et al. 2009). While the infectious dose of BVDV is variable and dependent on the route of transmission (Cook, Littlejohns & Jessep 1990; Houe 1999), the dose of BVDV present in beef was found to be higher than serum levels of the source PI cattle at slaughter (Bratcher et al. 2012).

There is no scientific evidence showing experimental or natural oral transmission of BVDV to cattle via consumption of carcase and carcase parts. Natural infection of pigs with BVDV through the consumption of bovine offal has been suggested (Le Potier, Mesplède & Vannier 2006). BVDV seroconversion was detected in pigs with diarrhoea, gastroenteritis and high mortality on a farm

that had a history of feeding bovine offal (Stewart et al. 1971). However, this report did not determine if the offal was infected with BVDV, nor examine the role of other transmission pathways such as contact with ruminants or administration of vaccines contaminated with BVDV (Falcone & Tollis 1999; Loeffen et al. 2009; Palomares et al. 2013). Additionally, the study (Stewart et al. 1971) did not address possible cross-reactivity between pestiviruses, such as border disease virus, that may occur in immunological testing (Hamers et al. 2001). There are no known experimental transmission studies to investigate the role of ingestion of carcase or carcase parts in BVDV infection in pigs.

BVDV can be present at the point of slaughter in parts of the bovine carcase infected with the virus. However, in the global context, the importation and consumption of beef and beef products from cattle sourced from BVDV-endemic areas to countries or regions free of BVDV has occurred for many years without evidence of transmission of BVDV to susceptible species. The OIE Code does not recommend any risk management measures for BVDV for international trade in meat and meat products (OIE 2016r).

4.5.3 Occurrence and control in the applicant countries

Japan

Both BVDV-1 and BVDV-2 are present in Japan, where it is a notifiable disease (Matsuno et al. 2007). Information provided by the Japanese Ministry of Agriculture, Fisheries and Forestry (MAFF) indicated that BVDV is distributed in many prefectures including areas of high livestock density such as Hokkaido. The predominant subgenotype is BVDV-1b but 1a, 1c, 1j, 1n, 1o and 2a have also been isolated (Matsuno et al. 2007; Minami et al. 2011; Sato et al. 2016). MAFF confirmed that in 2014, 260 cases of BVDV were reported to MAFF. However, seroprevalence for at least one subgenotype of BVDV amongst Japanese cattle has been reported as high as 54.5 per cent (Minami et al. 2011). Subgenotypes 1n and 1o have only been isolated in Japan, South Korea and China, but are rare (Sato et al. 2016). Information provided by MAFF indicated that culling of infected cattle is voluntary and vaccination may be used on affected properties.

The Netherlands

Information provided by the Dutch Ministry of Economic Affairs (EZ) confirmed that BVDV is not notifiable in the Netherlands. Since 1997, voluntary eradication programs have been in place. However the seroprevalence in cattle ranges from 57 to 65 per cent (Kramps et al. 1999; Mars & Van Maanen 2005) and in swine is 0.42 per cent (Loeffen et al. 2009). EZ has provided information to confirm that there is serological evidence of BVDV infection in wild animals. The subgenotypes circulating in the Netherlands have not been clearly defined. However, BVDV-2 has been associated with outbreaks of highly virulent disease (Promed Mail 2013).

New Zealand

BVDV is endemic in New Zealand, where 3.5 per cent of foetal losses are attributed to infection (Sanhueza, Heuer & West 2013). Seroprevalence for BVDV in New Zealand beef cattle was found to be around 65 per cent (Pérez, Wilks & Rice 1994; Sanhueza, Heuer & West 2013), although the New Zealand Ministry for Primary Industries (MPI) estimates it to be as high as 80 per cent. Prevalence may vary geographically with one study finding higher seroprevalence (73.4 per cent) on the North Island compared to the South Island (54.3 per cent) (Pérez, Wilks & Rice 1994). There is little information on the subgenotypes present in New Zealand. MAFF confirmed that BVDV-2 is notifiable and there is passive surveillance in place in New Zealand.

United States

Both BVDV genotypes are present in the United States. Seroprevalence varies geographically, with unvaccinated cattle herd seroprevalence being reported as 3.43 per cent in New York and 10.16 per cent in the midwestern states (Kirchgessner, Dubovi & Whipps 2013; Wittum et al. 2001). While the individual prevalence of PI animals is low (0.12–0.55 per cent), the herd prevalence for PI animals is moderate (8.8–16.7 per cent) (Fulton et al. ; Norton, Tranter & Campbell 1989; USDA 2010b). BVDV acutely infected and PI animals have also been found in alpacas and wildlife (Kim et al. 2009; Passler et al. 2008; Pogranichniy et al. 2008; Wolff et al. 2016). Prevalence in wildlife also varies widely based on geography. Seropositive rates in white tailed deer in New York were 7.48 per cent, but were as high as 80 per cent in mule deer in Nevada (Kirchgessner, Dubovi & Whipps 2013; Wolff et al. 2016). No cases of transmission of BVDV from wildlife to cattle have been documented (Van Campen 2010).

BVDV1a, 1b, 2a and 2b subgenotypes have been isolated in the United States (Ridpath 2005; Ridpath et al. 2010). The predominant subgenotype is BVDV-1b, although BVDV-1a and 2a are also frequently isolated from clinical samples (Fulton et al. 2005b; Fulton et al. 2009; Ridpath et al. 2010). Isolation of BVDV-2b is rare (Ridpath 2005; Ridpath et al. 2000).

BVDV is not nationally reportable in the United States (OIE 2010a; Van Campen 2010). However as part of the country's general surveillance program, cases identified are reported to the OIE. The OIE currently lists clinical disease being present in domestic animals, and disease suspected but not confirmed in wild species in the United States (OIE 2010a, 2016u).

Control of BVDV in the United States before 2004 predominantly relied on the widespread use of modified live and inactivated vaccines. This had implications for the interpretation of serological tests for disease diagnosis and their use for surveillance. Following the Academy of Veterinary Consultants support for BVDV control and eradication in 2003 (Van Campen 2010), a number of voluntary BVDV prevention and control programs have been established. These programs involve education about BVDV transmission, testing procedures and biosecurity practices, as well as appropriate vaccination protocols. However, no mandatory control or eradication programs for BVDV currently exist and vaccination is still widespread in many cattle operations (USDA 2010b; Van Campen 2010).

Vanuatu

BVDV has never been reported in Vanuatu (OIE 2016c). Biosecurity Vanuatu has confirmed that BVDV is a notifiable disease.

4.5.4 Current biosecurity measures in Australia

BVDV-2 is nationally notifiable in animals in Australia (Department of Agriculture and Water Resources 2016c). The current Australian Meat Standards (FRSC 2007) requires:

- an ante mortem inspection is carried out within 24 hours prior to slaughter
- a post mortem inspection of each carcase and its carcase parts is carried out by a meat safety inspector
- condemnation of the carcase and all carcase parts if acute BVDV infection with evidence of systemic involvement is detected during ante or post mortem inspections
- condemnation of the affected intestines if mucosal disease with lesions localised to the gastrointestinal tract is detected during ante or post mortem inspections.

4.5.5 Risk review

BVDV-1 is present in Japan, the Netherlands, New Zealand, the United States and Australia. BVDV-2 is present in Japan, the Netherlands, New Zealand and the United States, and is not present in Australia. There is no evidence that BVDV-1 and BVDV-2 is present in Vanuatu.

While BVDV can be present in the beef carcass and carcass parts, there is no evidence that either subgenotype of BVDV has been transmitted via the beef carcass or carcass parts after ante and post mortem examination. In addition, the OIE Code does not recommend any risk management measures for BVDV for international trade in meat and meat products.

4.5.6 Conclusion

The risk from BVDV associated with importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and achieves Australia's ALOP with respect to animal biosecurity risks. Therefore a risk assessment for BVDV is not required in relation to beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu in this review of conditions.

4.6 *Cysticercus bovis* infection (infection with metacestode of *Taenia saginata*)

4.6.1 Background

Cysticercus bovis is the metacestode (the intermediate life stage) of the human intestinal parasite *Taenia saginata*, commonly known as 'beef tapeworm'. The parasite, *T. saginata*, is a member of the Family Taeniidae. Cattle are the intermediate hosts in the transmission of this parasite. *C. bovis* infection in cattle is referred to colloquially as 'beef measles'.

The condition in cattle was recognised by the OIE as a reportable List B cattle disease until 2005. It has since been removed from the OIE list of reportable diseases, however is still addressed in the OIE Manual in a combined chapter on Cysticercosis (cestodes of the Family Taeniidae). Codex Alimentarius also has guidance on the control of *T. saginata* in domestic bovine meat (Codex Alimentarius Commission 2014) because of recognition of the economic impact of infection. The Guideline notes the economic significance being the result of:

- the resources taken up in routine meat inspection to detect infection
- the impact of downgrading and condemnation of affected carcasses and inactivation treatments
- the increased controls needed in herds from which detections have occurred.

The parasite, *T. saginata*, is globally one of the most widely distributed human tapeworms, found in humans on all continents. (Cabaret et al. 2002) summarised available data on human taeniasis (*T. saginata*) from published papers from 1973 to 2000. The authors described country prevalences as being relatively low but highly variable within a country and between countries, noting variability in prevalence is a result of personal hygiene, meat inspection quality, culinary habits and cultural behaviours. Prevalence rates in Europe vary between 0.01 per cent and 10 per cent with Slovakia and Turkey having the highest reportable prevalence (Cabaret et al. 2002). Incidence is usually estimated from the sale of taenical drugs (Dorny & Praet 2007).

Harmonised schemes for the monitoring and reporting of cysticercosis in animals and foodstuffs in the European Union have been proposed to improve the value of data available for analysis and interpretation (Dorny et al. 2010).

A Joint FAO/WHO Expert group, in providing advice and guidance to Codex Committee on Food Hygiene (CCFH) on 24 parasite-commodity combinations of particular concern, noted that despite global distribution of *T. saginata*, true prevalence in humans and cattle is underestimated because of imperfect diagnostic techniques, poor reporting systems and the largely asymptomatic nature of the disease in humans (FAO & WHO 2014).

Craig and Ito (2007) estimated 60 million human cases worldwide and cited prevalence estimates from other sources as high as 22 to 27 per cent in Bali, Tibet and East Africa. Cabaret et al. (2002) noted a prevalence of 36 per cent in the Russian Republic of Dagestan. Wandra et al. (2011) found during a field survey in Bali, from 2002 to 2009, 80 cases of *T. saginata* taeniasis, with two cases of combined *T. saginata*/*T. solium* (pork tapeworm) infection.

T. saginata and *T. asiatica* are closely related species although the intermediate host is cattle for the former and pigs for the latter. Yamane et al. (2012) described nuclear mitochondrial differences in a small number of adult *T. saginata* and *T. asiatica* worms (collected from humans on the Tibetan Plateau) and suggested hybridisation may be occurring in areas where the species are sympatrically endemic, that is found regularly in humans in the same or overlapping geographic areas. There is no evidence available however that *T. asiatica* has adapted to cattle as an intermediate host as a result of hybridisation, although Fan et al. (1988), cited by Galan-Puchades and Fuentes (2000) were able to experimentally infect calves (and monkeys, and goats), resulting in cysticerci in the livers. Chang et al. (2005) showed that metacestodes in experimental mice could cause tapeworm development in gerbils and hamsters which were fed the mice metacestodes.

Ito et al. (2008) point out that with the movement of people between the Asia Pacific and Africa, the Americas, Australia and New Zealand and Europe there is a need to re-evaluate the occurrence of *T. saginata* and *T. asiatica*.

4.6.2 Technical information

Agent properties

Each *C. bovis* cyst is composed of a single unhooked scolex surrounded by a fluid-filled bladder approximately 4 to 6 millimetres by 7 to 10 millimetres at maturity (Murrell et al. 2005).

Cysticerci take around 8 to 10 weeks to develop in situ. They can remain viable in the infected animal for extended periods from several months to years (Dorny et al. 2010).

Codex Guidelines for the control of *T. saginata* in meat of domestic cattle (Codex Alimentarius Commission 2014) notes that heating and freezing can be used as routine preventative control measures to denature infective cysts. The World Health Organization recommends temperatures of -10 °C for not less than 10 days or core temperature heating to 60 °C.

Hilwig, Cramer and Forsyth (1978) found that the tolerance to the lethal effects of freezing increased with the age of cysticerci; and time and temperature combinations which killed all cysticerci in frozen carcass meat from experimentally infected calves were 15 days at -5 °C, 9 days at -10 °C, and 6 days at -15, -20, -25 or -30 °C.

Deep muscle temperature no warmer than -12°C for not less than five days in carcasses or boned meat is the freezing treatment prescribed under the *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption: AS 4696:2007* (FRSC 2007) to treat the remainder of the carcase and parts passed conditionally fit for human consumption in light infections (small number of degenerated cysts).

Cooking of tissues can be a lethal treatment for viable cysts. Effective cooking may not be met in all forms of meat consumption and cooking practices. Various authors have published lethality parameters for cooking:

- for whole cuts of meat, cooking to at least 63°C (measured with food thermometer in thickest part of meat) then rested (remaining at 63°C) for 3 minutes before consuming, or ground meat cooked to at least 71°C (CDC 2013)
- boiling 2 kilogram pieces in an open boiler for three hours at steam pressure of 0.5 atmospheres (Murrell et al. 2005).
- Tändler (cited in van der Logt, Hathaway & Vose 1997) suggested that temperatures greater than 58°C would be lethal to viable *C. bovis* cysticerci.

A southern African study on biltong (Van den Heever 1965) concluded that with incomplete processing, transmission of *T. saginata* may occur from biltong. The study found however that with marinating and drying for six days that *C. bovis* cysts did not survive (Day 6 moisture content 27 per cent, salt content 7.7 per cent).

C. bovis cysts can be inactivated with low dose irradiation of 0.5 kilograys (WHO 1995).

An effective vaccine for the prevention of *T. saginata* cysticercosis in cattle was developed in the 1990s (Lightowlers, Rolfe & Gauci 1996) but has not been commercialised (Professor Marshall Lightowlers [University of Melbourne] 2016, pers. comm., 9 December).

Epidemiology

The lifecycle of *T. saginata* consists of three life stages – the adult tapeworm in the human intestine (the definitive host), free-living egg stage in the environment, and larval stage (metacestode) in cattle. Other ruminants have been reported as carrying the parasite cyst, including reindeer, sheep, camels, llamas, antelope, wildebeest, giraffes, lemurs, gazelles and wildebeest (Murrell et al. 2005; Pawlowski & Schultz 1972 cited by Public Health Agency of Canada 2012). However, the reports in llamas and a number of African wildlife has been questioned (Cabaret et al. 2002). An experimental study in Taiwanese pigs was able to demonstrate development of cysticerci in livers in Small Ear Miniature (SEM) pigs after feeding with *T. saginata* (Poland strain) eggs (Fan, Lin & Chung 1992).

Large numbers of eggs are shed from mature proglottids (up to 100 000 per proglottid), the motile adult worm segments, released from the anus of, or passed in faeces of infected individuals. The manner and extent of egg dispersal from the site of faecal deposition has been examined by a number of researchers, who highlighted the significance of the impact of wind and water movement, and the role of birds, insects and earthworms in the spread of infective eggs (Murrell et al. 2005).

The defaecation by humans in areas where animals are likely to be grazing, and the inadequate hygiene of animal handlers exposes cattle and their fodder and water to possible contamination with infective eggs. Sewage treatment facilities generally permit infective eggs to pass through

the system, so dispersal of treated sewage on cattle pastures is an effective method for transmitting infection on a large scale. Flooding of sewage treatment works and faulty operation of sewage tanks can increase the likelihood of extensive infection (Cabaret et al. 2002).

A joint report by the World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE) (Murrell et al. 2005) describes three main transmission patterns for *T. saginata*:

- hyperendemic, associated with pastoral societies in developing countries, where there is high level of infection in humans and cattle
- endemic, with small numbers of human carriers and wide dispersal of eggs in the environment and moderate prevalence of low intensity infection in cattle
- epidemic, such as feedlot outbreaks with high peaks of infection in cattle detected.

The eggs once ingested by cattle liberate larvae which move from the gastrointestinal system, through the lymph and blood system into muscle where they encyst. The cycle is completed when humans consume raw or undercooked meat containing live cysts, and the adult *T. saginata* tapeworm develops in the human small intestine.

From a national survey of cattle slaughtered in export abattoirs in Australia in February 2008, *C. bovis* prevalence in Australia was estimated to have declined considerably since 1966. A study conducted in Victorian abattoirs for the year of 1966 reported around 1 suspect case in 465 head slaughtered (Fewster 1967). The national survey conducted in 2008 estimated the prevalence of *C. bovis* to be less than 1 in 500 000 head (Pearse et al. 2010). However the researchers noted that with low sensitivity in post mortem inspection the prevalence is likely to be higher. In 2010 an outbreak of *C. bovis* infection was detected in feedlot cattle in NSW. An investigation into the event suggested imported contaminated coprameal in the feedlot diet to be the likely cause (Jenkins, Brown & Traub 2013). Otherwise, in Australia only very sporadic cases are detected in abattoir post mortem inspection.

Dorny and Praet (2007) summed up some of the intractable difficulties in addressing the transmission of *T. saginata* when discussing the options for improved control (in Europe). They point out that in addition to the low sensitivity of meat inspection allowing meat containing infective cysts to be released as fit for human consumption, European wastewater management contributes to egg dissemination in the environment, and it should be assumed that water streams and surface water are potentially contaminated making it beyond the control of animal owners to prevent light infection. The authors suggest that effective control requires integrated interventions by a range of stakeholders across the parasite lifecycle. They also suggest that the current detection methods should be improved. Their assessment of the difficulties in controlling the transmission of the parasite in low prevalence areas could be taken to be applicable globally.

Pathogenesis

Studies on experimentally infected calves identified predilection sites for cyst formation which differ from the sites used for inspection purposes.

Lopes et al. (2011) found after dissection of 25 experimentally infected cattle that of the cysticerci recovered 75.02 per cent were found in skeletal muscle and 24.98 per cent were in organs. The highest levels of cysticerci were found in; the shoulder clod (12.55 per cent), heart

(11.02 per cent), liver (9.48 per cent), masseter muscles (8.51 per cent), chuck (8.25 per cent), strip loin and full tenderloin (7.26), knuckle (6.63 per cent) and back ribs (5.53 per cent). Very low levels were recovered from the oesophagus (0.34 per cent). Only 3.06 per cent of the total cysticerci were found in the diaphragm and 1.98 per cent in the tongue, however of the 25 infected animals, 18 had lesions in diaphragm and 17 in the tongue.

In a study (Scandrett et al. 2009) examining the distribution of cysticerci, 42 calves (8 to 11 months of age) were experimentally infected with *T. saginata* eggs (varying concentrations) from Bangkok, Thailand. Canadian Food Inspection Agency routine inspection sites were compared with non-traditional sites for the presence of cysts. The study found that routine inspection of all traditional sites when compared to routine inspection of the heart alone, only identified two more infected animals, and that comprehensive inspection of these traditional sites only detected a single animal over comprehensive inspection of the heart alone (Scandrett et al. 2009). They did not find a decreasing trend in the ratio of heart cysts compared to traditional sites or the total carcass numbers over time, suggesting that the findings indicate the heart to be a reliable site for cysticercosis detection for at least a year after infection.

Similar findings of the site distribution of cysts after experimental infection were found by Soares et al. (2011).

Diagnosis

Clinical signs

There are no readily apparent clinical signs of disease associated with *C. bovis* infection in live cattle.

Pathology

The viable cyst initially appears clear to pearly white. As the cyst degenerates it becomes more apparent, changing to opaque white, with cyst contents becoming caseous then calcifying.

Testing

There is no 'gold standard' reference test for the detection of *C. bovis* in cattle, either for ante mortem or post mortem diagnosis.

Various serological tests for ante mortem identification have been developed. There are ELISAs based on antigen proteins or cyst excretory products, immunological peptides, monoclonal antibody assays for detection of circulating parasite antigen. There are difficulties in determining, for these tests, the sensitivities and specificities which are population specific and vary between natural and experimentally infected animals.

A scientific report by Dorny et al. (2010) noted (in detecting light infections) that developing a more sensitive ELISA will be extremely difficult and development of monoclonal antibodies with higher affinity (for use in tests) is likely to take years. They suggested that availability of serological tests on a commercial basis is limited until this problem is overcome. The report notes that visual inspection carried out at slaughterhouses is not sensitive enough to detect all positive cases so real prevalence is underestimated, but that there is no present alternative because serological methods are not fully validated.

Eichenberger et al. (2013) undertook a study to compare test characteristics of available ELISAs for serological diagnosis of *C. bovis* in slaughter cows in Switzerland. The best performing test

was an ELISA that uses excretory/secretory (ES) antigens of *T. saginata* metacestodes (TsmES) as developed by Ogunremi and Benjamin (2010).

Dugassa and Gabriel (2015) investigated the possibility of diagnosis of *C. bovis* in cattle using a milk antibody ELISA. A test methodology was developed using spiked milk samples. Further work was suggested to understand and evaluate the antibody levels in serum and milk throughout the lactation cycle, during mastitis, and in bulk versus individual animal samples.

Abattoir meat inspection is in practice the main method for identifying *C. bovis* infection in cattle both in Australia and overseas. Inspection programs normally include visual inspection of surfaces of prescribed predilection sites, palpation and designated cutting of tissues for internal examination.

A number of papers acknowledge the low sensitivity of routine post mortem inspection in detecting viable *C. bovis* cysts both in Australia and overseas (Laranjo-Gonzalez et al. 2016; Pearse et al. 2010).

Allepuz et al. (2012) in their cross-sectional study of 2073 animals slaughtered in 10 abattoirs in Catalonia found notable differences in visual inspection detection rates between abattoirs, and between visual inspection and serological findings using antigen ELISA testing (prevalence at visual inspection of 0.02 per cent versus seroprevalence of 0.76 to 1.75 per cent at a confidence interval of 95 per cent).

Eichenberger et al. (2013) conducted a study on the use of additional heart muscle incision to increase the sensitivity of post mortem inspection for *C. bovis*. They found that enhanced heart inspection (six additional heart cuts) doubled the number of infected animals detected at post mortem inspection in their study in three EU-approved abattoirs (1088 slaughtered cattle inspected).

However, the EFSA Panel on Biological Hazards (BIOHAZ) recommended in 2013 that post mortem incision of the cheek and heart muscles as a detection method for *C. bovis* had a limited public health or meat safety impact, and proposed that inspection be visual only in the EU in routinely slaughtered bovines that show no abnormalities at visual ante and post mortem inspection (EFSA Panel on Biological Hazards 2013). The recommendation was made on the premise that eliminating the use of palpation and incision will reduce the likelihood the risk of microbiological cross-contamination within and between carcasses with more significant food health pathogens (i.e. verocytotoxin-producing *E. coli* and *Salmonella* spp.). The report notes that further research is needed to determine the extent of cross-contamination that occurs with these invasive techniques, although acknowledging a number of similar earlier EFSA panel conclusions.

Modelling conducted in a Swiss study of diagnostic value of serological tests and EU-approved visual meat inspection estimated the sensitivity of EU-approved visual inspection at 15.6 per cent (Eichenberger et al. 2013). The authors noted also that additional heart incisions increased estimated sensitivity to 24.2 per cent.

In relation to the impact of any changes in detection practices (or *C. bovis* prevalence in meat) on human health and the prevalence of *T. saginata* in humans, a New Zealand study developed a risk assessment model for estimating human health effects with changes to prevalence of *C. bovis*

in meat either through importation or changes in detection practices (van der Logt et al. 1997). Using a scenario where no *T. saginata* post mortem inspection processes were applied, the model predicted an increase in the estimated mean number of human cases annually from 0.50 to 0.61 (export market) and 1.10 to 1.30 (domestic market). On the basis of this increase, the authors question the significance of *T. saginata* inspection procedures.

A review has also been undertaken into the impact of moving to a visual only post mortem inspection regime on the detection and control of *C. bovis* in meat in the UK (Hill et al. 2014). The UK study combines UK post mortem meat inspection prevalence data from 2008 to 2011 (0.008 per cent in calves and 0.032 per cent in adult cattle), the EU meat inspection prevalence underestimation rate of 3 to 10 times (Dorny & Praet 2007) and the New Zealand study estimates (20 per cent increase in human cases), and concludes that allowing non-conforming systems to undergo visual only inspection will increase risk to public health to low-medium from very low-low (Hill et al. 2014).

A Norwegian study (Skjerve 1999) modelled the effects based on the importation of prime beef cuts from a *C. bovis* endemic region in southern Africa. The model indicated that if the imported beef is ingested without adequate heat treatment, and despite the modelled low level of consumption (3 per cent of prime cut consumption) that importation would change the epidemiological pattern of *T. saginata* in the Norwegian population.

Transmission in carcase and carcase parts

T. saginata (*C. bovis*) is directly transmissible to humans through the consumption of viable cysts in raw or undercooked meat. However, the exposure to or consumption of infected carcase and carcase parts by species other than humans is not a transmissible pathway.

4.6.3 Occurrence and control in applicant countries

Japan

C. bovis infection is not a notifiable disease under relevant Japanese regulations.

Under the *Ordinance for Enforcement of the Food Sanitation Act* (the Food Sanitation Law) food-borne parasitic diseases human taeniasis are to be treated as cases of food poisoning and authorities must be notified of their occurrence. Yamasaki (2013) noted that since 1990, only sporadic cases of human taeniasis have been reported in Japan, with most cases being imported cases (infection occurring outside of Japan) of *T. saginata* until *T. asiatica* infections were confirmed in 2010 (mostly confined to the Kanto region).

The Netherlands

Information provided by the Dutch Ministry of Economic Affairs confirms that cysticercosis is present, however the number of cases is unknown. The Netherlands reported 557 cases in cattle in 2008 (Dorny et al. 2010).

Laranjo-Gonzalez et al. (2016), in a review of published literature on the prevalence of cysticercosis in Europe, could not identify reports of prevalence in the Netherlands after 1990. However, in a recommendation from the Director of the Office for Risk Assessment and Research to the Minister of Welfare, Health and Sport (VWS) and the Minister for Agriculture on the risks of tuberculosis and cysticercosis in veal calves in the event of changes in inspection policy (NVWA 2013), the Director provides data on prevalence from Dutch sources – around 2 per cent in the 1980s, decreasing to 0.3 per cent in cattle in 2011 with suspected *C. bovis* lesions found in

0.002 per cent of slaughtered veal calves (with one quarter of these estimated as infectious *C. bovis*). The Director found that there was no increased risk of *C. bovis* associated with restricting incisions of the masseter muscles to one either side in the innermost or outermost masseters or freeing the tongue and part of the tonsils (presented for inspection separately) prior to post mortem inspection of veal calves. He suggested that likelihood of detection could be improved by serological screening and incision of muscles of the extremities but questioned whether the costs could be justified.

Current legislation (European Council 2015) requires:

- visual examination and two deep incisions in external and one in internal cheek muscles parallel to the mandible
- tongue freed to allow visual examination and palpation
- visual examination of the heart, and incised lengthwise to open ventricles and to cut through the intraventricular septum
- visual examination of the diaphragm and oesophagus.

The European Food Safety Authority (EFSA) Scientific Panel on Biological Hazards provided recommendations on the evaluation of veal calf production systems for *T. saginata* risks at the individual farm level in an attempt to simplify the post mortem inspection procedure for *T. saginata* cysticercosis based on farm risk (EFSA BIOHAZ 2005). The report recommended that inspection for the parasite could be omitted from farms assessed as low risk, but suggested that the prescribed incisions, under the European Hygiene Regulation EC No 854/2004 (European Parliament & European Council 2004), remain pending validation of serological tests for veal calves. In 2013, an assessment by the Dutch authorities found that modifying or omitting meat inspection procedures for *C. bovis* would not lead to an increased risk of disease (NVWA 2013).

New Zealand

Bovine cysticercosis is a notifiable disease in New Zealand (MPI 2016a).

The New Zealand Ministry of Primary Industries reports that *C. bovis* occurs sporadically in New Zealand and was last detected in 2009 (and that it is not likely to be circulating in the national cattle herd).

An analysis of abattoir surveillance submissions of suspect lesions for *C. bovis* from 2000 to 2009 showed an average of 28 submissions per year (McFadden 2010). Of the 251 submissions, 122 contained cestode material or a parasitic granuloma (for the analysis, both positive and suspect lesions were considered to have resulted from infection of cattle with eggs from *T. saginata*).

McFadden (2010) suggests the spatial patterns observed (distribution throughout New Zealand with correlation to high density cattle areas) are more likely to result from infection by people who are closely associated with cattle in the course of their work, for example foreign workers or infected New Zealanders on farms, rather than overseas visitors and tourists.

Routine meat inspection in New Zealand involves visual inspection and palpation of masseter, tongue and heart muscles.

An investigation into an outbreak in 2009 on two dairy farms (with apparent prevalence of *C. bovis* cysts in cattle from one property ranging from 40 to 100 per cent across a number of kill lines) was unable to identify the source of infection but identified risk factors related to the

nationality of the farm workers, a dysfunctional septic tank and the distance between work areas and toilet facilities (McFadden et al. 2011a).

United States

A 1997 study reported *C. bovis* prevalence to be 0.0697, 0.0085, 0.0012, 0.0004 and 0.0003 per cent for cattle slaughtered in the western, southwestern, northeastern, southeastern, and central United States, respectively (Saini, Webert & McCaskey 1997). When APHIS is notified of *C. bovis* findings at slaughter, the affected animal is traced to its state of origin. The case is reported to state animal health officials; subsequently, APHIS veterinary medical officers perform outreach at the farm of origin.

The Code of Federal Regulations Title 9 (US Government 2016b) has specific requirements for the handling of carcasses and carcase parts which display lesions of *C. bovis* at post mortem inspection. Inspection sites are the heart, diaphragm and its pillars, muscles of mastication, oesophagus, tongue and muscle exposed during normal dressing operations. Carcase condemnation occurs when infection is extensive or musculature is discoloured or oedematous. Extensive infection is said to occur when lesions are found at least two of the routine inspection sites and in addition; found when the sites exposed by a cross section incision into the round of the muscle, and a transverse incision into each forelimb at a specified point above the olecranon. For carcasses not showing extensive infection, the carcase and parts can be passed after removal (and condemnation) of the cysts, tagging for freezing or cooking under Inspector control as specified in the regulation.

Vanuatu

Vanuatu's authorities reported that no clinical case of *C. bovis* has ever been reported. It has not been a notifiable disease since 2005 as only OIE-listed diseases are notifiable under Vanuatu Disease Control Act of 1992.

4.6.4 Current biosecurity measures in Australia

C. bovis is a nationally notifiable disease in Australia (Department of Agriculture and Water Resources 2016c). Detected cases must be reported to the relevant state veterinary authorities who are responsible for investigation and action.

Under the National Livestock Identification Scheme (NLIS), an animal identified as infected with *C. bovis* is assigned a status, and the property of origin's property identification code (PIC) is marked in the database for further investigation by the state authority. The database marker alerts abattoir staff of increased risk associated with animals or animal lots derived from the flagged property. Meat inspection activities can be adjusted to address increased risk. Follow-up investigation and control measures are conducted under state regulation. Each state determines the business rules that allow clearance of the database marker against the PIC following investigation.

For *C. bovis* in cattle, buffalo and deer, the Australian standard currently requires that additional post mortem inspection procedures are undertaken when cysts are detected or the condition suspected (FRSC 2007). Inspectors must incise masseter and heart muscles, tongue and diaphragm after removal of serous membranes and observe all muscle surfaces.

Where *C. bovis* is identified at post mortem in Australian abattoirs, a range of carcass dispositions are available depending on the extent of infection (number and distribution of

cysts). The Australian Standard provides direction on the disposition of infected carcasses. For general infestation, the carcass and all its parts is condemned. Where infection is light (small number of degenerated cysts), the Standard stipulates the condemnation of affected viscera, cysts and surrounding trimmings, with the remainder of the carcass and parts passed conditionally fit for human consumption subject to treatment by freezing (no warmer than – 12 °C deep muscle temperature for not less than five days in carcasses or boned meat).

Cysts are sampled for laboratory confirmatory diagnosis as part of state disease requirements. A real-time PCR assay developed by Cuttell et al. (2013) was compared to standard histology and published nested PCR in seeking improved diagnostic accuracy and efficiency of samples submitted through routine meat inspection. The real-time PCR showed improved sensitivity and specificity over histological examination, however the estimates were obtained on a relatively small sample size due to the low prevalence of bovine cysticercosis in Australia (Cuttell et al. 2013).

4.6.5 Risk review

C. bovis is recorded in Japan, the Netherlands, New Zealand, and the United States. There is no current evidence available of its presence in Vanuatu. *C. bovis* is present in Australia, where it is a nationally notifiable animal disease.

Transmission of *T. saginata* through the exposure to or consumption of carcass and carcass parts containing viable *C. bovis* cysts is not known to occur in species other than humans, who are the definitive host of this parasite. The lifecycle of the parasite requires cattle to ingest *T. saginata* eggs passed in human faeces. These eggs subsequently develop into *C. bovis* cysts in the muscle of the cattle that ingest the eggs. Cattle do not develop *C. bovis* cysts by ingesting contaminated meat. Therefore there is no direct animal biosecurity risk posed by the importation of carcass and carcass parts containing viable cysts.

There is however a food safety risk in that meat eaten raw or not fully cooked may lead to human infection. The lack of sensitivity of current post mortem inspection regimes both in Australia and overseas, particularly in low prevalence environments, will mean that not all risk to the consumer is addressed through abattoir inspection. There is supporting evidence however that sensitivity can be increased by increased heart incision and inspection. There is also evidence that reducing the level of inspection to visual inspection only will increase risk associated with transmission of the parasite to humans.

Although accurate data on the prevalence of *C. bovis* and the effectiveness of meat inspection procedures is elusive, it is concluded from this review that the applicant countries have a very low prevalence of *C. bovis* and therefore the risk to human health by the consumption of beef and beef products imported from applicant countries would be similar to the risk associated with the consumption of domestic beef.

4.6.6 Conclusion

Based on the preceding information, there is no direct animal biosecurity risk associated with the importation of *C. bovis* contaminated beef and beef parts and therefore an animal biosecurity risk assessment is not required. Risk management measures may be warranted to meet human health and food safety requirements if food safety risk assessment determines that applicant countries' disease prevalence and meat inspection programs do not meet Australian food standards.

The risk from *C. bovis* associated with importation of beef and beef products from the applicant countries is therefore considered negligible and achieves Australia's ALOP.

4.7 Echinococcosis

4.7.1 Background

Echinococcosis is a zoonotic disease caused by several species of the genus *Echinococcus*, cestode parasites in the family Taeniidae (Moro & Schantz 2009). Members of the genus *Echinococcus* have an indirect, two-host lifecycle (Jenkins, Romig & Thompson 2005).

Echinococcosis is a multiple species OIE-listed disease (OIE 2016p). Within Australia, echinococcosis is only notifiable in Tasmania and the Northern Territory.

Nine morphologically distinct species have been identified, but three predominantly cause disease in cattle: *E. granulosus sensu stricto*, *E. ortleppi* and *E. multilocularis*. The other species of *Echinococcus* are very host specific and have rarely been associated with disease in cattle. *E. canadensis* has only been reported in cattle in Africa and the Middle East (Abushhewa et al. 2010; Al Kitani et al. 2015; Omer et al. 2010). *E. granulosus sensu stricto* and *E. ortleppi* have only recently been considered separate species. Previously they were considered strains of the species *E. granulosus* (known as G1-G3 and G5 respectively) along with *E. equinus* (G4), *E. canadensis* (G6-G10) and *E. felidis*.

E. granulosus sensu lato can be used as a general term for all of these species (CFSPH 2011). The various species differ in morphology, development rate, host range, pathogenicity and geographical distribution (Thompson, Lymbery & Constantine 1995; Thompson & McManus 2001). A species that infects an intermediate host may be less able, or unable, to infect other intermediate hosts (Thompson & McManus 2001).

E. granulosus sensu stricto has an almost worldwide distribution including Australia. It is most prevalent in parts of Eurasia, North and East Africa, Australia and South America (AHA 2009a; McManus & Thompson 2003). There are no reports of *E. multilocularis* or *E. ortleppi* in Australia (AHA 2016a).

E. multilocularis rarely infects cattle, sheep and pigs and when exposure occurs the cysts may not be viable (OIE 2016f). The most significant zoonotic species are *E. granulosus sensu stricto* and *E. multilocularis* (Jenkins, Romig & Thompson 2005).

4.7.2 Technical Information

Agent properties

Echinococcus eggs are relatively resistant to environmental conditions and can be infective for several months outside of a host. *Echinococcus* eggs are inactivated by freezing at -80 °C for 48 hours or -70 °C for four days and by heat (hot water at 60 °C for 5 minutes) (CFSPH 2011; Colli & Williams 1972). *Echinococcus* protoscoleces are inactivated by heat (hot water at 50, 55, and 60 °C for five, two, and one minutes, respectively) (Moazeni & Alipour-Chaharmahali 2011). Boiling of livers and lungs containing *Echinococcus* cysts for up to 30 minutes has been demonstrated to inactivate the protoscoleces (Li et al. 2014).

Epidemiology

Carnivores are the definitive hosts for *Echinococcus* spp., with a large number of mammals (including ungulates and humans) acting as intermediate hosts (Torgerson & Budke 2003).

The definitive hosts for *E. granulosus sensu stricto* and *E. ortleppi* include dogs, coyotes, dingoes, foxes, hyenas, jackals and wolves. The intermediate hosts for *E. granulosus sensu stricto* are sheep and buffalo, but infection has also been reported in cattle and macropods (Banks, Copeman & Skerratt 2006). Cattle are the principal intermediate hosts for *E. ortleppi*, although cysts are occasionally isolated from humans (Grenouillet et al. 2014).

E. granulosus sensu stricto is found worldwide and is the only member of the genus found in Australia (Banks, Copeman & Skerratt 2006; Banks et al. 2006; Jenkins et al. 2014). *E. ortleppi* is prevalent in South America and South Africa, with rare reports in Europe (Balbinotti et al. 2012; Grenouillet et al. 2014; Mogoye et al. 2013). *E. multilocularis* is mostly distributed in the northern hemisphere (Deplazes & Eckert 2001). It has been reported in North America, the Netherlands and Japan (Dyachenko et al. 2008; Jenkins et al. 2012; Kimura et al. 2010; Maas et al. 2014; van der Giessen, Rombout & Teunis 2004). There are no reports of *E. multilocularis* or *E. ortleppi* in Australia (AHA 2016a).

E. granulosus sensu stricto cycles predominantly through canids and sheep. While cattle may become infected, the majority of metacestodes in cattle are infertile (Balbinotti et al. 2012; Mitrea et al. 2014). In North America, *E. granulosus* occurs in Alaska and Canada, but mainly involves a sylvatic cycle. In the continental United States, the parasite is mainly reported in the western states (Arizona, California, New Mexico and Utah) (Torgerson & Budke 2003).

An independent cycle of *E. granulosus sensu stricto* exists in Australia involving the dingo and marsupials of the family Macropodidae, serving as a wildlife reservoir of *E. granulosus* (Banks, Copeman & Skerratt 2006; Jenkins & Morris 2003; Rausch 1995). Of the intermediate hosts, the most commonly involved are eastern grey kangaroos (*Macropus giganteus*), red necked wallabies (*Macropus rufogriseus*), black-striped wallabies (*Macropus dorsalis*) and western grey kangaroos (*Macropus fuliginosus*) (Banks, Copeman & Skerratt 2006; Jenkins & Morris 2003; Thompson et al. 1988). *E. ortleppi* is transmitted mainly via domestic cycles involving dogs and cattle.

Foxes (genera *Vulpes* and *Alopex*) are the definitive hosts for *E. multilocularis* and to a lesser extent cats, dogs, coyotes and wolves. The intermediate hosts are principally rodents, but pigs (domestic and feral), dogs, monkeys, horses and river rats have also been reported as intermediate hosts in Europe and Japan (Eckert 1998; Kimura et al. 2010; Pfister et al. 1993; Sydler, Mathis & Deplazes 1998; Thompson 1977).

E. multilocularis is mainly transmitted within the predator-prey relationship between foxes and small mammals, especially voles. It is reported that cattle, sheep and pigs although sometimes exposed to infection, only develop small non-viable lesions of *E. multilocularis* and are therefore not involved in transmission (OIE 2016f).

Pathogenesis

The life cycle of *Echinococcus* begins with the gravid proglottids of the adult tapeworm living in the small intestine of the definitive host, which are then passed in the faeces. After ingestion by an intermediate host, the larvae contained in the oncospheres (eggs) hatch in the small intestine, penetrate the intestinal wall, and are carried in blood or lymph to the liver and then to the lungs. Some may be transported further to the brain, kidneys, spleen or other organs (Al Kitani et al. 2015; Balbinotti et al. 2012; Banks et al. 2006; Mitrea et al. 2014).

The oncospheres develop into metacestodes (cysts) in the organs, which can compress the surrounding parenchyma as they grow larger. Compression of the liver may result in biliary stasis and cholangitis. In *E. granulosus sensu stricto* and *E. ortleppi*, the metacestodes are fluid-filled spherical, unilocular cyst consisting of an inner germinal membrane and outer laminated layer. Each cyst is surrounded by a host produced granulomatous adventitial reaction. Small vesicles called brood capsules germinate from the inner germinal layer. Each brood capsule produces multiple protoscolices by asexual division. Protoscolices are embryonic cestodes. After ingestion by a definitive host, the protoscolices evaginate, attach to the small intestinal mucosa, and develop into adult *Echinococcus* (Romig 2003).

In *E. multilocularis* cysts, the germinal layer proliferates externally and produces root-like protrusions with small vesicles that continuously proliferate and infiltrate surrounding tissues (Eckert 1998). The term 'alveolar echinococcosis' symbolises the alveolar-like structure of the metacestode with agglomerates of small vesicles. *E. multilocularis* metacestodes behave similarly to a malignant neoplasm. The cysts eventually infiltrate the whole organ and also spread to other organs and tissues nearby. In addition, the germinal cells of a cyst can detach, migrate via blood or lymph, and give rise to distant metastatic foci in sites such as the central nervous system, lungs or bones (Thompson & McManus 2001).

Diagnosis

Clinical signs

Clinical manifestation of *Echinococcus* infection in livestock is rare as the animals are usually slaughtered before the cysts become large enough to cause clinical signs. Clinical signs, if any, are related to pressure of the growing cyst on surrounding organs and tissues, and are often overlooked (Eckert et al. 2001). Cysts in the brain or spinal cord may lead to earlier development of clinical signs.

Pathology

There are no definitive tests that can be performed during ante mortem inspection of cattle. The cysts can be identified in the organs during post mortem inspection. In cattle, the *E. granulosus sensu stricto* and *E. ortleppi* cysts are often multiple and unilocular. Cysts are common in the liver and lungs, and less frequently, in the spleen, heart, kidney, brain and other tissues (Al Kitani et al. 2015; Balbinotti et al. 2012; Mitrea et al. 2014; Rausch 1995). Most cysts are 1–7 cm in diameter but size is age-dependent. However, cysts in cattle are often not fertile, except where *E. ortleppi* present (Al Kitani et al. 2015; Balbinotti et al. 2012; Banks et al. 2006; Mitrea et al. 2014).

For *E. multilocularis*, there are no reports of cysts in cattle in the literature. Pigs develop small nodular (1–20 mm) lesions in the liver, and the metacestodes show suppressed development as they do not develop the protoscolices (Pfister et al. 1993; Sydler, Mathis & Deplazes 1998).

Testing

Identification of the *Echinococcus* in the intermediate host is based on the detection of the metacestode. Internal organs can be palpated or incised during post mortem to detect the cysts (Eckert et al. 2001). Genotyping of *E. granulosus* or *E. multilocularis* can be performed using DNA derived from protoscoleces or larval tissue (OIE 2016f).

The diagnosis of echinococcosis in definitive hosts requires the demonstration of the adult cestodes of *Echinococcus* spp. in their faeces or the small intestine or the detection of specific coproantigens or coproDNA.

Transmission in carcase and carcase parts

Echinococcus spp. can be transmitted via the carcase or carcase parts with fertile and viable cysts. Metacestodes can develop in the liver, lungs, spleen, heart, kidney, brain and other organs (Al Kitani et al. 2015; Balbinotti et al. 2012; Mitrea et al. 2014; Rausch 1995). *E. granulosus sensu stricto* being the predominant species worldwide, is the most common cause of metacestodes in cattle (Balbinotti et al. 2012). *E. granulosus sensu stricto* cysts in cattle are frequently sterile, while *E. ortleppi* are usually fertile (Balbinotti et al. 2012).

The OIE Code recommends post mortem inspection in abattoirs and either disposal or inactivation of metacestodes in offal as part of the risk management measures for Echinococcosis in meat products (OIE 2016k, l). No risk management measures are recommended for the international trade in meat.

4.7.3 Occurrence and control in applicant countries

Japan

E. granulosus sensu lato and *E. multilocularis* have been reported in regions of Japan (Kimura et al. 2010; Morishima et al. 2006; Yamashita 1956). Much of the recent research has focussed on *E. multilocularis*, which is endemic in Hokkaido (the northern most island) (Kimura et al. 2010). Echinococcosis is a notifiable disease only for dogs in Japan. Information provided by the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) indicated there is a low number of cases reported in dogs each year, with 2 or less cases reported from 2006 to 2014. There is no information available about the prevalence in cattle. Some prefectures have instituted surveillance at abattoirs for *E. multilocularis* in swine and horses (GotoY. et al. 2010; Kimura et al. 2010).

The Netherlands

In the Netherlands, *E. granulosus sensu lato* and *E. multilocularis* are notifiable infections in domestic animals. *E. multilocularis* density is increased in areas with fox population density increases (Romig, Dinkel & Mackenstedt 2006). However, no infections with *E. granulosus sensu lato* or *E. multilocularis* were reported in domestic animals in the Netherlands in 2015 (OIE 2016u). The Dutch Ministry of Economic Affairs confirmed that two cases of *E. multilocularis* infection were reported in wild animals and 64 cases in humans in 2015.

New Zealand

Infection with *E. granulosus sensu lato* was last reported in New Zealand in 1995 (Pharro & van der Logt 1997). The Ministry of Primary Industries (MPI), formerly the Ministry of Agriculture and Forestry, declared New Zealand provisionally free of *E. granulosus sensu lato* in 2002 (Pharro 2002). *E. multilocularis* and *E. ortleppi* has never been reported in New Zealand (OIE 2016u). All species of *Echinococcus* are notifiable in New Zealand. All animals slaughtered for human consumption undergo a post mortem inspection and any suspected cysts are investigated (Bingham, Kittelberger & Clough 2006).

United States

E. granulosus sensu stricto and *E. multilocularis* are present in the United States. *E. granulosus sensu stricto* is usually associated with the sheep raising areas in the south western states.

Sylvatic cycles of *E. granulosus sensu stricto*, involving wolves and wild ungulates, are also present (Foreyt et al. 2009). *E. multilocularis* is endemic in Alaska and the north central U.S. from Montana to central Ohio. *E. multilocularis* has been isolated in wild rodents (Holt et al. 2005) but has not been reported in domestic ruminants. *E. ortleppi* is not believed to be present in the United States (Thompson & McManus 2002). *E. canadensis* has been found in some northern states in cervids only (CFSPH 2011; Moro & Schantz 2009).

In the United States, echinococcosis is not a notifiable disease but there is a general surveillance program. In addition, under the U.S. Code of Federal Regulations 9 (CFR) 311.25, the USDA Food Safety and Inspection Service (FSIS) requires that organs or parts of carcasses infested with *Echinococcus* cysts be condemned during post mortem inspection and are not suitable for use in animal food (USDA:FSIS 2015a).

Vanuatu

Prior to 2014 infection with *Echinococcus* had not been reported in Vanuatu where it is a notifiable disease (OIE 2016u). The only human case of Echinococcosis (*E. granulosus sensu stricto*) reported in Vanuatu was likely acquired in the United Kingdom (Craig et al. 2012). Biosecurity Vanuatu confirmed that no clinical cases of echinococcosis have ever been reported in animals in Vanuatu.

4.7.4 Current biosecurity measures in Australia

Echinococcosis is notifiable in animals in Tasmania (*E. granulosus sensu lato* and *E. multilocularis*) and the Northern Territory (*E. granulosus sensu lato*). As part of the Australian standards, the carcass and carcass parts of each animal must have a post mortem inspection (FRSC 2007). Affected organs are condemned if echinococcosis is detected during post mortem inspection.

4.7.5 Risk review

There is evidence that *E. granulosus sensu stricto* and *E. ortleppi* can be transmitted via beef carcass parts.

E. granulosus sensu stricto is present in Australia, Japan, the Netherlands and the United States. *E. granulosus sensu stricto* is not present in New Zealand or Vanuatu. Metacestodes in cattle are usually sterile and do not play a major role in transmission.

E. ortleppi is not known to be present in cattle in applicant countries and is not present in Australia.

E. multilocularis is present in Japan, the Netherlands and the United States, but has not been reported in cattle, bison or buffalo. *E. multilocularis* is not present in Australia, New Zealand or Vanuatu. Cattle, although sometimes exposed to infection, only develop small non-viable lesions of *E. multilocularis* and are therefore not involved in transmission (OIE 2016f).

Post mortem inspection of the carcass and carcass parts is an effective way of detecting echinococcosis. Under the Australian Meat Standard, affected organs would be condemned if echinococcosis was detected at post mortem. Therefore further risk assessment for *Echinococcus* spp. is not required in this review in relation to imports of beef carcasses and carcass products from the applicant countries.

4.7.6 Conclusion

Post mortem inspection of the carcase is an effective way of detecting echinococcosis and reduces risks of it being in imported beef carcasses and carcase parts. The importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is unlikely to introduce *Echinococcus* spp. into Australia.

The OIE Code does not recommend any risk management measures for *Echinococcus* spp. for international trade in meat. However, the OIE Code recommends post mortem inspection in abattoirs, and either disposal or inactivation of metacestodes in offal as part of any risk management measures for Echinococcosis in meat products (OIE 2016k, l).

The risk from *Echinococcus* spp. associated with importation of beef and beef products from the applicant countries is therefore also considered negligible and achieves Australia's ALOP with respect to animal biosecurity risks. Risk management in relation to *Echinococcus* spp. is not applicable to imports of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu.

4.8 Paratuberculosis (*Mycobacterium avium* subspecies *paratuberculosis*)

4.8.1 Background

Mycobacterium avium subsp. *paratuberculosis* (*M. paratuberculosis*) is a bacterium which causes paratuberculosis or Johne's disease, a chronic enteritis and wasting disease of ruminants with a worldwide distribution (Buergelt, Bastianello & Michel 2004).

Paratuberculosis is a multiple species OIE-listed disease (OIE 2016). It is present in Australia and is a nationally notifiable disease (Department of Agriculture and Water Resources 2015). In 2009, the herd prevalence of paratuberculosis in south-eastern Australia was less than 1 per cent of beef herds and less than 20 per cent of dairy herds (AHA 2009). Up to and including 2016, approximately 1150 cattle herds in Australia had been classified as infected. Paratuberculosis is most common in dairy herds, but it also occurs in beef cattle, goats and alpacas. The first case of paratuberculosis in deer was detected in Victoria in 1999 (AHA 2016).

Relatively few beef herds are infected with paratuberculosis in Australia, but the disease occurs more frequently in the southern beef enterprises. Northern and Western Australia is relatively free of paratuberculosis (AHA 2016). Australia has no relevant movement controls for paratuberculosis on beef and beef products within Australia.

The consensus opinion, at present, is that the available information is insufficient to prove or disprove that *M. paratuberculosis* is a cause of Crohn's disease in humans (Grant 2005). Evidence for the zoonotic potential of *M. paratuberculosis* exists (Naser et al. 2014). Interdisciplinary collaboration among medical, veterinary and other public health officials may contribute to a better understanding of the potential routes of human exposure to *M. paratuberculosis* (Waddell et al. 2008).

4.8.2 Technical information

Agent properties

M. paratuberculosis is an obligate intracellular pathogen but persists in the environment. The bacterium is resistant to drying and acid conditions and remains infective under conditions of low temperature, moisture and protection from solar radiation. It can survive for at least one

year in faeces and on contaminated pasture and 287 days in cattle slurry (Buergelt, Bastianello & Michel 2004; Radostits et al. 2007c; Whittington et al. 2004).

Although mycobacteria are generally susceptible to heat treatment above 60 °C (Merkal & Whipple 1980), *M. paratuberculosis* is more resistant to heat than *M. bovis* and low levels of viable *M. paratuberculosis* might remain in milk after commercial pasteurisation (Eltholth et al. 2009; Foddai, Elliott & Grant 2010; Stabel et al. 2001). *M. paratuberculosis* has been cultured from raw ground muscle meat frozen at –18 °C. Humans are unlikely to be exposed to large numbers of *M. paratuberculosis* in intact or ground beef from *M. paratuberculosis* infected animals, particularly if the meat is cooked to a well done condition.

Epidemiology

Transmission in animals is mainly by the faeco-oral route, particularly during the post-natal period, and occasionally by direct (including transplacental transmission) or indirect contact (Sweeney, Whitlock & Rosenberger 1992; Whittington & Windsor 2009). Most animals become infected by ingestion of contaminated colostrum, milk or faecal material from infected dams or from grazing contaminated pastures, soil, water or feed (Sweeney 1996). *M. paratuberculosis* organisms might also spread on farms in aerosolised dust particles (Eisenberg et al. 2010). Epidemiological and experimental studies show that young animals are more susceptible to infection than older animals (Windsor & Whittington 2010). Older animals require higher doses of *M. paratuberculosis* for infection to occur (Whittington & Sergeant 2001). The lowest infectious oral dose of *M. paratuberculosis* in experimental infection of cattle was 103 bacteria but typically 109–1012 bacteria were administered, often repeatedly. However, naturally infected animals might become infected at lower doses with a corresponding increase in the time for lesions and clinical disease to develop (Begg & Whittington 2008; Hines et al. 2007).

High temperature, short time pasteurisation (71.7 °C for 15 seconds) of waste milk on dairies has been recommended to manage transmission of *M. paratuberculosis* to calves (Stabel et al. 2004). *M. paratuberculosis* has also been reported in chlorinated drinking water, possibly because of the water's relatively high pH and low temperature reducing the free chlorine level, allowing suspended cells of *M. paratuberculosis* to pass through the treatment plant with little inactivation (Luh & Mariñas 2007). *M. paratuberculosis* has been found to survive well for 365 days in biofilms present on livestock watering trough materials (Cook et al. 2010).

Infected animals can excrete *M. paratuberculosis* in faeces before clinical signs are evident and sometimes in colostrum, milk, uterine fluids and semen (Buergelt, Bastianello & Michel 2004). They can continue to shed the bacteria continuously or intermittently for the rest of their lives (Whittington & Sergeant 2001). Faecal shedding starts at a younger age in herds with high rates of infection. In dairy herds with a prevalence of *M. paratuberculosis* greater than 20 per cent, about 20 per cent of cattle less than two years old were positive on faecal culture (Weber et al. 2010).

The between and within herd prevalence of *M. paratuberculosis* infection is often underestimated because of a lack of accuracy of the tests or inadequate study design (Nielsen & Toft 2008b; Whittington & Sergeant 2001). A review of studies in Europe concluded that the true prevalence of *M. paratuberculosis* infection was approximately 20 per cent of cattle and more than 50 per cent of herds in France, Germany, Italy and Turkey (Nielsen & Toft 2008b). The prevalence estimates for paratuberculosis in beef cattle in Belgium, Canada and the United States has ranged between 0.5 and 10 per cent at the animal level and 3 and 63 per cent at the

herd level. In dairy cattle estimated prevalence at the animal level has ranged between 1 and 20 per cent and at the herd level between 22 and 94 per cent in Austria, Belgium, Canada, Denmark, the Netherlands, Switzerland and the United States (Lombard 2007).

M. paratuberculosis is endemic in cattle herds in most of the developed countries (Netherlands 54 per cent, Austria 7 per cent, United States (US) 41 per cent, and Belgium 18 per cent) (Muskens et al. 2000; Singh et al. 2010). It has been reported that the true prevalence of *M. paratuberculosis* positive dairy farms is difficult to determine due to the low sensitivity of diagnostic tests (Muskens et al. 2000).

M. paratuberculosis can infect several animal species but is particularly prevalent in dairy herds and causes disease in other domestic livestock such as sheep, goats, camelids and farmed deer, water buffalo and North American bison (Buergelt, Bastianello & Michel 2004; Radostits et al. 2007c). *M. paratuberculosis* occurs in wildlife species including Rocky Mountain goats, elk, Saiga antelope and white-tailed deer (Whittington, Marsh & Whitlock 2001). The organism has also been isolated in Scotland in wild rabbits and their predators: foxes, weasels and stoats (Beard et al. 2001; Judge et al. 2006) but not in rabbits in Australia (Abbott 2002; Department of Natural Resources and Environment 2002). *M. paratuberculosis* has been detected in scavenging mammals in the United States (coyote, feral cat, skunk, opossum, raccoon and red fox) but their role in the transmission of paratuberculosis to livestock is unknown (Anderson et al. 2007).

Macropods grazing with infected sheep might become infected with *M. paratuberculosis* but are not considered a reservoir of infection in Australia (Abbott 2002; Cleland et al. 2010; Department of Natural Resources and Environment 2002). Experimental infection of piglets orally with a cattle strain of *M. paratuberculosis* resulted in piglets shedding bacteria into the environment (Larsen, Moon & Merkal 1971). The occurrence of paratuberculosis infection has been documented in wild swine and has also been reported in the tissues of naturally infected pigs (Miranda et al. 2011). However, pigs are not considered of epidemiological importance in control programs. Experimental infection of horses, chickens and laboratory rodents (guinea pigs, hamsters, mice, rabbit and rats) with *M. paratuberculosis* is self-limiting (Begg & Whittington 2008).

Cattle, sheep and buffalo strains are distinguished by nucleic acid detection techniques, polymerase chain reactions and host range. Cattle are typically infected with a cattle (or C) strain, though cross infection with the sheep (or S) strain occurs (Collins et al. 1993; Moloney & Whittington 2008; Motiwala et al. 2003; Whittington et al. 2001). The cattle strain has also been detected in goats, alpaca, deer and a black rhinoceros in Australia (Cousins et al. 2000). In contrast, the sheep strain of *M. paratuberculosis* almost exclusively infects sheep and infection of cattle with this strain requires close contact between sheep and calves (Collins et al. 1993; Cousins et al. 2002; Whittington et al. 2001). Similarly, the sheep strain has been detected at very low prevalence in macropods grazing sheep pastures. The cattle strain has not been detected in macropods (Abbott 2002; Cleland et al. 2010; Department of Natural Resources and Environment 2002). A bison (or B) strain has been identified which has now been found frequently in both the United States and India. The bison strain was isolated in cattle in Queensland in 2012-2013 (Marsh & Whittington 2015). Bison type *M. paratuberculosis* isolates have been reported in Canadian dairy herds (Ahlstrom et al. 2015). An 'Indian bison type' strain has also been isolated from cattle, goats, sheep, buffalo (*Bubalus bubalus*) and nilgai in India (Singh et al. 2009; Stevenson 2015; Yadav et al. 2008).

M. paratuberculosis can also infect primates, including humans. Several studies have investigated the possibility of an association between Crohn's disease in humans and exposure to *M. paratuberculosis*. The majority of systematic reviews of these studies have concluded that although the cause of Crohn's disease is still uncertain, there is no substantiated causal link between paratuberculosis and Crohn's disease (FSANZ 2004; Grant 2005; Singh et al. 2010; Waddell et al. 2008). One review has concluded that *M. paratuberculosis* causes Crohn's disease in some inflammatory bowel disease patients (Naser et al. 2014). Considerable research has been undertaken on methods to detect *M. paratuberculosis* in water, animals and plant and animal products (Foods 2010).

Pathogenesis

After ingestion, *M. paratuberculosis* localises in the mucosa of the small intestine and associated lymph nodes and to a lesser extent in the tonsils and retropharyngeal lymph nodes. Bacteria multiply primarily in macrophages of the lamina propria and submucosa of the terminal small intestine and large intestine, leading to chronic diarrhoea and malabsorption and leakage of protein into the gastrointestinal tract resulting in muscle wasting, hypoproteinaemia and oedema. Dissemination occurs when bacteria are carried by macrophages to other tissues for example, uterus, foetus, mammary gland, testes, liver, kidneys and lungs (Buergelt, Bastianello & Michel 2004). Microgranulomas caused by *M. paratuberculosis* have been described in other lymph nodes and organs in mature cattle (Radostits et al. 2007c).

Cattle are usually exposed to *M. paratuberculosis* within the first few months of life and cattle older than ten months are relatively resistant to infection. Cell-mediated immune responses (CMI) are detectable early in the infection and remain present in a proportion of the subclinically infected carriers, but as the disease progresses, CMI wanes and may be absent in clinical cases. Serum antibodies are detectable later than CMI. They may also be present in carriers that have recovered from infection. Serum antibodies are present more constantly and are of higher titre as lesions become more extensive, reflecting the amount of antigen present (OIE 2014b). The humoral response to infection develops late in the course of disease and therefore does not provide protection. In the late stages of disease, a lack of immune response (anergy) might occur and neither cell-mediated nor humoral immune responses might be detectable (Radostits et al. 2007c).

Diagnosis

Clinical signs

Animals infected with *M. paratuberculosis* are classified into one of three groups, depending on whether they develop resistance after infection. The first group are infected but do not show clinical signs or shed bacteria in faeces. The second group do not show clinical signs but shed bacteria (carrier adult cattle) and the third group show clinical signs and shed bacteria intermittently or continuously (Radostits et al. 2007c).

The period between infection and the onset of clinical signs in naturally infected animals is prolonged, with clinical disease most common in cattle and sheep over two years old. High infective doses under experimental conditions can lead to a shorter incubation period and clinical signs within a year (Whittington & Sergeant 2001).

Clinical disease is characterised by a progressive weight loss leading to emaciation, oedema and poor coat quality. Frequently, chronic intractable diarrhoea occurs. Milk yield might drop by up to 20 per cent in infected herds of dairy cattle and the herd reproduction rate is reduced. The

persistent diarrhoea can result in severe dehydration, emaciation and weakness that may necessitate culling or result in death (Buergelt, Bastianello & Michel 2004).

Pathology

Diffuse thickening and corrugations of the mucosa of the distal jejunum and ileum are visible in more than half of clinically affected cattle (Buergelt, Bastianello & Michel 2004). The ileocaecal valve, caecum and proximal colon are often similarly affected. The intestinal serosal and mesenteric lymphatics are prominent, beaded and cord-like and the ileocaecal and mesenteric lymph nodes are oedematous and enlarged. Animals with advanced clinical disease might develop oedema of the abomasal wall and serous fluid in the abdominal and pericardial cavities. Calcification of the aorta and left atrium might occur in up to 25 per cent of clinically affected animals (Buergelt, Bastianello & Michel 2004; Radostits et al. 2007c). Lesions in North American bison are similar to those in cattle (Buergelt et al. 2000).

Testing

Detection of *M. paratuberculosis* infection in animals without clinical signs is limited by poor test sensitivity and specificity (Nielsen & Toft 2008a).

Histopathology of intestinal tissues and culture of intestinal tissues and faeces are the most sensitive tests. The most sensitive and specific test for serum antibodies to *M. paratuberculosis* is absorbed-enzyme-linked immunosorbent assay (Ab-ELISA). The sensitivity of the Ab-ELISA is about 50 per cent in adult subclinically infected cattle, about 15 per cent in low shedder cattle and about 30 per cent in low prevalence herds. The agar gel immunodiffusion test has a low sensitivity (10–30 per cent) in cattle and goats but in sheep has a sensitivity of 78–93 per cent and a specificity of 98–100 per cent (Cousins et al. 2002).

Bacteriological culture of faeces is the most sensitive herd level test (Whittington & Sergeant 2001). Polymerase chain reaction (PCR) assays for *M. paratuberculosis* in tissues and faeces are less sensitive than culture (Cousins et al. 2002). However, real time PCR assays have been used to detect *M. paratuberculosis* in the tissues and faeces of slaughter cattle (Bosshard, Stephen & Tasara 2006). Tests to detect paratuberculosis in cattle have not been validated for North American bison (Buergelt et al. 2000), although PCR tests on intestinal tissues and mesenteric lymph nodes detected all of 25 free ranging bison considered to have been infected with *M. paratuberculosis* (Ellingson et al. 2005). In water buffalo PCR assays of intestinal tissue and mesenteric lymph nodes have been used (Sivakumar, Tripathi & Singh 2005).

Transmission in carcass and carcass parts

At least one systematic review has recommended that the exposure of humans to *M. paratuberculosis* in meat (as well as milk, water and the environment) warranted further investigation (Wilhelm et al. 2009). Studies have shown that beef can be contaminated with *M. paratuberculosis* via the dissemination of the organism in infected tissues and that tissue distribution may be poorly correlated with clinical signs. The surface of carcasses can also be contaminated by *M. paratuberculosis* in faeces present on the hides of animals at slaughter (Eltholth et al. 2009). There is the suggestion that *M. paratuberculosis* is spread to extra-intestinal tissues via blood (Bower, Begg & Whittington 2010). Bacteraemia might be intermittent in the early stages of disease or undetectable in cows with advanced paratuberculosis (Mutharia et al. 2010).

At slaughtering plants in Canada and the United States, *M. paratuberculosis* was detected on the hides of 54–80 per cent of cull dairy and beef cows and 1–6 per cent of feedlot cattle. However, the prevalence of *M. paratuberculosis* decreased during processing and the organism was thought to present little risk of contamination to prime cuts of beef (Meadus et al. 2008; Wells et al. 2009).

M. paratuberculosis is found in the intestinal tract and mesenteric lymph nodes of infected cattle and might disseminate to the supramammary lymph nodes, udder and reproductive tract, liver, spleen, thoracic organs, mediastinal lymph nodes and lymph nodes of the head and liver and pre-scapular and popliteal lymph nodes of clinically normal cattle from affected herds (Ayele et al. 2004a; Bower, Begg & Whittington 2010; Brady et al. 2008; Sweeney 1996). *M.*

paratuberculosis was detected in ileocaecal lymph nodes of 34 per cent of dairy cows and 3 per cent of beef cows and the liver and other lymph nodes of 11 per cent of dairy cows and 0.7 per cent of beef cows in a study of thin cattle at three slaughter plants in the United States (Rossiter & Henning 2001). It was also found in the diaphragm muscle of 13 per cent of cull cows from beef and dairy farms in Spain (Alonso-Hearn et al. 2009).

Recent investigation showed that low numbers of *M. paratuberculosis* might be present in raw, chilled or frozen meat from infected animals but that the organism is likely to be inactivated when meat is well cooked (Mutharia et al. 2010). *M. paratuberculosis* was cultured in high numbers from raw hamburger patties seeded with chopped mesenteric lymph nodes from cows with advanced paratuberculosis. The same study found the organism in raw, chilled and frozen round steaks (semimembranosus, semitendinosus and biceps femoris muscles) from these animals. However, cooking at 70 °C or higher reduced the detection of *M. paratuberculosis* from 12 per cent to 2.5 per cent of meat samples.

M. paratuberculosis grows extremely slowly in culture and requires rigorous decontamination procedures to remove competing organisms. These procedures significantly reduce the analytical sensitivity of routine culture although the use of modified acid-pepsin methods of culture for muscle and peripheral lymph nodes were considerably more sensitive than previous routine culture techniques. The risk of human exposure to viable *M. paratuberculosis* through the consumption of meat is likely to be low, and measures to prevent the slaughter of clinically infected animals for human consumption further reduce this risk (Reddacliff et al. 2010). *M. paratuberculosis* was not detected in 200 ground beef samples obtained from three supermarkets in California between September and November 2005 (Jaravata et al. 2007). However evidence of the presence of viable *M. paratuberculosis* cells in ground beef products intended for human consumption has been reported (Savi et al. 2015).

It is generally agreed that the faecal-oral route is the most important natural route of exposure. Oral transmission of bovine strains of *M. paratuberculosis* obtained from homogenised infected tissue to cattle, goats, sheep, deer, chickens and laboratory animals, was demonstrated in numerous experiments and extensively reviewed (Begg & Whittington 2008; Hines et al. 2007).

Natural *M. paratuberculosis* infection is mainly transmitted to susceptible species via the oral route through pasture or livestock yards that are contaminated with faecal material containing *M. paratuberculosis*. The presence of *M. paratuberculosis* in carcase and carcase parts of subclinically infected cattle has been demonstrated from faecal contamination of the carcase, and/or disseminated from intestines, including offal and muscle (Gill, Saucier & Meadus 2011).

The occurrence of paratuberculosis infection has been documented in wild swine and *M. paratuberculosis* has also been reported in the tissues of naturally infected pigs (Miranda et al. 2011). Transmission of *M. paratuberculosis* to other species via the consumption of raw or undercooked beef and beef products has not been investigated. However, numerous experiments have demonstrated transmission of *M. paratuberculosis* to cattle, goats, sheep, deer, chickens and laboratory animals, which were dosed by mouth with bovine strains obtained from culture or homogenised infected tissue (Begg & Whittington 2008; Hines et al. 2007).

The OIE Code does not recommend any risk management measures for paratuberculosis for international trade in meat and meat products. Australia does not impose any domestic management measures for paratuberculosis on the domestic trade in meat and meat products.

4.8.3 Occurrence and control in the applicant countries

Japan

Japan has a low prevalence of paratuberculosis. In Japan, every dairy farm is tested for *M. paratuberculosis* every five years in accordance with the *Domestic Animal Infectious Diseases Control Act 1998*. About 1000 of the half-million head of officially tested cattle are diagnosed as having paratuberculosis annually but most of these exhibit only minor or no clinical signs.

Infection with *M. paratuberculosis* is a notifiable disease in Japan and national and provincial government programs are in place aimed to control and ultimately eradicate the disease. *M. paratuberculosis* is regarded as a potentially zoonotic organism in Japan.

The Domestic Animal Infectious Diseases Control Act requires that cattle officially diagnosed with *M. paratuberculosis* infection must be slaughtered.

The Ministry of Health, Labour and Welfare instructed that the milk and meat of cattle diagnosed with paratuberculosis should not be used for human consumption (Momotani 2012).

The range of disease controls in Japan is similar to that in Australia. Consequently the unrestricted risk of paratuberculosis associated with importation of beef and beef products from Japan is considered to be equivalent to that posed by domestically produced beef and beef products.

The Netherlands

Disease as a result of *M. paratuberculosis* is notifiable in the Netherlands. According to OIE reporting, clinical disease does not occur. However, serological evidence of the organism does exist.

The Netherlands has programs to control and reduce the prevalence of paratuberculosis. Reports indicate that herd prevalence is decreasing. Cattle that test positive to *M. paratuberculosis* are culled. Infection with *M. paratuberculosis* is a notifiable disease in the Netherlands and national programs are in place to control and reduce the prevalence of the disease.

Paratuberculosis control activities have been delivered via the 'Intensive Paratuberculosis Programme' since 1998. This provides certification of test-negative herds and guidelines for control of *M. paratuberculosis* in infected herds. A Milk Quality Assurance Programme (MQAP) was initiated in 2006 with the aim to reduce *M. paratuberculosis* contamination of bulk milk. Dairy producer participation (in either program) has been a requirement of dairy processors

(through terms of delivery) since 2010. Most milk processors do not collect milk from herds containing test positive cattle (Weber 2012).

Australia has no relevant movement controls for paratuberculosis on beef and beef product within Australia. The range of disease controls in the Netherlands is similar to that in Australia. Consequently the unrestricted risk of paratuberculosis associated with importation of beef and beef products from the Netherlands is considered to be equivalent to that posed by domestically produced beef and beef products.

New Zealand

A recent study in New Zealand reported *M. paratuberculosis* prevalence figures of 75 per cent for sheep flocks, 42.5 per cent for deer herds and 46.2 per cent for beef cattle herds (Verdugo 2013).

It was reported that 12 per cent of dairy herds were 'positive' based on diagnostic laboratory records which is likely to be an underestimate of herd prevalence (Burton 2002).

It is believed that more than 60 per cent of dairy farms have infected animals, but the level of clinical disease continues to remain low in the majority of herds. Disease prevalence is reported to be higher in the South Island of New Zealand than the North Island (Larking 2012).

New Zealand has no active program in place for paratuberculosis control.

The range of disease controls in New Zealand is similar to that in Australia. Consequently the unrestricted risk of paratuberculosis associated with importation of beef and beef products from New Zealand is considered to be equivalent to that posed by domestically produced beef and beef products.

United States

M. paratuberculosis occurs in bison, cattle, sheep and wild ruminants in the United States. A National Animal Health Monitoring Systems (NAHMS) study, Dairy 2007, found that 68.1 percent of participating U.S. dairy operations were infected with *M. paratuberculosis* (USDA:APHIS:VS 2010). Serological surveys showed that the prevalence of *M. paratuberculosis* infection in beef cattle varied between three and five per cent of animals and over 40 per cent of herds studied (Pence, Baldwin & Black 2003; Radostits et al. 2007c; Roussel et al. 2005; Thorne & Hardin 1997). However, participation in control programs for paratuberculosis is limited and only 3.2 per cent of beef operations were tested for *M. paratuberculosis* during the two years before 2008.

The United States has a range of national, state and voluntary control and surveillance programs and movement controls for paratuberculosis.

Regulations control 'movement of domestic animals that are positive to an official Johne's disease test'. Separation and segregation from healthy animals is required and movement is restricted to slaughter facilities (including interstate slaughter facilities) in accordance with Title 9, Code of Federal Regulations, part 80 (APHIS 2016).

A National Voluntary Bovine Johne's Control Program operates in 48 states using uniform standards approved by the Veterinary Services of the Animal and Plant Health Inspection Service within the United States Department of Agriculture (APHIS 2010; Gilsdorf 2006; Lombard 2007). The program is administered by each state and supported by industry and the

United States Federal Government. The National Veterinary Service Laboratory provides validation of paratuberculosis serological and agent detection tests and offers a faecal culture training course to laboratories (APHIS 2010). In 2007, 32 per cent of dairy operations participated in a paratuberculosis control or certification program (USDA:APHIS:VS 2010) and just over 1 per cent of beef operations participated in any programs to control paratuberculosis in the five years before 2008 (USDA 2010a). However, reduced funding has more than halved the number of tests performed for paratuberculosis since 2006 (APHIS 2009a). Estimation of paratuberculosis prevalence in some regions might be limited by the voluntary nature of the program and confidentiality of results (Anderson et al. 2007).

The disease is listed on the US National List of Reportable Animal Diseases (NLRAD) (USDA:APHIS 2016a).

The range of disease controls in the United States is similar to that in Australia. Consequently the unrestricted risk of paratuberculosis associated with importation of beef and beef products from the United States is considered to be equivalent to that posed by domestically produced beef and beef products.

Vanuatu

M. paratuberculosis is a notifiable disease. No clinical case has ever been reported.

Given the absence of paratuberculosis relevant movement controls on beef and beef product within Australia and the probable absence of the disease, the unrestricted risk of paratuberculosis associated with importation of beef and beef products from Vanuatu is considered to be equivalent to that posed by domestically produced beef and beef products.

4.8.4 Current biosecurity measures in Australia

Paratuberculosis is a nationally notifiable disease (Department of Agriculture and Water Resources 2016c). Prior to July 2016, it was controlled through state and territory regulation. From July 2016, the beef and dairy cattle industries transitioned to a farmer managed system.

4.8.5 Risk Review

There is evidence that *M. paratuberculosis* can be transmitted via the beef carcase or carcase parts after ante and post mortem examination.

Paratuberculosis is present in Australia, Japan, the Netherlands, New Zealand and the United States.

Paratuberculosis is currently a nationally notifiable disease in Australia and is subject to a range of control measures. The OIE Code does not recommend any risk management measures for paratuberculosis for international trade in meat and meat products. Australia does not have domestic movement restrictions on beef or beef products in relation to paratuberculosis.

4.8.6 Conclusion

The risk from *M. paratuberculosis* infection associated with the importation of beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu is considered negligible and therefore achieves Australia's ALOP with respect to animal biosecurity risks. Risk management measures additional to the veterinary ante and post mortem inspections and certification as per the Australian Meat Standard are not required. A risk assessment for

paratuberculosis is not required in relation to beef and beef products imported from the applicant countries in this review of conditions.

4.9 *Salmonella enterica* serotype Typhimurium DT104

4.9.1 Background

Salmonella enterica causes clinical and subclinical enteric infections in both livestock and humans, and is a leading cause of food-borne illness in the United States (FSIS 2015) and Europe (EFSA BIOHAZ Panel 2008).

Serotypes of *Salmonella enterica* are emerging that have multiple antibiotic resistance. The prevalence of multiple antibiotic resistant *Salmonella enterica* serotypes in livestock raises concerns about the management of livestock destined for the food chain and the transmission of multi-resistant pathogens to humans via food (Adhikari et al. 2009; Habing, Lo & Kaneene 2012; Loudon et al. 2012; Marrero-Ortiz et al. 2012; Ray et al. 2007; Van Boxtael et al. 2012).

In the early 1990s, a distinct multi-drug resistant strain of *Salmonella enterica* serotype Typhimurium became prominent as a pathogen of both livestock and humans in the United States and western Europe (Foley, Lynne & Nayak 2008; Poppe et al. 1998). The new strain, known as definitive type 104 R-ACSSuT displayed resistance to ampicillin, chloramphenicol, streptomycin, sulphonamides and tetracycline (ACSSuT) and continued to spread internationally during the 1990s (Helms et al. 2005). *S. enterica* serotype Typhimurium definitive type 104 R-ACSSuT is commonly referred to as DT104 and is now present in many countries (Glynn et al. 1998; Helms et al. 2005) including Japan, the Netherlands and the United States (Ahmed, Ishida & Shimamoto 2009; Esaki et al. 2004; Glynn et al. 1998; Kawagoe et al. 2007; van Duinkerken et al. 2002; Wells et al. 2001; Wright et al. 2005; Yokoyama et al. 2007).

Infection with DT104 has not been reported in Australian livestock or products derived from Australian livestock (Barlow & Gobius 2008). In addition, there is a low incidence of human DT104 infection in Australia, which when present is often associated with imported food or contracted overseas (Fisher et al. 2001; Helms et al. 2005). Australia imposes strict biosecurity measures on imported food and livestock, which may have contributed to the lack of establishment of DT104 in Australia (Helms et al. 2005).

Salmonellosis due to DT104 is not an OIE-listed disease (OIE 2016p). However, the OIE recognises that multiple antibiotic resistant *Salmonella* spp. are of increasing concern in both public health and primary production (OIE 2010d, 2016q).

Salmonellosis due to DT104 is not a nationally notifiable animal disease in Australia (Department of Agriculture and Water Resources 2016c). However, it is a serious zoonosis (OIE 2016q; Radostits et al. 2007a) and salmonellosis is a nationally notifiable disease for humans (Department of Health 2016).

4.9.2 Technical Information

Agent properties

Salmonella spp. are gram negative facultative anaerobic bacilli of the family Enterobacteriaceae, which are ubiquitous pathogens in the environment. Compared to other members of the family Enterobacteriaceae, *Salmonella* spp. are relatively resistant to various environmental factors.

The growth and survival of *Salmonella* spp. in foodstuffs is influenced by temperature, pH, water activity and the presence of preservatives.

Salmonella spp. proliferate between 5.2 and 46.2 °C (FSANZ 2013) but can survive frozen storage in food and drinks (Manios & Skandamis 2015; Uljas & Ingham 1999). DT104 strains are more tolerant of cold storage than other strains (Knudsen et al. 2011), and can proliferate quickly following cold exposure (Humphrey et al. 2011). Survival of DT104 in meat when heated is increased by muscle surface attachment (Humphrey 2001; Humphrey, Wilde & Rowbury 1997), lowered water activity (McCann, McDowell & Sheridan 2009) and higher fat content (Juneja & Eblen 2000). Attachment to muscle surface has also been shown to protect against the initial effects of refrigeration temperatures (4 °C) (Kinsella et al. 2007).

While *Salmonella* spp. will grow at a broad pH range of 3.8–9.5 (FSANZ 2013), some strains of DT104 can survive prolonged periods at pH 2.5 (Berk et al. 2005; de Jonge, Ritmeester & van Leusden 2003). *Salmonella* spp. are resistant to desiccation (Margas et al. 2014) and low water activity conditions (Mattick et al. 2000). This makes them capable of prolonged survival in dried faeces, dust, feedstuffs and other organic substrates (Radostits et al. 2007a).

Salmonella responses allow them to adapt to environmental conditions, which promotes survival in adverse conditions. The formation of biofilms (O'Leary et al. 2015), filaments (Humphrey et al. 2011; Mattick et al. 2000) and other stress responses (Humphrey et al. 2011; Humphrey 2001; Kinsella et al. 2007) have been observed in DT104 in response to sub-optimal environmental conditions.

Growth of *Salmonella* spp. may be inhibited by biocides such as benzoic acid, sorbic acid or propionic acid preservatives (FSANZ 2013; Menconi et al. 2013). *Salmonella* spp. do not sporulate and are destroyed by common phenol, chlorine and iodine based disinfectants (Ramírez et al. 2002), and are inactivated by heat and sunlight. The inhibitory effect of biocides may be enhanced by combining preservatives with reduced pH and freezing (Uljas & Ingham 1999). Increased contact times and higher active concentrations may be required for disinfection of surfaces with biofilms of *S. Typhimurium* (Wong et al. 2010).

Multiple antimicrobial resistance is widespread within DT104 strains. A penta-resistant phenotype (ACSSuT) is commonly associated with DT104 strains, however there is also emerging resistance to trimethoprim and quinolones (Ahmed, Ishida & Shimamoto 2009; Esaki et al. 2004; Helms et al. 2005; Lee & Lee 2007; Mindlin et al. 2013; Weill et al. 2006). The classical DT104 penta-resistance pattern includes four of the five most commonly used antimicrobials in veterinary medicine. In addition, multiple antimicrobial resistance of *S. Typhimurium* may be associated with greater resistances to biocides (Whitehead et al. 2011). (Liebana et al. 2002)

Antimicrobial selection pressure influences the emergence of multiple antimicrobial resistant *Salmonella* spp., although bacterial factors may also play a role (Butaye et al. 2006). The genes that encode the antimicrobial resistance of DT104 are contained in an area of the chromosome called the *Salmonella* genomic island 1 (SGI1). Horizontal transfer of SGI1 has been suggested to pass these resistance genes between *Salmonella* spp. (Hur, Jawale & Lee 2012; Levings et al. 2005). This resistance may then be maintained in the absence of selective pressure as SGI1 has been suggested to integrate into the chromosome.

Epidemiology

DT104 is not host specific, although it is commonly associated with cattle (Ahmed, Ishida & Shimamoto 2009; Esaki et al. 2004; Graziani et al. 2008; Kawagoe et al. 2007; Ray et al. 2007). DT104 has been isolated from other livestock such as sheep, goats, pigs, and poultry (Esaki et al. 2004; Kawagoe et al. 2007; Liebana et al. 2002; Van Boxtael et al. 2012; Wasyl et al. 2006). DT104 infection has been reported in companion animals such as cats, dogs and horses (Liebana et al. 2002; Philbey et al. 2014; Wright et al. 2005), and it has also been isolated from rodents and wildlife including wild birds and elk (Foreyt, Besser & Lonning 2001; Liebana et al. 2002; Yokoyama et al. 2007).

Infection in humans is well documented (Cawthorne et al. 2006; Graziani et al. 2008; Helms et al. 2005; Van Boxtael et al. 2012; Weill et al. 2006; Yokoyama et al. 2007). Human outbreaks of DT104 have been linked to a broad range of contaminated foodstuffs including beef (Dechet et al. 2006; Isakbaeva et al. 2005; Kivi et al. 2007; Mindlin et al. 2013; Radostits et al. 2007a; Wall et al. 1994; WHO 2005). Infections of DT104 in companion animals such as dogs and cats have been associated with outbreaks in humans (Wright et al. 2005).

The epidemiological patterns of salmonellosis differ between geographical areas depending on climate, population density, land use, farming practices, food harvesting and processing technologies, and consumer habits (EFSA & ECDC 2015b; EFSA BIOHAZ Panel 2008). Cattle infected with *Salmonella* spp. such as DT104 shed the bacteria in faeces resulting in environmental contamination and exposure of in-contact cattle. Indirect spread may also occur due to contamination of feed and water supplies, including by the use of infected slurry or sewage on pastures. A prolonged carrier state of up to 18 months in adult cattle infected by DT104 has been reported (Evans & Davies 1996), promoting transmission of DT104 when carrier cattle are introduced to a new herd. Animals that recover from infection with one strain of *S. Typhimurium* may possess cross-immunity against other strains (Kingsley & Bäumler 2000).

Transport stress can result in a significant increase in shedding of *Salmonella* spp. The prevalence of faecal shedding of *Salmonella* spp. in beef cattle was reported to increase from one per cent to greater than 20 per cent, and hide contamination increased from 20 per cent to greater than 50 per cent following transport from the farm to abattoir (Beach, Murano & Acuff 2002). Potential sources of *Salmonella* spp. cross contamination are numerous throughout the transport and slaughter process, and include transport vehicles, holding pens, killing pens, workers and equipment. Use of decontaminants and good hygiene practices are recommended to minimise the contamination of beef during processing at the abattoir (FAO & WHO 2015).

Salmonella spp., including multiple antimicrobial resistant strains, are frequently detected in meat. In a Danish study of food-borne pathogens in imported poultry, pork and beef conducted between 1998 and 2002, *Salmonella* spp. were isolated from 1078 of 9135 samples, of which 28% had multiple antimicrobial resistance (Skov et al. 2007). *S. Typhimurium* has been isolated from beef products in Denmark (Skov et al. 2007), Ireland (Kerr & Sheridan 2002), the Netherlands (Kivi et al. 2007), the UK (Mindlin et al. 2013), and the United States (FSIS 2015; Jackson et al. 2013). The probability of recovering an antibiotic resistant *Salmonella* isolate is higher in pork, than poultry and beef (Skov et al. 2007).

Pathogenesis

The primary route of infection for *Salmonella* spp. is faecal – oral transmission but respiratory and tonsillar routes have also been reported in swine (Fedorka-Cray et al. 1995). After surviving the low pH environment of the stomach, *Salmonella* spp. can colonise multiple sites including the small intestine, colon and caecum. Intestinal adhesion is mediated by fimbriae present on the bacterial cell surface. Adhered *Salmonella* spp. secrete virulence factors that promote epithelial uptake by vacuolation, survival within vacuoles, neutrophil migration, and ion imbalance in intestinal epithelial cells leading to diarrhoea (Foley & Lynne 2008). Intestinal lesions result from exfoliation of the intestinal epithelium and stunting of villi. After penetrating the intestinal epithelium, the bacteria are engulfed by phagocytes, and transported to regional lymph nodes and lymphoid tissues. Proliferation continues inside the phagocyte until it undergoes apoptosis, allowing the bacteria to escape to reinvade other epithelial or phagocytic cells.

Infections in livestock usually stay localised to the small intestines and mesenteric lymph nodes. However, bacteraemia can occur, especially in young animals, when spread beyond the mesenteric lymph nodes leads to infection in the reticuloendothelial cells of the liver and subsequent invasion of the bloodstream. A pyrexia reaction follows within 24–48 hours of invasion of the bloodstream. Septicaemia may be rapidly fatal, particularly in young calves (Morgan et al. 2004; Radostits et al. 2007a).

The occurrence and subsequent course of disease depends upon factors such as the age and immune system of the host, inoculum dose and serotype specific virulence factors (EFSA & ECDC 2015b; Jackson et al. 2013; Philbey et al. 2014). Subclinical adult carriers have been reported to be able to shed *Salmonella* spp. in their faeces for up to 18 months (Evans & Davies 1996). *Salmonella* spp. carrier status is associated with prolonged antibiotic use and disturbance of the microbiome (Croswell et al. 2009; Endt et al. 2010). The pathogenesis of infection with DT104 does not appear to differ from that of other strains of *S. Typhimurium*., although some DT104 strains are more tolerant of low pH than others (Berk et al. 2005; de Jonge, Ritmeester & van Leusden 2003) which may assist survival in the stomach. Human DT104 cases are associated with higher hospital admission rates and mortality than other *Salmonella* food-borne diseases (Wall et al. 1994).

Diagnosis

Clinical signs

Clinical signs due to infection with DT104 are consistent with those caused by other *S. Typhimurium* strains. Three syndromes are described: septicaemia, acute enteritis, and chronic enteritis. Disease is often more severe in young animals (Evans & Davies 1996; Morgan et al. 2004). Subclinical disease is common for *Salmonella* spp. (Falkenhorst et al. 2012; Rodriguez-Rivera et al. 2014). Within a dairy herd, prominent signs of infection include pyrexia, diarrhoea and a decrease in milk production (Sharp & Rawson 1992).

Enteritis with septicaemia typically occurs in neonatal animals but can occur in adults. Clinical signs include severe diarrhoea, depression, prostration, marked pyrexia and death within 24–48 hours (Costa et al. 2012; Radostits et al. 2007a).

Acute enteritis typically affects calves older than a week and adult cattle. Dysentery, with clots of whole blood or intestinal mucosa, agalactia and signs of abdominal pain may occur in severe enteritis (Costa et al. 2012; Radostits et al. 2007a). Chronic enteritis with diarrhoea, inappetence and ill-thrift (Evans & Davies 1996) may follow acute enteritis. Other clinical manifestations

include polyarthritis, which occurs commonly in infected calves (Izzo, Mohler & House 2011; Radostits et al. 2007a) and abortion, which has been reported in DT104, *S. Dublin* and *S. Newport* infections in cattle (Carrique-Mas et al. 2010; Evans & Davies 1996; Veterinary Laboratories Agency 2005).

Pathology

Pathology in animals due to infection with *S. Typhimurium* serotypes, including DT104, varies with the clinical syndrome observed. The enteric form of disease is typically associated with fibrino-necrotic enterocolitis and mesenteric lymph node enlargement. More severe inflammatory changes are present in acute enteritis than in chronic disease (Pope et al. 1998; Snider et al. 2014; Veterinary Laboratories Agency 2005). Chronic pneumonia, various localised inflammatory processes (for example, polyarthritis, osteomyelitis) and dermal infarcts may occur as a result of bacteraemic spread (Snider et al. 2014; Veterinary Laboratories Agency 2005) and often in association with chronic enteritis (Radostits et al. 2007a). Hepatomegaly, splenomegaly and engorgement of the gall bladder are also seen in septicaemic salmonellosis in cattle (Veterinary Laboratories Agency 2005).

Testing

Detection of *Salmonella* spp. is based on isolation of the organism either from tissues collected aseptically or from faeces, rectal swabs, carcase surfaces, food products, feedstuffs or environmental samples. The method of sample collection may have an impact on the sensitivity of the assay. In addition, sample enhancement techniques may also be used to improve the sensitivity. The gold standard technique for isolation is culture with biochemical tests to confirm identity. Molecular isolation methods have been developed in an effort to decrease turnaround time (Chen et al. 2012). However, molecular isolation tests require enrichment procedures due to inhibitory substances found in faecal and food samples, and have not been validated for use with environmental and faecal samples (OIE 2016q).

Serotyping of *Salmonella enterica* isolates is performed by slide agglutination using the Kauffmann-White scheme and pulsed-field gel electrophoresis (PFGE) is then used to identify strains (Wattiau, Boland & Bertrand 2011). In recent years, multiple-locus variable-number tandem repeat analysis (MLVA) is being increasingly adopted for strain identification (Lindstedt et al. 2012). Other molecular methods for serotype and strain characterisation have been described, however, these have not been validated for widespread diagnostic use (OIE 2010b, 2016q)

Identification of antimicrobial resistance patterns is an important step in *Salmonella* spp. isolate characterisation as significant variability in multiple antimicrobial resistance in *Salmonella* spp. have been reported (Habing, Lo & Kaneene 2012; Helms et al. 2005; Philbey et al. 2014). Standardised techniques that incorporate micro-dilution, commercially prepared kits (Barlow & Gobius 2008; Emborg, Baggesen & Aarestrup 2008) and automated systems (Hoelzer et al. 2011; Morar, Sala & Imre 2015) are now available to assess antimicrobial resistance.

Transmission in carcase and carcase parts

Undetected carriers of *Salmonella* spp. play a significant role in the contamination of carcase and carcase parts, and increase the risks to food safety. Subclinically infected cattle may shed *Salmonella* spp. in their faeces (Cummings et al. 2010; Rodriguez-Rivera et al. 2014; Wells et al. 2001), which may contaminate the hides of cattle during transport, the transport vehicle and lairage. Faecal *Salmonella* spp. shedding and hide contamination of cattle increases after

transport (Beach, Murano & Acuff 2002). The heaviest microflora contamination occurs in the distal leg and brisket due to contact with floors while standing or lying prior to slaughter (Antic et al. 2010; Buncic & Sofos 2012).

Salmonella spp. contamination of the hides of cattle or gastrointestinal spillage of subclinically infected cattle can cross-contaminate carcass and carcass parts, equipment and workers' hands during processing. During skinning, contamination commonly occurs at the opening cuts, i.e. the distal leg and brisket where hide contamination is highest, or at sites of hide contact, such as the rump and flank (Buncic & Sofos 2012). During dressing, spillage from the gastrointestinal tract can contaminate the carcass, equipment and workers' hands (Buncic & Sofos 2012). The potential *Salmonella* spp. gastrointestinal load can be enhanced by food withholding, which alters the rumen environment to make it more favourable for *Salmonella* spp. proliferation.

The presence of DT104 on carcass samples and beef products has been well documented (Brichta-Harhay et al. 2011; Kerr & Sheridan 2002; Little et al. 2008; McEvoy et al. 2003; Skov et al. 2007). However, good hygiene practices, processing, carcass decontamination and other interventions can decrease the level of *Salmonella* spp. contamination. In the United States, pre-harvest beef hide *Salmonella* spp. contamination rates range from 52.2 per cent (Beach, Murano & Acuff 2002) to 99.5 per cent (Schmidt et al. 2015) whereas, post processing rates were much lower, ranging from zero per cent (Schmidt et al. 2015) to 0.47 per cent (Brichta-Harhay et al. 2011). Consequently, where good hygiene practices are in place, estimates of prevalence of *Salmonella* spp. in cattle indicate the potential for contamination and not the contamination rate in carcass and carcass parts.

High *Salmonella* spp. contamination rates are found in ground beef (Bosilevac et al. 2009; Dechet et al. 2006; Isakbaeva et al. 2005; White et al. 2001). The use of fatty trim containing contaminated lymph nodes in ground beef (Gragg et al. 2013); mixing of beef from multiple origins (Martínez-Chávez et al. 2015); increased potential for contamination during food preparation (Martínez-Chávez et al. 2015); use of contaminated equipment (Papadopoulou et al. 2012); and undercooking of the ground beef may all contribute to the increased prevalence of *Salmonella* spp. (Fedorka-Cray et al. 1995).

4.9.3 Occurrence and controls in applicant countries

Japan

Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF) has confirmed that salmonellosis, including by *S. Typhimurium*, is notifiable in Japan in cattle, water buffalo, deer, pigs, wild boar, chickens, ducks, quail and turkeys. Information provided by MAFF demonstrates that salmonellosis in cattle has been reported across many prefectures including those with high livestock density from 2006 to 2014. This widespread distribution is consistent with a national survey which found 0.5 per cent of cattle faeces were positive for *Salmonella* spp. (Ishihara et al. 2009). Recent studies suggest the prevalence of *Salmonella* spp. on beef may be between 0.2 to 1.5 per cent depending on the assay (Hara-Kudo et al. 2013; Hiroi et al. 2012; Murakami et al. 2013).

In Japan, *S. Typhimurium* is the major serotype causing bovine salmonellosis. DT104 has been detected in cattle, pigs and poultry (Dahshan et al. 2010; Esaki et al. 2004; Kawagoe et al. 2007), but also in rodents and horses (Niwa et al. 2009; Yokoyama et al. 2007). Since its emergence in the 1990s, predominance of DT104 in Japanese cattle is now decreasing (Kawagoe et al. 2007;

Tamamura et al. 2011). In a study on *S. Typhimurium* isolated from cattle collected between 1977 to 2009, DT104 isolates made up only 27 from 2000-2009, whereas from 1990-1997, they made up 82 per cent (Tamamura et al. 2011). In samples from healthy and clinically ill cattle collected between 2002 and 2006, 22 out of 34 *S. Typhimurium* isolates were DT104 (Ahmed, Ishida & Shimamoto 2009), whereas, information provided by MAFF indicates that from 2006 to 2007 only 18.5 per cent of *S. Typhimurium* isolates were DT104. These results suggest that clonal replacement may be occurring in Japanese cattle.

Under Japanese legislation, livestock owners are required to comply with biosecurity standards prescribed by MAFF. This includes daily monitoring, animal health reporting, and at least annual inspection of herds by Livestock Hygiene Service Centre (LHSC) Animal Health Inspectors. Prefecture LHSC laboratories are responsible for isolation and identification of *Salmonella* spp. in any samples collected from healthy and clinically ill cattle in Japan. Cattle herds that test positive for *Salmonella* spp. are required to undergo further testing to identify the positive cattle. However, culling of *Salmonella* spp. shedding cattle is voluntary.

The Netherlands

The Dutch Ministry of Economic Affairs (EZ) confirmed that all *Salmonella* spp. infections are reportable by farmers, veterinarians and laboratories under Dutch legislation. It is estimated that 8-9.1 per cent of Dutch dairy herds are infected with *Salmonella* spp. (Bergevoet et al. 2009; van Schaik et al. 2007). Bovine salmonellosis in the Netherlands is predominantly due to *S. Typhimurium* and *S. Dublin* (van Duinkerken et al. 2002; Veldman et al. 2016). Information provided by EZ indicated that from 2009 to 2014, there were 125 (out of a total of 395) *S. Typhimurium* bovine salmonellosis serotypes reported. DT104 has been isolated in cattle, pigs, poultry and horses in the Netherlands (van Duinkerken et al. 2002; Vo et al. 2007). The prevalence of DT104 had increased from 1984 to 2001, so that in 2001 it was responsible for 10 per cent of bovine salmonellosis (van Duinkerken et al. 2002). Since then there is no information on the prevalence of DT104 in cattle or beef, however outbreaks of beef associated DT104 food-borne disease have been reported (Kivi et al. 2007).

In the Netherlands, extensive surveillance for *Salmonella* spp. is carried out by the National Institute of Public Health and the Environment (RIVM) and the EU reference laboratory. Random selections of *Salmonella* spp. isolate samples from cattle and beef are sent to the RIVM as part of the Monitoring of Antimicrobial Resistance and Antibiotic Usage in Animals in the Netherlands (MARAN) reports. In addition, European Union regulations prescribe sampling and testing requirements, and set limits for the presence of *Salmonella* spp. in specific food categories. Surveillance of retail beef in 2013 found that 2 out of 435 samples tested positive for *Salmonella* spp. (EFSA & ECDC 2015a). In 2014, 0 out of 420 retail beef samples were positive for *Salmonella* spp. contamination (EFSA & ECDC 2015b). Monitoring for *Salmonella* spp. at the abattoir is only performed if required by the importing country.

New Zealand

In New Zealand, only exotic *Salmonella* spp. serotypes are notifiable. Prevalence of *Salmonella* spp. in healthy cattle is considered low. In a recent study involving dairy farms across New Zealand, only 4.1 per cent of the 97 farms was positive for *Salmonella* spp. (Al Mawly et al. 2015). *S. Typhimurium* is the most frequently identified serotype isolate from cattle in New Zealand (ESR 2014). The New Zealand Ministry for Primary Industries (MPI) confirmed that *S. Typhimurium* DT104 infections in cattle are rare and the serotype is considered exotic to New

Zealand. MPI indicated that the last reported case of bovine *S. Typhimurium* DT104 was in August 1998, and that *S. Newport* is rarely reported in cattle and is also considered exotic in New Zealand. A study of uncooked retail meat in New Zealand found a low prevalence of *Salmonella* spp. contamination in beef (1 out of 232 samples) and unweaned veal (1 out of 183 samples (Wong et al. 2007).

In New Zealand, slaughter establishments for large animals (such as cattle) are required to have risk management programmes in place to control the hazards to public health including salmonellosis. The National Microbiological Database (NMD) programme was established to monitor organisms which pose a food safety risk. The NMD is a mandatory industry programme for all New Zealand primary processors of meat, poultry, game and ratites for both local and export markets. Under the NMD programme, there is mandatory testing for *Salmonella* spp. in beef carcass and carcass parts (excluding chilled carcasses), and *Salmonella* performance standards which require no *Salmonella* spp. detections in beef carcass and carcass products (MPI 2015b). All *Salmonella* spp. isolated under the NMD programme must be sent to the Institute of Environmental Science and Research (ESR) for serotyping. In addition all isolates belonging to internationally recognised multidrug resistant phage types (such as DT104) are tested for antimicrobial resistance by the ESR.

United States

In the United States, bovine salmonellosis is present and it is not a nationally notifiable disease (USDA:APHIS 2016a). The prevalence of *Salmonella* spp. positive herds is higher than the prevalence of individual subclinical carriers. A one year study of farms in 4 states (Michigan, Minnesota, New York and Wisconsin) found that 87.6 per cent of farms had at least one positive sample during the study period, whereas only 4.9 per cent of cattle were positive (Fossler et al. 2005). Similar results have been found in studies in dairy farms across the United States, and both herd and subclinical carrier prevalence may be increasing (USDA 2011). *S. Typhimurium*, *S. Newport* and *S. Dublin* are amongst the *Salmonella* spp. serotypes frequently isolated from cattle in the United States (Adhikari et al. 2009; Afema, Mather & Sisco 2015; Cummings et al. 2009; USDA 2011).

While *S. Typhimurium* is frequently found during monitoring of beef in the United States (USDA:FSIS 2015b), detection of DT104 isolates is infrequent in cattle. In a study by Wells and colleagues of 768 *Salmonella* isolates recovered, only ten isolates (1.3 per cent) were confirmed as DT104 (Wells et al. 2001). In addition, DT104 was not detected in a survey of clinically healthy dairy cattle in southwestern US in which a total of 292 *Salmonella* isolates were recovered over a year (Edrington et al. 2004). Salmonellosis by DT104 has also been occasionally reported in captive elk, dogs and cats in the United States (Foreyt, Besser & Lonning 2001; Wright et al. 2005).

In the United States, the Food Safety and Inspection Service (FSIS) has controls in place to prevent, eliminate and reduce the contamination of raw meat products with disease causing bacteria such as *Salmonella* spp. These controls include the requirement for slaughterhouse establishments and establishments that produce raw ground products (including beef) to have Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP), and *Salmonella* Performance Standards. FSIS verifies these controls using a risk based approach to focus on establishments with the highest detection rates for *Salmonella* spp. and greatest number of serotypes associated with human salmonellosis. In 2013 FSIS established the Caecal Sampling

Program, where samples of caecal contents from livestock and poultry from FSIS regulated abattoirs are analysed for presence and antimicrobial resistance of *Salmonella*, *Campylobacter*, *Escherichia coli* and *Enterococcus*. These samples are collected from dairy cattle, beef cattle, steers and heifers. Establishments are sampled based on their slaughter volume, so that the highest volume slaughterhouses will be sampled the most frequently. In 2012-13, FSIS monitoring found that *S. Typhimurium* made up 7.4 per cent (23/310) of *Salmonella* isolates from ground beef, 11.3 per cent (14/124) of beef caecal *Salmonella* isolates, and 6.8 per cent (21/310) dairy caecal *Salmonella* isolates (NARMS 2013).

Vanuatu

Biosecurity Vanuatu indicated that salmonellosis is not a notifiable animal disease in Vanuatu. In addition, Biosecurity Vanuatu confirmed that no clinical cases of *Salmonella enterica* serotypes associated with multiple antibiotic resistance in cattle have been reported in Vanuatu. A survey of bovine faecal samples from abattoirs in 1997, found that 4 out of 503 samples were positive for *Salmonella* spp. (Struthers & Troost 1998). *S. Atento*, *S. Mississippi* and *S. Ibadan* (2 isolates) were isolated in this study (Struthers & Troost 1998).

4.9.4 Current biosecurity measures in Australia

Salmonellosis is nationally notifiable in humans, and notifiable in animals in Victoria and Tasmania. The current Australian Meat Standard (FRSC 2007) requires:

- That an ante mortem inspection is carried out within 24 hours prior to slaughter.
- Animals that are not clean are not passed for slaughter or are subject to conditions to prevent cross-contamination during slaughter, dressing, post mortem and disposition.
- Slaughter and dressing to be performed in a manner that reduces the risk of contamination of carcasses and carcass parts, and ensures the food safety of meat and meat products.
- A post mortem inspection of each carcass and its carcass parts to be carried out by a meat safety inspector.
- Condemnation of the carcass and all carcass parts if evidence of salmonellosis (septicaemia septic arthritis) is found during ante or post mortem inspections.
- Handling, processing, package and storage procedures which reduce the risk of contamination of carcass and carcass parts, and ensure the food safety of meat and meat products.

The current Australian Meat Standard reduces but does not eliminate the presence of *Salmonella* spp. such as DT104 from beef carcass and carcass parts.

There are biosecurity measures currently in place to manage the risk of *Salmonella* spp. in imported pig and chicken meat. These include cooking, country or zone freedom and testing in accordance with the Food Standards Code.

4.9.5 Risk review

There is scientific evidence that DT104 is present in cattle in Japan, the Netherlands and the United States. There is no scientific evidence that DT104 is present in Australia, New Zealand or Vanuatu in cattle. There is scientific evidence that DT104 is present and can be transmitted via the beef carcass or carcass parts after ante and post mortem examination.

4.9.6 Conclusion

As there is scientific evidence that DT104 is present in some applicant countries, and that it may be transmitted via the beef carcass or carcass parts after ante and post mortem inspection, a risk assessment is required.

4.9.7 Risk assessment

Entry assessment

The following factors were deemed relevant to the possible presence of DT104 in imported beef and beef products.

- Transport of cattle (for example to slaughter facilities) may cause stress, which may increase the faecal shedding of *Salmonella* spp. (Beach, Murano & Acuff 2002).
- Faecal shedding of *Salmonella* spp. during transport and in holding pens before slaughter may result in contamination of hides of in-contact animals (Beach, Murano & Acuff 2002).
- Clinically normal adult animals may shed *Salmonella* spp. in their faeces for up to 18 months (Evans & Davies 1996).
- Ante mortem inspection would possibly detect animals with acute or septicaemic forms of salmonellosis. Ante mortem inspection would be less effective in detecting animals with chronic enteric disease.
- *Salmonella* spp. may be present on beef carcass and carcass parts due to faecal or hide contamination or cross-contamination of equipment during processing.
- Carcass inspection will detect gross (visibly detectable) faecal contamination of carcasses but not microscopic contamination.
- *Salmonella* spp. are common post-processing contaminants of beef carcass and carcass parts (Brichta-Harhay et al. 2011).
- DT104 and other *Salmonella* spp. are tolerant of adverse conditions such as chilling and/or freezing (Humphrey et al. 2011; Knudsen et al. 2011; Manios & Skandamis 2015).
- Ground beef is prepared from carcass parts from multiple animals, and trimmings and may be subjected to cross-contamination during preparation. Ground beef is reported to have higher *Salmonella* spp. contamination than other beef products (Martínez-Chávez et al. 2015).
- Physical inspection of packaged beef and beef products after arrival in Australia will not detect microscopic contamination.
- Small volumes of fresh beef and beef products are likely to be imported into Australia from the applicant countries.

Japan specific entry factors

- *S. Dublin*, *S. Enteritidis*, *S. Typhimurium* and *S. Chelone* are notifiable infectious diseases other than domestic animal infectious diseases (NIDs) in Japan.
- Information supplied by MAFF indicated that there have been 1707 notifications of nationally notifiable serotypes of *Salmonella* spp. in Japan between 2006-2014.
- Information supplied by MAFF indicated that these notifications were distributed across many prefectures in Japan, including those with high livestock density such as Hokkaido.
- Recent studies suggest that the prevalence of *Salmonella* spp. contamination on beef may be between 0.2 to 1.5 per cent depending on the assay (Hara-Kudo et al. 2013; Hiroi et al. 2012; Murakami et al. 2013).

- The DT104 prevalence in Japanese cattle is now decreasing (Kawagoe et al. 2007; Tamamura et al. 2011). In a study on *S. Typhimurium* isolated from cattle collected between 1977 to 2009, DT104 isolates made up only 27 per cent from 2000-2009, whereas from 1990-1997, they made up 82 per cent (Tamamura et al. 2011).
- Under Japanese legislation, livestock owners are required to comply with biosecurity standards prescribed by MAFF. This includes daily monitoring, animal health reporting, and at least annual inspection of herds by LHSC Animal Health Inspectors.
- Prefecture LHSC are responsible for isolation and identification of *Salmonella* spp. in samples collected from healthy and clinically ill cattle in Japan.
- Cattle herds that test positive for *Salmonella* spp. are required to undergo further testing to identify the positive cattle. However culling of *Salmonella* spp. shedding cattle is voluntary.

The Netherlands specific entry factors

- All *Salmonella* spp. infections are notifiable by farmers, veterinarians and laboratories under Dutch animal health and public health legislation to the Netherlands Food and Consumer Product Safety Authority (NVMA).
- European Union regulations prescribe sampling and testing requirements, and set limits for the presence of *Salmonella* spp. in specific food categories.
- Extensive surveillance for *Salmonella* spp. is carried out by the RIVM and the EU reference laboratory. Random selections of *Salmonella* spp. isolate samples from cattle and beef are sent to the RIVM as part of the MARAN reports.
- The Netherlands also reports *Salmonella* isolates and associated antimicrobial resistance to the European Food Safety Authority (EFSA).
- In 2014, on farm faecal monitoring of 8131 cattle in the Netherlands found a 9.63 per cent of cattle sampled were positive for *Salmonella* spp. (EFSA 2014).
- DT104 has been isolated from cattle, pigs, poultry and horses in the Netherlands (van Duijkeren et al. 2002; Vo et al. 2007).
- The prevalence of DT104 increased from 1984 to 2001, so that in 2001 it was responsible for 10 per cent of bovine salmonellosis (van Duijkeren et al. 2002). Since then there is no information on the prevalence of DT104 in cattle or beef; however, outbreaks of beef associated DT104 foodborne disease have been reported (Kivi et al. 2007).
- Surveillance of retail beef in 2013 found that 2 out of 435 samples tested positive for *Salmonella* spp. (EFSA & ECDC 2015a). In 2014, 0 out of 420 retail beef samples were positive for *Salmonella* spp. contamination (EFSA & ECDC 2015b).
- Information provided by the EZ indicated that there were 25 *S. Typhimurium* and 1 *S. Newport* isolates out of a total of 47 *Salmonella* serotypes isolated from cattle in the Netherlands in 2014. From 2009 to 2013, there were 100 *S. Typhimurium* and 7 *S. Newport* isolates out of 348 *Salmonella* serotypes isolated from cattle.
- From 2013 to 2015, *S. Typhimurium* was the most common serovar isolated from cattle (Veldman et al. 2016). *S. Newport* is less commonly isolated from cattle (Veldman et al. 2016).
- DT104 is characterised by resistance to ampicillin, chloramphenicol, streptomycin, sulphonamides and tetracycline. Under current EU legislation, streptomycin is no longer part of the mandatory panel for antimicrobial resistance profiling. As a result EU antimicrobial resistance testing no longer detects the pentaresistance profile associated with DT104. However, ACSuT resistance has declined in 2015 (Veldman et al. 2016).

- Monitoring for *Salmonella* spp. at the abattoir is only performed if required by the importing country.

New Zealand specific entry factors

- In New Zealand, exotic *Salmonella* spp. serotypes are notifiable.
- Prevalence of *Salmonella* spp. in healthy cattle is considered low. In a recent study involving dairy farms across New Zealand, 4.1 per cent of the 97 farms were positive for *Salmonella* spp. (Al Mawly et al. 2015).
- *S. Typhimurium* is the most frequently identified serotype isolate from cattle in New Zealand (ESR 2014). However DT104 infections in cattle are rare and the serotype is considered exotic by the MPI and is therefore notifiable.
- Slaughter establishments for large animals (such as cattle) are required to have risk management programmes in place to control the hazards to public health including salmonellosis.
- The MPI established the NMD programme in 1997 to monitor organisms which pose a food safety risk. The NMD is a mandatory industry programme for all New Zealand primary processors of meat, poultry, game and ratites for both local and export markets.
- Under the NMD programme, there is mandatory testing for *Salmonella* spp. in beef carcass and carcass parts (excluding chilled carcasses) and *Salmonella* performance standards have been developed (MPI 2015b). The performance standards cover the procedures for trace back and noncompliance.
- The NMD programme sampling regime varies depending on the market and commodity, and is seasonal to coincide with the seasonal nature of processing of some commodities. For the domestic market, each establishment must sample one fresh beef carcass using a multiple swab technique (3 sites) each week for at least 16 weeks beginning at the start of the processing season. Sampling of primal cuts, bulk meat and post chill carcasses is required for the export market only.
- NMD programme compliant establishments have decreased sampling windows in future seasons (weekly for 6 weeks not 16). Establishments that detect *Salmonella* spp. in a commodity or product type, must commence another 16 week sampling period.
- *Salmonella* performance standards require no *Salmonella* spp. detections in beef carcass and carcass parts (MPI 2015b).
- All *Salmonella* spp. isolated under the NMD programme must be sent to the ESR for serotyping. In addition, all isolates belonging to internationally recognised multidrug resistant phage types (such as DT104) are tested for antimicrobial resistance by the ESR.
- Antimicrobial resistance of New Zealand isolates of *Salmonella* spp. is low, with the majority (94.3 per cent) of isolates from animals, food or the environment being susceptible to all antimicrobials tested in 2014 (ESR 2014). Multidrug resistance was reported in 2.9 per cent of animal, food or environmental isolates in 2014, of which none were DT104 (ESR 2014).
- A study of uncooked retail meat in New Zealand found low prevalence of *Salmonella* spp. in beef (1 out of 232 samples) and unweaned veal (1 out of 183 samples) (Wong et al. 2007).

United States specific entry factors

- *Salmonella* spp. are prevalent in US dairy and beef operations. A 2011 study of feedlots in 12 states, found a property prevalence of 60.3 per cent and that 35.6 per cent of pen environmental samples in feedlots were positive (USDA 2011). Herd prevalence for dairies was reported as 39.7 per cent and 13.7 per cent of individual cows tested positive in an earlier study in US dairies across 17 states (APHIS 2009b).

- Available data indicate that DT104 has a low prevalence within USA herds but infected herds (i.e. in which at least one animal is infected) are reasonably common (Fossler et al. 2005; USDA 2011).
- *Salmonella* spp. were isolated from caecal samples collected from 7.9 per cent of beef cattle, and 21 per cent of dairy cattle in FSIS regulated abattoirs in 2013 (NARMS 2013).
- FSIS has controls in place to prevent, eliminate and reduce the contamination of raw meat products with disease causing bacteria such as *Salmonella* spp. These controls include the requirement for slaughterhouse establishments and establishments that produce raw ground products (including beef) to have a PR/HACCP; sampling programs to verify controls; and *Salmonella* Performance Standards.
- The *Salmonella* Performance Standards specify the percent positive level for *Salmonella* contamination in a sample set that must not be exceeded for the standard to be met. These standards are the estimation of national prevalence, based on FSIS testing programs and nationwide surveys.
- Regulatory testing for disease causing bacteria used carcass swabs of cows, bulls, steers and heifers from 1997 to 2010, and found very low numbers of positive samples. Consequently sampling in cows/bulls, and steers/heifers was suspended in 2011 and 2012 respectively. Verification sampling is now conducted in ground beef only.
- FSIS samples based on risk based criteria to focus on establishments with highest detection rates for *Salmonella* spp. and greatest number of serotypes associated with human salmonellosis.
- FSIS classifies establishments into categories based on regulatory testing. At the end of 2014, 88.4 per cent of all ground beef establishments were in category 1 (consistent process control), 6.1 per cent in category 2T (transitioning from variable to consistent process control), 4 per cent in category 2 (variable process control) and 1.5 per cent in category 3 (highly variable process control) (USDA:FSIS 2015b).
- *Salmonella* Performance Standards provide a tolerance for detection of *Salmonella* spp. in ground beef which in 2016 is 5 positive tests per 53 samples tested (USDA:FSIS, 2016). In 2014, there were 182 sets of ground beef testing conducted, with 97.8 per cent of them meeting the then *Salmonella* Performance Standards (USDA:FSIS 2015b).
- In 2013 FSIS established the Caecal Sampling Program, where samples of caecal contents from livestock and poultry from FSIS regulated abattoirs are analysed for presence and antimicrobial resistance of *Salmonella*, *Campylobacter*, *Escherichia coli* and *Enterococcus*. These samples are collected from dairy cattle, beef cattle, steers and heifers. Establishments are sampled based on their slaughter volume, so that the highest volume slaughterhouses will be sampled the most frequently.
- In 2012-13, FSIS monitoring found *S. Typhimurium* made up 7.4 per cent (23/310) of *Salmonella* isolates from ground beef, 11.3 per cent (14/124) of beef caecal *Salmonella* isolates and 6.85 (21/310) dairy caecal *Salmonella* isolates (NARMS 2013). The pentaresistance pattern (ACSSuT) associated with DT104 was present in 30 per cent of the ground beef *Salmonella* isolates, 29 per cent of the beef caecal *Salmonella* isolates and 62 per cent of the dairy caecal *Salmonella* isolates (NARMS 2013).

Vanuatu specific entry factors

Salmonellosis in cattle is not notifiable in Vanuatu.

- Surveillance for *Salmonella* spp. in bovine faecal samples collected at abattoirs in 1997, found only 4 out of 503 samples were positive (Struthers & Troost 1998). *S. Typhimurium* was not isolated in any of these samples.

- Meat Industry (Approved Establishments) Regulations in Vanuatu require that all carcasses of bovine animals over 6 months old must be submitted to the veterinary authority for inspection.
- Meat industry (Approved Establishments) Regulations require that cattle which show signs of a disease at ante mortem inspection which is communicable to humans or animals, or may make their meat unfit for human consumption, are not slaughtered.
- Meat industry (Approved Establishments) Regulations require that post mortem inspections must be conducted by an official veterinarian and that every part of the animal slaughtered in the approved establishment is inspected.

Conclusion

A proportion of beef and beef products imported from Japan, the Netherlands and the United States could be contaminated with DT104.

Based on the proportion of product imported from Japan, the Netherlands and the United States that is likely to be contaminated with viable DT104, and the estimated volume of trade, the likelihood of entry of DT104 with beef and beef product derived from applicant countries where DT104 is present (Japan, the Netherlands and the United States) is considered to be high.

The likelihood of entry of DT104 with beef and beef products derived from applicant countries where there is no evidence that DT104 is present in susceptible livestock (New Zealand and Vanuatu) is not considered significant. Importation of beef and beef products from New Zealand and Vanuatu with appropriate veterinary health certification is therefore considered to achieve Australia's ALOP in relation to DT104 and will not be considered further in this risk assessment.

Exposure assessment

The exposure assessment is an estimate of the likelihood of susceptible animals in Australia being directly exposed to and infected with DT104 via contaminated imported beef and beef products not consumed by humans. It is based on the estimated proportion of imported contaminated product that would be exposed to susceptible animals leading to an incident case. The exposure assessment also describes the plausible biological pathways necessary for that exposure.

DT104 is a significant pathogen of humans. Aspects relating to the direct exposure of contaminated imported beef and beef products to humans will be assessed separately by the Department of Health (DoH).

Most steps in the exposure pathways are product dependent, not pathogen dependent. The product dependent factors are discussed in the exposure assessment section of Chapter 2 "Method". Pathogen specific factors relevant to steps in the pathways are discussed in the following sections. Both product dependant and pathogen dependant aspects will be considered in this exposure assessment to estimate the likelihood of susceptible animals becoming infected due to exposure to contaminated imported beef and beef products.

DT104 specific factors affecting exposure to the disease agent in imported beef and beef products *Distribution*

- Only small volumes of beef and beef products are likely to be imported into Australia from applicant countries.

- Imports of primal cuts of beef are likely to be very high value product and waste generated would be very low. Ground beef would be a lower value product although would generate proportionally less waste.
- During preparation of beef carcass and carcass parts for sale and processing, trimming might result in removal of some lymph nodes which may harbour *Salmonella* spp. (Gragg et al. 2013). However, much of the trimmed material would probably be used in processed or ground beef. Trimmings not directed for human consumption would be discarded for disposal.

Consumer

- Excess fat, sinew, lymph nodes and bone are in many cases removed before cooking beef and disposed of, leaving mainly muscle tissue for food consumption.
- *Salmonella* spp. are susceptible to heat treatment; however, meat must be adequately cooked to destroy the bacteria. *Salmonella* spp. can proliferate in temperatures up to 46.2 °C (FSANZ 2013). Higher fat content meat may increase the tolerance of DT104 to temperatures of up to 58 °C (Juneja & Eblen 2000). Meats cooked rare or medium-rare are cooked to a core temperature of 50–55 °C. Otherwise meat and offal are cooked (for example, stewed, slow-cooked) to a core temperature exceeding 70 °C.
- Consumption of undercooked beef products (for example steak tartare, biltong) is associated with transmission of DT104 to humans (Kivi et al. 2007; Mindlin et al. 2013).
- Unconsumed cooked foods are usually disposed of as rubbish, petfood or via in-sink food waste disposal units.

Disposal

- *Salmonella* spp. are resistant to desiccation (Margas et al. 2014) and capable of prolonged survival in dust, feedstuffs and other organic substrates (Radostits et al. 2007a).
- *Salmonella* spp. are also capable of prolonged survival in frozen storage (Manios & Skandamis 2015).
- *Salmonella* spp. are inactivated by heat and sunlight. However, it is probable some *Salmonella* spp. would survive in uncooked or partially cooked beef and beef products protected in rubbish bins and other waste containers.

Management of material not consumed as food

Beef and beef products not consumed as food could be disposed of as follows:

- Disposal of unconsumed material in landfill — *Salmonella* spp. can survive for several months in cold, dark environments but are susceptible to inactivation by sunlight and heat. DT104 has demonstrated greater survival to temperature extremes when attached to muscle (Humphrey 2001; Humphrey, Wilde & Rowbury 1997; Kinsella et al. 2007). Consequently, it is probable that *Salmonella* spp., including DT104, would survive in beef waste in landfill should animals locate and consume it.
- Disposal of unconsumed material as scraps, litter and bait — *Salmonella* spp. use stress responses to adapt to environmental conditions, but are inactivated by heat and sunlight. DT104 has demonstrated greater survival to temperature extremes when attached to muscle (Humphrey, Wilde & Rowbury 1997; Kinsella et al. 2007). Consequently, in temperate environments in Australia it is probable that DT104 would survive in beef waste disposed of as scraps, litter and bait by the time animals locate and consume it.
- Recycling of unconsumed material by rendering — the rendering process destroys *Salmonella* spp..

- Recycling of unconsumed material as petfood — most petfoods are sold as retorted food or processed dry food. Raw or undercooked beef and beef products may be fed to pets. Infection of household pets (cats and dogs) with DT104 is well documented (Wright et al. 2005).

Factors affecting exposure of susceptible animal groups to DT104 in imported beef and beef products

In 1996, a voluntary ban of the feeding of ruminant-derived meat and bone meal (MBM) to ruminants was implemented as a measure to protect the national herd against BSE. Legislation to enforce the ban was introduced in each Australian jurisdiction in 1997. In accordance with international recommendations the ruminant feed ban was subsequently expanded to an inclusive ban on the feeding to ruminants of all vertebrate-derived meals. However, MBM is a rendered (heat-treated) product. Any *Salmonella* spp. present in beef and beef products used in MBM production would be inactivated by the rendering process.

Domestic pigs, companion animals (cats, dogs, horses and birds) and poultry are also susceptible to infection by DT104 (Liebana et al. 2002; Philbey et al. 2014; Wright et al. 2005). Within this exposure group, small holdings of pigs (backyard and/or small commercial piggeries), backyard poultry and companion animals (mainly cats and dogs) were considered to be most at risk of exposure. Food containing beef and beef products has been inadvertently fed to pigs exhibited at agricultural shows by members of the public, and illegal swill-feeding of pigs by producers has also been reported (Schembri et al. 2010).

There is a potential pathway for imported beef and beef products to all livestock species via feedstuffs that are contaminated with MBM derived from the imported products. However, this pathway will not be considered further as rendering would effectively inactivate *Salmonella* spp. (including DT104).

The most probable exposure pathways of domestic ruminants is considered to be via contaminated scraps, baits and litter.

The most probable exposure pathway of non-ruminants was via the feeding of meat scraps. Susceptible species include pigs, poultry and companion animals (for example, dogs and cats).

The most probable exposure pathway of wild and feral animals was via scavenging for scraps, litter and/or bait, or for waste at landfills and rubbish tips in peri-urban and remote regions.

Chapter 2 discusses possible exposure pathways. It describes the distribution of beef and beef products, disposal and waste management, Australia's controls on ruminant derived MBM, potential exposure groups and other factors affecting exposure.

Facts relevant to an estimate of the likelihood of susceptible animals being directly exposed to and infected with DT104 via imported beef and beef products include:

- *Salmonella* spp., including DT104, can infect susceptible animals of all ages. Infection is usually by oral ingestion of contaminated materials (for example, pasture, feed, water). This may occur via direct consumption of contaminated meat products (omnivores, carnivores) or in herbivores via consumption of contaminated materials (for example, pasture, feed, water).

- In temperate environments in Australia, *Salmonella* spp. are capable of persisting in the environment for a considerable time in beef waste disposed of as scraps or litter, potentially sufficient to enable transmission to occur.
- Although feeding of swill containing meat and meat products to pigs and poultry is banned in all jurisdictions, illegal feeding does occasionally happen (Schembri et al. 2010).
- Metropolitan landfills are under the control of local councils and are usually fenced and covered, and managed to prevent access by wild and feral animals. Rural landfills may be less well controlled.
- People in peri-urban areas without access to roadside waste collection generally dispose of food waste by feeding it to their pets, pigs and poultry, by composting or at small rubbish tips.
- Domestic ruminants are unlikely to have direct access to waste from imported beef and beef products. In addition, salmonellosis in domestic ruminants due to direct exposure to discarded meat and meat products prepared for human consumption has not been confirmed or suspected.
- Feral pigs have been observed to scavenge private rubbish tips in some peri-urban, rural and remote areas and other feral animals (for example, dogs, cats, foxes, birds and rodents) may also scavenge for meat and meat products in this manner.
- Rendering is an effective method for inactivation of *Salmonella* spp. (including DT104). Also, Australia's ruminant feeding regulations reduce the likelihood of ruminants being exposed to MBM. Therefore, MBM derived from imported beef and beef products is not considered a significant source of DT104.

Conclusion

Based on these exposure factors, imported contaminated beef and beef products:

- do not have a significant potential exposure pathway to domestic ruminants.
- do have a significant potential exposure pathway to domestic non-ruminants, especially backyard and/or small commercial piggeries, backyard poultry and companion animals (mainly cats and dogs).
- do have a significant potential exposure pathway to wild and feral animals.

The potential for exposure to domestic non-ruminants, wild and feral animals would be considerably lower for high value beef (for example, primal cuts) compared with ground beef and other lower value products.

The likelihood of exposure of domestic ruminants with imported contaminated beef and beef products leading to clinical cases is considered negligible.

The likelihood of exposure of imported contaminated beef and beef product to domestic non-ruminants, and wild and feral animals leading to a clinical case is considered low.

Consequence assessment

The consequence assessment considers both the likelihood and consequences (impacts) of establishment and spread of the disease (outbreak) as a result of exposure to contaminated imported product (the incident cases).

Both direct and indirect effects (animal health, environmental and socioeconomic) are considered in assessing consequences.

Likelihood of establishment and spread

The following are relevant to estimating the likelihood of establishment and spread (i.e. an outbreak) following exposure and infection of susceptible animals with DT104:

- DT104 has not been reported in Australian livestock or products derived from Australian livestock (Barlow & Gobius 2008).
- Salmonellosis due to DT104 is not nationally notifiable in animals (Department of Agriculture and Water Resources 2016c).
- Bovine salmonellosis due to *S. Typhimurium* and other *Salmonella* serotypes (for example, Dublin, Zanzibar, Bovismorbificans, Newport) occurs in Australia (Izzo, Mohler & House 2011) and is not nationally notifiable.
- Pigs and poultry are also hosts of DT104 (Liebana et al. 2002). Porcine salmonellosis due to *S. Typhimurium* and other *Salmonella* serotypes (for example, Anatum and Infantis) occurs in Australia (Bensink, Ekaputra & Taliotis 1991; Ward et al. 2013), and is not a nationally notifiable disease. The poultry *Salmonella* diseases, pullorum (*S. Pullorum*) and fowl typhoid (*S. Gallinarum*), are not present in Australia and are notifiable (Department of Agriculture and Water Resources 2016c).
- DT104 has also been reported in horses in other countries (Niwa et al. 2009; Vo et al. 2007). Only equine salmonellosis by the serotype Abortusequi is nationally notifiable in Australia (Department of Agriculture and Water Resources 2016c).
- DT104 has a broad host range and is capable of infecting most species. In addition to domesticated livestock, feral pigs, foxes, dogs, cats, wild birds and wildlife would be susceptible to infection (Bensink, Ekaputra & Taliotis 1991; Iveson et al. 2014; Pennycott, Park & Mather 2006; Philbey et al. 2014; Ward et al. 2013; Wright et al. 2005).
- In the event of detection of new subtypes of *S. Typhimurium* (for example, DT104) in domestic or wild susceptible animals, there is no national strategy to conduct eradication.
- Faecal shedding by infected animals, especially cattle, would probably result in environmental contamination and facilitate the spread of infection to in-contact cattle, as well as other in-contact animals.
- Infection with DT104 can result in a persistent carrier state of up to 18 months (Evans & Davies 1996) further facilitating spread when infected and carrier animals are moved.
- Cattle movement is a feature of the beef cattle industry in Australia. Between 2002 and 2004, nearly six million cattle were moved through cattle saleyards each year and over 300 000 non-slaughter cattle were moved per annum to and from Western Australia, Northern Territory and Tasmania (Services 2006).
- Establishment and spread within pig herds would be facilitated by movement of pigs for breeding and/or fattening.
- Wildlife and feral animals may be infected by *Salmonella* spp. such as DT104 (Bensink, Ekaputra & Taliotis 1991; Iveson et al. 2014; Ward et al. 2013) but are not considered to be more susceptible or to have a more important role than livestock in the epidemiology of DT104 (Poppe et al. 1998; Rabsch et al. 2002).
- *Salmonella* spp. serotypes, including DT104, can be identified at reference laboratories in Australia.
- The Escherichia coli and *Salmonella* monitoring programme (ESAM) requires all export establishments to collect and analyse samples from carcass surfaces of livestock slaughtered in Australia for counts of aerobic colonies, *E. coli* and *Salmonella* spp..

- There are state based monitoring and accreditation programmes for *Salmonella* spp. in poultry.
- Consumption of raw or undercooked meat products that have been contaminated by DT104 may lead to cases of human salmonellosis.

Following exposure of domestic ruminants, pigs, poultry or feral pigs to DT104, there is potential for the infection to establish and spread to other livestock populations through movement of infected animals before infection was diagnosed. Animal health authorities would then consider the feasibility and effectiveness of implementing strategies to minimise disease agent spread. As a subclinical carrier state may persist for up to 18 months, it is doubtful that effective measures, other than prohibition of movement of susceptible livestock from affected states/territories, could be implemented.

The movement of feral animals across state/territory borders may be reduced but not prevented. Some control might be achieved by culling of feral animals (for example, pigs). However, DT104 may become endemic within the feral pig herds, and in other feral animals and wildlife.

In the event of infection of susceptible animals due to direct exposure to contaminated imported product, there is potential for outbreaks to occur leading to DT104 becoming established in Australia. Based on the above establishment and spread factors, the likelihood for DT104 to become established in Australia following an individual incident case is considered to be **low**.

Consequences of outbreaks

The previous section on the likelihood of establishment or spread of DT104 identified plausible outbreak scenarios.

Adverse effects (consequences) associated with an outbreak of DT104 were evaluated in terms of seven (two direct and five indirect) criteria which have animal health, environmental and socioeconomic impacts (Chapter 2).

The following outbreak scenario was assessed as the most plausible and with the most potential to occur with significant consequences:

DT104 establishes in the directly exposed animal population, spreads to other populations, including other exposure groups, is not eradicated and becomes endemic in Australia.

The main factors considered with this scenario are impacts within the livestock population. As it is a zoonosis, there may also be significant human health impacts which will be considered separately by the DoH.

Direct effects

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

- Bovine salmonellosis due to infection with *S. Typhimurium* is an important infectious disease of cattle that is already present in Australia. DT104 is not present in Australia's livestock population.
- In the literature reviewed, no evidence was found that DT104 is more pathogenic to animals than other strains of *S. Typhimurium* that are present in Australia

- Available evidence indicates that DT104 may establish a carrier state for up to 18 months in cattle (Evans & Davies 1996) thereby facilitating establishment and spread.
- DT104 is more resistant to adverse conditions such as low pH and temperature extremes than other *Salmonella* spp. (Humphrey et al. 2011; Humphrey, Wilde & Rowbury 1997; Knudsen et al. 2011), increasing the transmission potential of environmental contamination.
- Animals that recover from infection with one strain of *S. Typhimurium* may possess cross-immunity against other strains of *S. Typhimurium* (Kingsley & Bäumlér 2000).
- DT104 is characterised by resistance to at least five antimicrobials (ampicillin, chloramphenicol, streptomycin, sulphonamides and tetracycline). Horizontal transfer of the SGI1 (which includes these resistance genes) has been suggested to transfer antimicrobial resistance to between *Salmonella* spp. (Hur, Jawale & Lee 2012; Levings et al. 2005). Multiple antimicrobial resistance may result in an increased mortality rate in clinical cases where antibiotic treatment is indicated (for example septicaemia, acute enteritis).
- Infection in pigs with *S. Typhimurium*, including DT104, is often subclinical. Clinical disease is more likely to occur in piglets and is characterised by anorexia, vomiting, pyrexia and diarrhoea. The reported mortality rate for swine salmonellosis is variable but morbidity and mortality are higher for clinical cases.
- Infection in feral animals and wildlife would probably be sporadic and, based on other strains of *Salmonella* spp. that are present in Australian feral animals and wildlife, mild or subclinical. Sporadic high mortality events associated with salmonellosis have been reported in wild birds (Pennycott, Park & Mather 2006).
- Management practices to prevent or reduce the occurrence of salmonellosis in livestock enterprises in Australia will also be effective in preventing or reducing the occurrence of DT104.

Based on these factors, the effect to Australia on the life or health (including production effects) of livestock populations in Australia of outbreaks of DT104 is considered to be **very low**.

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

- There is no evidence of a significant environmental impact of DT104 in any of the literature or reports reviewed.
- Although DT104 has a broad host range, there is no evidence that DT104 would have a more significant effect on the environment than other *S. Typhimurium* phage types already present in Australia. Consequently, DT104 is not considered to have any direct effect on the environment.

Based on these factors, the effect to Australia on the living environment of outbreaks in Australia of DT104 was estimated to be negligible.

Indirect effects

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

- Salmonellosis caused by DT104 is not a nationally notifiable animal disease in Australia.
- In the event of detection of DT104, there is no formal national strategy to conduct eradication.
- Due to public health concerns there may be an increased focus on processing standards and monitoring for antimicrobial resistant pathogens at food processing establishments. This would require the involvement of relevant national and state/territory food safety agencies.

- Although there is limited domestic consumption of meat from feral animals (game meat) in Australia, public health concerns may also lead to an increased focus on processing standards and monitoring for antimicrobial resistant pathogens in game abattoirs.

Based on these factors, the effect to Australia of eradication, control, monitoring or surveillance and compensation strategies or programs to address outbreaks in livestock in Australia of DT104 was estimated to be **very low**.

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

- As a result of detecting DT104, it is not anticipated that restrictions would be imposed on the sale or movement of livestock from infected and potentially infected properties.
- If human cases of DT104 salmonellosis were diagnosed, and attributed to contaminated meat, adverse publicity may result in a small to moderate decrease in human consumption of meat causing some disruptions to the domestic trade and industry. The effect on public opinion would be similar to other food safety contamination issues. The disruption to consumption is likely to be temporary.

Based on these factors, the effect to Australia on domestic trade or industry of outbreaks in livestock in Australia of DT104 was estimated to be **very low**.

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

- DT104 is present in livestock populations in most countries. Its detection in Australia is unlikely to result in any reduction in access to international markets for live cattle or beef and beef products or other livestock commodities including pork and poultry.
- It is anticipated that existing food processing requirements and standards would continue to apply to meet international market requirements.
- Under ESAM, all export establishments test carcasses of livestock slaughtered in Australia for aerobic colony counts, *E. coli* and *Salmonella* spp..
- The presence of DT104 in Europe, Japan and the United States does not appear to have had any significant effect on international trade in meat or livestock. Nonetheless, additional measures to minimise carcass contamination may need to be implemented at all export abattoirs.

Based on these factors, the effect to Australia on international trade of outbreaks in livestock in Australia of DT104 was estimated to be **very low**.

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

- As a national eradication program is not anticipated, there would be no discernible indirect effects on the environment (including biodiversity) associated with disposal of carcasses and decontamination.
- Industry standard disinfection and decontamination procedures would be undertaken on infected properties to reduce bacterial contamination. This is not expected to affect the environment.

Based on these factors, the effect to Australia on the environment of outbreaks in Australia of DT104 was estimated to be **negligible**.

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

- The beef, dairy, pork and poultry industries are important to the economies of many local communities in Australia.
- It is doubtful that the effects of widespread establishment of DT104 in livestock would significantly differ from the effects of other *S. Typhimurium* serotypes present in Australia.
- No significant effects are anticipated at abattoirs that process either domestic or feral animals (for example, pigs) for export.

Based on these factors, the effect to Australia on communities of outbreaks of DT104 in livestock in Australia was estimated to be **negligible**.

Conclusion

Based on the above establishment and spread factors:

- In the event of infection of susceptible animals due to direct exposure to contaminated imported beef and beef products, there is a **low** likelihood of DT104 becoming established in Australia.
- The overall consequence of outbreaks in animals of DT104 in Australia is considered very low primarily associated with possible animal health, control, monitoring and surveillance strategies and programs; and an adverse effect on domestic consumption.

4.9.8 Risk Estimation

Risk estimation is the integration of likelihood of outbreaks of DT104 occurring as a result of importation of beef and beef products, and the consequences of these outbreaks.

- The likelihood of entry of DT104 with imports of beef and beef products from applicant countries where there is no evidence that DT104 is present in the cattle population (New Zealand and Vanuatu) is not considered significant (negligible).
 - Therefore, the importation of beef and beef product from New Zealand and Vanuatu with appropriate veterinary health certification is considered to achieve Australia's ALOP in relation to DT104.
- The likelihood of entry of DT104 with imports of beef and beef products from applicant countries where DT104 is endemic (Japan, the Netherlands and the United States) is considered to be high. The likelihood of entry would be higher with ground beef and low value mixed beef pieces compared to primal beef cuts.
- The likelihood of exposure of domestic ruminants with imported contaminated beef and beef products leading to clinical cases is considered negligible. However, there is a significant exposure pathway of imported contaminated beef and beef product to domestic non-ruminants, and wild and feral animals, especially backyard and/or small commercial piggeries, backyard poultry and companion animals (mainly cats and dogs). The likelihood of exposure of an imported contaminated beef or beef product to these exposure groups leading to an incident case is considered to be low.
- Based on the estimated likelihood of entry and the likelihood of exposure, the likelihood of entry and exposure of DT104 with imports of beef and beef products from applicant countries where DT104 is endemic (Japan, the Netherlands and the United States) is considered to be low. The potential for exposure to domestic non-ruminants, and wild and feral animals would be considerably lower for high value beef (for example, primal cuts) compared with ground beef and other lower value products. However, ground beef may be less likely to lead to waste than higher value products.

- In the event of infection of susceptible animals due to direct exposure to contaminated imported product, there is potential for DT104 becoming established in Australia.
- The likelihood for DT104 to establish and spread in Australia following an individual incident case is considered to be low.
- Based on an estimated low likelihood of entry and exposure and the low likelihood of establishment and spread, the likelihood for DT104 becoming established in Australia due to imports of beef and beef products from applicant countries where DT104 is endemic (Japan, the Netherlands and the United States) is considered to be very low.
- The overall consequence of outbreaks in animals of DT104 is considered very low primarily associated with possible animal health, control, monitoring and surveillance strategies, and programs; and adverse effects on domestic consumption.

Using Table 2 the overall likelihood of outbreaks occurring (very low) was combined with the consequences of the outbreaks (very low), which resulted in a risk estimation of negligible. Therefore, the importation of beef and beef product from Japan, the Netherlands and the United States with appropriate veterinary health certification is considered to achieve Australia's ALOP in relation to animal biosecurity issues relating to DT104.

Table 2 Risk estimation matrix

Likelihood of pest entry, establishment and spread	Consequences of pest entry, establishment and spread					
	Negligible	Very low	Low	Moderate	High	Extreme
High	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Moderate	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Low	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk	High risk
Very low	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
Extremely low	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
Negligible	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk

However, there is also a direct pathway to humans as the product is specifically imported for human consumption. A small but significant proportion of imported meat would be consumed raw or rare. Preliminary analysis of the risk to human health associated with imports of beef and beef products from Japan, the Netherlands and the United States has shown that there is an unrestricted risk that needs to be managed. Further analysis is currently being conducted to assess this risk more fully.

Importation of these products from Japan, the Netherlands and the United States does not achieve Australia's ALOP with respect to human biosecurity and risk management is required to address this risk.

4.9.9 Risk management measures

New Zealand and Vanuatu

The overall unrestricted risk of DT104 associated with importation of beef and beef products from applicant countries where DT104 is not present in the livestock population (New Zealand and Vanuatu) is considered **not significant** and therefore achieves Australia's ALOP.

No DT104 risk management measures are warranted for beef and beef products imported from New Zealand and Vanuatu.

Japan, the Netherlands and the United States

The overall unrestricted risk of DT104, relevant to animal biosecurity, associated with imports of beef and beef products from applicant countries where DT104 is present in the livestock population (Japan, the Netherlands and the United States) is considered **negligible**.

No specific DT104 risk management measures are warranted for beef and beef products imported from Japan, the Netherlands and the United States to address animal biosecurity concerns.

Preliminary analysis of the risk to human health associated with imports of beef and beef products from Japan, the Netherlands and the United States has shown that there is an unrestricted risk that needs to be managed. Further analysis is currently being conducted to assess this risk more fully.

The importation of beef and beef products from Japan, the Netherlands and the United States does not achieve Australia's ALOP with respect to human biosecurity and risk management is required to address this risk.

The following risk management options are considered sufficient, reasonable and practical to address the unrestricted risk to human biosecurity of DT104 from the importation of beef and beef products from countries where it is endemic in livestock, for example in Japan, the Netherlands and the United States:

- The country of origin must have a documented, regulated *Salmonella* surveillance and reduction system with specified *Salmonella* performance standards which is deemed acceptable by the Australian Government through audit and equivalence determinations, in abattoirs processing beef for export to Australia; and
- An agreed pre-export sampling and testing regime for *Salmonella* Typhimurium, with regard to DT104 or an equivalent regime as assessed by the Department of Agriculture and Water Resources.

4.10 Vesicular stomatitis

4.10.1 Background

Vesicular stomatitis (VS) is an insect-transmitted viral disease that primarily affects horses, cattle, and pigs. The infective agent is vesiculovirus (VS virus), a single-stranded RNA virus in the genus *Vesiculovirus* of the family Rhabdoviridae (Tordo et al. 2005). Two serologically distinct serotypes exist, Indiana (IND) serotype (with three subtypes) and New Jersey (NJ) serotype (OIE 2015; Reis et al. 2009).

VS is a notifiable disease in Australia (Department of Agriculture and Water Resources 2016c) and has never been reported in Australia. In 2014, the OIE General Assembly elected to remove

VS from the OIE disease list on the basis that it did not meet the listing criteria adopted in 2012 (OIE 2014a). Australia considers it significant for trade reasons because clinically it is indistinguishable from foot-and-mouth disease (Reis et al. 2009).

VS virus (VSV) causes vesicular disease in equids (donkey, horse, mule), cattle and pigs. Goats and sheep are more resistant to clinical disease and are rarely affected (Reis et al. 2009). Antibodies to VS virus have been detected in a wide range of vertebrate species including primates (human and non-human), bovids, camelids, coyotes, foxes, dogs, hamsters, marsupials, rodents and birds (Jimenez et al. 1996; Johnson, Tesh & Peralta 1969). In addition, the virus has been isolated from many haematophagous and non-haematophagous insect species including sand flies, black flies, mosquitoes, culicoides, house flies, eye gnats and grasshoppers (Drolet, Stuart & Derner 2009; Rodriguez 2002). A component of the saliva of some insects (for example, black flies) may enhance VS virus replication and transmission (Reis et al. 2009). VS has not been reported in bison and buffalo.

VS is limited to the American continents although outbreaks have been described in Europe and South Africa from the late 1800s to mid 1900s associated with the export of horses from the United States (OIE 2015; Reis et al. 2009).

The NJ and IND-1 serotypes are endemic in livestock in areas of southern Mexico, Central America, Bolivia, Venezuela, Colombia, Ecuador and Peru, with the NJ serotype causing the majority of the clinical cases. Sporadic activity of NJ and IND-1 serotypes has been reported in northern Mexico and the western United States. IND-2 has only been isolated in Argentina and Brazil and only from horses. IND-3 subtype has been identified sporadically, in Brazil only where it is reported to cause disease more frequently in horses than cattle (Reis et al. 2009).

VS is zoonotic and can cause an influenza-like illness in humans who come into direct contact with infected livestock (Letchworth, Rodriguez & Barrera 1999; Reif et al. 1987).

4.10.2 Technical information

Agent properties

VS virus is resistant to freezing while susceptible to sunlight, ultraviolet light, formaldehyde and most disinfectants (Hanson 1952).

The virus is stable for prolonged periods at low temperatures (Galasso 1967), able to survive in soil at temperatures ranging from 4–6 °C but is inactivated by exposure at 58 °C for 30 minutes (McCluskey & Mumford 2000; Shahan 1946). Another study found that VS virus was inactivated within four minutes at 55 °C or 20 minutes at 50 °C (Zimmer, Summermatter & Zimmer 2013). When inoculated into fermented edible waste material, the virus was inactivated within two hours of incubation at various temperatures ranging from 5–30 °C (Wooley et al. 1981). This was proposed to be the result of enzymes within the waste material or its low pH. Zimmer, Summermatter and Zimmer (2013) also demonstrated VSV survival for up to eight days when dried onto glass and polystyrene at 22 °C. Survival on stainless steel was between six and eight days.

Epidemiology

Epidemiological data indicate that in cattle herds where the disease is endemic, up to 90 per cent of animals may be seropositive with only 10 per cent presenting typical clinical signs (Reis et al. 2009). Cattle and horses under one year of age are rarely affected clinically. Mortality is close to

zero in both cattle and horses, although high mortality rates have been observed in pigs affected by the NJ serotype (OIE 2015). Morbidity rates vary widely between outbreaks and can be as high as 96 per cent (Reis et al. 2009).

It is generally assumed that animals acquire infection either through the bite of an infected competent insect vector, exposure to a clinically affected host (McCluskey & Mumford 2000; Smith et al. 2012), or possibly ingestion of immature stages of grasshoppers infected with VS virus (Drolet, Stuart & Derner 2009).

Due to the lack of detectable viremia, the natural transmission of VS virus to vectors is not well understood. Mead (2000) demonstrated horizontal transmission between infected and uninfected flies that fed concurrently on non-viraemic deer mice. Smith et al. (2013) confirmed that flies acquire the virus by feeding on active lesions but also that un-infected flies contracted the virus after feeding on sites where infected flies had previously fed. The sites were shown to remain infectious to recipient flies for at least 24 hours, even in the absence of lesions.

Vesicular fluids contain extremely high concentrations (in excess of 10⁸ TCID₅₀/mL) of virus (Clarke, Stallknecht & Howerth 1996; Scherer et al. 2007) and prominent vesicular lesions are necessary for efficient animal-to-animal contact transmission (Reis et al. 2009). Within herd spread is facilitated by direct contact with clinically affected animals and contact with contaminated fomites (for example feed, water troughs), the virus being shed in saliva and lesions (Leder et al. 1983; Smith et al. 2012).

Pasture grasses can harbour viable VS virus. Grasshoppers fed on contaminated plant meal were found to harbour viable virus at least 28 days after feeding (Nunamaker et al. 2003). Grazing cattle consume significant numbers of grasshoppers during the insect's immobile moulting phases (Drolet, Stuart & Derner 2009), providing a plausible basis for a cattle-grasshopper-cattle transmission cycle. Pfadt, cited by Drolet, Stuart and Derner (2009), explains that migratory grasshoppers are known to travel greater than 48 km per day which could explain the pattern of VSV spread to distant areas during outbreaks.

Geographical disease spread tends to follow natural features such as valleys and rivers rather than predictable human or animal routes (Letchworth 1996). Experience in the United States is that, during outbreaks, a majority of VS positive premises are not contiguous with other VS positive premises (McCluskey, Hurd & Mumford 1999; Velazquez-Salinas et al. 2014) demonstrated the migration of a particular genetic lineage of virus from endemic areas of Mexico northward to the United States where it caused outbreaks.

Viraemia (after experimental infection) has been reported in rodents, including laboratory mice, spiny rats, Syrian hamsters and deer mice and it has been suggested that deer mice and/or other native American rodents may be involved in the epidemiology of VS (Cornish et al. 2001).

VS may be distinguished epidemiologically from foot-and-mouth disease as the latter does not cause disease in horses (Reis et al. 2009; Schmitt 2002).

Pathogenesis

The course of disease depends on the site of inoculation. Clinical disease occurs after an incubation period of one to three days. Infected insects bite susceptible livestock on the mouth, nostrils or coronary band area and vesicular lesions develop (Mead et al. 2009; Scherer et al. 2007; Smith et al. 2012). By contrast, insect feeding (and viral inoculation) at the flank, neck, ear

and peri-ocular areas does not cause the formation of vesicles but the development of low levels of neutralising antibody (Mead et al. 2009; Smith et al. 2012). Infection of susceptible hosts appears to be enhanced by minor abrasions or trauma to skin or mucosal surfaces when compared to inoculation of unbroken surfaces (Howerth et al. 2006). Lesions typically resolve after seven to 14 days (McCluskey & Mumford 2000).

Viral shedding from an active lesion appears to cease within six to seven days after lesion formation (Katz et al. 1997; Smith et al. 2012). Persistent shedding of infective VS virus from recovered animals is not known to occur (McCluskey & Mumford 2000). Viraemia has not been detected in cattle, horses or pigs as a result of infection (Mead et al. 2009; Scherer et al. 2007).

Diagnosis

Clinical signs

The incubation period is variable but vesicles are usually visible within 24 to 72 hours of virus inoculation (Reis et al. 2009). Clinical signs of VS in cattle, pigs and horses are mild pyrexia and the presence of vesicular lesions on the tongue, palate, gum, lips, snout (pigs), teats, prepuce, interdigital space and coronary band (McCluskey et al. 2013; Reis et al. 2009).

Oral lesions cause animals to salivate excessively and to refuse feed resulting in weight loss; lameness may occur due to interdigital lesions and coronitis (Bridges et al. 1997; Schmitt 2002). VS is rarely fatal but mastitis, anorexia, dehydration and weight loss result in significant production losses in cattle (Bridges et al. 1997).

Pathology

Pathology associated with VS is related to the vesicular lesions. The virus is epitheliotropic thus distribution is restricted to lesions of the skin, anterior alimentary tract mucosa and associated draining lymph nodes (Scherer et al. 2007).

Over time, vesicles rupture and progress to erosions or ulcerations (McCluskey & Mumford 2000).

Testing

In clinically affected livestock, VS virus can be isolated from saliva and swabs of the throat, epithelial tags from vesicular lesions and vesicular fluids (Letchworth 1996; Schmitt 2002). Viral RNA can be detected from epithelial tissue and vesicular fluid by conventional and real-time reverse-transcriptase polymerase chain reaction (RT-PCR). The preferred immunological methods for identifying viral antigens are the enzyme-linked immunosorbent assay (ELISA), the complement fixation test (CFT) and fluorescent antibody staining of epithelial tissues, inoculated embryos or cell cultures. The virus neutralisation test is more time-consuming (OIE 2015). For diagnostic specimens, real-time RT-PCR may be more sensitive than viral isolation or CFT (Letchworth 1996).

Transmission in carcase and carcase parts

VS virus has been detected in epithelial tissues and associated draining lymph nodes of experimentally inoculated cattle, hence the virus may be present in selected tissues of an infected carcase (Reis et al. 2009).

There is little data available on oral transmission of VS virus. One study explored the potential transmission of VS virus by feeding infected epithelial tissues (snout, feet and skin) to uninfected pigs. Clinical signs of infection were observed only in subjects where scarification of the skin on

the snout had occurred prior to feeding. Otherwise, subject pigs did not develop disease. It was concluded that although VS virus may be spread by the feeding of infective tissues, transmission appeared to have resulted from these tissues coming in contact with abraded skin, rather than by ingestion of the contaminated material (Patterson, Jenney & Holbrook 1955). There are no known studies that assess transmissibility in meat.

Prior to the removal of VS from the OIE Code, the OIE did not recommend any risk management measures for VS virus for international trade in meat and meat products (OIE 2013b).

4.10.3 Occurrence and control in applicant countries

Japan

VS is not present in Japan. It is a notifiable disease and is designated as a Domestic Animal Infectious Disease (DAID) under the Act on Domestic Animal Infectious Disease Control. A suspected case of a DAID is required to be immediately reported to the prefectural governor in accordance with the Act. This notification is then immediately reported to the Minister of Agriculture, Forestry and Fisheries.

Given it is a differential diagnosis for similar presenting signs as FMD, VS is noted in Japan's Guideline for Control of Specific Domestic Animal Infectious Diseases concerning FMD. Response and control measures are rapidly implemented on any suspicion of FMD.

The Netherlands

VS is not present in the Netherlands. If disease is detected, all affected and susceptible animals present on the farm must be slaughtered as per European legislation implemented under the Animal Health and Welfare Act. Vaccination against VS is prohibited.

New Zealand

VS is not present in New Zealand. It is a notifiable disease and is managed with passive surveillance.

United States

VS is present in the United States. Outbreaks of VS have occurred sporadically throughout the history of the United States with major epidemics occurring in 1889, 1906, 1926, 1937, 1963 and 1964 (Schmitt 2002). Outbreaks have tended to occur at approximately ten year intervals (Rodriguez 2002) but have been more frequent in the last decade (in 2004, 2005, 2006, 2009, 2010, 2012, 2014, 2015-2016) (USDA:APHIS 2016b).

VS is a reportable disease in all states in the United States and according to the National List of Reportable Animal Diseases (NLRAD) (USDA:APHIS 2016a). The United States Department of Agriculture, Animal and Plant Health Inspection Service Veterinary Services (USDA APHIS VS) monitors outbreaks and provides index case definitions (McCluskey et al. 2013; Pelzel-McCluskey 2015). Cases of VS are reportable to State and Federal animal health officials especially because of its similarity to other vesicular diseases such as foot and mouth disease. Once the first VS case is confirmed in a state, suspect horses are quarantined based on clinical signs without confirmatory testing. Suspect cattle are investigated by a Foreign Animal Disease Diagnostician from a State or Federal veterinary service.

Section 309.15 of the United States Code of Federal Regulations (CFR) outlines the ante mortem inspection requirements for livestock with VS (USDA:FSIS 2016a). Livestock that have been

quarantined due to vesicular disease are not permitted to be sent for slaughter until quarantine is removed. If livestock present for ante mortem inspection with VS in acute stages, these animals will be identified as condemned and removed from processing for human consumption.

Section 311.32 of the United States CFR outlines the requirements for partial or full condemnation of carcasses affected by vesicular diseases at post mortem (USDA:FSIS 2016b).

The disease occurs seasonally in the warmer months, generally between April and October and typically in the southern states of the United States, particularly in Arizona, Colorado, New Mexico, Texas and Utah (McCluskey et al. 2013). The appearance of cases outside the southern region of the United States may be associated with transport of infected livestock rather than direct contact with the disease agent in the environment (McCluskey & Mumford 2000).

Animal health data from recent outbreaks in the United States demonstrate that disease distribution and the number of clinically affected animals can vary greatly between outbreaks. Information from the USDA's APHIS webpage for VS shows that in 2012, just two mainland states and 36 premises were placed under quarantine with 51 positive horses. By contrast, in the most recent outbreak which began on 29 April 2015, eight states have been affected with 823 premises placed under quarantine (USDA:APHIS 2016b).

Vanuatu

VS is not present in Vanuatu. It is a notifiable disease.

4.10.4 Current biosecurity measures in Australia

VS does not occur in Australia and is a notifiable disease (Department of Agriculture and Water Resources 2016c). Although under review, an AUSVETPLAN disease strategy manual for VS is available on the Animal Health Australia website (AHA 1996).

Due to the potential to import live virus from horses, semen and embryos, Australia currently has import conditions for these commodities from the United States.

4.10.5 Risk review

VS is present in the United States and is not present in Australia, Japan, the Netherlands, New Zealand, or Vanuatu where it is a nationally notifiable animal disease.

The likelihood of entry of VS with imports of beef and beef products that have passed ante and post mortem inspection is considered not significant based on the following:

- subclinical infection is short-lived (about one week) and a carrier state does not occur (McCluskey & Mumford 2000)
- there is no evidence that meat tissue harbours virus particles
- United States' law requires notification of any cases of VS and quarantining of affected properties until resolution of disease
- Ante and post mortem controls in the United States substantially reduce the potential for an infected carcass to pass inspection.

4.10.6 Conclusion

Based on the preceding information, the likelihood of entry of VS with imports of beef and beef product from the applicant countries which was derived from domesticated bovines which

passed ante and post mortem inspection is considered negligible and achieves Australia's ALOP. Risk management is therefore not applicable.

5 Risk management

5.1 Introduction

Risk management measures aim to reduce the likelihood of entry, exposure, establishment and spread of disease agents of biosecurity concern. Risk management measures should either be consistent with the OIE Code or the result of a risk assessment.

The OIE Code states at Article 2.1.5 that:

Risk management is the process of deciding upon and implementing measures to address the risks identified in the risk assessment, whilst at the same time ensuring that negative effects on trade are minimised.

Australia has determined that to achieve its ALOP, the unrestricted risk estimate associated with animals and animal products must be at most 'very low'. In the risk assessment chapter, the unrestricted risk estimate was assessed for each disease agent to ascertain whether it met Australia's ALOP.

Where the unrestricted risk estimate did not achieve Australia's ALOP, risk management options were considered to reduce the risk to an acceptable level, that is, 'very low' or 'negligible'. The risk management aims to identify and evaluate measures applied alone or in combination which could be used to reduce biosecurity risks to 'very low'. Risk management may also be required as determined by the Director of Human Biosecurity to manage the risks to human life or health associated with the importation of beef and beef products.

1.1.2 Compliance or equivalence with Australian standards

As part of the risk assessment, the following standards were considered in the assessment of the unrestricted risk estimate:

- *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption* (2007) (Australian Meat Standard) (FRSC 2007).
- *Bovine spongiform encephalopathy (BSE): requirements for the importation of beef and beef products for human consumption – effective 1 March 2010* (Australian BSE requirements) (FSANZ 2010).
- *Imported Food Control Act 1992* which requires imported food to comply with the *Australia New Zealand Food Standards Code*.

Compliance with these Australian standards, or an equivalence determination as appropriate, is required in determining whether an applicant country may be eligible to export beef and beef products to Australia.

FSANZ undertakes assessments of countries to ensure compliance with Australian BSE requirements and advises the department of the BSE risk management measures required before beef and beef products can be imported. FSANZ also monitors assessed countries for any change in BSE status that may impact on a favourable BSE categorisation that was issued after finalising a BSE Food Safety Risk Assessment Report for that country. An applicant country's ability to meet the Australian Meat Standard and the *Imported Food Control Act 1992* is determined by the department through an audit process before fresh beef and beef products can be imported.

5.1.1 Competent authorities and veterinary certification

Evaluation of the competent authority (CA) and its application of relevant risk management measures is an integral component of an assessment of the biosecurity risk associated with imports from a particular country.

The department takes into account the following criteria, as well as any other relevant information, when considering the approval of countries to export animals and their products to Australia (AQIS 1999):

- the animal health status of the country
- the effectiveness of veterinary services and other relevant certifying authorities
- legislative controls over animal health, including biosecurity policies and practices
- the standard of reporting to the OIE of major contagious disease outbreaks
- the effectiveness of veterinary laboratory services, including compliance with relevant international standards
- the effectiveness of systems for control over certification/documentation of products intended for export to Australia.

OIE Code Article 5.2.2 provides guidelines on certification procedures.

5.1.2 Risk management measures for the importation of fresh beef and beef products from applicant countries

Recognition of country free status

Where the department determines that a disease agent is not present in the applicant country, certification of country freedom from the disease may be required.

When assessing country freedom, the department evaluated information derived from the applicant country, the OIE Code, the World Animal Health Information Database (WAHID), and other sources regarding the animal health status and competent authority of the applicant country and its neighbours.

For the applicant countries, the following disease agents, which were evaluated in the risk review process (Chapter 2) and deemed to be of biosecurity concern, were identified as hazards that may require certification of country freedom:

- brucellosis (*Brucella melitensis*)
- contagious bovine pleuropneumonia
- Crimean-Congo haemorrhagic fever
- foot and mouth disease
- haemorrhagic septicaemia
- lumpy skin disease
- Rift Valley fever
- surra (*Trypanosoma evansi*)
- theileriosis (*Theileria annulata* and *T. parva*)
- trypanosomiasis (Tsetse transmitted)

- Wesslesbron disease

No risk management was required for rinderpest as the disease was declared globally eradicated by the OIE in 2011.

Additional biosecurity measures

The risk assessment determined that the risk of the following disease agents with the importation of fresh beef and beef product from the applicant countries was considered negligible, provided there is compliance or equivalence with Australian standards:

- anthrax
- Aujeszky's disease
- brucellosis (*B. abortus* and *B. suis*)
- bovine tuberculosis
- bovine viral diarrhoea virus
- *Cysticercus bovis*
- echinococcosis
- paratuberculosis
- *Salmonella enterica* serotype Typhimurium DT104
- vesicular stomatitis

The department referred the above hazards to DoH and FSANZ. It was determined that *Salmonella enterica* serotype Typhimurium DT104 represented the hazard of most concern for human health.

Preliminary analysis of the risk to human health associated with imports of beef and beef products from Japan, the Netherlands and the United States has shown that the unrestricted risk to human health of DT104 is above Australia's ALOP and therefore needs to be managed.

For this disease agent, relevant information pertaining to both the animal biosecurity risk and human biosecurity risk is summarised below to provide context for proposed risk management measures.

DT104 has not been detected in Australian livestock or products derived from Australian livestock. It has never been reported in Vanuatu and is considered exotic in New Zealand. However, it is widespread in cattle populations in the United States, Japan and the Netherlands. DT104 contamination of carcasses and beef products has been documented, and outbreaks of salmonellosis in humans due to DT104 have occurred due to the consumption of contaminated beef.

Salmonellosis due to DT104 is not a nationally notifiable disease in Australia, nor is it an OIE listed disease. However, it is a serious zoonosis and the OIE recognises that multiple antibiotic resistant *Salmonella* spp. are of increasing concern in both public health and primary production.

The likelihood of entry of DT104 with imports of beef and beef products from applicant countries where DT104 is not present in the cattle population (New Zealand and Vanuatu) is not

considered significant (negligible). Risk management in relation to DT104 is not applicable to imports of beef and beef products from New Zealand and Vanuatu.

The likelihood of DT104 becoming established in Australia due to imports of beef and beef products from applicant countries where DT104 is endemic (Japan, the Netherlands and the United States) is very low. The consequences of the outbreaks in animals of DT104 are very low. Consequently, the resultant risk estimation was considered negligible. Therefore, the importation of beef and beef product from Japan, the Netherlands and the United States achieves Australia's ALOP in relation to animal biosecurity issues.

However, there is also a direct pathway to humans as the product is specifically imported for human consumption. A small but significant proportion of imported meat would be consumed raw or rare. A preliminary assessment of the risk to human health associated with imports of beef and beef products from Japan, the Netherlands and the United States has shown that the unrestricted risk to human health of DT104 is above Australia's ALOP.

Risk management is required to address this risk.

The following risk management options are considered sufficient, reasonable and practical to address the unrestricted risk of DT104 to humans from the importation of beef and beef products from Japan, the Netherlands and the United States:

- The country of origin (Japan, the Netherlands or the United States) must have a documented, regulated *Salmonella* surveillance and reduction system, with specified *Salmonella* performance standards, which is deemed acceptable by the Australian Government through audit and equivalence determinations, in abattoirs processing beef for export to Australia; **and**
- An agreed pre-export sampling and testing regime for *Salmonella* Typhimurium, with regard to DT104, or an equivalent regime as assessed by the Department of Agriculture and Water Resources.

5.1.3 Meeting Australia's food standards

Imported food for human consumption must satisfy Australia's food standards. Australian law requires that all food, including imported food such as beef and beef products, meets the standards set out in the Australia New Zealand Food Standards Code. FSANZ is responsible for developing and maintaining the Australia New Zealand Food Standards Code, including Standard 1.4.2, maximum residue limits, available on the [Legislation](#) website. The standards apply to all food in Australia, irrespective of whether it is grown domestically or imported.

5.1.4 Proposed biosecurity requirements for the importation of fresh beef and beef products from applicant countries

Eligibility

- 1) Importation under these conditions is restricted to beef and beef products from approved countries only.
- 2) Importation of beef and beef products is restricted to meat, bone and offal of domesticated American bison (*Bison bison*), buffalo (*Bubalus bubalis*—water buffalo or domestic Asian water buffalo) or cattle (*Bos taurus* and *Bos indicus*) as fresh (chilled or frozen) beef and beef products derived from fresh beef. Offal means the heart, oesophagus, organs of the abdominal cavity other than reproductive organs, the muscular tissues of the head, tissues

of the diaphragm, the tail or tendons. It specifically excludes brain, all pulmonary and reproductive organs, and udders (and associated lymph nodes). Blood and blood products, excepting that which is naturally contained in meat flesh after slaughter and bleeding, are also excluded from importation under these conditions.

- 3) Excluded from importation under these conditions (as separate requirements exist) are: milk, dairy products, gelatine and collagen derived from bovine skins and hides (including casings produced from this type of material), edible bovine fats or bovine tallows included as a minor ingredient of a processed product, natural casings, heat-processed meat-based flavours, and retorted beef and beef products for human consumption.

Documentation

- 1) Under the *Biosecurity (Prohibited and Conditionally Non Prohibited Goods) Determination 2016*, an import permit is not required for the importation of beef and beef products from New Zealand; however, all other requirements as detailed below apply.
- 2) For imports from other approved countries, a permit application to import beef and beef products must be lodged with the department. All permit applications must be lodged through BICON.
 - a) The application to import must specify the following:
 - i. the name and address of the importer and exporter;
 - ii. the name and identification number of the approved abattoir and, if applicable, approved cutting-up establishment, approved processing establishment and approved storage establishment in the approved source country;
 - iii. trade description of the cut or cuts (trade description) of the meat/product to be imported;
 - iv. the anticipated port or ports of entry of the beef and beef products.
 - b) The application will be assessed on the above criteria as well as any other criterion which is considered relevant by the Director of Biosecurity (hereinafter called the Director).
- 3) Each consignment of beef and beef product must be accompanied by:
 - a) a valid import permit issued by the Director for all approved countries except New Zealand;
 - b) an international veterinary health certificate consistent with the OIE Terrestrial Animal Health Code, signed by an Official Veterinarian of the country of export (requirements of this certification are specified below).
- 4) Any inadequacies in certification may result in the consignment being returned to the country of origin at the importer's expense or the destruction of the product without recompense.

Requirements

- 1) Each consignment must be accompanied by official certification in accordance with these requirements and will require, on arrival, an "AIMS Entry" issued by the department.
- 2) The border release from biosecurity control for each consignment will remain subject to examination of accompanying documentation and may be inspected by a Biosecurity Officer.

- 3) The product and consignment details must correspond exactly with documentation and, for applicant countries other than New Zealand, the Permit to Import.
- 4) The animals must be slaughtered and the meat prepared in establishments currently approved by the Director in the approved country. The standard of construction and facilities of the slaughter establishments, the establishment where the meat was prepared and the establishment where it was stored must meet the current Australian Standard for the Hygienic Production and Transportation of meat for Human Consumption, or any standards agreed by the department to be equivalent. The department may take into account existing approvals granted by the relevant overseas veterinary authorities.
- 5) While preparing product for Australia, establishments must conduct slaughter, preparation and storage of the meat in accordance with quality assurance principles such as the HACCP approach.
- 6) The beef and beef product for export to Australia must comply with the department's biosecurity requirements. These products must also comply with the requirements in the *Imported Food Control Act 1992*. This includes compliance with the Australia New Zealand Food Standards Code (the Code) and mandatory government certification requirements that are specified on the Department's website and that are consistent with Australia's BSE policy.
- 7) Under the *Imported Food Control Act 1992*, the department may also inspect, sample, hold and test imported beef and beef product to determine compliance with the requirements in the *Imported Food Control Act 1992*, such as labelling, packaging and food composition standards in the Code. Information on the Code may be obtained from FSANZ.
- 8) The Biosecurity Officer at the port of entry may note the number of containers which have been off-loaded at the port of call, and their identifying marks and seal numbers.

Veterinary Health Certification for fresh beef and beef product exported to Australia

Each consignment must be accompanied by a Veterinary Certificate in accordance with the OIE Terrestrial Animal Health Code signed by an Official Veterinarian.

- 1) The certificate must provide details of:
 - a) the packaging of the meat including details of the labelling, and
 - b) the addresses and identification numbers of establishments at which the animals from which the meat was derived were slaughtered, the cutting-up establishment at which it was prepared and the establishment at which it was stored prior to export, and
 - c) the names and addresses of the exporter and the consignee, and
 - d) the cut or cuts (trade description) of the meat/product in the consignment.
- 2) The Official Veterinarian of the source country must certify in English and also in a language understood by the Official Veterinarian of the approved country if required, that:
 - a) The source approved country has been assessed by FSANZ as having a Category 1 or Category 2 BSE risk status.
 - b) The cattle, buffalo or bison from which the meat was derived have been continuously resident in the <insert approved country> since birth and were slaughtered on (dates).

- c) The cattle, buffalo or bison from which the meat was derived passed ante and post mortem veterinary inspection under official veterinary supervision; the meat is considered to be fit for human consumption.
- d) All of the following risk management measures apply:
 - i. The cattle, buffalo or bison from which the meat was derived have been kept since birth in <insert approved country> which is free from foot and mouth disease without vaccination.
 - ii. The cattle, buffalo or bison from which the meat was derived have been kept since birth in <insert approved country> which is free from lumpy skin disease, Crimean-Congo haemorrhagic fever, Rift Valley fever, contagious bovine pleuropneumonia, haemorrhagic septicaemia, surra, theileriosis (*Theileria annulata*, *T. parva*), trypanosomiasis (*Trypanosoma congolense*, *T. vivax* and *T. brucei brucei*), Wesselsbron disease and *Brucella melitensis*.
 - iii. For approved countries where *Salmonella* Typhimurium DT104 is endemic in livestock (for this review: Japan, the Netherlands, and the United States):
 - the source approved country has a documented, regulated *Salmonella* surveillance and reduction system with specified *Salmonella* performance standards, which is deemed acceptable by the Australian Government through audit and equivalence determinations in abattoirs processing beef for export to Australia, and
 - a representative sample of carcasses and/or meat in the consignment has undergone pre-export testing for *Salmonella* Typhimurium DT104 with negative results in accordance with an Australian approved sampling and testing regime.
- e) The establishment(s) where the cattle, buffalo or bison from which the meat was derived were slaughtered, and where the meat was prepared and stored, have current departmental approval for facilities and hygienic operation.
- f) Officials of the Veterinary Authority of the source approved country were present in plants at all times when cattle, buffalo or bison were being slaughtered for export to Australia.
- g) The establishment where the meat was prepared did not prepare or process meat not eligible for export to Australia while meat was being prepared for export to Australia.
- h) The meat has been prepared for export and packed on (dates), and the bags, wrappers or packing containers were clean and new.
- i) The identification number of the slaughtering establishment and the establishment where the meat was prepared is readily visible on the meat or, where the meat is wrapped or packed, was marked on the package or wrapping containing the meat, in such a way that the numbers cannot readily be removed without damaging the meat, package or wrapping.
- j) The meat was not exposed to contamination prior to export.
- k) The meat is being transported to Australia in a clean packing container sealed with a seal bearing the number or mark ; the container contains only meat eligible for entry into Australia.

Review

The Department of Agriculture and Water Resources may review the import policy after the first year of trade or when there is reason to believe that the disease or phytosanitary status in the approved country has changed.

Glossary

Term or abbreviation	Definition
Appropriate level of protection (ALOP) for Australia	The <i>Biosecurity Act 2015</i> defines the appropriate level of protection (or ALOP) for Australia as a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to very low, but not to zero.
Approved country	An applicant country becomes an approved country once it has been fully assessed for the importation of this commodity into Australia. This includes receiving a favourable bovine spongiform encephalopathy (BSE) categorisation by Food Standards Australia New Zealand (FSANZ), an assessment of other human and animal biosecurity risks, undertaken respectively by the Department of Agriculture and Water Resources and the Department of Health, and subsequently a successful audit of the competent authority of the exporting country and its ability to meet import requirements.
Animal Health Australia	A not-for-profit public company that facilitates partnerships between governments, major livestock industries and other stakeholders to protect animal health and the sustainability of Australia's livestock industry. Animal Health Australia aims to keep Australia free of new and emerging diseases and to improve animal health, enhance market access and foster resilience and integrity of the Australian animal health system.
<i>The Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption 2007</i> (Australian Meat Standard)	<i>The Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption 2007</i> harmonises standards for the production and transportation within Australia of meat and meat products.
Beef	Meat derived from the whole or part of the carcase of cattle including meat flesh, bone and offal. For the purpose of this review, offal is considered the heart, oesophagus, organs of the abdominal cavity (other than reproductive organs), the muscular tissues of the head, tissues of the diaphragm, the tail, and tendons. Blood and blood products are not considered as beef in this review excepting that which is naturally contained in meat flesh after slaughter and bleeding.
Beef products	A product containing beef.
Biosecurity	The prevention of the entry, establishment or spread of unwanted pests and infectious disease agents to protect human, animal or plant health or life, and the environment.
Biosecurity measures	The <i>Biosecurity Act 2015</i> defines biosecurity measures as measures to manage any of the following: biosecurity risk, the risk of contagion of a listed human disease, the risk of listed human diseases entering, emerging, establishing themselves or spreading in Australian territory, and biosecurity emergencies and human biosecurity emergencies.
Biosecurity risk	The <i>Biosecurity Act 2015</i> refers to biosecurity risk as the likelihood of a disease or pest entering, establishing or spreading in Australian territory, and the potential for the disease or pest causing harm to human, animal or plant health, the environment, economic or community activities.
BSE risk materials	Tonsils and distal ileum from bovine animals of any age; brains, eyes, spinal cord, skull and vertebral column of bovine animals over 30 months of age as defined in the Bovine Spongiform Encephalopathy (BSE) Requirements for the Importation of Beef & Beef Products for Human Consumption – Effective 1 March 2010 (FSANZ 2010).
Carcase	The body of a slaughtered animal after bleeding.
Carcase part	Any tissue or structure removed from a carcase and includes, for example, the head, viscera, offal and blood.
Carrier state	The state of harbouring a pathogenic organism, with the ability to transmit the organism and therefore disease to other susceptible animals.

Term or abbreviation	Definition
Casings	Means intestines and bladders that, after cleaning, have been processed by tissue scraping, defatting and washing, or derived from bovine skins and hides, and have been treated with salt
Codex Alimentarius	A 'Food Code' established by the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organization (WHO) to develop harmonised international food standards, which protect consumer health and promote fair practices in food trade.
Competent Authority	The Veterinary Authority or other Governmental Authority of a Member Country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations (OIE 2016h).
Contamination	The condition of being exposed to presence of an infectious agent or foreign material that adulterates, renders impure, makes unsafe or remains on or in the item that is exposed.
Country Freedom	Within a country, the absence of a certain disease under consideration where requirements, as specified in the OIE Terrestrial Code, or determined by the Department of Agriculture and Water Resources, have been demonstrated. Within the country, appropriate official veterinary control is effectively applied for animals and animal products, and their transportation.
Domesticated animal	A domesticated animal means an animal that: (a) has been husbanded in the manner of a farmed animal; and (b) has not been killed in the field.
Emerging disease	A new occurrence in an animal of a disease, infection or infestation, causing a significant impact on animal or public health resulting from: a) a change of a known pathogenic agent or its spread to a new geographic area or species; or b) a previously unrecognised pathogenic agent or disease diagnosed for the first time (OIE 2016h).
Endemic	Belonging to, native to, or prevalent in a particular geography, area or environment.
Equivalence	The state wherein the sanitary measure(s) proposed by the exporting country as an alternative to those of the importing country, achieve(s) the same level of protection as those prescribed by the importing country.
Establishment	A place of business or residence and everything connected with it, a property, place or organisation where animals are born, raised or slaughtered, and meat and meat products are processed or manufacturer, stored or transported
Exotic	Means when referring to a disease, not present in the country of concern, and for which measures are in place to either prevent or detect possible incursion of the disease into the country.
FMD-free country	A country that the Director of Biosecurity is satisfied is free from foot-and-mouth disease, and that is specified in a list published on the website of the Department of Agriculture and Water Resources.
The Australia New Zealand Food Standards Code	Australia New Zealand Food Standards Code (the Code) operates under the <i>Food Standards Australia New Zealand Act 1991</i> and the <i>Imported Food Control Act 1992</i> . The Code is a legislative instrument that lists requirements for food. Enforcement and interpretation of the Code is the responsibility of state and territory departments and food agencies within Australia, the Department of Agriculture and Water Resources for imported food into Australia and the Ministry for Primary Industries in New Zealand.
Gelatine	A protein product prepared from collagen in animal skin, bone or other collagenous material, or any combination of those things.
Granuloma	A localised, nodular area of granulation tissue, produced in response to infection, inflammation or the presence of a foreign substance.

Term or abbreviation	Definition
Ground beef	Also known as minced beef, that is, beef that has been finely chopped using knives or using a meat grinder or mincer. The grade or specifications of ground beef is determined by fat content and presence of additives including water. Ground beef may contain a number of different meat tissues
HACCP	Hazard Analysis Critical Control Point – a system that identifies, evaluates and controls hazards that are significant for food safety (FRSC 2007).
Hazard	A biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause adverse consequences associated with the importation of that agent in a contaminated good.
Health certificate	For an animal or a part of an animal that is to be brought or imported into Australian territory from a place outside Australian territory (the overseas place), means a certificate for the animal or part of the animal that: (a) is in a form approved by the Director of Biosecurity; and (b) has been signed by an official veterinarian from the overseas place.
Host	An organism that harbours a parasite, mutual partner, or commensal partner, typically providing nourishment and shelter.
Import permit	Import permit means a permit granted under section 179 of the <i>Biosecurity Act 2015</i> that authorises a person to bring or import particular goods into Australian territory.
Incidence	The number of new cases or outbreaks of a disease that occur in a population at risk in a particular geographical area within a defined time interval (OIE 2016h).
Incubation period	The period which elapses between the introduction of the pathogen into the animal and the occurrence of the first clinical signs of the disease related to that pathogen.
Infection	The entry and development or multiplication of an infectious agent in the body of humans or animals (OIE 2016h)
Infective period	The longest period during which an affected animal can be a source of infection (OIE 2016h)
Laboratory	A properly equipped institution staffed by technically competent personnel under the control of a specialist in veterinary diagnostic methods, who is responsible for the validity of the results. The Veterinary Authority approves and monitors such laboratories with regard to the diagnostic tests required for international trade (OIE 2016h).
Meat and bone meal	The solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acid (OIE 2016h).
Meat	The whole or part of the carcass of any buffalo, cattle or permitted animal, slaughtered other than in a wild state.
Meat-based flavour	Flavouring that has been derived from meat but contains no discernible pieces of meat.
Meat flesh	Skeletal muscle of any slaughtered animal, and any attached animal rind, fat, connective tissue, nerve, blood and blood vessels
Mechanically separated meat	Meat produced from meat recovery systems using meat/bone separation machines. The process involves the comminuting, grinding or pulverising of bones to retrieve attached muscle portions (as defined in the <i>Bovine Spongiform Encephalopathy (BSE) Requirements for the Importation of Beef & Beef Products for Human Consumption – Effective 1 March 2010</i> (FSANZ 2010)
Metacestode	Larval stage of a tapeworm that develops from the oncosphere and is found in the intermediate host as a cyst.
Natural casings	Means intestines and bladders that, after cleaning, have been processed by tissue scraping, defatting and washing, and have been treated with salt (OIE 2016h).

Term or abbreviation	Definition
Non-regulated risk analysis	Refers to the process for conducting a risk analysis that is not regulated under legislation (<i>Biosecurity import risk analysis guidelines 2016</i>).
Not significant	A conclusion of not significant in the risk assessment for a particular hazard means not worth considering. The terms negligible and not significant may be used interchangeably in this review.
Notifiable disease	When used in relation to a disease of animals, means a disease, the presence or suspected presence of, that must be notified or reported (however this is expressed) under a law of the state or territory in which the disease is present or suspected of being present (FRSC 2007).
Offal	Those parts of the carcass such as brain, heart, kidney, liver, pancreas, spleen, thymus, tongue and tripe, but excludes meat flesh, bone and bone marrow, and blood.
Official control program	A programme which is approved, and managed or supervised by the Veterinary Authority of a Member Country for the purpose of controlling a vector, pathogen or disease by specific measures applied throughout that Member Country, or within a zone or compartment of that Member Country.
Official veterinarian	A veterinarian authorised by the Veterinary Authority of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities and, when appropriate, to certify importing country requirements
Oncosphere	The larval stage of a tapeworm once it has been ingested by the intermediate host.
Outbreak	The occurrence of one or more cases in an epidemiological unit.
Pathogen	A biological agent that can cause disease to its host.
Prevalence	The total number of cases or outbreaks of a disease that are present in a population at risk, in a particular geographical area, at one specified time or during a given period (OIE 2016h).
Primal cuts	The pieces of meat initially separated from a carcass during butchering.
Processed meat	A meat product where meat either singly or in combination with other ingredients or additives, has undergone a method of processing other than boning, slicing, dicing, mincing or freezing. Processed meat includes manufactured meat (processed meat containing no less than 660g/kg of meat), cured and/or dried meat flesh in whole cuts or pieces.
Production	Of meat and meat products, means: a) the admission of animals for slaughter for meat and meat products; and b) the slaughter and dressing of animals from which meat and meat products are derived; and c) the preparation of meat and meat products; and d) the storage, processing and packaging of meat and meat products (FRSC 2007).
Proglottid	A segment of tapeworms, which contains the reproductive system, usually both male and female reproductive organs.
Protoscolices	Juvenile stage of <i>Echinococcus</i> spp. formed from the germinal layer of the metacestode.
Quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing or treatment.
Reportable disease	When used in relation to a disease of animals, means a disease, the presence or suspected presence of, that must be notified or reported (however this is expressed) under a law of the state or territory in which the disease is present or suspected of being present (FRSC 2007).
Restricted risk	Risk estimate with phytosanitary measure(s) applied.

Term or abbreviation	Definition
Retorted	Animal products have been retorted if they have been heated in a hermetically-sealed container to a minimum core temperature of 100 °C, obtaining an F0 value of at least 2.8. Goods (other than animal products) have been retorted if they have been heated in a hermetically-sealed container for a time, and to a temperature, sufficient to make the contents commercially sterile.
Risk analysis	Refers to the technical or scientific process for assessing the level of biosecurity risk associated with the goods, or the class of goods, and if necessary, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or class of goods to a level that achieves the ALOP for Australia.
Risk assessment	The evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard. In this qualitative risk assessment the likelihood of entry and exposure of a hazard and the magnitude of its consequences are expressed using non-numerical terms: significant and not significant.
Significant	A conclusion of significant in the risk assessment for a particular hazard means worth considering. The terms non-negligible and significant may be used interchangeably in this review.
Sanitary measure	A measure destined to protect animal or human health or life within the territory of a country from risks arising from the entry, establishment and/or spread of a hazard (OIE 2016h).
Scolex	The anterior segment or head of a tapeworm or metacestode, provided with organs of attachment. It develops singly or in multiples in the larval stage; when it reaches the final host it gives rise to the chain of segments by growth from its posterior end or neck.
Slaughter	Means the killing of an animal and includes stunning, sticking and bleeding (FRSC 2007).
Slaughterhouse/abattoir	Premises, including facilities for moving or lairaging animals, used for the slaughter of animals to produce animal products and approved by the Veterinary Services or other Competent Authority (OIE 2016h).
SPS Agreement	World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures which is an international agreement that applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. The Agreement was established to ensure that WTO members apply measures only to the extent necessary to protect human, animal or plant life or health, and that measures are based on scientific principles and not maintained without sufficient scientific evidence
Stakeholders	Government agencies, individuals, community or industry groups or organizations, whether in Australia or overseas, including the proponent/applicant for a specific proposal, who have an interest in the policy issues.
Sticking	Means the severing of the large blood vessels to induce effective bleeding (FRSC 2007).
Stunning	Any mechanical, electrical, chemical or other procedure which causes immediate loss of consciousness; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; in the absence of slaughter, the procedure would allow the animal to recover consciousness (OIE 2016h).
Surveillance	The systemic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information so that action can be taken (OIE 2016h).
Unrestricted risk	The biosecurity risk associated with the import of the commodity without any sanitary measures applied over and above the existing domestic requirements in Australia.

Term or abbreviation	Definition
Vector	An insect or any living carrier that transports an infectious agent from an infected individual to a susceptible individual or its food or immediate surrounding. The organism may or may not pass through a development cycle with the vector (OIE 2016h).
Veterinary Authority	The government authority of a country, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations of the OIE Terrestrial Code in the whole territory (OIE 2016h).
Viscera	The organs of the thoracic and abdominal cavity (FRSC 2007).
Wildlife	Animals that have live independent of direct human supervision or control, including feral animals, captive wild animals and wild animals.
Zoonosis	Any disease or infection which is naturally transmissible from animals to humans Any disease or infection which is naturally transmissible from animals to humans (OIE 2016h).

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