

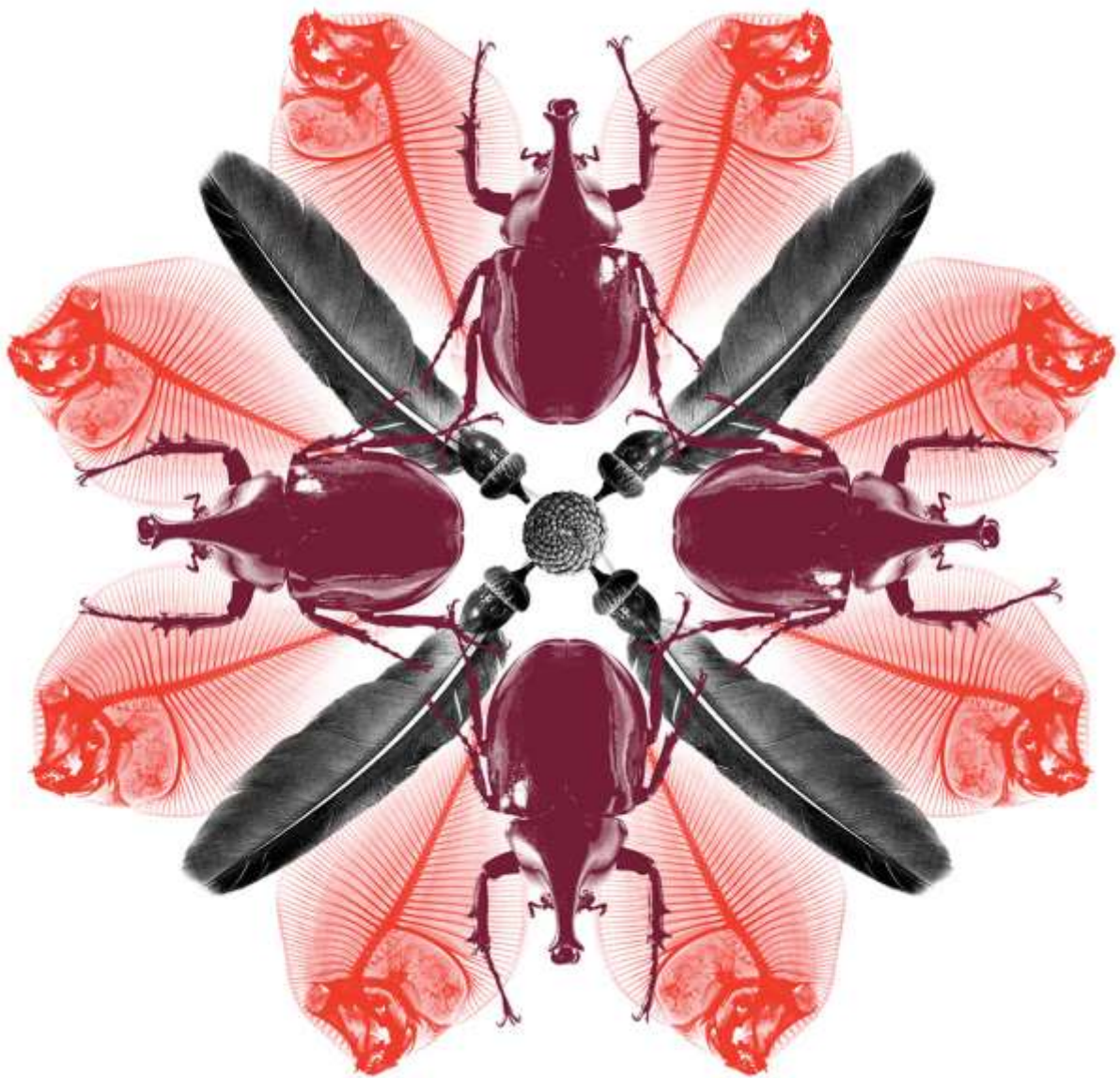


Australian Government
Department of Agriculture
and Water Resources

Importation of captive non-human primates

Review of import conditions
Final Report

March 2017



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Acronyms and abbreviations

Term or abbreviation	Definition
ABPM	Animal Biosecurity Policy Memorandum
AQPM	Animal Quarantine Policy Memorandum
ALOP	appropriate level of protection
BA	Biosecurity Advice
BICON	the Australian Department of Agriculture and Water Resources biosecurity import conditions system
CDC	Centers for Disease Control and Prevention
CITES	Convention on International Trade in Endangered Species
Code	OIE Terrestrial Animal Health Code
ELISA	enzyme-linked immunosorbent assay
Fomite	an object (e.g. a syringe or piece of clothing) that may be contaminated with infectious organisms and serve in their transmission
IATA	International Air Transport Association
IRA	import risk analysis
OIE	World Organisation for Animal Health
PCR	polymerase chain reaction
PAQ	Pre-arrival quarantine facility.
PEQ	Post-entry quarantine facility.
Pre-arrival quarantine	official confinement and isolation of animals in the country of export for observation, or for further testing or treatment before export to Australia
Post-entry quarantine	official confinement and isolation of animals arriving from abroad for observation, or for further testing or treatment
SOPs	standard operating procedures
SPS Agreement	WTO agreement on the Application of Sanitary and Phytosanitary Measures
WTO	World Trade Organization
ZAA	Zoo and Aquarium Association

Summary

This review considers the biosecurity risks for Australia associated with the importation of captive non-human primates. The last review of biosecurity measures for the importation of non-human primates into Australia was conducted in 2003, resulting in an update of existing interim import conditions.

This review takes into account new and relevant peer-reviewed scientific information, advice from scientific experts, and relevant changes in industry practices and operational practicalities.

Australia permits the importation of captive non-human primates, that is, only those born and kept in zoos and research institutions, from any country.

This review proposes that the importation of captive non-human primates to Australia from any country continue to be permitted, subject to a range of biosecurity measures.

This review identifies hazards that require biosecurity measures to manage risks to a very low level in order to achieve Australia's appropriate level of protection (ALOP). The hazards requiring measures are: rabies and tuberculosis.

This review proposes a combination of risk management measures and operational systems that will reduce the risk associated with the importation of captive non-human primates from any country into Australia to achieve Australia's ALOP, specifically:

- general risk management measures specific to zoo animals (for example, sourced from controlled environment, compulsory pre-arrival and post-entry quarantine)
- premises freedom
- diagnostic testing.

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

The proposed biosecurity measures recommended in this review differ from current biosecurity measures for several diseases, including:

- the country freedom requirement for yellow fever was removed; the risk for this disease is considered to be managed by Australia's general risk management measures for zoo animals
- the premises freedom requirements for hepatitis B, measles, simian haemorrhagic fever and simian immunodeficiency syndrome were removed; the risk for these diseases is considered to be managed by Australia's general risk management measures for zoo animals
- all testing for tuberculosis was moved to the pre-arrival period and the premises freedom requirement was reduced from five years to two years to be consistent with the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code.

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 and diseases entering, establishing and spreading in Australia, thereby threatening Australia's unique fauna and flora and 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* located on the [Australian Government Department of Agriculture and Water Resources](#) website.

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 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

Non-human primates are classified in the order Primates, which is divided into two suborders, the Strepsirrhini and the Haplorrhini, which are further divided into 13 families. The Strepsirrhini include lemurs (*Lemuriformes*) and lorises (*Lorisiformes*). The Haplorrhini include New World monkeys (Platyrrhini), Old World monkeys (Catarrhini), and tarsiers (*Tarsiiformes*). Lesser apes (*Hylobatidae*), great apes (*Ponginae* and *Gorillinae*), and humans (*Homininae*) are included in the Hominoidea superfamily within the Catarrhini parvorder (Perelman et al. 2011; Rowe 1996).

Non-human primates have a natural geographical range covering Africa, Central and South America, and parts of Asia, including islands and small land masses adjacent to these continents

(Rowe 1996). The wide assortment of species, habitat and geographical range means that disease agents affecting this order are diverse.

Non-human primates are subject to the provisions of the Convention on International Trade in Endangered Species (CITES) under the *Environmental Protection and Biodiversity Conservation Act 1999* (legislation.gov.au/Details/C2016C00777), the EPBC Act. CITES-listed species may only be imported in a manner that is not threatening to species survival and in all cases where importation occurs, imported animals must not be taken from wild populations and must be accompanied by documentation to certify their status.

Primates in Australian zoos

Representative species of many non-human primates are currently held in Australian zoos. Having separate populations around the world allows breeding programs to maintain genetic diversity in the face of dwindling numbers of animals. Furthermore, separate maintenance of global breeding populations helps to manage risks (such as diseases and natural disasters) that can adversely affect international conservation programs.

Zoos and wildlife parks also provide the opportunity for the public to see and appreciate wildlife, including non-human primates, from all parts of the world. This assists conservation of biodiversity through education leading to appreciation of these animals and their habitat requirements.

The direct exposure of the public to zoonotic diseases in zoos and wildlife parks is limited. However, handlers and carers are at a greater risk by virtue of the nature of their work. Furthermore, it is very difficult to limit the access of other species such as birds and small vertebrates to zoos and wildlife parks, therefore potential disease/disease agent exposure pathways exist for those species.

Primates for research

The use of non-human primates for biomedical research within Australia is allowed subject to relevant Commonwealth and State/Territory legislation. Those laws impose controls to assess whether the science is of sufficient importance to warrant the use of non-human primates.

The laws of Australia's states and territories also specify requirements to ensure appropriate care of non-human primates used in research programs. Under those laws, sourcing and use of appropriate species and numbers of non-human primates for any specific research purposes can only be arranged after the work has been approved as ethically justified by a properly constituted Animal Ethics Committee.

Four breeding colonies to maintain non-human primate species of biomedical importance exist in Australia. These facilities are highly specialised and purpose built with quality management systems that include preventive disease control programs and staff competency requirements that include training in biosecurity. From time-to-time demand exceeds the capacity of these facilities and/or involves species that they do not supply. In addition, these facilities may need to import breeding stock to avoid in-breeding of the breeding colony.

When non-human primates for research are imported into Australia, they will come to these dedicated breeding colony facilities, greatly reducing the biosecurity risk. Nevertheless, there are some risks to handlers and carers through direct exposure and, in rare cases, by less direct transmission routes. However, these facilities are well designed to prevent access by other animal species so only indirect transmission to animals is possible.

1.2.2 Scope

The scope of this review is to consider the biosecurity risks that may be associated with the importation of captive non-human primates that is, those born and kept in zoos and research institutions, from all countries. The scope of this review does not include sourcing of non-human primates from wildlife populations. The review only allows for importation that is consistent with Australia's international commitment to CITES, which effectively places restrictions on the importation of captive-bred non-human primates for reasons other than non-commercial applications that are deemed necessary (e.g. biomedical research) and that do not present a threat to species survival.

1.2.3 Existing policy

Import conditions

Import conditions exist for non-human primates from all countries. An interim policy for the importation of non-human primates was developed and import conditions introduced in December 1996, pending completion of an import risk analysis (IRA). In March 1998, *Animal Quarantine Policy Memorandum* (AQPM) 1998/27 advised the commencement of an IRA for the importation of non-human primates to Australia. As advised by *Animal Biosecurity Policy Memorandum* (ABPM) 2003/8, a technical issues paper identifying hazards was issued for stakeholder comment in March 2003. The hazard identification reviewed all agents known to infect non-human primates and listed those agents of biosecurity concern deemed as requiring further risk assessment. Due to conflicting priorities, the IRA was not progressed.

The interim conditions were subsequently reviewed and updated in 2002 and 2003 (ABPMs 2002/50, 2003/13 and 2003/23 refer). Importation has occurred under the updated interim conditions.

The [import requirements](#) for non-human primates can be found on the department's website.

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

Domestic arrangements

The Australian Government is responsible for regulating the movement of animals and animal products into and out of Australia. The state and territory governments have primary responsibility for animal health and environmental controls within their jurisdictions. Legislation may be used by state and territory governments 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 Next Steps

Stakeholders were given the opportunity to comment on the technical aspects of the proposed biosecurity measures. In particular, comments were sought on the appropriateness of the measures or alternative measures that would provide equivalent risk management outcomes.

The department considered formal submissions on this review. The department then prepared a final report, taking into account stakeholder comments.

The final review is published on the department's website along with a notice advising stakeholders of the release. The department will notify the proposer, the registered stakeholders

and the 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 form the basis of any future importations.

2 Method

The World Organisation for Animal Health (OIE), in its Terrestrial Animal Health Code (OIE 2016c), hereafter referred to as ‘the Code’, describes ‘General obligations related to certification’ in Chapter 5.1.

The 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 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 Code are:

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

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

2.1 Risk review

Although not defined or described in the 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 or animal product for which relevant current biosecurity measures exist.

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

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

- the Code (OIE 2016c)

- the *Draft generic import risk analysis of nonhuman primates - technical issues paper* (Biosecurity Australia 2003)
- current and previous requirements for importation of non-human primates into Australia
- a review of relevant scientific literature
- expert opinion.

Risk is defined by the 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’. It is dynamic in nature, changing over time. Consequently, risk and risk management measures should be regularly reviewed.

2.2 Review of hazard identification

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

In accordance with the Code, a disease agent was considered to be a potential hazard relevant to the importation of non-human primates if it was assessed to be:

- appropriate to non-human primates
- OIE-listed, emerging and/or capable of producing adverse consequences in Australia.
- not present in Australia, or present in Australia and a notifiable disease or subject to official control or eradication
- present in the country of export.

Due to the close taxonomic relationship between humans and non-human primates, hazard identification also focused on public health. A disease agent was also considered to be a potential hazard if it was assessed to be:

- a significant zoonosis
- a national notifiable disease of public health concern.

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 non-human primates in disease transmission.

2.3 Review of risk assessment

Details of the risk assessment process relevant to live animals are provided in Chapter 2.1 of the Code.

A review of risk factors relevant to the release, exposure and consequence assessment of hazards identified for further review was conducted to identify any significant changes in disease agent attributes and/or geographic distribution that would be relevant to biosecurity considerations for Australia.

A review of peer-reviewed scientific literature was conducted for each hazard retained for risk review. If definitive information on risk factors was not found through literature review or contact with relevant experts, any uncertainties were identified and documented.

Based on the information reviewed, a conclusion was reached for each hazard about whether a significant change in biosecurity risk had occurred that was relevant to the importation of captive non-human primates into Australia. Any assumptions and/or judgements made in drawing conclusions for each hazard retained for further review were documented in the relevant risk review section (Chapter 4).

2.4 Review of risk management

This review focussed on determining whether risk management was warranted for each of the hazards identified for the importation of captive non-human primates. If it was concluded that risk management was not warranted, then risk management was not proposed. Conversely, if it was concluded that risk management was warranted, previous risk management measures were reviewed to determine if they were appropriate. If it was concluded that previous risk management measures were not able to achieve Australia's ALOP, alternative and/or complementary risk management measures, which were considered to provide an appropriate risk management option, were proposed.

The current risk management measures were reviewed in the context of updated scientific information, including expert advice where available, as well as operational feasibility and practicality. For example, the adoption of advanced technologies for disease management and prevention (such as diagnostic techniques, vaccine manufacture) for certain hazards were considered appropriate for implementation, not simply on the basis of technical efficacy to achieve Australia's ALOP, but also as measures that would be less resource intensive from an administrative perspective.

This review also incorporated long stand policy designed to manage the risk and animal welfare issues associated with the importation and handling of zoo animal species. Those risk management measures include:

- The animal must be resident in an approved, licensed or registered zoo or wildlife park in the exporting country since birth or for at least two years immediately before export, unless otherwise approved by the department; the residency requirement may be achieved in more than one country or holding institution if specifically authorised by the department and the conditions for each country of residence and holding institution must be met.
- The premises of origin (zoo or wildlife park) must be under veterinary supervision and have a health monitoring program.
- The animal must be held in isolation (pre-arrival quarantine) for at least 30 days, during which it is inspected at least daily for signs of disease, treated for internal and external parasites, and tested for diseases in accordance with recommendations arising from the policy review.
- The animal must be transported to a quarantine approved premises in Australia in a manner that ensures no direct exposure to Australian animals en route, and must undergo a period of post-entry quarantine of at least 30 days.
- The receiving institution must be approved under relevant Australian State or Territory legislation to hold the species being imported.

2.5 Risk communication

Risk communication is defined in the 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 import risk analyses and policy reviews, the department consults, where relevant, with the Australian Government Department of Health to ensure that public health considerations are included in the development of Australia's animal biosecurity policies. In May 2016, the department released a draft of the review for comment by stakeholders. Comments were mainly of a technical nature. The majority of suggested changes were accepted, and those that were not accepted were discussed with stakeholders.

A formal process of consultation with external stakeholders is a standard procedure for all import risk analyses and policy reviews to enable stakeholder assessment and feedback on draft conclusions and recommendations about Australia's animal biosecurity policies.

2.6 Special considerations

For non-human primates, some special considerations are applicable to the review of hazard identification, risk assessment and risk management processes.

Zoo import policy

The general risk management measures included in Australia's zoo animal import policies mean that each non-human primate will be sourced from a controlled environment and will be maintained in a controlled environment in Australia. Therefore, there is no risk of the animals coming into contact with wild non-human primates and minimal risk of contact with other animals other than their human handlers.

The health status of each non-human primate will be well documented, that together with sourcing from a controlled environment and the compulsory pre-arrival and post-entry quarantine periods minimises the risks of many potential hazards.

Zoonotic diseases

Many diseases that affect non-human primates also affect humans. As such, special attention should be paid to the zoonotic potential of each potential hazard. Since there are no wild or feral non-human primates in Australia, biosecurity risks posed by their importation are mostly limited to the potential introduction of human diseases, although there may be some risk to other animals. Some of the zoonotic diseases of non-human primates are already endemic in humans in Australia. Therefore, the introduction of a small number of infected animals into facilities in which there will be little direct contact with humans does not pose a significant increase in biosecurity risk. When considering whether or not biosecurity measures are required for zoonotic diseases, it is important to consider whether such diseases could be equally likely introduced by an infected human and if those diseases are already present in the Australian human population. It would be unreasonable to require onerous biosecurity measures for the importation of small numbers of non-human primates.

Recommendations in the OIE Terrestrial Animal Health Code

Chapter 6.11 of the Code provides recommendations for the importation of non-human primates to manage the risk of zoonoses transmitted by non-human primates (OIE 2015c). The recommendations are related to the region of origin of the species concerned as well as the environment they are maintained in (uncontrolled environment or under veterinary supervision). In addition, there are guidelines (Article 6.11.7) on precautionary measures for staff working with non-human primates.

It is appropriate to consider the recommendations in Chapter 6.11 of the Code in the hazard identification in this review.

3 Hazard identification

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

- diseases listed by the OIE as multiple species diseases affecting non-human primates (OIE 2015c)
- diseases identified in the *Draft generic import risk analysis of nonhuman primates - technical issues paper* (Biosecurity Australia 2003) and import policy, conducted by the department
- other diseases identified as being of importance in non-human primates.

The method of hazard identification and refinement is described in Chapter 2 and takes into account the special considerations outlined in Section 2.6. The preliminary list of diseases/disease agents is shown in Table 1. This table summarises the results of the hazard refinement process, including the reason for removal or retention of each identified hazard

The list of hazards included parasitic infestations. Routine monitoring for external and internal parasites and treatment as appropriate are standard practice in zoos and research institutes, and for movement of animals from zoos and research institutes (A. Reiss, ZAA, pers. comm. December 2011). Accordingly, a risk review was not conducted for parasites where treatment occurs as routine standard practice as part of the importation process. Parasite resistance to treatments was not considered in the review.

Many disease agents are ubiquitous or common commensals and may be present in Australia. There are others that are opportunistic, not reported to be pathogenic, or of uncertain relevance in commodity due to limited or insufficient information. These disease agents were considered when compiling the list of potential hazards, but due to insufficient information they were not included in the list of potential hazards.

Non-human primates are frequently used as models for the study of human disease agents and there is an abundance of literature relating to experimental infections of non-human primates with human disease agents for research purposes. Unless the research was matched by evidence of natural infections, in the wild or captivity, with the same disease agents, these disease agents were not included in the list of potential hazards.

Disease agents that infect non-human primates but that do not infect humans or other animals were not included in the list of potential hazards. As there are no wild or feral non-human primates in Australia, such disease agents are not considered to be biosecurity hazards. As each non-human primate will be sourced from a controlled environment and will be maintained in a controlled environment in Australia, control of such disease agents will be the responsibility of the importing facility.

It is appropriate to provide a list of disease agents that were not deemed to be potential hazards here, not only to indicate that they were considered, but also in the event that new evidence about any diseases arises subsequent to finalisation of this policy review.

Bacteria: *Aeromonas hydrophila*, *Actinobacillus* spp., *Actinobaculum* spp., *Actinomyces* spp., *Arcanobacterium* spp., *Bacillus* spp., *Bacteroides* spp., *Bordetella bronchiseptica*, *Burkholderia* spp., *Chromobacterium violaceum*, *Clostridium* spp., *Corynebacterium* spp., *Coxiella burnetti*, *Dermatophilus* spp., *Erysipelothrix* spp., *Fusobacterium* spp., *Haemophilus influenza*, *Helicobacter pylori*, *Klebsiella* spp., *Leptospira* spp., *Listeria monocytogenes*, nontuberculous

Mycobacterium spp., *Mycoplasma* spp., *Nocardia* spp., *Pasteurella* spp., *Plesiomonas shigelloides*, *Proteus* spp., *Pseudomonas* spp., *Rhodococcus equi*, *Serratia marcescens* and *Streptococcus* spp.

Fungi and yeasts: *Absidia* spp., *Actinomyces* spp., *Aspergillus fumigates*, *Candida albicans*, *Coccidioides immitis*, *Conidiobolus* spp., *Cryptococcus neoformans*, *Entomorphthora* spp., *Histoplasma* spp., *Microsporum* spp., *Mortierella* spp., *Mucor* spp., *Paracoccidioides brasiliensis*, *Pneumocystis carini*, *Rhizomucor* spp., *Rhizopus* spp., *Trichophyton* spp. and *Trichosporon beigelii*.

Protozoa: *Babesia* spp., *Balantidium* spp., *Blastocystis hominis*, *Chilomastix* spp., *Cyclospora cayentanensis*, *Cryptosporidium parvum*, *Eimeria* spp., *Encephalitozoon cuniculi*, *Entamoeba* spp., *Enterocytozoon bienusi*, *Entopoloypoides macaci*, *Giardia* spp., *Haemogregarina cynomolgi*, *Hepaticystis* spp., *Isospora* spp., *Neospora* spp., *Pentatrichomonas* spp., *Plasmodium* spp., *Sarcocystis* spp., *Trichomonas* spp., *Tritrichomonas* spp., *Toxoplasma gondii*, *Troglodytella* spp. and *Trypanosoma* spp.

Viruses: astrovirus, ateline herpesvirus 2, baboon orthoreovirus, cercopithecine herpesviruses (1, 2, 9 and 16), chimpanzee varicella herpesvirus, Coxsackie virus, cytomegalovirus (African green monkey cytomegalovirus, rhesus macaque cytomegalovirus), encephalomyocarditis virus, endogenous simian type D retroviruses, exogenous simian type D retroviruses, GB viruses (A, B and C), gibbon ape leukaemia virus, herpesvirus aotus types 1 and 3, herpesvirus saguinus, polyomavirus papionis-1 (SA12), human immunodeficiency viruses, human T-lymphotropic virus, influenza viruses (A, B and C), marmosetpox virus, mumps virus, oropouche virus, polyomavirus cercopithecii (lymphotrophic virus), saimirine herpesvirus 1 (herpesvirus tamarinus), saimirine herpesvirus 2, lymphocryptoviruses, parainfluenza viruses (types 1, 2, 3 and 4), polyomaviruses, primate calicivirus, respiratory syncytial virus, rhinoviruses, rotaviruses, rubella virus, severe acute respiratory syndrome (SARS) coronavirus, simian adenoviruses, simian enterovirus A, simian foamy virus, simian haemorrhagic fever virus, simian immunodeficiency viruses, simian Mason-Pfizer retrovirus, simian parvovirus, simian sarcoma virus, varicella zoster virus (chicken pox) and vesicular stomatitis virus.

The diseases retained after hazard identification and refinement in Table 1 are listed at the end of this chapter.

Table 1 Hazard identification and refinement

Disease (disease agent)	Susceptible species	OIE-listed / emerging disease?	Present in Australia?	Zoonosis?	Australian national notifiable disease (public health)?	Retained for risk review?
Callitrichid hepatitis (Lymphocytic choriomeningitis virus)	Humans, non-human primates and rodents	No	Yes	Yes	No	No: no evidence captive non-human primates play a significant role in disease epidemiology
Cestodes affecting non-human primates	Non-human primates and other mammals	Yes (<i>Echinococcus granulosus</i> and <i>E. multilocularis</i>) No (other species)	Possible (some species)	Possible (some species)	No	All imported non-human primates to be treated for endoparasites and will be sourced from a controlled environment ⁶
Chikungunya fever (Chikungunya virus)	Multiple species including birds, humans, non-human primates and rodents	No	No ¹	Yes	Yes	Yes: not present in Australia and a national notifiable disease for public health
Dengue fever (Dengue virus)	Humans and non-human primates	No	No ²	Yes	Yes	No: cases are regularly reported in Australia in humans that acquired the disease overseas and non-human primates will be sourced from a controlled environment ⁶
Ebola haemorrhagic fever (Bundibugyo ebolavirus, Reston ebolavirus, Sudan ebolavirus, Tai Forest ebolavirus, and Zaire ebolavirus)	Bats, duiker (forest antelope), humans, non-human primates, pigs and rodents.	No	No	Yes	Yes (viral haemorrhagic fever)	Yes: not present in Australia and a national notifiable disease for public health
Enteric bacterial disease (<i>Escherichia coli</i> , <i>Salmonella</i> spp., <i>Shigella</i> spp., <i>Yersinia</i> spp., <i>Campylobacter</i> spp.)	Multiple species including humans and non-human primates	No	Yes	Yes	No – yersiniosis Yes - others	Yes: national notifiable diseases for public health and in Chapter 6.11 of the Code ⁷
Japanese encephalitis (Japanese encephalitis virus)	Birds, humans, non-human primates, horses and pigs	Yes	No ³	Yes	Yes	No: no evidence captive non-human primates play a significant role in disease epidemiology

Disease (disease agent)	Susceptible species	OIE-listed / emerging disease?	Present in Australia?	Zoonosis?	Australian national notifiable disease (public health)?	Retained for risk review?
Hepatitis A (Hepatitis A virus)	Humans, non-human primates	No	Yes	Yes	Yes	No: the disease is present in Australia and non-human primates will be sourced from a controlled environment ⁶
Hepatitis B (Hepatitis B virus)	Humans, non-human primates	No	Yes	Yes	Yes	Yes: national notifiable disease for public health and in Chapter 6.11 of the Code ⁷
Herpes B (Cercopithecine herpesvirus 1)	Humans, non-human primates (macaques)	No	Yes	Yes	No	No: present in Australia, not a national notifiable disease for public health and non-human primates will be sourced from a controlled environment ⁶
Kyasanur Forest disease (Kyasanur Forest disease virus)	Multiple species including humans, non-human primates and rodents	No	No	Yes	No	No: not a national notifiable disease for public health and non-human primates will be sourced from a controlled environment ⁶
Lyme disease (<i>Borrelia burgdorferi</i>)	Multiple species including humans and non-human primates	No	No ¹	Yes	No	No: no evidence captive non-human primates play a significant role in disease epidemiology
Marburg haemorrhagic fever (Marburg virus)	Bats, humans and non-human primates	No	No	Yes	Yes (viral haemorrhagic fever)	Yes: not present in Australia and a national notifiable disease for public health
Mayaro fever (Mayaro virus)	Birds, humans and non-human primates	No	No	Yes	No	No: not a national notifiable disease for public health and non-human primates will be sourced from a controlled environment ⁶
Measles (Measles virus)	Humans and non-human primates	No	No ⁴	Yes	Yes	Yes: not present in Australia and a national notifiable disease for public health
Mites affecting non-human primates	Non-human primates and other mammals	No	Possible (some species)	Possible (some species)	No	All imported non-human primates to be treated and inspected for ectoparasites and will be sourced from a controlled environment ⁶

Disease (disease agent)	Susceptible species	OIE-listed / emerging disease?	Present in Australia?	Zoonosis?	Australian national notifiable disease (public health)?	Retained for risk review?
Monkeypox (Monkeypox virus)	Birds, humans, non-human primates and rodents	No	No	Yes	No	No: not a national notifiable disease for public health and non-human primates will be sourced from a controlled environment ⁶
Nematodes affecting non-human primates	Non-human primates and other mammals	No	Possible (some species)	Possible (some species)	No	All imported non-human primates to be treated for endoparasites and will be sourced from a controlled environment ⁶
New World screwworm (<i>Cochliomyia hominivorax</i>)	Mammals	Yes	No	Yes	No	All imported non-human primates to be treated and inspected for ectoparasites and will be sourced from a controlled environment ⁶
Old World screwworm (<i>Chrysomya bezziana</i>)	Mammals	Yes	No	Yes	No	All imported non-human primates to be treated and inspected for ectoparasites and will be sourced from a controlled environment ⁶
Papillomas Papilloma viruses	Humans, non-human primates, other mammals	No	Yes	No	No	No: not a national notifiable disease for public health and non-human primates will be sourced from a controlled environment ⁶
Plague (<i>Yersinia pestis</i>)	Multiple species including humans, non-human primates and rodents	No	No	Yes	Yes	No: no evidence captive non-human primates play a significant role in disease epidemiology
Poliomyelitis (Poliovirus)	Human, non-human primates	No	No ⁵	Yes	Yes	No: no evidence captive non-human primates play a significant role in disease epidemiology
Rabies (Rabiesvirus)	Mammals, including humans and non-human primates	Yes	No	Yes	Yes	Yes: not present in Australia, is an OIE-listed disease and a national notifiable disease for animal and public health
Tanapox (Tanapox virus)	Humans and non-human primates	No	No	Yes	No	No: not a national notifiable disease for public health and non-human primates will be sourced from a controlled environment ⁶

Disease (disease agent)	Susceptible species	OIE-listed / emerging disease?	Present in Australia?	Zoonosis?	Australian national notifiable disease (public health)?	Retained for risk review?
Ticks affecting non-human primates	Non-human primates and other mammals	No	Possible (some species)	Possible (some species)	No	All imported non-human primates to be treated and inspected for ectoparasites
Trematodes affecting non-human primates	Non-human primates and other mammals	No	Possible (some species)	Possible (some species)	No	All imported non-human primates to be treated for endoparasites and will be sourced from a controlled environment ⁶
Tuberculosis (<i>Mycobacterium</i> spp.)	Mammals including humans and non-human primates	Yes (<i>M. bovis</i>)	No (<i>M. bovis</i>) Yes other spp.	Yes	Yes	Yes: OIE-listed disease (<i>M. bovis</i>) and national notifiable disease for animal (<i>M. bovis</i>) and public health (<i>M. tuberculosis</i> complex)
Tularaemia (<i>Francisella tularensis</i>)	Multiple species including humans, non-human primates and rodents	Yes	Yes (<i>F. tularensis</i> type B)	Yes	Yes	Yes: OIE-listed disease and national notifiable disease for animal and public health
West Nile fever (West Nile virus)	Multiple species including humans and non-human primates	Yes	Some strains present in Australia	Yes	Yes	No: no evidence captive non-human primates play a significant role in disease epidemiology
Yabapox (Yaba monkey tumour virus)	Humans and non-human primates	No	No	Yes	No	No: not a national notifiable disease for public health and non-human primates will be sourced from a controlled environment ⁶
Yellow fever (Yellow fever virus)	Humans and non-human primates	No	No ¹	Yes	Yes	Yes: not present in Australia and a national notifiable disease for public health
Zika fever (Zika virus)	Humans and non-human primates	No	No ¹	Yes	Yes (Flavivirus infection)	Yes: not present in Australia and a national notifiable disease for public health

¹ Occasional cases have been reported in Australia in humans that acquired the disease overseas.

² Dengue virus is not endemic in Australia. Imported cases are reported annually in Australia in humans that acquired the disease overseas.

³ Japanese encephalitis is absent from mainland Australia and Tasmania. Occasional cases occur in Torres Strait Islands or in Australia in humans that acquired the disease overseas.

⁴ Measles was eradicated from Australia in 2014. Occasional cases are reported in Australia in humans that acquired the disease overseas.

⁵ Australia has been free of poliomyelitis since 2000. New cases in Australia that are acquired overseas are rare, the last reported case was in 2007.

⁶ All non-human primates must be free from signs of disease for at least 30 days before export and will only be sourced from approved, licensed or registered zoos, wildlife parks or research institutions that have health monitoring programs and are under veterinary supervision.

⁷ Not an OIE-listed disease, but is considered by the OIE to be an important transmissible zoonotic disease.

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

- chikungunya fever
- Ebola haemorrhagic fever
- enteric bacterial disease
- hepatitis B
- Marburg haemorrhagic fever
- measles
- rabies
- tuberculosis
- tularaemia
- yellow fever
- Zika fever.

4 Risk reviews

4.1 Chikungunya fever

4.1.1 Background

Chikungunya fever is caused by chikungunya virus, an RNA virus of the family *Togaviridae*, which is closely related to Ross River virus (Weaver et al. 2005). The disease is endemic in large areas of Africa, Madagascar, India and associated islands, and South-East Asia (Sudeep & Parashar 2008). In late 2013, chikungunya virus was found for the first time in the Americas on islands in the Caribbean (CDC 2015a). Humans and non-human primates are the principal hosts. Bats, birds and rodents have been identified as animal reservoirs (Diallo et al. 1999; Woodall 2001). African green (vervet) monkeys (*Chlorocebus aethiops*), rhesus macaques (*Macaca mulatta*), Chacma baboons (*Papio ursinus*) and African prosimians, including the lesser bushbaby (*Galago senegalensis*) are commonly infected (Woodall 2001).

Chikungunya fever is not an OIE-listed disease (OIE 2016a).

Chikungunya fever is not present in Australia and it is not a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Chikungunya fever is a zoonosis and is a nationally notifiable disease of public health concern (Department of Health 2015).

4.1.2 Technical information

Epidemiology

There are two epidemiological transmission cycles of chikungunya fever: a sylvatic cycle, occurring primarily in Africa mainly between wild non-human primates and mosquitoes, where humans are accidental hosts; and an urban human-mosquito-human transmission cycle that more typically occurs in cities in Asia (CDC 2015a).

The mosquitoes *Aedes aegypti* and *Ae. albopictus* are the principal vectors in Asia and *Ae. fuscifer* is the main vector in South Africa (Jupp & McIntosh 1988). Different mosquito species are dominant vectors in different regions of Africa (Diallo et al. 1999; Woodall 2001). *Ae. albopictus* was incriminated in the rapid spread of a 2005–2006 outbreak in the Reunion Islands (Promed Mail 2006).

In the outbreak in the Reunion Islands, some infants (six babies between three and five days old) were believed to have been infected vertically by their mothers who had acute infections within 48 hours before giving birth (Paquet et al. 2006; Promed Mail 2006).

The incubation period in humans is normally two to three days (range of one to twelve days). Humans develop a marked viraemia during the first two days of illness which declines by day five (Johnston & Peters 1996; Woodall 2001). Experimental studies in macaques indicate a similar incubation period and viraemia duration (Labadie et al. 2010).

Prevalence of chikungunya fever is subject to seasonal variation with periods of high rainfall increasing prevalence, particularly in the sylvatic cycles in Africa (Jupp & McIntosh 1988). In Africa, the disease is characterised by periodic occurrence with silent intervals of three to seven years. This probably relates to the immune status of non-human primates, and the number of susceptible animals in any given non-human primate population (Diallo et al. 1999; Jupp &

McIntosh 1988). Baboons and vervet monkeys are believed to circulate chikungunya virus during epidemics but this is likely a spill over from other hosts (Gear 1998).

Clinical signs

In humans the disease can be subclinical or it may present with a sudden onset of a biphasic fever accompanied by arthralgia, leukopaenia and often a maculopapular rash appearing one to ten days after onset. Haemorrhagic symptoms have been seen, but they are rare (Johnston & Peters 1996; Jupp & McIntosh 1988). Infections in wild non-human primates are usually subclinical. Experimentally infected macaques developed pyrexia, skin rashes and gingival bleeding (Labadie et al. 2010). Naturally occurring disease has not been reported in non-human primates (Wachtman & Mansfield 2012).

Diagnosis

Several methods can be used for diagnosis. Serological tests, such as enzyme-linked immunosorbent assays (ELISA) can confirm the presence of antibodies, which peak three to five weeks after infection. Virus may be isolated from blood, but because of the short period of viraemia, virus isolation is unlikely to be successful unless done within two to three days of the onset of pyrexia (Tesh 1982). Virus has been isolated from serological samples collected from wild long-tailed macaques (*Macaca fascicularis*) in Malaysia (Apandi et al. 2009). Various reverse transcriptase–polymerase chain reaction (RT–PCR) methods are also available but are of variable sensitivity (Mardekian & Roberts 2015).

Current biosecurity measures

There are no current biosecurity measures for chikungunya fever.

4.1.3 Risk review

Chikungunya fever is present in exporting countries and it is not present in Australia.

The following key points are relevant to the biosecurity risk of chikungunya fever in non-human primates:

- Chikungunya fever is present in Africa, Asia and the Americas.
- Chikungunya fever is not a nationally notifiable animal disease; however, it is a nationally notifiable disease of public health concern.
- Chikungunya fever is a vector transmitted disease and the mosquito vector *Aedes aegypti* is present in Australia (widespread distribution in Queensland).
- Infection in non-human primates is typically subclinical.
- Experimental studies indicate the incubation and viraemic periods in non-human primates are short.
- There is no evidence of natural outbreaks of chikungunya fever amongst captive non-human primates.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.1.4 Conclusion

Accordingly and based on the preceding information, risk management for chikungunya fever is not warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

4.2 Ebola haemorrhagic fever

4.2.1 Background

Ebola haemorrhagic fever (EHF) is a severe infectious disease affecting humans and non-human primates. Ebola virus belongs to the family Filoviridae and the genus Ebolavirus. There are five known species in the genus Ebolavirus including Bundibugyo ebolavirus, Reston ebolavirus, Sudan ebolavirus, Tai Forest ebolavirus and Zaire ebolavirus (ICTV 2014). As of 2016, each species has a single member. These members are Bundibugyo virus (BDBV), Reston virus (RESTV), Sudan virus (SUDV), Tai Forest virus (TAFV) and Ebola virus (EBOV), respectively.

Humans and non-human primates are very susceptible to EHF. Other animals reported to be infected include duiker (forest antelope), porcupines, pigs and rodents. Fruit bats of the Pteropodidae family are the most likely reservoir hosts for ebolaviruses (Leroy et al. 2005; Olival & Hayman 2014).

The disease typically occurs in the tropical regions of sub-Saharan Africa. However, a major outbreak began in West Africa in 2013, which spread from Guinea to the neighbouring countries of Liberia and Sierra Leone (Marí Saéz et al. 2015). The three viruses BDBV, SUDV and EBOV are associated with large outbreaks in Africa. Only one species, which contains RESTV, has been reported outside Africa, in China and the Philippines (Miranda & Miranda 2011). RESTV was identified during an outbreak of haemorrhagic fever in cynomolgus macaques imported from the Philippines into a research facility in Virginia in the United States (Rollin et al. 1999). This virus does not seem to affect humans (Peters, Sanchez & Rollin 1996), but it can cause fatal illness in some species of non-human primates (Miranda & Miranda 2011). RESTV has also been detected in pigs in China and the Philippines during outbreaks of porcine reproductive and respiratory syndrome. However, RESTV alone does not seem to cause disease in pigs (Miranda & Miranda 2011). There are no reports in the literature about outbreaks of EHF in non-human primates in zoological facilities.

Ebola haemorrhagic fever is not an OIE-listed disease (OIE 2016a).

Ebola haemorrhagic fever is not present in Australia and it is not a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Ebola haemorrhagic fever is a zoonosis and is a nationally notifiable disease of public health concern (Department of Health 2015).

4.2.2 Technical information

Epidemiology

EHF is transmitted from wild animals to humans through hunting and collection of sick or dead wild animals and handling or consumption of uncooked bush meat. Collection of fruit contaminated with bat faeces, saliva and urine, is also considered to be a source of infection. Although the original source of infection in non-human primates is unclear, most evidence indicates direct infection from one or more natural hosts as well as forest fruits contaminated with bat body fluids (OIE 2015a).

In humans, human-to-human transmission occurs through direct contact with body fluids such as blood, faeces, saliva, semen, urine and vomit of an infected person. The role direct

transmission plays in spreading the disease between non-human primates is unclear. However, in the Philippines, there is evidence that RESTV was transmitted between macaques by direct contact, fomites and aerosolisation (Miranda et al. 1999; Miranda & Miranda 2011). There is nothing in the literature to suggest that non-human primates are long-term carriers or that they play any role in the maintenance of the disease.

The incubation period of EHF in humans is 2–21 days. EHF due to experimental infection with RESTV has an incubation period of 7–14 days in non-human primates. Once clinical signs occur, progression to death is rapid. In animals that survive, virus is cleared from the circulation in parallel with the appearance of antibodies, which appear after 14–21 days (Fisher-Hoch et al. 1992).

Field studies and epidemiological surveys in Africa have demonstrated widespread evidence of antibodies to ebolaviruses in fruit bats and insectivorous free-tailed bats (*Mops condylurus*) are considered possible sources of ebolaviruses (Marí Saéz et al. 2015). Bats from Bangladesh, China and the Philippines have antibodies reactive to EBOV and RESTV.

The overall seroprevalence of antibodies to ebolaviruses amongst non-human primate populations is not well documented. Non-lethal EBOV infection occurs in some non-human primates and a seroprevalence of 12.9 per cent has been reported in wild-born chimpanzees and 6.7 per cent in gorillas in Central Africa (Leroy et al. 2004). There is evidence of great apes being severely affected by EBOV (Karesh & Reed 2005; National Geographic News 2003) with populations of western lowland gorillas (*Gorilla gorilla gorilla*) and common chimpanzees (*Pan troglodytes*) having declined by approximately 80 per cent in parts of Central Africa (Leroy et al. 2004).

Clinical signs

Non-human primates are severely affected by ebolaviruses and wild chimpanzees and gorillas are often found dead. Clinical signs of EHF in non-human primates include anorexia, coughing, diarrhoea, dyspnoea, emaciation, epistaxis, hair loss, nasal discharge, petechiae, pyrexia and vomiting. African species of ebolaviruses are usually more pathogenic than RESTV with more severe clinical signs including haemorrhaging and a high mortality rate (CFSPH 2014).

Diagnosis

Definitive diagnosis is achieved by enzyme-linked immunosorbent assay (ELISA), polymerase chain reaction (PCR) assays and virus isolation. Certain species of wild non-human primates frequently test positive on ELISA indicating natural exposure, but with no evidence of active infection (CFSPH 2014).

Current biosecurity measures

There are no current biosecurity measures for Ebola haemorrhagic fever.

4.2.3 Risk review

Ebola haemorrhagic fever is present in exporting countries and it is not present in Australia.

The following key points are relevant to the biosecurity risk of Ebola haemorrhagic fever in non-human primates:

- Ebola haemorrhagic fever is present in Africa.
- Only RESTV has been reported outside Africa, in China and the Philippines.

- Ebola haemorrhagic fever is not a nationally notifiable animal disease; however, it is a nationally notifiable disease of public health concern.
- Infection in non-human primates typically results in severe clinical signs and high mortality.
- Experimental studies indicate the incubation and viraemic periods in non-human primates are short.
- There is no evidence that non-human primates are long-term carriers or that they play any role in the maintenance of the disease.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.2.4 Conclusion

Accordingly and based on the preceding information, risk management for Ebola haemorrhagic fever is not warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

4.3 Enteric bacterial diseases

4.3.1 Background

The main pathogenic enteric bacteria of importance found in non-human primates are: *Campylobacter coli*, *C. jejuni*, *Escherichia coli* (enterotoxigenic, enteropathogenic and verocytotoxin producing strains), *Salmonella* spp., *Shigella* spp. and *Yersinia enterocolitica*, *Y. pseudotuberculosis*.

Campylobacter spp. are motile, non-spore forming Gram-negative rod-shaped bacteria with worldwide distribution. The two most common isolates from non-human primates are *C. coli* and *C. jejuni*, with *C. foetus*, *C. hyointestinalis*, *C. laridis* and *C. sputorum* found less frequently (Simmons & Gibson 2012).

Escherichia coli is a non-spore forming, Gram-negative, rod-shaped bacterium that has worldwide distribution. There is great variation within the species in terms of virulence. Six pathotypes are associated with diarrhoea and are referred to as diarrhoeagenic *E. coli*. These include: shiga toxin-producing (STEC), verocytotoxin-producing VTEC) or enterohaemorrhagic *E. coli* (EHEC); enterotoxigenic *E. coli* (ETEC), which produces a heat labile or heat stable enterotoxin, or both; enteropathogenic *E. coli* (EPEC), which are associated with infantile diarrhoea; enteroinvasive *E. coli* (EIEC), which invades cells of the colonic epithelium, enteroaggregative *E. coli*; and diffusely adherent *E. coli* (DAEC) (CDC 2015b). Any of these pathotypes can be found in non-human primates with or without clinical signs (Simmons & Gibson 2012).

Salmonella spp. are motile, non-encapsulated, non-spore forming Gram-negative rod-shaped bacteria with worldwide distribution. Over 2500 serovars of *Salmonella* spp. are recognised. *S. choleraesuis*, *S. typhimurium*, *S. arizonae* and *S. enteritidis* are the *Salmonellae* most commonly associated with non-human primates and are all regarded as subspecies of *S. enterica* (Paul-Murphy 1993).

Shigella spp. are non-motile, non-encapsulated, non-spore forming Gram-negative rod-shaped bacteria. There are four serogroups of *Shigella* including *S. dysenteriae* (15 serotypes), *S. flexneri*

(8 serotypes), *S. boydii* (19 serotypes) and *S. sonnei* (1 serotype) (CDC 2015c). The serogroup *S. flexneri* is the most common cause of shigellosis in captive non-human primates. This serogroup has worldwide distribution and is readily transmissible to humans (Kennedy et al. 1993; Mulder 1971).

Yersinia spp. are non-motile, Gram-negative rod-shaped bacteria that are facultative anaerobes and are commonly associated with enteric disease in many species including humans and non-human primates. (Little et al. 1994; Sutherland & Bayliss 1994). There are two *Yersinia* spp. of medical importance for captive non-human primates; *Y. enterocolitica*, which causes yersiniosis and *Y. pseudotuberculosis*, which causes pseudotuberculosis (Simmons & Gibson 2012).

Enteric bacterial diseases are not OIE-listed diseases (OIE 2016a).

Enteric bacterial diseases are present in Australia and are not nationally notifiable animal diseases (Department of Agriculture and Water Resources 2015).

Enteric bacterial diseases are zoonoses and are nationally notifiable diseases of public health concern (campylobacteriosis, salmonellosis, shiga toxin and verocytotoxin-producing *E. coli*, and shigellosis) (Department of Health 2015).

4.3.2 Technical information

Epidemiology

Enteric bacteria inhabit the intestinal tract of many animals including birds, laboratory animals (rats, mice, hamsters, guinea pigs, non-human primates) and humans. Transmission is via the faecal-oral route and can cause severe gastrointestinal disease. Non-human primates are usually infected by direct contact or through exposure to contaminated food or water (Simmons & Gibson 2012). Habitat contamination is another potential source of infection for captive non-human primates and secondarily for personnel handling those animals. Aerosols contaminated with faecal material (as with high pressure hose cleaning) can also play a significant role in transmission (Kennedy et al. 1993). The incubation period is short and infections often run an acute course. Subclinically infected carriers of all the bacteria listed occur (Simmons & Gibson 2012). Outbreaks of gastrointestinal disease due to these species of bacteria are often precipitated by stress, such as with transport, quarantine and social disruption due to introduction of new animals.

Clinical signs

Infection in non-human primates can range from a subclinical carrier state to severe clinical signs depending on the bacteria involved. Clinical signs may include anorexia, diarrhoea, pyrexia, septicaemia, vomiting with progression to dysentery in severely affected non-human primates. Death may occur due to dehydration and secondary renal failure (Simmons & Gibson 2012).

Diagnosis

There are no pathognomonic clinical signs and a definitive diagnosis can only be made by culture and isolation of the causative organism. Both carriers and actively infected animals can be detected by culture of faecal samples. Various selective media specific for each bacterial species are needed for successful culture and isolation (King 1998; Schiemann 1982; Simmons & Gibson 2012). As the bacteria may only be excreted intermittently, repeat sampling may be needed to achieve isolation (Simmons & Gibson 2012).

Polymerase chain reaction-based tests are available and may be more sensitive than the culture technique as well as being able to provide earlier results (Dutta et al. 2001; Sur et al. 2004).

4.3.3 Current biosecurity measures

There are no current biosecurity measures for enteric bacterial diseases.

4.3.4 Risk review

Enteric bacterial diseases are present in exporting countries and are present in Australia.

The following key points are relevant to the biosecurity risk of enteric bacterial diseases in captive non-human primates:

- Enteric bacterial diseases have worldwide distribution including Australia.
- Enteric bacterial diseases are not nationally notifiable animal diseases; however, they are nationally notifiable diseases of public health concern.
- Non-human primates can become carriers, and subclinical shedders of *E. coli*, *Campylobacter* spp., *Salmonella* spp., *Shigella* spp. and *Yersinia* spp.
- Non-human primates are maintained in secure facilities and enclosures and have limited contact with the general public. However, non-human primates can have direct contact with other non-human primates as well as zoo and laboratory staff.
- Having appropriate health and safety protocols in place manages the risk of enteric bacterial diseases for zoo and laboratory staff.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.3.5 Conclusion

Accordingly and based on the preceding information, risk management for enteric bacterial diseases is not warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

4.4 Hepatitis B

4.4.1 Background

Hepatitis B is caused by hepatitis B virus (HBV), an enveloped DNA virus in the genus *Orthohepadavirus* in the family *Hepadnaviridae* (Bielitzki 1999; Mason et al. 2005). Strains of HBV have been identified in a range of primate species, including humans.

Human HBV has high genetic variability with eight genotypes (A–H) and many subgenotypes (Schaefer 2007; Sugauchi et al. 2001). HBVs also infect the greater and lesser apes - gorillas, chimpanzees, orangutans and gibbons. Infection of other primates is either rare or experimental (AAZV 2013). New world monkeys are rarely affected (Sa-nguanmoo et al. 2009), although a HBV strain has been described in the woolly monkey (*Lagothrix lagotricha*) (Lanford et al. 2003; Lanford et al. 1998).

HBV strains distinct from human strains have been described in both captive and wild populations of chimpanzees, gibbons, orangutans, and gorillas; e.g. chimpanzee HBV (Norder et

al. 2004). Recent findings also demonstrate recombination between HBV strains to produce novel strains, e.g. human and chimpanzee, gorilla and chimpanzee (Bonvicino et al. 2014).

Distribution of human HBV is worldwide. Prevalence in humans varies from less than 2 per cent in North America, Australia, Europe, Central and tropical Latin America; 4 per cent in the Caribbean, Andean and southern regions of Latin America to an estimated 8 per cent in West Africa, Asia, parts of the Middle East and the Amazon Basin (WHO 2013). High seroprevalence (40–46 per cent) of HBV infection was reported in wild gibbons (*Hylobates* spp. and *Nomascus* spp.) and orangutans (*Pongo pygmaeus*) in Asia (Sa-nguanmoo et al. 2008). HBV is widespread in captive non-human primate colonies around the world.

Hepatitis B is not an OIE-listed disease, but is considered by the OIE to be an important transmissible zoonotic disease (OIE 2016a).

Hepatitis B is present in Australia and it is not a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Hepatitis B is a zoonosis and is a nationally notifiable disease of public health concern (Department of Health 2015).

4.4.2 Technical information

Epidemiology

HBV is a blood-borne virus and present in most body fluids including saliva and semen. Transmission of HBV is horizontal and vertical (mother to infant) and results from exposure to infectious blood or to body fluids containing blood. Humans are a natural host for HBV with infection rates as high as 25 per cent in some populations. Humans may serve as a reservoir for infections of captive non-human primates.

Recombination between human and non-human primate strains and potential ability for zoonotic spread of such strains warrants consideration as research continues. While there is a potential for humans handling non-human primates to become infected from bite wounds or other penetrating injuries, true zoonotic transmission of non-human primate strains of HBV has not been reported (Noppornpanth et al. 2003; Paraskevis et al. 2013; Sa-nguanmoo et al. 2009). Anthroponotic transmission of human-sourced HBV genotypes to non-human primates is, however, well documented (AAZV 2013; Bonvicino et al. 2014). The incubation period in humans is 45–120 days, and 15–100 days in chimpanzees and gibbons (Payne 2004).

Clinical signs

A spectrum of clinical signs may be seen depending on HBV strain, host immunity and species, and environmental factors. HBV infection (non-human and human strains) of chimpanzees and gorillas as detected by serology is often subclinical. Experimental infection of chimpanzees produces mild anorexia, lethargy and icterus (Wachtman & Mansfield 2012). Infection with non-human primate strains can lead to severe clinical disease in gibbons and woolly monkeys with clinical manifestations of weight loss, lethargy, anorexia, icterus, abdominal discomfort, nausea and vomiting (AAZV 2013; Lanford et al. 1998; Wachtman & Mansfield 2012).

Diagnosis

Diagnosis of HBV infection relies mainly on detection of antigens and/or antibodies in serum, depending on the phase of HBV infection. Serological markers, particularly hepatitis B surface antigen (HBsAg), antibodies to hepatitis B core antigen (anti-HBc), and antibodies to hepatitis B surface antigen (anti-HBs) are used to differentiate between acute, resolving, and chronic

infection (AAZV 2013). Serological assays are available commercially for all markers except HBcAg because there is no free HBcAg circulating in blood. In chimpanzees, carriers may be seropositive for HBsAg for many months or even years (Thung et al. 1981).

Prevention

Risk of HBV exposure when handling susceptible species can be minimised by using protective gloves and clothing and by following appropriate health and safety standards for working with these species. People may be vaccinated using a subunit vaccine containing hepatitis B surface antigen produced by recombinant technology.

Vaccination can be used in some non-human primate species, especially the apes, and has been used to reduce the risk of HBV spread in zoo collections (Payne et al. 2003). A vaccination schedule has been developed to protect the offspring of chronic HBV carriers. Gibbons at Perth zoo developed a serological response consistent with vaccine-induced immunity after being vaccinated soon after birth and with a booster at eight months (Payne et al. 2003).

4.4.3 Current biosecurity measures

The animal must come from premises where there were no cases or other evidence of hepatitis B in any animal for at least six months before export.

4.4.4 Risk review

Hepatitis B is present in exporting countries and it is present in Australia.

The following key points are relevant to the biosecurity risk of hepatitis B in captive non-human primates:

- Hepatitis B has worldwide distribution, including Australia.
- Hepatitis B is not a nationally notifiable animal disease; however, it is a nationally notifiable disease of public health concern.
- HBV does not exclusively infect humans but is also found in non-human primates in the families Hominidae (chimpanzee, gorilla and orangutan) and Hylobatidae (gibbon).
- HBV strains distinct from human strains have been described in both captive and wild populations of chimpanzees, gibbons, orangutans, and gorillas.
- Recombinant HBV strains are also found in non-human primates.
- Most HBV infections in non-human primates are subclinical.
- Zoonotic transmission of HBV to humans from non-human primates has not been reported, but is theoretically possible.
- Non-human primates are maintained as controlled populations in secure facilities and enclosures and have limited contact with the general public. However, non-human primates can have direct contact with other non-human primates as well as zoo and laboratory staff.
- Having appropriate health and safety protocols in place manages the risk of HBV infection for zoo and laboratory staff.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.4.5 Conclusion

Accordingly and based on the preceding information, specific risk management for hepatitis B is no longer warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

4.5 Marburg haemorrhagic fever

4.5.1 Background

Marburg haemorrhagic fever (MHF) is caused by a member of the genus Marburgvirus, in the family Filoviridae (ICTV 2014). Marburgvirus contains a single species, Marburg marburgvirus (formerly Lake Victoria marburgvirus), and two individual viruses, Marburg virus and Ravn virus, within this species (CFSPH 2014).

Humans and non-human primates are very susceptible to MHF. Fruit bats (*Rousettus aegyptiacus*) of the Pteropodidae family are considered to be the primary reservoir hosts for Marburgvirus (Towner et al. 2009; Towner et al. 2007).

MHF was first described in 1967 during outbreaks in Germany and the former Yugoslavia. The outbreaks were linked to laboratory exposure to tissue samples from wild-caught monkeys imported from Uganda (Bausch et al. 2003). Since then, cases have been limited to East Africa and southern Africa, and have not been linked to non-human primates.

Marburg haemorrhagic fever is not an OIE-listed disease (OIE 2016a).

Marburg haemorrhagic fever is not present in Australia and it is not a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Marburg haemorrhagic fever is a zoonosis and is a nationally notifiable disease of public health concern (Department of Health 2015).

4.5.2 Technical information

Epidemiology

Although the original source of Marburgvirus infection in non-human primates is unclear, it is probable it is like Ebolavirus where direct infection is attributed to contact with one or more natural hosts as well as forest fruits contaminated with bat body fluids (OIE 2015a).

In humans, initial infection may occur through exposure in mines or caves inhabited by *Rousettus* bat colonies (Towner et al. 2009; Towner et al. 2007). Subsequent human-to-human transmission occurs through direct contact with body fluids such as blood, faeces, saliva, semen, urine and vomit of an infected person (WHO 2005a).

In non-human primates under experimental conditions, Marburgvirus is transmitted by direct contact, fomites and aerosolisation (Alves et al. 2010).

The incubation period of MHF in humans is 3–9 days (WHO 2005a) and long-term carriers have not been reported. The incubation period is 2–6 days in experimentally infected non-human primates (Alves et al. 2010; Nakayama & Saijo 2013). There is nothing in the scientific literature to implicate non-human primates as long-term carriers or that they play a role in maintenance of the disease.

Antibodies to Marburgvirus have been detected in healthy, free roaming and wild caught baboons and vervet monkeys (Johnson et al. 1982), indicating infection is not always lethal. There are no details of the overall seroprevalence of antibodies to Marburgvirus in non-human primates reported in the scientific literature.

Clinical signs

The initial clinical signs are non-specific and are similar to those of more common infections. In humans, clinical signs can begin abruptly and include marked pyrexia, headache and malaise. In fatal cases, death most often occurs 8–9 days after the onset of clinical signs (WHO 2005a). The manifestations of Marburgvirus infection in non-human primates are similar to those in humans. Anorexia, cough, and decreased activity and vocalisation are quickly followed by death (Schou & Hansen 2000).

Diagnosis

Various methods can be used to detect IgM or IgG against Marburgvirus. Enzyme-linked immunosorbent assay (ELISA) as well as Western blot are mainly used due to their higher sensitivity and specificity. Definitive evidence of acute infection is mostly based on virus isolation or viral antigen/RNA detection (Schou & Hansen 2000).

Current biosecurity measures

There are no current biosecurity measures for Marburg haemorrhagic fever.

4.5.3 Risk review

Marburg haemorrhagic fever is present in exporting countries and it is not present in Australia.

The following key points are relevant to the biosecurity risk of Marburg haemorrhagic fever in non-human primates:

- Marburg haemorrhagic fever is present in Africa.
- Marburg haemorrhagic fever is not a nationally notifiable animal disease; however, it is a nationally notifiable disease of public health concern.
- Infection in non-human primates is typically severe with high mortality.
- Experimental studies indicate the incubation period in non-human primates is short.
- There is no evidence that non-human primates are long-term carriers or that they play any role in maintenance of the disease.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.5.4 Conclusion

Accordingly and based on the preceding information, risk management for Marburg haemorrhagic fever is not warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

4.6 Measles

4.6.1 Background

Measles virus is an enveloped RNA virus of the Morbillivirus genus, family Paramyxoviridae (ICTV 2014). Other viruses in the genus include peste des petits ruminants virus, canine and phocine distemper viruses and rinderpest virus (Lamb et al. 2005). Measles virus has one serotype (Lowenstine 1993). Humans are the primary host for measles. The susceptibility among non-human primates is variable and the disease has been reported in African green (vervet) monkeys (*Chlorocebus aethiops*), baboons (*Papio* spp.), chimpanzees (*Pan* spp.), colobus monkeys (*Colobus guereza*), macaques (*Macaca* spp.), marmosets (*Saguinus* and *Callithrix* spp.), silvered leaf-monkeys (*Presbytis cristatus*) and squirrel monkeys (*Saimiri* spp.) (Wachtman & Mansfield 2012). All non-human primate species are presumed to be susceptible.

Measles has a worldwide distribution, and Africa, parts of the Middle East and South-East Asia have the highest incidence (WHO 2010a). In 2014, the World Health Organization (WHO) announced that measles elimination had been achieved by Australia, Macao (China), Mongolia and the Republic of Korea (Department of Health 2014). Measles elimination does not mean the complete absence of the disease. Cases will still occur in infected travellers from countries where the disease is prevalent and may sometimes result in small and localised outbreaks in individuals not immune to the disease.

Measles is not an OIE-listed disease (OIE 2016a).

Measles is not present in Australia and it is not a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Measles is a zoonosis and a nationally notifiable disease of public health concern (Department of Health 2015).

4.6.2 Technical information

Epidemiology

Measles virus is transmitted by aerosols and is highly contagious (Lowenstine 1993; Wachtman & Mansfield 2012). Transmission may be from humans to non-human primates, non-human primates to humans, and between non-human primates (Wachtman & Mansfield 2012).

The incubation period is six to ten days (Mansfield & King 1998). The virus replicates in regional lymph nodes leading to viraemia and dissemination of virus to lymphoreticular organs and epithelial surfaces (Hall et al. 1971; Mansfield & King 1998).

Serological evidence indicates that measles can be a common infection in captive non-human primates. It is primarily an anthroponosis, though once the disease is in a non-human primate population, it can become endemic, or epizootic with devastating results (Lowenstine 1993; Wachtman & Mansfield 2012). Epizootics are seen primarily in large captive colonies. Measles does not occur in wild non-human primates in their natural habitats (Wachtman & Mansfield 2012).

Clinical signs

Clinical signs vary depending on the species affected. In otherwise healthy macaques, measles is usually mild or subclinical, but immunosuppressed or stressed animals become ill.

Following the incubation period, infected animals may develop pyrexia and a maculopapular exanthema. Marmosets (*Callitrichidae* family) and colobus monkeys (*Colobi*) are particularly

susceptible with disease progressing rapidly and gastrointestinal signs predominating (Hunt, Anderson & Chalifoux 1978; Mansfield & King 1998; Wachtman & Mansfield 2012). In marmosets, clinical signs include lethargy, eyelid oedema, mucous nasal discharge and occasionally a maculopapular rash. Death can occur rapidly, eight to 18 hours after onset of clinical signs (Levy & Mirkovic 1971). Susceptibility of marmosets varies according to the strain of virus. Mortality in marmosets can reach 100 per cent (Albrecht et al. 1980; Hunt, Anderson & Chalifoux 1978; Mansfield & King 1998). Colobus monkeys may die without evidence of clinical signs (Hime, Keymer & Baxter 1975).

Rhesus macaques are also very susceptible and epizootics have followed transportation, with high morbidity. In some cases respiratory signs are sometimes present and there is a lowered resistance to gastrointestinal and other bacterial infections (Mansfield & King 1998; Montrey et al. 1980; Welshman 1989).

Diagnosis

Presumptive diagnosis may be made based on seroconversion and characteristic clinical, histopathological and ultrastructural findings. Definitive diagnosis is achieved by virus isolation and identification (Wachtman & Mansfield 2012).

Prevention

Vaccination may be used as part of a preventative health program for non-human primates. A modified live measles vaccine designed for human use may be given to non-human primates (Wachtman & Mansfield 2012).

4.6.3 Current biosecurity measures

The animal must come from premises where there were no cases or other evidence of measles in any animal for at least six months before export.

4.6.4 Risk review

Measles is present in exporting countries and is not present in Australia.

The following key points are relevant to the biosecurity risk of measles in captive non-human primates:

- Measles has a wide distribution around the world.
- Measles was eliminated from Australia in 2014; however, occasional cases are reported in people that acquire the disease overseas.
- Measles is not a nationally notifiable animal disease; however, it is a nationally notifiable disease of public health concern.
- The incubation period in non-human primates is typically six to ten days.
- Clinical signs vary depending on the species affected.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.6.5 Conclusion

Accordingly and based on the preceding information, risk management for measles is no longer warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

4.7 Rabies

4.7.1 Background

Rabies virus is a member of the *Lyssavirus* genus of the family *Rhabdoviridae* (Tordo et al. 2005). There are currently 14 species in the *Lyssavirus* genus including the type species rabies virus (ICTV 2014). Rabies virus causes a progressively fatal encephalitis that can affect all species of mammals. Rabies is seen predominantly in domestic dogs, with other species of the order Carnivora (particularly canids) and Chiroptera (bats) recognised as wildlife reservoirs (ARMCANZ 1996; WHO 2005b). Rabies has been reported in a range of non-human primate species (Wachtman & Mansfield 2012). The common marmoset (*Callithrix jacchus jacchus*) in Brazil is host to a unique strain of rabies, which has resulted in human fatalities. These animals act as a reservoir and maintain the circulating virus in the wild (Favoretto et al. 2013; Favoretto et al. 2001). There have been limited reports of rabies in captive non-human primates (T-W-Fiennes 1972; Gautret et al 2014).

Rabies is present virtually worldwide and is common on all continents except Australia and Antarctica. Many island countries, territories and states are also free of rabies.

Australia is free of classical rabies. However, a lyssavirus has been isolated from bats that causes disease in bats, humans (Field, McCall & Barrett 1999; Gould et al. 1998; Greene & Rupprecht 2006) and horses (Shinwari et al. 2014).

Rabies is an OIE-listed disease (OIE 2016a).

Rabies is not present in Australia and it is a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Rabies is a zoonosis and a nationally notifiable disease of public health concern (Department of Health 2015).

4.7.2 Technical information

Epidemiology

The dog is the chief source of infection but a wide variety of species of the orders Carnivora and Chiroptera can act as reservoirs (Geering & Forman 1987; WHO 2005b). Transmission is normally through biting when virus in the infected animal's saliva enters the new host through broken skin. In dogs, virus may be present in the infected animal's saliva up to 14 days before the onset of clinical signs. Rabies virus may be transmitted between species, resulting in either a dead-end infection (where there is no further transmission of the virus), or transmission of the virus by the new host. Spill over infections can cause sporadic cases of rabies without further transmission due to there being no other species to interact with, low salivary shedding of virus or failure of infection to induce biting behaviour (Bingham 2005). Rabies transmission to humans via bites and scratches from non-human primates has been reported (Wachtman & Mansfield 2012).

The incubation period in all species is variable and may be prolonged. It is influenced by the quantity of virus introduced, proximity of the bite site to the head, the sensory innervation at the bite site, the age of the animal and the biotype of the rabies virus involved (Kaplan 1969; Niezgoda, Hanlon & Rupprecht 2002). In canids, incubation is normally four to eight weeks, but

can be as short as four days or greater than a year in very rare cases (Kaplan 1969; Swanepoel et al. 1993). On rare occasions, circumstantial evidence has pointed towards incubation periods in humans as long as several years (Geering & Forman 1987; Smith et al. 1991). Information on cases in non-human primates is limited but the incubation period has been estimated to range from several weeks to months (Brack 1987; T-W-Fiennes 1972) and can be regarded as corresponding to that in humans (T-W-Fiennes 1972). OIE recommendations are based on an incubation period of six months (OIE 2015b).

Clinical signs

The initial clinical signs of rabies are non-specific and may include inappetance, malaise and pyrexia. Hydrophobia, paresis and paralysis are common. Death usually results from cardiac or respiratory failure (Rupprecht 1999). Non-human primates tend towards the dumb rather than furious expression of rabies (Boulger 1966; Mansfield & King 1998; T-W-Fiennes 1972).

Diagnosis

No satisfactory test will detect rabies in the incubation and prodromal stages of the disease. In animals, diagnosis is confirmed at post-mortem. The most widely used test for rabies diagnosis is the indirect fluorescent antibody test recommended by World Health Organization (WHO), Centers for Disease Control and Prevention (CDC) and OIE. This test may be used direct on a brain smear and takes only a few hours to perform (CDC 2010; OIE 2016b).

Prevention

Vaccination may be used as part of a preventative health program for non-human primates (Nieves et al. 1996). Vaccination with killed vaccines induces a neutralising antibody response, although how effective this is at preventing transmission in non-human primates is unknown (Wachtman & Mansfield 2012). Attenuated vaccines have been implicated in occurrences of vaccine-induced disease in non-human primates (Wachtman & Mansfield 2012). Recombinant vaccines have demonstrated high and sustained rabies neutralising titres but are not suited to post-exposure prophylactic use (Xiang et al 2014; Faber 2014). DNA vaccines have been shown to protect non-human primates against rabies virus challenge (Ullas et al 2012).

4.7.3 Current biosecurity measures

The animal must come from premises where there were no cases or other evidence of rabies in any animal for at least six months before export.

4.7.4 Risk review

Rabies is present in exporting countries and is not present in Australia, where it is a nationally notifiable animal disease.

The following key points are relevant to the biosecurity risk of rabies in captive non-human primates:

- Rabies is endemic in most countries across Africa, Asia and the Americas.
- Rabies is a nationally notifiable animal disease and a nationally notifiable disease of public health concern.
- Rabies is a multiple species OIE-listed disease.
- The incubation period in all species is variable and may be prolonged.

- Rabies has been reported in wild non-human primate species across Africa, Asia and the Americas.
- Rabies transmission to humans via bites and scratches from non-human primates has been reported.
- Rabies occurrence in captive non-human primates is extremely rare.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.7.5 Conclusion

Accordingly and based on the preceding information, risk management continues to be warranted.

The department proposes premises freedom as a measure to reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

Australia's biosecurity measures for rabies for captive non-human primates are:

- For 180 days before export the animal did not reside on any premises in the country of export where clinical, epidemiological or other evidence of rabies occurred during the previous six months before export.

4.8 Tuberculosis

4.8.1 Background

Tuberculosis is caused by *Mycobacterium* spp. in the family Mycobacteriaceae. They are non-motile, non-spore forming, weakly Gram-positive, acid fast, facultative intracellular bacteria. Those species pathogenic for humans and animals belong to the slow-growing group (Gibson 1998; Good & Shinnick 1998) and are referred to as the *Mycobacterium tuberculosis* complex. Members of the *M. tuberculosis* complex include: *M. africanum*, *M. bovis*, *M. canettii*, *M. caprae*, *M. microti*, *M. orygis*, *M. pinnipedii* and *M. tuberculosis*. The two most common causes of tuberculosis in non-human primates are *M. tuberculosis* – accounting for the majority of cases – and *M. bovis* (King 1993; McClure 1980; Montali, Mikota & Cheng 2001). This risk review will deal with tuberculosis caused by *M. bovis* and *M. tuberculosis*.

Humans are the natural host for *M. tuberculosis* and cattle are the natural host for *M. bovis* ('bovine tuberculosis'). *M. tuberculosis* has also been identified in elephants, non-human primates, non-domesticated ungulates, carnivores and psittacine birds (Montali, Mikota & Cheng 2001). Many cloven hoofed species have established natural infections with *M. bovis*. In the wild, the badger in the United Kingdom and Australian brush tail possum in New Zealand have also established reservoir infections (Radostits et al. 2007). Tuberculosis (*M. bovis* and *M. tuberculosis*) occurs in all non-human primate species, but susceptibility varies. Young macaques are the most susceptible and New World monkeys the least (Simmons & Gibson 2012). Tuberculosis 'infection' includes any animals harbouring the mycobacterium in their body regardless of whether or not they display clinical signs.

M. tuberculosis occurs worldwide. It is detected at low prevalence within Australia and there are concerns that new strains of the bacteria with differing pathogenicity may be imported with non-human primates if risk management is not applied.

M. bovis is present in most countries but it was eradicated from Australia and freedom in accordance with the Code was declared in 1997.

Bovine tuberculosis is an OIE-listed disease (OIE 2016a).

Bovine tuberculosis is not present in Australia and it is a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015). It is essential that a definitive diagnosis be made for any animal in Australia with signs that could be due to this disease organism to maintain that status.

Tuberculosis (from all causative agents) is a zoonosis and a nationally notifiable disease of public health concern (Department of Health 2015).

Bovine tuberculosis (*M. bovis*) is a disease of significant economic importance to Australia. In the context of non-human primates there is considerable difficulty distinguishing between tuberculosis species, including *M. bovis* and *M. tuberculosis*. The implication of this is that Australia must assess animals that exhibit clinical signs or test results consistent with having undefined tuberculosis as potentially infected with *M. bovis*.

4.8.2 Technical information

Epidemiology

Transmission of tuberculosis in non-human primates is primarily through aerosols, with lesions being predominantly in lungs. Alimentary lesions occur to a lesser extent through ingestion of infected material, while contact with contaminated fomites may also be a source of infection (Gibson 1998; King 1993).

Most cases of tuberculosis in captive non-human primates have been caused by *M. tuberculosis*, although some *M. bovis* infections have been reported including a large outbreak in a captive baboon colony (McLaughlin 1978). Bovine tuberculosis may be transmitted by aerosols, milk or meat from infected animals (Good & Shinnick 1998).

Africa and South-East Asia have the highest global incidence of human tuberculosis, while Australasia, Europe and North America have the lowest (Roche, Merianos & National TB Advisory Committee 2001; WHO 2010b). In Australia the disease is concentrated in indigenous Australians, people born overseas and people over 70 years of age (Roche, Merianos & National TB Advisory Committee 2001).

Clinical signs

Clinical signs in non-human primates are generally non-specific and may take several years to develop (Jones 1982). A persistent cough is a sign of respiratory infection, and lethargy, anorexia, weight loss and exertional dyspnoea are common. In advanced cases, lymphadenopathy, with or without draining abscesses, hepatomegaly and splenomegaly, may be detected (Gibson 1998). On occasion, animals may be found dead with no premonitory signs.

Infection of non-human primates has a spectrum of clinical outcomes including no overt disease, rapidly progressive disease, or more commonly, a chronic debilitating disease (Lerche et al 2008). As in humans, not all infections of non-human primates result in active tuberculosis. The development of latent infections without overt disease is well documented. While latent infection with these organisms is not infectious there is a significant risk of reactivation and development of active tuberculosis with potential direct spread (Lerche et al 2008; Capuano et al 2003; Gormus et al 2004; Flynn 2001).

In humans, latent infection occurs in 90 per cent of tuberculosis cases and reactivation may occur decades after the initial infection (Lin & Flynn 2012). In non-human primates infection can vary widely by species. An experiment in three species of Old World monkeys revealed African

green monkeys (*Chlorocebus aethiops*) to be extremely sensitive with rapid, uniform progression to clinical disease. Rhesus macaques demonstrated a more variable clinical course, and cynomolgus macaques a more chronic course (Motzel et al 2003). A non-human primate model in cynomolgus macaques demonstrated latent disease in 50 per cent of cases (Lin & Flynn 2012).

Diagnosis

No single test is 100 per cent effective at diagnosing tuberculosis. As already stated, it is difficult to differentiate between tuberculosis caused by *M. tuberculosis* and *M. bovis* with existing tests.

Test specificity and sensitivity depend on the stage of disease, type of mycobacterial infections and other confounding factors. Certain tests used in the clinical setting for the diagnosis of tuberculosis – such as radiographs and culture – are also limited in their use as screening tests as they are more suited to confirming an infected status.

In non-human primates, the main diagnostic test that has been used to date is the intradermal tuberculin skin test (TST), which uses tuberculin protein to elicit a delayed-type hypersensitivity reaction (King 1993). The TST involves injection of tuberculin at the eyelid or a demarcated site on the abdomen according to established protocols, with reactions measured 24, 48, and 72 hours after injection. A standardized scoring system for intrapalpebral reactions uses a 0 to 5 grading system. Reactions graded 0, 1, or 2 are considered negative, a grade 3 reaction is considered suspect, and grades 4 and 5 are considered positive. Abdominal skin reactions are scored on a similar 0 to 3 scale. Reactions graded 0 or 1 are considered negative, a grade 2 reaction is considered suspect, and grade 3 is considered positive (Kramer, Ford & Capuano 2012; Lecu et al. 2013).

Non-human primates other than orangutans appear to require more tuberculin than humans to elicit a positive intradermal tuberculin test. Mammalian old tuberculin, which is less purified but has more tuberculin units than purified protein derivative (PPD), is the preferred reagent to use in non-human primates (Bushnitz et al. 2009). The upper eyelid is the usual site of choice for the intradermal injection, but in the case of very small monkeys, the skin on the abdomen may be preferred. From time of infection it takes at least three weeks for the individual's immune response to be activated sufficiently and thereby demonstrate a reaction if a TST is applied. For animals undergoing quarantine for importation a series of consecutive tests at two-week intervals are recommended when using the TST (Bushnitz et al. 2009; Lerche et al. 2008; OIE 2015c). The TST has limitations in that it is unable to reliably identify animals with latent tuberculosis infections (Bushnitz et al. 2008; Lerche et al. 2008). False positive and false negative test results are common (Lecu et al. 2013; Lerche et al. 2008). False negative results may be due to underlying disease causing immunosuppression. Incorrect injection technique, subjectivity in the interpretation of the TST, or use of suboptimal concentration of tuberculin can also result in false negative test results. False positive results may be due to previous exposure to injection adjuvant or non-specific reactions to contaminants or exposure to atypical or saprophytic mycobacteria (Bushnitz et al. 2009).

In the majority of Australian zoos the comparative tuberculin skin test (CTST) is the standard screening test for non-human primates (A. Reiss, ZAA, pers. comm. January 2016). The CTST compares the response to avian tuberculin with the response to bovine PPD tuberculin and helps rule out false positives from non-specific reactions due to exposure to atypical mycobacteria. A CTST is interpreted as positive if the bovine PPD-swelling is greater than the avian PPD-induced swelling. The CTST is interpreted as negative if the avian PPD-induced swelling is greater than the bovine PPD-induced swelling, or if there is no reaction to either injection.

Healthy captive orangutans, with no known exposure to pathogenic mycobacteria, frequently respond to TSTs. The interpretation of TSTs in orangutans is challenging as relatively high levels of false positives from TSTs in this species have been documented. To assist with test interpretation, a modified CTST together with culture, radiography and an enzyme-linked immunosorbent assay may assist in those circumstances (Dench et al. 2015; Lecu et al. 2013; Lerche et al. 2008; OIE 2015c).

A serological assay technique has been developed that measures the in vitro production of gamma interferon when whole blood is stimulated with PPD. It compares three results - when blood is stimulated with bovine PPD, avian PPD and a negative control (Kramer, Ford & Capuano 2012). One example of this type of test is the PRIMAGAM™. Whole blood from the test animal is incubated overnight with PPD and, if activated, lymphocytes produce IFN- γ in response to the PPD stimulation (Garcia et al. 2004). However, there are species-specific differences in IFN- γ response that should be taken into consideration (Garcia et al. 2004; Lerche et al. 2008). The PRIMAGAM™ is best used in parallel with the TST for maximal overall sensitivity in a tuberculosis screening program (Garcia et al. 2004; Lerche et al. 2008). All gamma interferon assays are very sensitive to sample collection, handling, storage, and transport conditions (A. Reiss, ZAA, pers. comm. July 2016). A good understanding of these requirements and careful preparation is needed in order to ensure reliability of test results.

Serological tests that detect antibodies against *Mycobacterium*-specific antigens have some value as an immunodiagnostic method for tuberculosis. The PrimaTB STAT-PAK® assay employs a selective array of recombinant *M. tuberculosis* and *M. bovis* proteins. Scientific validation of this test has been limited to rhesus macaques, cynomolgus macaques, and African green monkeys (*Cercopithecus aethiops sabaeus*). Test results for other non-human primates should be interpreted cautiously, as sensitivity and specificity values are not available for species other than these three validated species (Lyashchenko et al. 2007). The PrimaTB STAT-PAK® has been succeeded by the Dual Path Platform (DPP) VetTB assay, which works on similar principles. The DPP VetTB is available for Elephants and Cervids but has been used in a wide array of animals including rhinoceroses and domestic felids (Chambers 2013). Scientific validation of this test for non-human primates was not located in the literature.

Thoracic radiography may provide confirmation of pulmonary disease but cannot reliably distinguish between tuberculosis and pneumonia due to other causes (Keeling, Frochlich & Ediger 1969; Keeling & Wolf 1975; Lecu et al. 2013). Digital and film-screen radiography have a limiting spatial resolution between 0.17-0.08mm, making them unsuitable for screening for microscopic disease or carrier animals that do not have extensive lesions or pathology patterns (Thrall 2007). More developed pathology may still be missed, e.g. non-mineralised pulmonary nodules are not visible on radiography until they exceed a critical diameter of between 5-10mm (Thrall 2007). In latent infection granulomas can be smaller than 1mm (Lin & Flynn 2012).

A positive culture for *M. tuberculosis* complex confirms the diagnosis of tuberculosis infection and is considered to be the gold standard (Lecu et al. 2013). However, it takes at least eight weeks to confirm a negative culture. Collection of appropriate samples from non-human primates can be difficult and intermittent shedding of low numbers of bacteria may result in false negative results (Simmons & Gibson 2012).

Polymerase chain reaction (PCR) can be used to detect mycobacterial DNA in any biological samples and intrinsically has the advantage of being much quicker than the conventional culture methods of diagnosis. Lecu et al 2013 suggests that the sensitivity of PCR is likely lower compared to pure culture when applied to biopsy or faecal samples, however other sources do not recognise this as a limitation (Simmons & Gibson 2012; Bushnitz et al 2008).

No single test meets all the requirements for accurate and efficient tuberculosis screening in non-human primates. Therefore recommendations include multiple tests to increase the sensitivity and specificity of the testing protocol (Lerche et al. 2008).

As stated previously, in non-human primates there is considerable difficulty distinguishing between tuberculosis due to *M. bovis* and *M. tuberculosis*. Bovine tuberculosis is a disease of significant economic importance to Australia. Australia proclaimed freedom from bovine tuberculosis in 1997 and maintains an active surveillance program for this disease. The implication of this is that Australia must assess animals that exhibit clinical signs or test results consistent with having undefined tuberculosis with a view to definitive diagnosis that confirms or rules out *M. bovis* as the causal agent.

Treatment

Mycobacterial diseases in any species are difficult to treat successfully. Multi-drug therapy has been reported as successful in some non-human primate cases, but animals that appear to be recovered should not be assumed to be free from infection (Simmons & Gibson 2012). Anti-tuberculin drugs have been administered for long periods, sometimes for years but on occasions have only held infection in check (Jones 1982). In cases that have been treated successfully, the organism was isolated and antibiotic sensitivity was determined beforehand (Bushnitz et al. 2009; Simmons & Gibson 2012). Treatment is typically prolonged and multimodal antibiotic therapy may be required (Simmons & Gibson 2012).

4.8.3 Current biosecurity measures

The animal must come from premises where no case of tuberculosis (disease due to infection with *Mycobacterium tuberculosis* or *M. bovis*) occurred in primates during the five years before export.

AND

The animal must be tested during the 12 months before export, with negative results, by:

- an intradermal tuberculin test using 0.1 ml of mammalian old tuberculin, or
- bovine PPD tuberculin 0.1ml containing at least 50 000 IU/ml, or
- a comparative tuberculin skin test using 0.1ml of bovine PPD tuberculin containing at least 20 000 IU/ml in one site, and 0.1ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site, or
- a gamma interferon assay (Primagam™, CSL Ltd).

AND

During post-entry quarantine, the animal must be tested for tuberculosis, with negative results, using intradermal mammalian old tuberculin testing as per the manufacturer's instructions or the gamma interferon assay (Primagam™). The animal must be kept in buildings or enclosures that preclude direct contact with other primates or ungulates until it has been tested for tuberculosis with negative results.

4.8.4 Risk review

The following key points are relevant to the biosecurity risk of tuberculosis in captive non-human primates:

- Tuberculosis has a worldwide distribution, but bovine tuberculosis is not present in Australia.
- Bovine tuberculosis, due to *M. bovis*, is a nationally notifiable animal disease.
- Bovine tuberculosis is a disease of significant economic importance to Australia.
- Bovine tuberculosis is an OIE-listed disease.
- Bovine tuberculosis is considered to be rare in captive non-human primates.
- Tuberculosis (*Mycobacterium tuberculosis* complex) is a nationally notifiable disease of public health concern.
- Transmission of *M. tuberculosis* can occur via respiratory aerosols.
- Tuberculosis caused by *M. tuberculosis* is common in captive non-human primates.
- Infections in non-human primates may be active or latent.
- Treatment of tuberculosis is not reliable at eliminating infection.
- Non-human primates are sourced from and maintained in secure facilities that have health monitoring programs and are under veterinary supervision.

4.8.5 Conclusion

Accordingly and based on the preceding information, risk management continues to be warranted.

The department proposes premises freedom and diagnostic testing in pre-arrival quarantine as measures to reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

Australia's biosecurity measures for tuberculosis for captive non-human primates are:

For two years immediately before export, or since birth if the animal is less than two years of age, the animal did not reside on any premises in the country of export where clinical, epidemiological or other evidence of tuberculosis (*Mycobacterium tuberculosis* complex) occurred during the previous two years before export.

AND

The non-human primate was subjected to a combination of two tests for tuberculosis, with negative results, at least 14 days apart, during the 30 days before export, by:

- An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, **or**
- An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
- A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site, **or**
- A gamma interferon assay that has been approved for use by the department (e.g. Primagam™)[#]

[#]If a gamma interferon assay is used, the other test used must be an intradermal tuberculin test or comparative tuberculin skin test.

OR

The non-human primate was subjected to a gamma interferon assay that has been approved for use by the department (e.g. Primagam™) and a second test for tuberculosis, with negative results, during the 30 days before export, by:

- An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, **or**
- An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
- A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site.

OR

The non-human primate was subjected to two tests for tuberculosis, with negative results, with the first test during the six months before export and second test[†] during pre-arrival quarantine, by:

- An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, **or**
- An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
- A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site **or**
- A gamma interferon assay that has been approved for use by the department (e.g. Primagam™)

[†]The second test during pre-arrival quarantine must be an intradermal or comparative tuberculin skin test

Note: Reactions should be measured 24, 48, and 72 hours after injection. Reactions graded 0, 1, or 2 (out of 5) are considered negative for a palpebral intradermal tuberculin test and reactions graded 0 or 1 (out of 3) are considered negative for an abdominal intradermal tuberculin test. The comparative tuberculin skin test is negative if the avian PPD-induced swelling is greater than the bovine PPD-induced swelling.

Unweaned animals accompanying eligible dams are exempt from testing.

4.9 Tularaemia

4.9.1 Background

Tularaemia is a zoonotic disease caused by *Francisella tularensis*, a non-motile, Gram-negative coccobacillus. Tularaemia occurs endemically in temperate regions of the Northern Hemisphere, including North America, China, parts of Europe, Japan, Korea and Russia (Greene & Rupprecht 2006). The highly virulent *F. tularensis* (type A) is found in North America, whereas the less virulent *F. tularensis holarctica* (type B) is found throughout the Northern Hemisphere. In 2002, *F. tularensis novicida*, a less virulent subspecies, was isolated from a human in Australia (Whipp et al. 2003). A human case due to *F. tularensis holarctica* was identified in 2011 in a wildlife carer in Tasmania who had been in close contact with possums (Jackson et al. 2012).

The natural reservoir hosts are certain species of rodents and lagomorphs, and their associated parasites, which includes ticks, mosquitoes, fleas and horseflies are vectors (Goddard 1998). *Francisella* can also infect many other mammals, amphibians, birds and fish (Hoelzle et al. 2004).

Outbreaks have been reported in captive non-human primates. A small group acquired disease through fleas that came from wild squirrels around their cages. Four of seven monkeys died. The veterinarian treating these monkeys was bitten by an infected monkey and also acquired the disease (Nayar, Crawshaw & Neufeld 1979; Preiksaitis et al. 1979). Another zoo outbreak was attributed to contamination of food by faeces and urine from infected mice (*Mus musculus*). Mice were observed dying before deaths of non-human primates. In this case, Type B *F. tularensis* was isolated (Calle, Bowerman & Pape 1993). An outbreak of Type A *F. tularensis* was reported in a group of captive Bornean orangutans (*Pongo pygmaeus pygmaeus*) where the source of infection was believed to be through contact with an infected cottontail rabbit (*Sylvilagus floridanus*), which had gained access to the orangutan's outdoor enclosure (Ketz-Riley et al. 2009).

Humans may suffer serious clinical disease when infected (Hoelzle et al. 2004). Non-human primates appear to be more susceptible than humans (Nayar, Crawshaw & Neufeld 1979). New World monkeys appear particularly susceptible with natural infections reported in tamarins (*Sanguinus* spp.), marmosets (*Callithrix* spp.) and squirrel monkeys (*Saimiri* spp.) (Eng, Orr & Leslie 2002; Hoelzle et al. 2004; Ott-Joslin 1993).

Tularaemia is a multiple species OIE-listed disease (OIE 2016a).

Tularaemia (*F. tularensis* type A) is not present in Australia and it is a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

A single case of Tularaemia (*F. tularensis* type B) infection in a human was diagnosed in Tasmania in 2012, but the organism has not been isolated in Australia. It is a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Tularaemia is a zoonosis and is a nationally notifiable disease of public health concern (Department of Health 2015).

4.9.2 Technical information

Epidemiology

In humans, Type A infection is generally considered more serious than Type B. In non-human primates, Type B is a significant pathogen (Calle, Bowerman & Pape 1993).

Transmission of *F. tularensis* occurs through a variety of modes, including bites of infected vectors, direct contact with infected animals or tissues, ingestion of the organism in contaminated food or drink, and through inhalation (Feldman 2003; Greene & DeBey 2006). Water, mud, dust and fomites may carry the infective organism. Reservoir hosts include certain species of rodents and lagomorphs. Biting flies and ticks are chief vectors with fleas considered to be poor vectors. The incubation period is generally 3–6 days, but can be between one and 14 days (Ketz-Riley et al. 2009).

Tularaemia occurs mostly in the Northern Hemisphere – North America, China, parts of Europe, Japan, Korea and Russia. Prevalence in Scandinavia and Western Europe is very low (Hoelzle et al. 2004).

Clinical signs

The clinical presentation of tularaemia varies with the route of infection. The disease usually starts with nonspecific signs such as anorexia, depression, diarrhoea, lethargy, pyrexia, vomiting or peracute death without prior clinical signs. The severity of disease in non-human primates varies between species. In New World monkeys, the condition can be peracute and often animals are found dead or close to death without signs of illness. Clinical disease in experimentally

infected monkeys was shown to be similar to that in humans, but with a higher mortality rate (Calle, Bowerman & Pape 1993; Hoelzle et al. 2004; Ketz-Riley et al. 2009; Nayar, Crawshaw & Neufeld 1979).

Diagnosis

Diagnosis in most cases of infection in non-human primates is made post mortem (Eng, Orr & Leslie 2002). *F. tularensis* is a fastidious organism which requires enriched medium for growth (Ellis et al. 2002).

Because of the difficulty in culturing *F. tularensis*, many human cases of tularaemia are diagnosed on the basis of clinical picture and/or serology. Diagnosis of human cases of tularaemia is usually confirmed by demonstrating an antibody response to *F. tularensis*, which occurs about two weeks after onset of disease (Hoelzle et al. 2004). In an outbreak in captive orangutans, antibody titres measured five months after the outbreak confirmed previous exposure to *F. tularensis* (Ketz-Riley et al. 2009).

4.9.3 Current biosecurity measures

There are no current biosecurity measures for tularaemia.

4.9.4 Risk review

Tularaemia (*F. tularensis* type A) is present in exporting countries and it is not present in Australia, where it is a nationally notifiable animal disease.

The following key points are relevant to the biosecurity risk of tularaemia in captive non-human primates:

- Tularaemia is present in North America, China, parts of Europe, Japan, Korea and Russia.
- Tularaemia (*F. tularensis* type A) is not present in Australia.
- The presence of *F. tularensis* (type B) in Australia is uncertain. A few human cases have been reported.
- Tularaemia is a nationally notifiable animal disease and a nationally notifiable disease of public health concern.
- Tularaemia is a multiple species OIE-listed disease.
- Transmission of *F. tularensis* occurs through a variety of modes, including bites of infected vectors.
- The incubation period is generally 3–6 days, but can be between one and 14 days.
- Tularaemia in captive non-human primates is quite rare.
- Non-human primates will be inspected and treated for ectoparasites as part of standard import policy for zoo animals.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.9.5 Conclusion

Accordingly and based on the preceding information, risk management for tularaemia is not warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

4.10 Yellow fever

4.10.1 Background

Yellow fever virus (YFV) is a mosquito-borne virus belonging to the family *Flaviviridae*, genus *Flavivirus*. YFV causes disease in humans as well as several species of non-human primates. Yellow fever is confined to the tropical parts of Africa and South America (Monath 2001b; Monath & Vasconcelos 2015).

Mosquitoes are the reservoir hosts and determine the geographic distribution and persistence of the virus in nature. Most species of primates are susceptible to yellow fever but there is marked variation in severity of infection. Humans are highly susceptible (WHO 2009). Natural infection is rarely severe or fatal in Old World monkeys, but New World monkeys from South America are highly susceptible (Hunt, Anderson & Chalifoux 1978; Wachtman & Mansfield 2012). Non-human primates from Africa are probably the original hosts and include many Cercopithecidae, the chimpanzee and baboon. The bush baby (*Galago* spp.) also becomes infected (Brack 1987; Mansfield & King 1998). Many New World monkeys become infected in the Americas (Brack 1987; Mansfield & King 1998; WHO 1998).

Yellow fever is not an OIE-listed disease (OIE 2016a).

Yellow fever is not present in Australia and it is not a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Yellow fever is a zoonosis and a nationally notifiable disease of public health concern (Department of Health 2015).

4.10.2 Technical information

Epidemiology

Transmission occurs between primates and blood-feeding mosquitoes belonging to the genera *Haemagogus* and *Aedes* in South America and Africa, respectively. A new vector, *Sabethes albiprivus*, has been implicated in transmission of yellow fever in Argentina (Goenaga et al. 2012). Vertical transmission occurs in mosquitoes, including *Ae. aegypti* and *Ae. albopictus*, enabling them to act as vector and reservoir (CDC 2015d).

There are three epidemiological transmission cycles: sylvatic, intermediate and urban, with spill overs between cycles sometimes occurring. All three occur in Africa but only the sylvatic and urban cycles are reported in South America.

The sylvatic cycle involves transmission between mosquitoes and non-human primates and vice versa. Some spill-over into other species, including humans, may occur. The intermediate cycle, probably the most common cycle in Africa, involves villages that border forests containing non-human primates. The mosquitoes infect both non-human primates and unvaccinated humans. The urban cycle involves transmission between humans and domestic mosquitoes, primarily *Aedes aegypti*, and disease spreading through the susceptible unvaccinated population. Non-human primates are not involved. This can result in large scale epidemics (CDC 2015d; Monath & Vasconcelos 2015).

Ae. aegypti is an efficient arthropod vector due to its feeding behaviour of taking blood from multiple hosts during a single gonotrophic cycle (Gubler 2004). *Ae. aegypti* is widely distributed in Queensland, Australia. The introduction of yellow fever virus to the Australian mosquito population could theoretically result in an urban outbreak of human disease. Other mosquito species present in Australia, *Ae. albopictus* and *Ae. notoscriptus* are competent vectors under laboratory conditions but their competency under field conditions remains uncertain (van den Hurk et al. 2011).

The incubation period of yellow fever in humans varies from 3–6 days and viraemia is of short duration (Monath 2001b). Patients with fatal infection tend to experience longer duration viraemia than survivors (Gubler 2004). In non-human primates, viraemia generally lasts 2–9 days and the virus is eliminated as neutralising antibodies are produced (Mansfield & King 1998; Vainio & Cutts 1998). There is no evidence of a carrier state in non-human primates (Wachtman & Mansfield 2012).

Clinical signs

Clinical signs of yellow fever in humans range from subclinical infection to severe systemic disease including haemorrhage, icterus, nausea, pyrexia, vomiting and renal failure. The majority of infections (90 per cent) occur in Africa and present as mild to severe pyrexial illness (Barnett 2007). A similar range of clinical signs are seen in non-human primates. Infection of African species is typically subclinical. Cases in naturally infected New World non-human primates are generally recognised by increased mortality in susceptible species, at times when there are human cases in the geographical vicinity.

Diagnosis

In humans, YFV can be isolated from blood four days after the onset of clinical signs and may be isolated as long as 12 days after. Detection of IgM is taken as presumptive diagnosis, the capture-ELISA being the preferred test (Monath 2001a). For non-human primates in colonies in endemic areas, the Federation of Laboratory Animal Science Associations (FELASA) recommends using serum neutralisation, enzyme-linked immunosorbent assays (ELISA) and complement fixation testing to screen for presence of disease (Weber et al. 1999).

4.10.3 Current biosecurity measures

The animal must come from premises located in a country where there were no cases of yellow fever were reported in the 12 months before export.

4.10.4 Risk review

Yellow fever is present in exporting countries and it is not present in Australia.

The following key points are relevant to the biosecurity risk of yellow fever in captive non-human primates:

- Yellow fever is present in the equatorial rainforests of Africa and the Amazon Basin in the Americas.
- Yellow fever is not a nationally notifiable animal disease; however, it is a nationally notifiable disease of public health concern.
- Yellow fever is a vector transmitted disease and the mosquito *Aedes aegypti*, the main vector in urban transmission, is present in Australia (widespread distribution in Queensland).

- Infection in non-human primates from Africa is typically subclinical; however, non-human primates from South America may succumb to fatal infection.
- The incubation and viraemic periods in non-human primates are short and there is no evidence of a carrier state.
- There is no evidence of natural outbreaks of yellow fever amongst captive non-human primates.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.10.5 Conclusion

Accordingly and based on the preceding information, risk management for yellow fever is no longer warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

4.11 Zika fever

4.11.1 Background

Zika fever is caused by Zika virus, an RNA virus of the family *Flaviviridae*, which is closely related to dengue fever virus (ICTV 2014). The disease circulates in Africa, the Americas, Asia and the Pacific. Humans and non-human primates are the principal hosts. There are no reports in the scientific literature of other animals developing Zika fever or of being able to spread Zika virus to humans.

Zika fever is not an OIE-listed disease (OIE 2016a).

Zika fever is not present in Australia and it is not a nationally notifiable animal disease (Department of Agriculture and Water Resources 2015).

Zika fever is a zoonosis and is a nationally notifiable disease of public health concern (Department of Health 2015).

4.11.2 Technical information

Epidemiology

In East Africa, Zika virus is thought to be maintained in a sylvatic cycle involving non-human primates and mosquitoes (*Aedes* spp.) in tropical forests. In West Africa and Asia (South-East Asia), serological surveys suggest circulation of Zika virus is silent. Antibodies have been detected in various animals including orangutans in Borneo, zebra, elephants and rodents (ECDC 2014; Wolfe et al. 2001). The increased number of outbreaks that do not involve non-human primates suggests humans are an amplifying host as is seen with other arboviral diseases.

The incubation period in humans is 3–12 days. Viraemia probably lasts 3–5 days (Fonseca et al. 2014). Details about length of incubation period and viraemia in non-human primates are not available. However, they are likely to be of similar duration to those of humans as is seen with other similar *flavivirus* infections (Mansfield & King 1998; Vainio & Cutts 1998).

Clinical signs

In humans clinical signs are usually mild lasting 2–7 days and include pyrexia, skin rashes, conjunctivitis, muscle and joint pain, lethargy and headaches. During outbreaks in French Polynesia and Brazil, both in 2015, potential neurological and auto-immune complications have been associated with Zika virus infection (WHO 2016). Only a few naturally and experimentally infected non-human primates have exhibited clinical signs, which included a mild, transient pyrexia (CDC 2016). Experimental infection in Rhesus macaques resulted in a localised skin rash at the site of virus inoculation (AVRL 2016).

Diagnosis

Diagnostic tests for Zika virus infection include polymerase chain reaction (PCR) assays on acute-phase serum samples, which detect viral RNA, serological tests that detect specific antibodies against Zika virus and virus isolation. Serological tests often show cross-reactions to secondary *flavivirus* infections (ECDC 2014). PCR assays have been used in experimental studies in macaques (AVRL 2016).

Current biosecurity measures

There are no current biosecurity measures for Zika fever.

4.11.3 Risk review

Zika fever is present in exporting countries and it is not present in Australia.

The following key points are relevant to the biosecurity risk of Zika fever in non-human primates:

- Zika fever is present in Africa, the Americas, Asia and the Pacific.
- Zika fever is not a nationally notifiable animal disease; however, it is a nationally notifiable disease of public health concern.
- Zika fever is a vector transmitted disease and the mosquito vectors *Aedes* spp. are present in Australia.
- The incubation and viraemic periods for Zika virus infection are of short duration in humans and are probably also of short duration in non-human primates as is seen with other flavivirus infections.
- Non-human primates are sourced from and maintained in facilities that have health monitoring programs and are under veterinary supervision.

4.11.4 Conclusion

Accordingly and based on the preceding information, risk management for Zika fever is not warranted.

The department proposes that the general risk management measures included in Australia's zoo animal import policies, reduce the risks associated with importation of captive non-human primates, which would achieve Australia's ALOP.

5 Proposed biosecurity measures for the importation of captive non-human primates

The biosecurity measures described in this review apply to the importation of captive non-human primates kept in zoos, wildlife parks and research institutes, from all countries.

There are general risk management measures common to most Australian import policies for zoo and research animals that are required, including:

- The animals must be resident in an approved, licensed or registered zoo, wildlife park or research institute in the exporting country since birth or for at least 12 months immediately before export, unless otherwise approved by the Department of Agriculture and Water Resources. The residency requirement may be achieved in more than one country or holding institution if specifically authorised by the department and the biosecurity measures for each country of residence and holding institution are met.
- The premises of origin (registered zoo, wildlife park or research institute) must be under veterinary supervision and have a health monitoring program.
- The animal must be held in pre-arrival quarantine for at least 30 days, during which it is inspected at least daily for signs of disease, treated for internal and external parasites, and tested for diseases in accordance with recommendations arising from the review.
- The animal must be transported to a quarantine approved premises (QAP) in Australia in a manner that ensures no direct exposure to Australian animals en route and must undergo a period of post-entry quarantine of at least 30 days.
- The receiving institution must be approved under relevant Australian State or Territory legislation to hold the species being imported.

The Code recommends periods of premises residency and periods in which premises should remain free from certain diseases ranging from less than 30 days up to two or more years. This applies to the time period before an animal enters pre-arrival isolation, if applicable.

For disease agents of biosecurity concern that have no recommendations in the Code for the periods of premises residency and/or disease freedom, the periods are based on the epidemiology and information detailed in the relevant sections in Chapter 4.

The biosecurity measures for the importation of captive non-human primates are in Section 5.1. The residency periods and timing of tests in Section 5.1 are based on recommendations in the Code (where applicable) and are amended for consistency and clarity of certification.

The operational and quarantine facilities requirements apply to all non-human primates. An example of the biosecurity measures for a hypothetical exporting country, Country X, is provided in Section 5.2.

5.1 Proposed biosecurity measures for the importation of captive non-human primates from all countries

5.1.1 Documentation

Each non-human primate must travel with an original international veterinary certificate that conforms to Article 5.10.2. of the Code, signed by the Official Veterinarian of the country of export.

These biosecurity requirements apply to captive non-human primates.

An **Official Veterinarian** means a veterinarian authorised by the Veterinary Authority of the country of export to perform certain official tasks associated with animal health and/or public health, and inspections of commodities and, when appropriate, to certify in conformity with the Certification Procedures of Chapter 5.2 of the Code.

The veterinary certificate must:

- be written in English and a language understood by the Official Veterinarian of the country of export
- meet the requirements of the 'certification before export' section and state that all the pre-arrival quarantine requirements have been met
- provide identification for each non-human primate (International Standards Organisation (ISO) microchip number) including description, species, sex and age
- include the name and address of the zoological or research institution of origin
- include the name and address of the exporter and importer and identify the import permit against which it was issued.

The Official Veterinarian must:

- provide a separate veterinary certificate for each non-human primate
- sign, date and stamp (with the stamp of the Veterinary Authority) each page of the veterinary certificate and all attached documents (e.g. laboratory reports) that form part of the extended veterinary certification
- confirm the microchip number of each non-human primate
- endorse each page of copies of supporting documents with date, signature and Official Veterinarian stamp
- record his/her name, signature and contact details on the veterinary certificate.

5.1.2 Pre-arrival quarantine requirements

Pre-arrival quarantine

Any variation from the **pre-arrival quarantine requirements** must be specifically authorised by the Department of Agriculture and Water Resources.

Location

The pre-arrival quarantine facility must be located within a government registered or licensed zoological institution, wildlife park or research institute that is under veterinary supervision and in which the animals held in the premises are subject to a health monitoring program.

Facilities

- 1) The pre-arrival quarantine facility must meet the country and premises requirements specified in the certification before export section.
- 2) The entire pre-arrival quarantine facility must be surrounded by a physical barrier that provides sufficient security to isolate the non-human primates in pre-arrival quarantine from all other animals except those that meet all the conditions in these biosecurity measures.

- 3) The pre-arrival quarantine facility including buildings, yards, fences, feeding and watering arrangements must address animal welfare considerations.
- 4) The pre-arrival quarantine facility must be constructed so that it can be cleaned and disinfectant applied and must be maintained in good order.
- 5) The institution where the pre-arrival quarantine facility is located must utilise a separate area for the cleaning and disinfection of vehicles for transporting non-human primates, and facilities for the safe loading and unloading of non-human primates.
- 6) The institution where the pre-arrival quarantine facility is located must have facilities for veterinary examination and collection of samples as needed, and must manage biosecurity requirements should it be necessary to utilise these facilities for animals in pre-arrival quarantine.

Operation

- 1) The pre-arrival quarantine facility must have current approval from the Department of Agriculture and Water Resources and the Veterinary Authority of the exporting country before commencement of pre-arrival quarantine.
- 7) The Department of Agriculture and Water Resources may audit the approved pre-arrival quarantine facility.
- 8) All pre-arrival quarantine operations and procedures must be detailed in Standard Operating Procedures (SOPs), consistent with a risk-based approach and approved by the Department of Agriculture and Water Resources.
- 9) The Official Veterinarian must inspect the pre-arrival quarantine facility within 72 hours before commencement of pre-arrival quarantine and must ensure that the facility was cleaned and disinfectant applied to his/her satisfaction.
- 10) Pre-arrival quarantine must be under the supervision of the Official Veterinarian.
- 11) The pre-arrival quarantine period commences from the time the last non-human primate in the export consignment has entered the pre-arrival quarantine facility and all non-human primates have been examined by the Official Veterinarian or a veterinarian authorised by the Official Veterinarian.
- 12) All equipment used in feeding, handling and treating non-human primates in pre-arrival quarantine must be new or cleaned and disinfected before entry, and must be used only in the facility during pre-arrival quarantine.
- 13) During pre-arrival quarantine, the facility should be occupied only by non-human primates of the export consignment. If other non-human primates are present, they must meet all the conditions in these biosecurity measures.
- 14) Only personnel specifically authorised by the Official Veterinarian are permitted entry to the pre-arrival quarantine facility. Details of all visitor entries must be recorded.
- 15) All veterinary visits, health problems, tests, test results, treatments and reasons for removal from the pre-arrival quarantine facility of any animal, must be reported to the Official Veterinarian within 24 hours, and to the Department of Agriculture and Water Resources within 48 hours. The sole exceptions to this are inspections, visits and treatments required for certification.
- 16) A detailed health record must be kept for each non-human primate and be available to the Official Veterinarian and to the Department of Agriculture and Water Resources on request.

- 17) Non-human primates that leave the facility during pre-arrival quarantine for any reason not authorised by the Department of Agriculture and Water Resources cannot re-join the consignment during pre-arrival quarantine.

5.1.3 Certification

The Official Veterinarian must certify:

- 1) During pre-arrival quarantine:
 - a) the non-human primate was not vaccinated
 - b) all non-human primates in the pre-arrival quarantine facility remained free from evidence of infectious or contagious disease and had no contact with non-human primates except those that meet all the conditions in these biosecurity measures
 - c) all samples for testing were taken by the Official Veterinarian or a veterinarian authorised by the Official Veterinarian
 - d) all testing was conducted in a laboratory recognised and monitored by the Veterinary Authority in the country of export.

- 18) All of the following risk management measures apply:

Rabies

For 180 days before export the non-human primate did not reside on any premises in the country of export where clinical, epidemiological or other evidence of rabies occurred during the previous 180 days before export and the disease is compulsorily notifiable.

Tuberculosis

- a) For two years immediately before export, or since birth if the animal is less than two years of age, the non-human primate did not reside on any premises in the country of export where clinical, epidemiological or other evidence of tuberculosis (*Mycobacterium tuberculosis* complex) occurred during the previous two years before export.

AND

- b) The non-human primate was held in pre-arrival quarantine for at least 30 days immediately before export. During this time the non-human primate was isolated from animals not of equivalent health status.

AND

- c) During pre-arrival quarantine the non-human primate was subjected to a combination of two tests for tuberculosis, with negative results, at least 14 days apart, by:
 - i. An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, or
 - ii. An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
 - iii. A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site, **or**
 - iv. A gamma interferon assay that has been approved for use by the department (e.g. Primagam™)#

#If a gamma interferon assay is used, the other test used must be an intradermal tuberculin test or comparative tuberculin skin test.

OR

- d) The non-human primate was subjected to a gamma interferon assay that has been approved for use by the department (e.g. Primagam™) and a second test for tuberculosis, with negative results, during the 30 days before export, by:
 - i. An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, **or**
 - ii. An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
 - iii. A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site.

OR

- e) The non-human primate was subjected to two tests for tuberculosis, with negative results, with the first test during the six months before export and the second test[†] during pre-arrival quarantine, by:
 - i. An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, **or**
 - ii. An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
 - iii. A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site **or**
 - iv. A gamma interferon assay that has been approved for use by the department (e.g. Primagam™)

[†]The second test during pre-arrival quarantine must be an intradermal or comparative tuberculin skin test

Note: Reactions should be measured 24, 48, and 72 hours after injection. Reactions graded 0, 1, or 2 (out of 5) are considered negative for a palpebral intradermal tuberculin test and reactions graded 0 or 1 (out of 3) are considered negative for an abdominal intradermal tuberculin test. The comparative tuberculin skin test is negative if the avian PPD-induced swelling is greater than the bovine PPD-induced swelling.

Unweaned animals accompanying eligible dams are exempt from testing.

- 1) The non-human primate was examined by the Official Veterinarian or a veterinarian authorised by the Official Veterinarian within 72 hours before leaving the pre-arrival quarantine facility for the port of export and was found to be:
 - a) free from evidence of infectious or contagious disease
 - b) visibly free of external parasites
 - c) healthy and fit to travel
- 2) Vehicles and transport containers used for transporting non-human primates from the pre-arrival quarantine facility to the port of export, and to Australia, were new or were cleaned

and disinfected to the satisfaction of the Official Veterinarian before entering the pre-arrival quarantine facility to load the non-human primates.

- 3) The non-human primate was sealed in its travel container with tamper-evident seals before leaving the pre-arrival quarantine facility for the port of export.
- 4) At the port of export a government officer authorised by the Veterinary Authority of the exporting country must certify:
 - a) during transport to the port of export, the non-human primate had no contact with other animals except those that meet all the conditions in these biosecurity measures.
 - b) the seals on the travel containers were intact on arrival at the port of export.

5.1.4 Transport

- 1) Exporters or their agents must have detailed plans to cover procedures including contingency plans, for transporting the animal from pre-arrival quarantine until arrival in Australia.
- 2) Animals must be consigned to Australia by a route approved by the Department of Agriculture and Water Resources.
- 3) Animals must travel in a container recommended for that particular species under the International Air Transport Association (IATA) Live Animal Regulations.
- 4) The use of hay or straw as bedding during transport is not permitted. Treated wood shavings, sterilised peat and soft board can be used.
- 5) Animals must remain isolated from all animals except those that meet all the conditions described in these biosecurity measures, during transport from the pre-arrival quarantine facility until arrival in Australia.
- 6) Insect netting must be carried on the flight at all times for contingencies. There must be sufficient insect netting to cover all travel containers completely. Insect netting must be in good condition to minimise entry of insect vectors into the travel containers.

Transit and transhipment

- 1) Animals must transit or tranship only at an approved airport. Any transhipment requires the prior approval of the Department of Agriculture and Water Resources. Animals are not to leave the airport and must not be removed from their travel containers during transit or transhipment.
- 2) Animals must remain on board the aircraft at approved transit airports. Cargo doors can be opened at approved transit airports to allow for unloading or loading of freight. Immediately after the cargo hold doors are closed, a knockdown aerosol insecticide must be sprayed throughout the cargo hold, in the manner recommended by the manufacturer.
- 3) In cases where animals in travel containers are to be unloaded, before opening the cargo door, the travel containers must be completely covered in netting to prevent insect access to the animals. The netting must remain in place until the animals are reloaded onto an aircraft. Immediately after the animals are reloaded onto an aircraft and the cargo hold doors are closed, a knockdown aerosol insecticide spray must be sprayed throughout the cargo hold in the manner recommended by the manufacturer. The insect netting must not be removed until 30 minutes after spraying.

Delayed take off and unscheduled landings

- 1) Exporters or their agents must have contingency plans for the management of delayed take off and unscheduled landings.
- 2) If the aircraft lands at any airport other than in an approved country, the department must be informed immediately and the animal must not proceed to Australia without approval from the department. The decision as to whether the animal can continue to travel to Australia, and additional biosecurity measures that may be required, will be made by the Department of Agriculture and Water Resources on a case-by-case basis after assessing the risks.

Arrival in Australia

- 1) Importers or their agents must have a plan developed in consultation with the Department of Agriculture and Water Resources to cover post-entry procedures. The plan must include roles and responsibilities for their staff, vehicles for transporting animals to the quarantine approved premises (QAP) and road transport arrangements including contingency plans for vehicle and equipment failures.
- 2) Vehicles for transporting the animals from the port of entry to the QAP must be cleaned and disinfected to the satisfaction of the Australian government officer before loading the animals. The Department of Agriculture and Water Resources must be advised of the transport route to the QAP.
- 3) After the animals arrive at an Australian airport they must be transferred in their transport containers onto vehicles, along with personnel and equipment, and proceed directly to the QAP.
- 4) All biosecurity risk material (e.g. bedding, feed, water and waste material) remaining at the airport must be sealed in bags, ordered into quarantine and disposed of under supervision of the Department of Agriculture and Water Resources.
- 5) All other equipment used during transport that has been in contact with the animal (including the inside of the crate, bedding, waste and water) must be cleaned and disinfected under supervision of the Department of Agriculture and Water Resources before leaving the airport.

5.1.5 Post-entry quarantine requirements**Post-entry quarantine**

The minimum post-entry quarantine period of 30 days applies.

Any variation from the post-entry quarantine requirements must be specifically authorised by the Department of Agriculture and Water Resources.

Location

The QAP must be located within a secure part of a zoo, wildlife park or research institute approved under relevant Australian State or Territory legislation to hold the species being imported, separated from public access areas and where it is under regular supervision by a registered veterinarian.

Facilities

The post-entry quarantine facility must meet the Department of Agriculture and Water Resources requirements of a QAP class 7.9 facility.

Operation

- 1) The QAP must be approved by the department before entry of an animal into the QAP.
- 2) All post-entry quarantine operations and procedures must follow those outlined for a QAP class 7.9 facility and also include:
 - a) A registered veterinarian must inspect the QAP within 72 hours before entry of any animal to ensure it has been cleaned and disinfectant has been applied to his/her satisfaction.
 - b) The post-entry quarantine period will commence from the time of entry into the facility of the last animal.
 - c) Vehicles for transporting animals must not leave the QAP until thoroughly cleaned and disinfected.
 - d) If any animal dies during post-entry quarantine, the Department of Agriculture and Water Resources must be notified within 24 hours and the animal must undergo a post mortem examination by a registered veterinarian to determine the cause of death.
 - e) The Department of Agriculture and Water Resources is to be advised within 24 hours of any disease incident and its outcome.
 - f) Animals must not leave the QAP during post-entry quarantine without permission of the Department of Agriculture and Water Resources.
 - g) At the satisfactory completion of post-entry quarantine, the animals will be released from quarantine into premises approved by the appropriate State or Territory governments for the holding of non-human primates.

5.2 Proposed biosecurity measures for the importation of captive non-human primates from Country X

5.2.1 Documentation

Each non-human primate must travel with an original international veterinary certificate that conforms to Article 5.10.2. of the Code, signed by the Official Veterinarian of the country of export.

These biosecurity requirements apply to captive non-human primates.

An **Official Veterinarian** means a veterinarian authorised by the Veterinary Authority of the country of export to perform certain official tasks associated with animal health and/or public health, and inspections of commodities and, when appropriate, to certify in conformity with the Certification Procedures of Chapter 5.2 of the Code.

The veterinary certificate must:

- be written in English and a language understood by the Official Veterinarian of the country of export
- meet the requirements of the 'certification before export' section and state that all the pre-arrival quarantine requirements have been met
- provide identification for each non-human primate (International Standards Organisation (ISO) microchip number) including description, species, sex and age
- include the name and address of the zoological or research institution of origin
- include the name and address of the exporter and importer and identify the import permit against which it was issued.

The Official Veterinarian must:

- provide a separate veterinary certificate for each non-human primate
- sign, date and stamp (with the stamp of the Veterinary Authority) each page of the veterinary certificate and all attached documents (e.g. laboratory reports) that form part of the extended veterinary certification
- confirm the microchip number of each non-human primate
- endorse each page of copies of supporting documents with date, signature and Official Veterinarian stamp
- record his/her name, signature and contact details on the veterinary certificate.

5.2.2 Pre-arrival quarantine requirements

Pre-arrival quarantine for the importation of captive non-human primates from Country X

Any variation from the **pre-arrival quarantine requirements** must be specifically authorised by the Department of Agriculture and Water Resources.

Location

The pre-arrival quarantine facility must be located within a government registered or licensed zoological institution, wildlife park or research institute that is under veterinary supervision and in which the animals held in the premises are subject to a health monitoring program.

Facilities

- 1) The pre-arrival quarantine facility must meet the country and premises requirements specified in the **certification before export** section.
- 2) The entire pre-arrival quarantine facility must be surrounded by a physical barrier that provides sufficient security to isolate the non-human primates in pre-arrival quarantine from all other animals except those that meet all the conditions described in the import permit.
- 3) The pre-arrival quarantine facility including buildings, yards, fences, feeding and watering arrangements must address animal welfare considerations.
- 4) The pre-arrival quarantine facility must be constructed so that it can be cleaned and disinfectant applied and must be maintained in good order.
- 5) The institution where the pre-arrival quarantine facility is located must utilise a separate area for the cleaning and disinfection of vehicles for transporting non-human primates, and facilities for the safe loading and unloading of non-human primates.
- 6) The institution where the pre-arrival quarantine facility is located must have facilities for veterinary examination and collection of samples as needed, and must manage biosecurity requirements should it be necessary to utilise these facilities for animals in pre-arrival quarantine.

Operation

- 1) The pre-arrival quarantine facility must have current approval from the Department of Agriculture and Water Resources and the Veterinary Authority of the exporting country before commencement of pre-arrival quarantine.
- 2) The Department of Agriculture and Water Resources may audit the approved pre-arrival quarantine facility.
- 3) All pre-arrival quarantine operations and procedures must be detailed in Standard Operating Procedures (SOPs), consistent with a risk-based approach and approved by the Department of Agriculture and Water Resources.
- 4) The Official Veterinarian must inspect the pre-arrival quarantine facility within 72 hours before commencement of pre-arrival quarantine and must ensure that the facility was cleaned and disinfectant applied to his/her satisfaction.
- 5) Pre-arrival quarantine must be under the supervision of the Official Veterinarian.
- 6) The pre-arrival quarantine period commences from the time the last non-human primate in the export consignment has entered the pre-arrival quarantine facility and all non-human primates have been examined by the Official Veterinarian or a veterinarian authorised by the Official Veterinarian.
- 7) All equipment used in feeding, handling and treating non-human primates in pre-arrival quarantine must be new or cleaned and disinfected before entry, and must be used only in the facility during pre-arrival quarantine.
- 8) During pre-arrival quarantine, the facility should be occupied only by non-human primates of the export consignment. If other non-human primates are present, they must meet all the conditions described in the import permit.

- 9) Only personnel specifically authorised by the Official Veterinarian are permitted entry to the pre-arrival quarantine facility. Details of all visitor entries must be recorded.
- 10) All veterinary visits, health problems, tests, test results, treatments and reasons for removal from the pre-arrival quarantine facility of any animal, must be reported to the Official Veterinarian within 24 hours, and to the Department of Agriculture and Water Resources within 48 hours. The sole exceptions to this are inspections, visits and treatments required for certification.
- 11) A detailed health record must be kept for each non-human primate and be available to the Official Veterinarian and to the Department of Agriculture and Water Resources on request.
- 12) Non-human primates that leave the facility during pre-arrival quarantine for any reason not authorised by the Department of Agriculture and Water Resources cannot re-join the consignment during pre-arrival quarantine.

5.2.3 Certification before export

The Official Veterinarian must certify:

- 1) Since birth, or for at least two years immediately before export, each non-human primate for export was continuously resident in an approved government licensed or registered zoological institution or wildlife park or research institute that provided separation from other animal populations, was under veterinary supervision and has a health monitoring program in Country X.
- 2) The non-human primate was held in pre-arrival quarantine for at least 30 days immediately before export in a facility that meets the requirements specified in the pre-arrival quarantine requirements. During this time the non-human primate was isolated from animals except those that meet all the conditions described in the import permit.
- 3) During pre-arrival quarantine:
 - a) the non-human primate was not vaccinated.
 - b) all non-human primates in the pre-arrival quarantine facility remained free from evidence of infectious or contagious disease and had no contact with non-human primates except those that meet all the conditions described in the import permit.
 - c) all samples for testing were taken by the Official Veterinarian or a veterinarian authorised by the Official Veterinarian.
 - d) all testing was conducted in a laboratory recognised and monitored by the Veterinary Authority in Country X.
- 4) During the 30 days immediately before export, each non-human primate was treated with broad spectrum parasiticides for internal and external parasites (active ingredient/s, dose and date/s of treatment stated on the veterinary certificate).
- 5) For two years before export, or since birth if less than two years of age, the non-human primate did not reside on any premises in Country X where clinical, epidemiological or other evidence of tuberculosis (*Mycobacterium tuberculosis* complex) occurred in the previous two years before export.
- 6) For 180 days immediately before export the non-human primate did not reside on any premises in Country X where clinical, epidemiological or other evidence of rabies occurred in the previous 180 days before export and the disease is compulsorily notifiable.

7) Tuberculosis

- a) During pre-arrival quarantine the non-human primate was subjected to a combination of two tests for tuberculosis, at least 14 days apart, with negative results, by:
- i. An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, **or**
 - ii. An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
 - iii. A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site, **or**
 - iv. A gamma interferon assay that has been approved for use by the department (e.g. Primagam™)[#]

[#]If a gamma interferon assay is used, the other test used must be an intradermal tuberculin test or comparative tuberculin skin test.

OR

- b) During pre-arrival quarantine the non-human primate was subjected to a gamma interferon assay that has been approved for use by the department (e.g. Primagam™) and a second test for tuberculosis, with negative results, by:
- i. An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, **or**
 - ii. An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
 - iii. A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site.

OR

- c) The non-human primate was subjected to two tests for tuberculosis, with negative results, with the first test during the six months before export and the second test[†] during pre-arrival quarantine, by:
- i. An intradermal tuberculin test using 0.1 ml Mammalian Old Tuberculin, **or**
 - ii. An intradermal tuberculin test using 0.1 ml bovine PPD tuberculin containing at least 25 000 IU/ml, **or**
 - iii. A comparative tuberculin skin test using 0.1 ml bovine PPD tuberculin containing at least 20 000 IU/ml in one site and 0.1 ml of avian PPD tuberculin containing at least 20 000 IU/ml in another site **or**
 - iv. A gamma interferon assay that has been approved for use by the department (e.g. Primagam™).

[†]The second test during pre-arrival quarantine must be an intradermal or comparative tuberculin skin test

- d) Note: Reactions should be measured 24, 48, and 72 hours after injection. Reactions graded 0, 1, or 2 (out of 5) are considered negative for a palpebral intradermal tuberculin test and reactions graded 0 or 1 (out of 3) are considered negative for an

abdominal intradermal tuberculin test. The comparative tuberculin skin test is negative if the avian PPD-induced swelling is greater than the bovine PPD-induced swelling.

- e) Unweaned animals accompanying eligible dams are exempt from testing.
- 8) The non-human primate was examined by the Official Veterinarian or a veterinarian authorised by the Official Veterinarian within 72 hours before leaving the pre-arrival quarantine facility for the port of export and was found to be:
 - a) free from evidence of infectious or contagious disease
 - b) visibly free of external parasites
 - c) healthy and fit to travel
- 9) Vehicles and transport containers used for transporting non-human primates from the pre-arrival quarantine facility to the port of export, and to Australia, were new or were cleaned and disinfected to the satisfaction of the Official Veterinarian before entering the pre-arrival quarantine facility to load the non-human primates.
- 10) The non-human primate was sealed in its travel container with tamper-evident seals before leaving the pre-arrival quarantine facility for the port of export.
- 11) At the port of export a government officer authorised by the Veterinary Authority of the Country X must certify:
 - a) After due enquiry, during transport to the port of export, the non-human primate had no contact with other animals except those that meet all the conditions described in the import permit.
 - b) the seals on the travel containers were intact on arrival at the port of export.

5.2.4 Transport

- 1) Exporters or their agents must have detailed plans to cover procedures including contingency plans, for transporting the animal from pre-arrival quarantine until arrival in Australia.
- 2) Animals must be consigned to Australia by a route approved by the Department of Agriculture and Water Resources.
- 3) Animals must travel in a container recommended for that particular species under the International Air Transport Association (IATA) Live Animal Regulations.
- 4) The use of hay or straw as bedding during transport is not permitted. Treated wood shavings, sterilised peat and soft board can be used.
- 5) Animals must remain isolated from all animals except those that meet all the conditions described in the import permit, during transport from the pre-arrival quarantine facility until arrival in Australia.
- 6) Insect netting must be carried on the flight at all times for contingencies. There must be sufficient insect netting to cover all travel containers completely. Insect netting must be in good condition to minimise entry of insect vectors into the travel containers.

Transit and transhipment

- 1) Animals must transit or tranship only at an approved airport. Any transhipment requires the prior approval of the Department of Agriculture and Water Resources. Animals are not

to leave the airport and must not be removed from their travel containers during transit or transshipment.

- 2) Animals must remain on board the aircraft at approved transit airports. Cargo doors can be opened at approved transit airports to allow for unloading or loading of freight. Immediately after the cargo hold doors are closed, a knockdown aerosol insecticide must be sprayed throughout the cargo hold, in the manner recommended by the manufacturer.
- 3) In cases where animals in travel containers are to be unloaded, before opening the cargo door, the travel containers must be completely covered in netting to prevent insect access to the animals. The netting must remain in place until the animals are reloaded onto an aircraft. Immediately after the animals are reloaded onto an aircraft and the cargo hold doors are closed, a knockdown aerosol insecticide spray must be sprayed throughout the cargo hold in the manner recommended by the manufacturer. The insect netting must not be removed until 30 minutes after spraying.

Delayed take off and unscheduled landings

- 1) Exporters or their agents must have contingency plans for the management of delayed take off and unscheduled landings.
- 2) If the aircraft lands at any airport other than in an approved country, the Department of Agriculture and Water Resources must be informed immediately and the animal must not proceed to Australia without approval from the Department of Agriculture and Water Resources. The decision as to whether the animal can continue to travel to Australia, and additional biosecurity measures that may be required, will be made by the Department of Agriculture and Water Resources on a case-by-case basis after assessing the risks.

Arrival in Australia

- 1) Importers or their agents must have a plan developed in consultation with the Department of Agriculture and Water Resources to cover post-entry procedures. The plan must include roles and responsibilities for their staff, vehicles for transporting animals to the quarantine approved premises (QAP) and road transport arrangements including contingency plans for vehicle and equipment failures.
- 2) Vehicles for transporting the animals from the port of entry to the QAP must be cleaned and disinfected to the satisfaction of a Department of Agriculture and Water Resources officer before loading the animals. The Department of Agriculture and Water Resources must be advised of the transport route to the QAP.
- 3) After the animals arrive at an Australian airport they must be transferred in their transport containers onto vehicles, along with personnel and equipment, and proceed directly to the QAP.
- 4) All biosecurity risk material (e.g. bedding, feed, water and waste material) remaining at the airport must be sealed in bags, ordered into quarantine and disposed of under supervision of the Department of Agriculture and Water Resources.
- 5) All other equipment used during transport that has been in contact with the animal (including the inside of the crate, bedding, waste and water) must be cleaned and disinfected under supervision of the Department of Agriculture and Water Resources before leaving the airport.

5.2.5 Post-entry quarantine requirements

Post-entry quarantine requirements for the importation of captive non-human primates from Country X

Any variation from the **post-entry quarantine requirements** must be specifically authorised by the Department of Agriculture and Water Resources.

The non-human primate must be held in post-entry quarantine for at least 30 days. During this time the non-human primate must be isolated from animals except those that meet all the conditions described in the import permit.

Location

The QAP must be located within a secure part of a zoo, wildlife park or research institute approved under relevant Australian of State Territory legislation to hold the species being imported, separated from public access areas and where it is under regular supervision by a registered veterinarian.

Facilities

The post-entry quarantine facility must meet the Department of Agriculture and Water Resources requirements of a QAP class 7.9 facility.

Operation

- 1) The QAP must be approved by the Department of Agriculture and Water Resources before entry of an animal into the QAP.
- 2) All post-entry quarantine operations and procedures must follow those outlined for a QAP class 7.9 facility and also include:
 - a) A registered veterinarian must inspect the QAP within the 72 hours before entry of any animal to ensure it has been cleaned and disinfectant has been applied to his/her satisfaction.
 - b) The post-entry quarantine period will commence from the time of entry into the facility of the last animal.
 - c) Vehicles for transporting animals must not leave the QAP until thoroughly cleaned and disinfected.
 - d) If any animal dies during post-entry quarantine, the Department of Agriculture and Water Resources must be notified within 24 hours and the animal must undergo a post mortem examination by a registered veterinarian to determine the cause of death.
 - e) The Department of Agriculture and Water Resources is to be advised within 24 hours of any disease incident and its outcome.
 - f) Animals must not leave the QAP during post-entry quarantine without permission of the Department of Agriculture and Water Resources.
 - g) At the satisfactory completion of post-entry quarantine, the animals will be released from quarantine into premises approved by the appropriate State or Territory governments for the holding of non-human primates.

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