

Review of rabies virus risk in imported dogs, cats and canine semen from approved countries

Draft report

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Stakeholder submissions on draft reports

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

Submissions should be sent to the Department of Agriculture, Fisheries and Forestry and must meet the conditions specified in the relevant [Biosecurity advice notice](#)

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Summary

The Department of Agriculture, Fisheries and Forestry has prepared this draft risk review to assess the rabies virus risk from the importation of dogs, cats and canine semen from approved countries into Australia.

This risk review takes into account new and relevant scientific information, and relevant changes in industry practices and operational practicalities.

Australia permits the importation of dogs, cats and canine semen from approved countries (including approved territories and jurisdictions) into Australia. However, there has been significant changes to the volume of imports and increasing commercialisation of trade, which has increased the rabies biosecurity risk for the importation of dogs and cats.

This draft risk review proposes revised rabies risk management measures that will reduce the risk associated with the importation of dogs and cats from approved countries into Australia to achieve Australia's appropriate level of protection (ALOP). The proposed revised rabies risk management measures for the importation of dogs and cats from approved countries are outline below.

For imports from all approved countries:

- Implantation with an ISO compatible microchip before commencing pre-export preparation.
- Direct imports must be only from approved countries.
- The animal has been examined within 5 days of export and showed no clinical signs of rabies.

For imports from group 1 approved countries:

- Residency within group 1 approved countries or Australia for 180 days (or since birth) before export to Australia.
- Animals from group 1 approved countries do not require post-entry quarantine (PEQ).

Imports from group 2 approved countries:

- Residency within group 1 or 2 approved countries or Australia for 180 days (or since birth) before export to Australia.
- A declaration by an official veterinarian, should accompany the import permit application, certifying that they have scanned the animal's microchip, that the animal is microchipped with the stated microchip number and the location of the microchip.
- Animals from group 2 approved countries continue to require a PEQ period of 10 days.

Imports from group 3 approved countries:

- Residency within approved countries or Australia for 180 days (or since birth) before export to Australia.
- A declaration by an official veterinarian, should accompany the import permit application, certifying that they have scanned the animal's microchip, that the animal is microchipped with the stated microchip number and the location of the microchip.
- Vaccination with an inactivated rabies virus (RABV) vaccine approved by the competent authority in the country of export (produced in accordance with the methods prescribed in the World Organisation for Animal Health Manual of Diagnostics Tests and Vaccines for Terrestrial Animals 2022 (WOAH Manual)), in accordance with the manufacturer's recommendations. Rabies vaccination must be current according to the manufacturer's recommendations at all times from when blood was taken for RNATT and up to the time of export.
- An RNATT of at least 0.5 IU/mL within 12 months (365 days) immediately before export.
- An interval of at least 180 days and not more than 12 months (365 days) between the date of the blood sample for the RNATT arriving at the laboratory and the date of export to Australia.
- PEQ of at least 30 days if imported dogs and cats have been prepared in compliance with the pre-export measures.
- Where considered relevant by the department based on document assessment and/or analysis of trade patterns and intelligence data, additional post-entry verification activities to verify compliance with the pre-export measures. In such cases, animals may be held in PEQ for up to 180 days.

There are no risk management measures proposed for the importation of canine semen for rabies from approved countries into Australia as the unrestricted biosecurity risk achieves ALOP.

This draft risk review contains details of the risk review for rabies and the proposed biosecurity measures to allow interested parties to provide comments and submissions to the Department of Agriculture, Fisheries and Forestry within the consultation period.

1 Background

Rabies is a zoonotic, viral disease caused by neurotropic RNA viruses of the genus *Lyssavirus* in the family *Rhabdoviridae* (WHO 2021a; WOA 2022c). Lyssaviruses are transmissible to all mammals and cause death with indistinguishable fatal encephalitis. Rare cases of natural infection have been reported in birds (Baby et al. 2015) but they are not considered important in the epidemiology of the disease. Historical records of rabies outbreaks date back at least 4,000 years in different continents (Fisher, Streicker & Schnell 2018).

Rabies virus (RABV) is the most important lyssavirus for public and animal health (WHO 2021a; WOA 2022c). This virus can establish in new host species and geographical areas despite effective pre- and post-exposure vaccination regimens (Fisher, Streicker & Schnell 2018). RABV causes approximately 59,000 human deaths each year globally, 95% of which occur in Africa and Asia (WHO 2021a; WOA 2022b). Domestic dogs are estimated to be responsible for transmission to humans in up to 99% of cases (WHO 2021a).

Lyssaviruses are generally maintained in specific mammalian reservoir hosts, from which spill over into other mammals may occur. These spill over infections tend to lead to a dead end in the transmission chain. However, RABV is distributed more widely than other lyssaviruses and strains may have host shifts (ICTV 2021). Establishment and sustained circulation of RABV in new hosts have been documented (ICTV 2021).

Infection with RABV and Australian bat lyssavirus (ABLV) are nationally notifiable animal diseases in Australia (DAFF 2022). Due to the serious public health implications, infection with RABV and ABLV are listed in Australia's Emergency Animal Disease Response Agreement (EADRA) as Category 1 diseases. In the event of an outbreak, the Australian government will provide 100% of the funding necessary for the emergency response (AHA 2021b).

Rabies is classified as a Neglected Tropical Disease (NTD) by the World Health Organization (WHO) (WHO 2021a). Infection with rabies virus is also a World Organisation for Animal Health (WOAH)-listed disease (WOAH 2022a). The WOAH Terrestrial Animal Health Code (the WOAH Code), defines a rabies case as 'any animal infected with rabies virus' and 'dog-mediated rabies is defined as any case caused by rabies virus maintained in the dog population (*Canis lupus familiaris*) independently of other animal reservoir species, as determined by epidemiological studies' (WOAH 2022b). For the purposes of international trade, the WOAH Code recommends measures for RABV and not other lyssaviruses (WOAH 2022b).

1.1 Global distribution

RABV is found almost worldwide, exceptions include Antarctica, Australia, New Zealand, Singapore, Japan and Hawaii (Singh et al. 2017; WHO 2021a). Other lyssaviruses appear to have more restricted geographical and host range (WOAH 2022c). The geographical distribution of RABV, based only on international reporting of human and domestic animal cases, is considered unreliable unless free-ranging wildlife cases are also included (Rupprecht, Stohr & Meredith 2001).

The WHO defines a dog-mediated RABV-free country as a country with no recorded indigenously acquired dog-mediated RABV cases in humans, dogs or any other animal species

for at least 24 months (WHO 2018b). The WOA (2022b) defines a country or zone as free from infection with RABV when:

- Infection with RABV is a notifiable disease in the entire country.
- No case of rabies has been confirmed and there is ongoing surveillance for the past 24 months.
- There is an appropriate recording and reporting system of animal diseases, and investigations are carried out for all susceptible animals showing clinical signs suggestive of rabies.

1.1.1 Africa

Africa has the highest per capita human death rate from RABV infection of any continent (Scott et al. 2015). There are also substantial livestock losses as a result of RABV infection in Africa (Jibat, Hogeveen & Mourits 2015). Dogs are the reservoir and principal vectors for RABV (Cliquet & Picard-Meyer 2004). However, several countries in Africa have self-declared freedom from dog-mediated RABV infections – including Cape Verde, Congo, Libya and Mauritius (Singh et al. 2017). In 2008 and 2010, South Africa had two outbreaks of RABV infection. Several hundred dogs were suspected to have been infected and two human deaths were reported (Thys et al. 2021). Both outbreaks were brought under control through free mass vaccination of dogs (Thys et al. 2021).

1.1.2 Asia

Domestic dogs are the most significant reservoir of RABV throughout Asia, with wildlife believed to play a lesser role (Rupprecht, Stohr & Meredith 2001). The disease is generally not notifiable and largely uncontrolled in most Asian countries. Thousands of human cases are reported annually (Cliquet & Picard-Meyer 2004). The South Asian region has the highest numbers of RABV infections, with most outbreaks occurring in India and Bangladesh (Singh et al. 2018). Cambodia, China, Lao, Malaysia, Mongolia, the Philippines and Vietnam are considered high risk for rabies in the Western Pacific region (WHO 2021b).

WHO declared Taiwan rabies free in 1961 (Shih et al. 2018). In mid-2013 Taiwan reported multiple confirmed RABV cases in wild Taiwanese ferret badgers based on testing of historical brain specimens collected during May 2010 to December 2012 (Huang et al. 2015; OIE 2013). Spill over cases of RABV into six masked palm civets, a house shrew and a dog were documented by December 2017 (Huang et al. 2015; Shih et al. 2018). RABV is now considered endemic in wildlife in Taiwan (WOA 2022h).

Since 2013, Malaysia has responded to several outbreaks in both Peninsular Malaysia and Sarawak. In Peninsular Malaysia, RABV incursions have been associated with suspected illegal movements of dogs from neighbouring countries via land and fishing boats (OIE 2015). Vaccination and public education campaigns have been effective in resolving incursions of RABV in Peninsular Malaysia. However, there has been an outbreak of RABV in Sarawak since mid-2017 (OIE 2021a). Both human and domestic animal cases have been recorded in Sarawak since the start of this outbreak. This RABV incursion is thought to have originated from southern Kalimantan (Indonesia), where RABV has been endemic since 1906 (Sim et al. 2021). The local Sarawak government has declared the RABV infection is an evolving epidemic in Sarawak (Sim

et al. 2021). To June 2021, 35 human cases have been recorded, with only two survivors with severe neurological complications (Outbreak News Today 2021).

1.1.3 Australia

Australia is free from RABV. The last reported suspected case of rabies in animals was in 1867 (AHA 2021a, b). Two human cases of overseas-acquired rabies were reported in 1987 and 1990 (AHA 2021b). Historically, Australia was considered free from lyssaviruses until the discovery of ABLV in 1996 (Field 2018). ABLV is genetically distinct from RABV but similar antigenically (AHA 2021b). ABLV has been isolated from flying foxes and is widespread in Australian bat taxa (Field 2018). Infection with both RABV and ABLV are nationally notifiable animal diseases in Australia (DAFF 2022) and are classified as EADRA category 1 diseases, meaning the costs for any disease response would be covered by the Australian government (AHA 2021b). No other lyssaviruses have been identified in Australia (AHA 2021b).

1.1.4 North America

The United States and Canada are considered to be free from dog-mediated rabies. The last documented locally acquired cases of RABV in domestic dogs were in the mid-1970s and mid-1960s respectively (Fehlner-Gardiner 2018). RABV is still endemic in wildlife in North America. Control of rabies is difficult in North America as it is epizootic in raccoons, skunks, and several species of bats and foxes (Fehlner-Gardiner 2018; Fisher, Streicker & Schnell 2018).

There have been four imported cases of rabies in dogs in the United States since 2015 (OIE 2021b; Pieracci et al. 2021; ProMED 2020, 2021), and two cases in Canada, one in 2021 and another one in 2022 (OIE 2021d, 2022). Five cases of rabies in domestic dogs were reported in the southern part of Mexico in 2015 (Fehlner-Gardiner 2018).

1.1.5 Central and South America

RABV is enzootic in wildlife throughout Central and South America, including the Caribbean islands (Cliquet & Picard-Meyer 2004; Meske et al. 2021; Seetahal et al. 2018). Dog-mediated rabies has been controlled in most countries in Central and South America in the last decade following intense public vaccination campaigns (Campos et al. 2020). Over the past 35 years, RABV cases in dogs and humans have declined by 95% in the region (PAHO 2018). Dog-mediated rabies is still endemic in Bolivia, Guatemala, Haiti and the Dominican Republic (WOAH 2022g, e, f, d) and they contribute to most rabies cases in Central and South America. The remaining cases are isolated reports from Argentina, Brazil, Cuba, Peru and Venezuela (PAHO 2018).

The common vampire bat (*Desmodus rotundus*) is now the major sylvatic RABV reservoir in South America (Meske et al. 2021). Meske et al. (2021) found that around 70% of human RABV cases were transmitted by bats in South America. Rabies control programs in wildlife are still not well established in Central and South America due to financial constraints (OIE 2021b).

1.1.6 Europe

Rabies is notifiable in most of Europe (Cliquet, Picard-Meyer & Robardet 2014). The red fox (*Vulpes vulpes*) is the most important reservoir host of RABV in Europe (Gossner et al. 2020). Western and central European countries have implemented effective oral rabies vaccination programs for foxes (Cliquet, Picard-Meyer & Robardet 2014; Fisher, Streicker & Schnell 2018).

Many European countries have declared freedom from dog-mediated rabies but RABV still persists in wildlife and farmed animals (Gossner et al. 2020; Vega et al. 2021). The number of animal RABV infections in the European Union has dropped from more than 800 cases in 2010 to only 4 cases in 2019 (Gossner et al. 2020). The majority of human RABV cases in Europe are travel-related with infection acquired in other parts of the world (Gossner et al. 2020).

2 Technical information

2.1 Taxonomy

There are eighteen identified lyssaviruses. The International Committee on Taxonomy of Viruses (ICTV) categorises lyssaviruses into two phylogroups with one unclassified virus and three additional species considered independent from these two phylogroups, based on genetic similarity and serological cross-reactivity (ICTV 2021). The taxonomy of lyssaviruses, their geographic range and reservoir hosts are summarised in Table 1 below.

Recently lyssa-like viruses have been identified in amphibians and reptiles by screening of publicly available sequence data (Horie et al. 2021; Oberhuber et al. 2021). The significance of this finding is unclear and further work is required.

Table 1: Classification of the species of the genus *Lyssavirus*, geographical distribution and their common reservoirs

Phylogroup	Virus name	Distribution /Countries of virus isolation	Most common reservoir based on virus detection
I	Aravan virus	Central Asia / Kyrgyzstan	Lesser mouse-eared bat
	Australian bat lyssavirus	Australia / Australia	Frugivorous and insectivorous bats (Black flying fox, yellow-bellied sheath-tailed bat)
	Bokeloh bat lyssavirus	Europe / France and Germany	Natterer's bat
	Duvenhage virus	Southern Africa / Kenya and South Africa	Insectivorous bats
	European bat lyssavirus 1	Europe/ Belgium, Denmark, France, Germany, the Netherlands, Poland, Russia, Slovakia, Spain and Ukraine	Insectivorous bats (Serotine bat)
	European bat lyssavirus 2	Europe / Denmark, Finland, France, Germany, the Netherlands, Norway, Switzerland and the United Kingdom	Insectivorous bats (Daubenton's bat)
	Gannoruwa bat lyssavirus	Asia / Sri Lanka	Indian flying fox
	Irkut lyssavirus	East Siberia / China and Russia	Insectivorous bats (Greater tube-nosed bat)
	Khujand virus	Central Asia / Tajikistan	Insectivorous bats (Whiskered bat)
	Taiwan bat lyssavirus	Asia /Taiwan	Japanese house bat
	Rabies virus	Worldwide (except several islands including Australia)	Carnivores and bats

Phylogroup	Virus name	Distribution /Countries of virus isolation	Most common reservoir based on virus detection
II	Lagos bat virus	Africa / Central African Republic, Ethiopia, France [#] , Ghana, Nigeria, Senegal, South Africa and Zimbabwe	Numerous frugivorous bats
	Mokola virus	Sub-Saharan Africa / Cameroon, Central African Republic, Ethiopia, Nigeria, South Africa and Zimbabwe	Shrews, rodents and domestic cats
	Shimoni bat virus	East Africa / Kenya	Commerson's leaf-nosed bat
Independent	Ikoma lyssavirus	Africa / Tanzania	African civet
	Lleida bat lyssavirus	Europe / Spain	Common bent-winged bat
	West Caucasian bat lyssavirus	Caucasian region / Russia	Insectivorous bats (Common bent-winged bat)
Unclassified	Kotolahti bat lyssavirus	Europe / Finland	Brandt's bat

[#] It is unknown whether the infected animals arrived in France from Egypt or Togo. (Fooks et al. 2017; ICTV 2021; Lan et al. 2017; Vega et al. 2021; WHO 2018b).

2.2 Agent properties

RABV is an enveloped bullet-shaped negative-stranded RNA virus of the Rhabdoviridae family (Fisher, Streicker & Schnell 2018; WHO 2021a). RABV is small, with a compact genome of about 12 kb encoding five proteins (Brunker & Mollentze 2018).

RABV is rapidly inactivated outside a host. It is sensitive to both very low and very high pH (OIE 2014). RABV can be inactivated by desiccation, sunlight, and a range of chemicals including sodium hypochlorite, 45-75% ethanol, quaternary ammonium disinfectants in 1:500 dilution, 5-7% iodine solution, formaldehyde, phenol, ether, trypsin, and hydrogen peroxide (OIE 2014; Willoughby 2015; Wu et al. 2017).

2.3 Epidemiology

2.3.1 Lyssaviruses and their hosts

Most lyssaviruses have natural reservoir hosts as outlined above in Table 1. These natural reservoir hosts are usually within the Carnivora and Chiroptera orders and have a global distribution (Fooks et al. 2017; WHO 2021a). Sixteen of the eighteen lyssaviruses have bats as reservoir hosts and have limited public and animal health implications (Vega et al. 2021; WOA 2022c). While some of these lyssaviruses have reservoir hosts and geographical ranges that are well documented (for example EBLVs in Europe), others are poorly defined.

Cross-species transmission (spill over) is the ability of a virus to infect a member of a new host species. For lyssaviruses, this normally results in 'dead-end' infections with no further spread to other hosts (Fooks et al. 2017). Reported spill over hosts of RABV include all mammals such as humans, cattle, horses, cats, and wildlife; for example, foxes, skunks, wolves, racoons and monkeys. Poultry, rodents and lagomorphs can also be spill over hosts of RABV but this rarely occurs (Baby et al. 2015; Fitzpatrick et al. 2014).

Some species show more resistance to RABV infection than others, requiring a higher exposure dose to induce infection (Niezgoda, Hanlon & Rupprecht 2002). Species regarded as moderately

susceptible include felids, mustelids (badgers, ferrets and minks), primates and ungulates (Niezgoda, Hanlon & Rupprecht 2002). Cats are effective vectors for transmission; however, there are no known RABV strains adapted to felids (Rupprecht, Stohr & Meredith 2001). Lagomorphs, rodents, and insectivores are considered most resistant (Niezgoda, Hanlon & Rupprecht 2002).

Potential wild or feral hosts (foxes, wild canids and feral cats) are widespread in Australia. In some places, foxes and wild canids are in sufficient densities to become maintenance hosts for RABV. It was estimated that foxes (*Vulpes vulpes*) and wild dogs inhabit about 76% and 83% of Australia, respectively (West 2008). There are large populations of free-roaming community dogs in communities in Northern Australia. Feral cats are also potential spill over hosts.

The susceptibility of Australian native animals to infection with RABV is unknown (AHA 2021b). Rare cases of RABV have been documented in American marsupials (Virginia opossum) (Diana, Mitchell & Feldman 2015) and this may indicate that Australian marsupials are also susceptible. It is possible that if infected, Australian native mammals in the orders Chiroptera, Carnivora (dingoes) and Dasyuromorphia (antechinus, dunnart, quoll, Tasmanian devil) could contribute to the maintenance of a sylvatic cycle of RABV.

2.3.2 RABV and its epidemiological cycles

RABV is different from other lyssaviruses as it has multiple independent transmission cycles established in a broad range of reservoir hosts (WHO 2018b). RABV has adapted to each reservoir independently, leading to host-specific maintenance cycles. These are known as the urban and sylvatic cycles (Singh et al. 2017). Dogs are the main reservoir host in the urban RABV cycle which is dominant in Africa, Asia, and Central America (Singh et al. 2017; WHO 2021a). The sylvatic cycle is the predominant cycle in the North and South America, and Europe (Fisher, Streicker & Schnell 2018; Meske et al. 2021; WHO 2018b). Both cycles are present simultaneously in some parts of the world.

RABV transmits sporadically from the primary reservoir hosts to domestic animals and humans. These spill over transmissions rarely lead to the establishment of new maintenance cycles (Brunker & Mollentze 2018; OIE 2014; WHO 2018b). Different independent maintenance cycles may occur simultaneously within one geographic region (WHO 2018b). Table 2 outlines the typical reservoirs host for RABV and their geographic location.

Table 2: Typical host reservoirs for RABV and their geographic location

Geographic location	Typical carnivore reservoir hosts for RABV
Africa	domestic dog (<i>Canis lupus familiaris</i>) jackals (<i>Canis adustus</i> and <i>C. mesomelas</i>) mongoose (<i>Herpestes</i> spp.)
Middle East and Asia	domestic dog (<i>Canis lupus familiaris</i>) red fox (<i>Vulpes vulpes</i>) ferret badger (<i>Melogale moschata</i>) golden jackals (<i>Canis aureus</i>)
Europe	red fox (<i>Vulpes vulpes</i>) raccoon dog (<i>Nyctereutes procyonoides</i>)
North America	raccoon (<i>Procyon lotor</i>) grey fox (<i>Urocyon cinereoargenteus</i>) striped skunk (<i>Mephitis mephitis</i>) coyote (<i>Canis latrans</i>)
South America	common vampire bat (<i>Desmodus rotundus</i>) domestic dog (<i>Canis lupus familiaris</i>) crab-eating fox (<i>Cerdocyon thous</i>) marmoset (<i>Callithrix jacchus</i>)
Caribbean islands	domestic dog (<i>Canis lupus familiaris</i>) small Indian mongoose (<i>Herpestes auropunctatus</i>)
Eurasian and American arctic and subarctic regions	arctic fox (<i>Alopex lagopus</i>)

(Meske et al. 2021; WHO 2018b)

2.3.3 Transmission

Transmission of RABV usually occurs via bites from rabid animals, which shed the virus in their saliva. RABV then enters the body via these wounds (transdermal inoculation) or by direct contact on skin lesions or mucous membranes (WHO 2021a). RABV cannot penetrate intact skin (WHO 2021a) but may enter through scratches and abrasions (Fisher, Streicker & Schnell 2018). Rarely, oral exposure, for example licks and consumption of carcasses of infected animals has resulted in clinical rabies or immunity, depending on the dose of virus (Fisher, Streicker & Schnell 2018; Niezgodna, Hanlon & Rupprecht 2002).

Indirect transmission can occur but is rare as the virus inactivates rapidly in the environment (Rupprecht, Hanlon & Hemachudha 2002). RABV transmission by aerosols has also been reported but is limited to environments with high concentrations of virus (Bowen-Davies & Lowings 2000; Fisher, Streicker & Schnell 2018). These include bat caves with large groups of bats or in laboratories (Bowen-Davies & Lowings 2000; Fisher, Streicker & Schnell 2018). No hematogenous or congenital transmission of RABV has been reported. Blood, urine, and faeces of rabid animals have not been shown to transmit RABV (Willoughby 2015).

Dogs

Dogs are the main reservoir host in the urban RABV cycle (OIE 2014).

Dog semen

There is no evidence of transmission of lyssaviruses including RABV through dog semen (AHA 2021b).

Cats

Cats may shed RABV in saliva (Trimarchi, Rudd & Abelseth 1986). Despite being able to transmit RABV effectively, cats (domestic or wild) are not usually maintenance hosts (Rupprecht, Hanlon & Hemachudha 2002). Rabid cats are spill over infections of the dominant geographic biotype from maintenance host species. However, vaccination programs for domestic cats are present in countries such as Sri Lanka, where cats are free to roam, to reduce the transmission of rabies from stray cats and dogs to humans (Jayasundara 2020).

Humans

In Africa and Asia, human RABV infections are mainly transmitted through bites from rabid dogs (Begeman et al. 2018). As dog-mediated RABV infection is well controlled by vaccination programs, bats have become important in transmission to humans in the past decade, especially in South America (Begeman et al. 2018; Meske et al. 2021). Human-to-human transplacental transmission of RABV and by tissue and organ transplants has been reported (Zhou et al. 2016). There are rare instances of human survival of clinical rabies without post-exposure prophylaxis (PEP), which generally involved bat variants. This is most likely due to infection with less neurotropic and less uniformly lethal wild strains of RABVs rather than carnivore RABVs (Fisher, Streicker & Schnell 2018).

2.4 Pathogenesis

Following a bite from a rabid animal, the virus enters and replicates within myocytes or macrophages in muscle, where it sequesters during the incubation period. RABV then crosses the neuromuscular junction and enters the exposed neuronal terminals of sensory and motor peripheral nerves (Begeman et al. 2018; Fisher, Streicker & Schnell 2018; Singh et al. 2017). Replication continues once the virus is within neuronal tissue (Singh et al. 2018).

RABV ascends to the central nervous system (CNS) via retrograde transport within neuronal axons, utilising cellular transport mechanisms (Begeman et al. 2018; Fisher, Streicker & Schnell 2018; Singh et al. 2017). This centripetal movement often occurs via multiple motor and/or sensory nerves (Begeman et al. 2018; Fisher, Streicker & Schnell 2018). Speed of RABV spread to the CNS is variable but can be fast, with up to 100mm/day reported (Singh et al. 2017).

RABV may also be transmitted by the intranasal route. In these rare cases, the virus enters trigeminal nerves and ganglia en route to the CNS via branches of the cranial nerves (Greene 2013). Transmission via the oro-gastrointestinal route, is thought to require mucosal abrasions to allow viral passage into innervated muscle or neuronal tissue in the gastrointestinal tract (Fisher, Streicker & Schnell 2018).

Within neuronal tissue, RABV spreads via synapses connecting the axons or dendrites (Begeman et al. 2018). From the spinal cord, RABV spread to the cerebral cortex, cerebellum, diencephalon, midbrain, pons, and medulla oblongata using synaptically connected neurons in sensory or motor tracts.

Within the brain, RABV is disseminated preferentially to the limbic areas, thalamic nuclear, reticular formation, and trigeminal and vagal nuclei (Greene 2013). Disease is caused by neuronal dysfunction rather than damage in these areas (Greene 2013; Singh et al. 2018). Infection within the limbic area results in behavioural changes, including loss of fear of humans and aggression, which contributes to the ongoing transmission of RABV through bites (Singh et

al. 2018). Death ultimately occurs due to the interference with cardiorespiratory control (Greene 2013).

From the brain, RABV is then transported centrifugally via nerves to the peripheral tissue at a rate of 100-400mm/day (Begeman et al. 2018; Fisher, Streicker & Schnell 2018; Greene 2013). The virus is most commonly found in neurons, although it can enter any other cell type (Begeman et al. 2018; Greene 2013). RABV may enter the acinar cells of the salivary glands, where it will replicate and be shed into the saliva, enabling transmission to the next host (Begeman et al. 2018; Dietzschold et al. 2008; Greene 2013; Singh et al. 2017). Sometimes death may occur before peripheral spread to the salivary gland (Greene 2013).

Pathogenesis may vary between RABV strains (Katz et al. 2016; Mesquita et al. 2017; Morimoto et al. 1996). More pathogenic RABV strains appear to be more neuroinvasive and better able to sequester from the immune response (Scott & Nel 2016). Experimentally, highly attenuated RABV strains were associated with more robust immune responses and non-lethal outcomes compared to wild strains in dog models (Gnanadurai et al. 2015).

2.5 Incubation period

In natural RABV infections, the incubation period varies. Shorter incubation periods are associated with the transmission of a high viral load, at a site close to the CNS, and where there is a high degree of exposed peripheral neuronal terminals (for example skin and skeletal muscles) (Begeman et al. 2018; Fekadu 1982; Greene 2013; Ward & Brookes 2021).

The incubation period for RABV can range from 10 days to 6 months (Greene 2013; Sparkes et al. 2015). The WOAHA Code defines the incubation period of infection with RABV as six months (WOAHA 2022b). The majority of animals infected with RABV will develop clinical disease within this time period (WOAHA 2022b). Cases in dogs and cats with incubation periods over six months are rare (AHA 2021b).

The Australian Veterinary Emergency Plan (AUSVETPLAN) for lyssaviruses states the incubation period of rabies to be from 10 days to 6 months (AHA 2021b).

2.6 Clinical signs

There are no pathognomonic clinical signs for rabies (Niezgoda, Hanlon & Rupprecht 2002; WOAHA 2022c) and atypical signs are common (Greene 2013). Clinical signs occur once the virus reaches the CNS (Sparkes et al. 2015). Once clinical signs appear, the disease is usually fatal (Singh et al. 2018; Sparkes et al. 2015). Death occurs within ten days of clinical signs appearing in dogs (Niezgoda, Hanlon & Rupprecht 2002; Tepsumethanon et al. 2004).

Increased aggression and the tendency to bite are commonly seen in rabid dogs (Hampson et al. 2009). The WOAHA (2022b) defines a suspected case for the purpose of surveillance as 'a susceptible animal that shows any change in behaviour followed by death within 10 days, or that shows any of the following clinical signs: hypersalivation, paralysis, lethargy, abnormal aggression, abnormal vocalisation'.

The frequently observed clinical signs are summarised in Table 3. Not all cases progress through each phase or type.

Table 3: Frequently observed clinical signs of rabies in dogs and cats

Phase or type	Dogs	Cats
Prodromal phase	Length 2 to 3 days Variable fever Licking wound site Apprehensive, nervous, anxious Friendly animals become shy or irritable Fractious animals become docile and affectionate Pupillary dilation +/- sluggish palpebral or corneal reflexes	Length 1 to 2 days Fever spike Unusual or erratic behaviour
Furious/psychotic type	Length 1 to 7 days Restless, irritable, photophobic, hyperaesthetic, vicious, cage aggression Roaming, hiding Pica Muscle incoordination, disorientation or grand mal seizures May be followed by a short paralytic phase Death during a seizure	Length 2 to 5 days Most common form in cats Erratic and unusual behaviour Anxious, cage aggression Muscle tremors and weakness, incoordination, staggering Blank eyes Run until they die
Paralytic type	Length 2 to 4 days Lower motor neuron paralysis spreading from the wound site until the entire CNS is affected Change in bark Excessive salivation (paralysis of laryngeal muscles preventing swallowing) Dropped jaw (paralysis of the masticatory muscles) Deep laboured breathing Coma and death due to respiratory failure	Length 2 to 10 days (death usually occurs after 3 to 4 days of paralytic signs) Sometimes no furious phase first Paralysis of bitten extremity then paraparesis Incoordination Ascending or generalised paralysis Increased vocalisation frequency and change in voice pitch Coma and death due to respiratory failure

(Greene 2013).

2.7 Pathology

RABV infection does not cause gross pathological changes (Greene 2013; Singh et al. 2017). In the early centripetal stage of the disease, histopathological lesions are not present at the entry site or in the peripheral nerves (Begeman et al. 2018).

Histopathological changes within the CNS can vary in severity and be completely absent in some areas of the CNS (Begeman et al. 2018). Changes tend to be more pronounced the longer the disease course (Greene 2013) but some histopathological changes are always found at the end stage of the disease (Begeman et al. 2018).

Histopathological changes in the brain and spinal cord may include gliosis, neuron necrosis, perineural and perivascular infiltration of mononuclear cells (lymphocytes, plasma cells) and neutrophils, neuronophagia, and eosinophilic inclusions (Negri bodies) in the cytoplasm of neuronal cells (Begeman et al. 2018; Singh et al. 2017). Most of these histopathological changes are found within the hypothalamus (Plotkin 2000). Thrombosis may also be seen in the brain stem, hypothalamus and limbic system (Singh et al. 2017). In cats, spongiform lesions may

appear as vacuolation in the neuropile of the thalamus and inner layers of the cerebral cortex (Greene 2013).

Following centrifugal spread of RABV to the periphery, Wallerian degeneration and mononuclear cell infiltration can be found in peripheral nerves. Neuronal necrosis and mononuclear cell infiltration can be seen in dorsal root ganglia (Begeman et al. 2018). At the end stage of disease, degeneration of non-neuronal tissue can sometimes be seen in the salivary glands, lacrimal glands, pancreas and adrenal medullae (Jackson 2003; McKay & Wallis 2005).

2.8 Diagnosis

Due to the non-specific and variable clinical signs of rabies, a diagnosis based on clinical signs only is not possible. Common clinical signs may lead to a suspicion of rabies, which should then be confirmed by testing. Diagnostic tests that identify the virus or some of the virus' specific components are required to make a definitive diagnosis (WOAH 2022b, c). Recommended samples for these tests in animals are brain tissue, however, other samples (such as salivary glands) have also been used with variable sensitivity and specificity (WOAH 2022c). Laboratory technicians should take suitable precautions when handling potentially infected brain tissue (Singh et al. 2018; Singh et al. 2017).

2.8.1 Identification of the agent

A range of brain tissues should be tested for rabies to reduce the occurrence of false negative results (AHA 2021b; WOH 2022c). The WOH (2022c) recommends that these brain tissues should include brain stem, Ammon's horn, thalamus, cerebral cortex, cerebellum and medulla oblongata.

Immunochemical identification of rabies virus antigens

The direct fluorescent antibody test (DFA test or dFAT) is recommended by the WHO and WOH for confirmation of population freedom and clinical cases, and for surveillance and eradication programs (WOH 2022c). Fluorescein-labelled antibody conjugate is used to detect virus nucleocapsid protein antigens. Due to the antigenic similarity of all lyssavirus nucleoproteins, this test does not differentiate between lyssaviruses (AHA 2021b).

The DFA test is recommended to be run on a direct impression smear of fresh composite brain tissue, which includes the brain stem and cerebellum (WOH 2022c). The DFA test has a 100% sensitivity, however, this will be reduced if the tissue samples are autolysed or are not composite samples (Singh et al. 2017). The specificity of the test is between 96-99% (WOH 2022c).

The DFA test is rapid and results can be provided in under two hours (Singh et al. 2018; Singh et al. 2017; WOH 2022c). The test reagents are low cost, however, the fluorescence microscope required to read the result is costly.

A direct rapid immunohistochemical test (dRIT) is also available for the detection of rabies antigens (Madhusudana et al. 2012; Singh et al. 2018; WOH 2022c). This test is often used in low- and middle-income countries where diagnostic laboratories do not have access to a fluorescence microscope (Scott et al. 2015; WOH 2022c). The sensitivity and specificity of the dRIT has been shown to be similar to the DFA test (Ali et al. 2014; Scott et al. 2015). Its efficacy

for local RABV strains should be validated before application due to regional diversity of lyssaviruses (WOAH 2022c).

Enzyme-linked immunosorbent assays (ELISA) have also been developed for the detection of lyssavirus antigens. These are useful for large epidemiological surveys. The efficacy for the local circulating lyssaviruses should be assessed before application (WOAH 2022c).

Virus isolation

Isolation of RABV from brain tissue can be used as a confirmatory test when other tests are inconclusive. Virus isolation by cell culture is preferred over the mouse inoculation test (WOAH 2022c).

Polymerase chain reaction

The WOA (2022c) describes two polymerase chain reaction (PCR) assays for the detection of lyssavirus RNA. If composite brain tissue samples (which include the brain stem and cerebellum) are used, these have a similar sensitivity and specific to the DFA test or dRIT (WOAH 2022c). These assays may be used for confirmation of population freedom and clinical cases, and for surveillance and eradication programs (WOAH 2022c).

A number of other PCR assays, which are highly specific for a particular strain of lyssavirus, have also been described. An inconclusive result on a strain-specific PCR assay should be confirmed by other diagnostic means. Sequencing can be used to determine specific viral types (AHA 2021b; WOA 2022c).

2.8.2 Histological identification of characteristic cell lesions

Examination of histopathological lesions is no longer recommended as a routine diagnostic tool for RABV (WOAH 2022c). The process is expensive, time consuming and has a low sensitivity as 'classical' Negri bodies are not always detectable (Singh et al. 2017; WOA 2022c).

2.8.3 Serological tests

Serological tests should not be used for the diagnosis of RABV (AHA 2021b; Greene 2013; Singh et al. 2018; WOA 2022c). Animals infected with RABV may not produce sufficient antibodies pre-mortem to be reliably detected in the serum (Greene 2013; Singh et al. 2018).

Virus neutralisation serological tests are more commonly used to detect serologic responses to RABV vaccination (AHA 2021b; WOA 2022c). The fluorescent antibody virus neutralisation test (FAVN) and the rapid fluorescent focus inhibition test (RFFIT) are recommended for measuring vaccination response before international animal movement or trade (WOAH 2022c). These tests are referred to collectively as rabies neutralising antibody titre tests (RNATT). The WOA Code has set the standard for demonstration of an adequate serological response to RABV vaccination before international animal movement at 0.5 international units (IU)/mL (WOAH 2022b).

There are ELISAs available which can detect RABV antigens. However, none are validated for their application in international animal movement or trade (WOAH 2022c). These ELISAs have been used to detect serological response in post mass vaccination surveys; for example, oral vaccination campaigns. ELISAs should be validated before being applied in each local setting due to significant variations in animal species being surveyed and the circulating RABV strains (WOAH 2022c). Until further information is available, ELISAs cannot be considered to replace

RNATTs for validation of serological response to vaccination before international movement of an animal (WOAH 2022c).

2.9 Immunology

RABV is well adapted to avoiding and suppressing the host immune system. These mechanisms occur at the exposure site and include sequestration of innate immune responses, which negatively impact the later development of adaptive immune responses. This also allows the virus to replicate more efficiently in the muscle tissue, assisting neuroinvasion (Scott & Nel 2016). Clinically, there is a distinct absence of serological responses during this incubation phase (Fisher, Streicker & Schnell 2018). Within nerve tissue, the virus causes minimal neuronal cell damage and apoptosis, which reduces the release of antigens; induces peripheral immunosuppression; and attracts non-RABV specific lymphocytes into the CNS, reducing lymphocytes in the periphery (Lafon 2002; Singh et al. 2018; Wiktor, MacFarlan & Koprowski 1985). RABV may also be able to utilise immune cells to assist spread throughout the peripheral nervous system (Scott & Nel 2016). In contrast, attenuated RABV strains have been shown in experimental studies to induce stronger immune response, which is associated with protection from lethal outcomes (Gnanadurai et al. 2015).

Fatal infections produce little or no virus neutralising antibody titre in serum (Gerber et al. 1985; Manickam, Basheer & Jayakumar 2008; Swanepoel 1994). Low level serological responses have been reported in some experimental infections in dogs (Fekadu & Baer 1980; Gnanadurai et al. 2015). Gnanadurai et al. (2015) reported serum virus neutralising antibodies were on average 0.12 IU/mL and 0.31 IU/mL at 7 and 21 days post intramuscular infection with a wild RABV strain in a dog model. All dogs showed clinical signs consistent with rabies at 19 to 30 days post infection and were euthanased when they developed hind limb paralysis at 21 to 31 days post infection (Gnanadurai et al. 2015).

Reports of dogs surviving infection are rare. In addition to their rarity, reports of survival due to natural immunity are unclear as dogs are often euthanised before 180 days post challenge (Fekadu & Baer 1980; Manickam, Basheer & Jayakumar 2008). Variable fatality rates ranging from 32% to 85% were reported in experimental infections in cats dependent upon the RABV strain and dose (Soulebot et al. 1981; Vaughn, Gerhardt & Paterson 1963).

Age, timing of exposure, sex, temperature and genetics have been shown to affect the immune response to infection in mouse models (Bell & Moore 1974; Lodmell 1983). Higher ambient temperatures have been associated with longer incubation (Bell, Clark & Moore 1977).

2.10 Vaccination

2.10.1 Types of vaccines

Attenuated live virus vaccines. These vaccines use viruses that were processed to reduce their pathogenicity in target and non-target host species. Due to safety reasons such as self-inoculation of the vaccinator or vaccine induced rabies in the animal, live attenuated RABV vaccines are no longer recommended (Esh, Cunningham & Wiktor 1982; WOAH 2022c; Yang et al. 2013).

Inactivated cell culture vaccines. Virtually all commercially available rabies vaccines contain inactivated viruses. Commercial inactivated RABV vaccines for use in animals are produced from a number of RABV biotypes (Bowen-Davies & Lowings 2000). The virus is inactivated by

chemical or physical means so it cannot cause infection but can still induce immunity (WOAH 2022c).

Recombinant vaccines. Recombinant vaccines do not contain live RABV. They are manufactured by inserting RABV nucleic acid into a benign virus vector such as vaccinia or canary pox virus. The recombinant canary pox vaccine is registered for use in cats in the United States; however, its present formulation does not stimulate immunity in dogs (Day, Horzinek & Schultz 2010). Recombinant RABV vaccines have now been developed for use as oral rabies vaccine (ORV) baits for use in wildlife rabies control (Maki et al. 2017).

Plasmid DNA vectors encoding the RABV glycoprotein G elicited strong, antigen-specific immune responses in dogs and cats (Lodmell et al. 2003; Osorio et al. 1999; Tesoro Cruz et al. 2006). Antibodies induced by plasmid DNA vaccines have been shown to be protective in dogs under experimental conditions (Bahloul et al. 2006).

ORVs have been used as part of control programs on a wide range of wildlife in many countries; for example, red foxes and golden jackals in Israel, foxes in Europe, raccoon dogs in South Korea and coyotes, foxes, raccoons and skunks in the United States (Maki et al. 2017). ORV baits are thermostable and suitable for aerial distribution. Baits contain an edible bait-attractant and biomarkers to allow identification and monitoring of uptake. Eight ORVs are licenced for use in wildlife (WHO 2018a). There has been widespread use of ORVs in Western and Central Europe, which has allowed many countries to have well controlled rabies, including Austria, Belgium, the Czech Republic, Finland, France, Germany, Italy, Lichtenstein, Luxembourg, the Netherlands and Switzerland (Müller et al. 2015).

2.10.2 Phylogroups covered

The World Organisation for Animal Health Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2022 (WOAH Manual) recommends that the RABV strain selected for vaccine production should protect against any RABV variant of phylogroup I (WOAH 2022c). Current rabies vaccines protect against all known strains as well as the ABLV. They provide variable protection against most other known lyssaviruses but are ineffective against phylogroup II (Lagos bat virus and Mokola virus) and the West Caucasian bat lyssavirus (Hanlon et al. 2005; Horton et al. 2010; WOAH 2022c).

2.10.3 Manufacturing controls

The WOAH Manual provides recommendations for development and manufacture of rabies vaccines for use in animals (WOAH 2022c). Vaccines should confer protective immunity for at least one year in target species.

To provide protection, vaccines must be efficacious and stored and administered according to manufacturer's instructions. The efficacy of commercial vaccines varies. Each country is responsible for registration of vaccines in its own jurisdiction.

2.10.4 Vaccination guidelines

A summary of vaccination guidelines is provided in Table 4.

Table 4: Guidelines for the vaccination of dogs and cats

Vaccine	Primary course (≤ 16 weeks)	Primary course (> 16 weeks)	Revaccination recommendation
Dogs			
Rabies (killed parenteral)	Administer one dose as early as 12 weeks of age. If vaccination performed earlier than 12 weeks, the puppy should be revaccinated at 12 weeks. In high-risk areas, a second dose may be given 2–4 weeks after the first dose	Administer a single dose	Canine rabies vaccines with either a 1- or 3-year DOI are available. Timing of boosters is determined by this licensed DOI, but in some areas may be dictated by statute
Cats			
Rabies (Canary pox virus-vectored recombinant, non-adjuvanted, parenteral)	Administer a single dose as early as 12 weeks of age, with revaccination 1 year later	Administer as single dose	Annual booster is required
Rabies (1 and 3 year killed, adjuvanted products are available, parenteral)	Administer a single dose as early as 12 weeks of age, with revaccination 1 year later	Administer 2 doses, 12 months apart	Booster as for licensed DOI (1 or 3 years) or as required by local regulations

DOI = duration of immunity (Day et al. 2016)

2.10.5 Protection after vaccination

Vaccination has been shown to induce an effective and relatively long-lasting humoral immune response in dogs and cats (Bahloul et al. 2006; Coyne et al. 2001; Fooks 2001; Lakshmanan et al. 2006). RABV specific virus neutralising antibodies produced as a result of vaccination provide a reliable indicator that an animal can withstand challenge with virulent RABV (Moore & Hanlon 2010; Wilsmore et al. 2006). Consequently, the standard for demonstration of an adequate serological response to RABV vaccination before international animal movement is 0.5 IU/mL (WOAH 2022b). Cell mediated immunity is also an important component of the protection induced by vaccination, however, this is not readily quantified.

The duration of immunity induced by vaccination of dogs and cats with some commercially available inactivated RABV vaccines is at least three years as measured by challenge and may be as long as seven years based on serological responses (Day, Horzinek & Schultz 2010; Sharpee, Nelson & Beckenhauer 1985; Soulebot et al. 1981). However, all current commercial vaccines for dogs and cats recommend boosters be given from 1 to 3 years after a primary course (Day et al. 2016).

The occurrence of rabies in vaccinated dogs and cats has been documented, but investigations indicate this is rare (Clark et al. 1981; Clark & Wilson 1996; De Benedictis et al. 2009; Murray, Holmes & Hanlon 2009). This may be due to poor responses to the vaccination such as in very young animals. The presence of maternal antibodies in very young animals can interfere with the development of active immunity following vaccination. Rabies vaccines should therefore only be administered to animals at 12 weeks of age or older (Day et al. 2016).

The effectiveness of rabies vaccination may also be affected by the vaccine type, breed, size, age, and health status of the animal. Small and mixed breeds dogs respond better serologically to primary rabies vaccination than large and purebred animals (Berndtsson et al. 2011; Tasioudi et al. 2018; Wallace et al. 2017). Lower body condition scores have been associated with poorer serologic responses to vaccination in dogs (Wera et al. 2021). Berndtsson et al. (2011) found a difference in serological response between two inactivated vaccines (Nobivac Rabies and Rabisin), with Rabisin associated with more dogs achieving an RNATT of at least 0.5IU/mL 6 to 12 months following vaccination. This response was seen for both single and multiple doses suggesting a difference in immunogenicity between the two vaccines.

Immunologically naïve dogs also have higher rates of failure to produce prolonged adequate serological responses (that is RNATT less than 0.5IU/mL) than those given multiple doses of vaccine (Berndtsson et al. 2011; Cliquet & Picard-Meyer 2004; Kaila, Marjoniemi & Nokireki 2019; Pimburage et al. 2017; Tasioudi et al. 2018; Trujillo, Martínez-Gutierrez & Ruiz-Saenz 2018; Watanabe et al. 2013; Wera et al. 2021). In particular, juvenile dogs (less than 1 year of age) have higher rates of vaccine failure compared to older animals vaccinated only once (Pimburage et al. 2017; Wera et al. 2021). Immune responses in geriatric dogs (12 years or older) to RABV vaccination may also be reduced serologically compared to younger dogs (HogenEsch et al. 2004).

2.10.6 Correlation between protection after vaccination and virus neutralising titre

The immunological basis of protection against rabies following vaccination is not fully understood. Both humoral and cellular immune responses are induced by rabies vaccines and are important in providing protective immunity (Lafon 2002; Schultz 2006). Virus neutralising antibodies are useful for evaluating vaccine efficacy, but absence of these antibodies does not preclude protective immunity (Wilsmore et al. 2006).

The WHO considers that a virus neutralising antibody titre of at least 0.5 IU/mL is a reliable indicator of protective immunity in animals and humans (WHO 2006, 2018a). This minimum titre has also been accepted by the WOAHA as the international standard for safe movement of dogs and cats (WOAHA 2022b). The current WOAHA Code recommends that vaccinated dogs and cats undergo an RNATT with a result of at least 0.5 IU/mL no less than 3 months and no longer than 12 months before shipment (WOAHA 2022b).

RABV neutralising antibody titres generally peak at about four weeks following vaccination and then decline (Manickam, Basheer & Jayakumar 2008; Mansfield et al. 2004). A significant number of animals, young or naïve, may not achieve prolonged serological responses following a single rabies vaccination. A single dose in naïve dogs failed to produce RABV neutralising antibody titres greater than 0.5 IU/mL, which lasted for a year, in 23.1 to 57.1% of dogs (Pimburage et al. 2017; Watanabe et al. 2013). In comparison, most animals receiving two or more doses of rabies vaccine had titres of at least 0.5 IU/mL for at least one year post vaccination (Briggs et al. 1998; Watanabe et al. 2013).

Animals infected before, or at the time of, vaccination can continue to incubate the virus despite developing an antibody titre (Blancou et al. 1989; De Benedictis et al. 2009). For dogs and cats from RABV endemic countries a waiting period of six months, following the development of

post-vaccinal immunity is required to allow expression of clinical signs if infection was acquired before vaccination (Fooks, McElhinney & Pollitt 2000).

2.11 Changes to trade in companion animals

Since the review in 2013, there have been significant changes to the trade in companion animals.

2.11.1 Increased demand

Following the review in 2013, the post entry quarantine (PEQ) period for dogs and cats from approved countries was reduced to 10 days which created increased capacity of the PEQ facilities at that time. Further in late 2015, all (PEQ for dogs and cats from approved countries (excluding group 1 countries, which do not require PEQ) was consolidated in one facility in Melbourne, Victoria. This facility has larger capacity than the previous facilities combined. The 2013 Importation of dogs, cats and their semen from approved countries: final policy review (2013 review) reported an average of 3,713 dogs and 1,949 cats imported each year in the years 2010 to 2012 (Department of Agriculture 2013). However, demand has increased since then, especially for dog imports, as indicated in Table 5.

Table 5: Dog and cat import permits issued and imports from 2014 to 2021

Year	Dogs imported	Cats imported	Total imports	Permits issued
2014	5,935	2,423	8,358	6,078
2015	5,744	2,367	8,111	5,620
2016	5,516	2,240	7,756	6,695
2017	6,342	2,606	8,948	6,722
2018	5,923	2,484	8,407	7,325
2019	6,215	2,692	8,907	7,159
2020	4,180	1,767	5,947	5,339
2021	3,362	1,524	4,886	6,621

Numbers of imported animals and import permits granted during the SARS-CoV-2 pandemic in 2020 and 2021 remained relatively high despite flight restrictions and decreased capacity in the PEQ facility due to public health measures affecting resourcing. This reflects an unforeseen surge in demand from people returning to Australia with their pets during this period. Many owners were unprepared for the robust biosecurity measures and complex logistics of relocating their pets to Australia. Despite this, the number of dogs imported in 2020 exceeded the numbers reported in the 2013 review (4,180 dogs imported compared to an average of 3,713 in 2010 to 2012).

In addition, demand for companion animals increased during the SARS-CoV-2 pandemic. A study in Israel found that dog adoption rates and potential dog adopters increased as social distancing and lockdown measures were implemented (Morgan et al. 2020). The same study also found an increase worldwide in internet searches regarding dog adoption on google during the pandemic (Morgan et al. 2020). Similar increases in demand were reported in media in many countries including Australia (Kinsella 2020; Pieracci et al. 2021; Wynne 2021).

2.11.2 Changing profile of exporting countries

New Zealand is consistently the top exporting country for dogs and cats being imported into Australia. This has not changed since the 2013 review. However, dogs and cats being imported from New Zealand do not require an import permit and do not undergo PEQ on arrival.

The profile of other exporting countries has changed since the time of the 2013 review. At the time of the 2013 review, 60% of the import permits granted were for dogs and cats for export from the United States and the United Kingdom, with another 15% from Canada, South Africa and Singapore (Department of Agriculture 2013). In comparison, import permits for the United States and the United Kingdom, made up only 40% of those issued in 2021. Permits from Canada, South Africa and Singapore made up 21% for the same period.

In 2021, the top ten exporting countries were (in descending order based on import permits issued) the United States, the United Kingdom, Hong Kong, Singapore, South Africa, Canada, United Arab Emirates, South Korea, Japan and Germany. These countries accounted for 81% of import permits issued during this period.

2.11.3 Increasing commercialisation

At the time of 2013 review, the majority of imported companion animals were considered to be pets accompanying owners relocating to Australia. However, there is increasing commercialisation of pet movements internationally. The United Kingdom, European Union, and Canada recognise a difference in risk profile (biosecurity and welfare) for these movements by having different import conditions for commercial consignments of dogs and cats.

Within Australia, there have been changes in state and territory legislation to regulate the companion animal breeding industry and to improve animal welfare (Goncalves Costa et al. 2020). This may have led to a decrease in local supply which fuelled an increase in online purchasing of pets located overseas. This may have been further exacerbated by down-scaling of local breeding operations during the SARS-CoV-2 pandemic within Australia (Kinsella 2020).

Internationally, there has been significant growth within the companion animal breeding industry with large scale commercial breeding organisations, increasing international trade and use of the internet to facilitate sales (Maher & Wyatt 2021). In Europe, there is growing evidence that criminal networks are becoming involved in lucrative puppy imports (Maher & Wyatt 2019, 2021; Zucca et al. 2020). This illegal puppy trade, and online puppy sales scams, were reported to have increased during the pandemic (Better Business Bureau 2020; British Broadcasting Corporation 2020). Norman, Stavisky and Westgarth (2020) conducted a survey of pet importers and found that people importing rescue dogs into the United Kingdom used social media to find suitable dogs and rescue groups to handle the importation. Most respondents seemed unaware of the import conditions, as 89% reported their dog had been imported under the European Union Pets Travel Scheme, which they were not eligible for (Norman, Stavisky & Westgarth 2020).

Importation of very young puppies for resale is increasing in other countries. In 2017, the United States specifically targeted illegal puppy movements in Operation Dogcatcher (Houle 2017). Young puppies which could not have met rabies vaccination requirements were being imported into many countries (Cocchi et al. 2021; Houle 2017; Pieracci et al. 2021; Zucca et al. 2020). During the SARS-CoV-2 pandemic, increases in non-compliance with rabies biosecurity

requirements were seen in 2020 in the United States (falsified vaccination certificates) and Europe (inadequate serological responses) (Cocchi et al. 2021; Pieracci et al. 2021). However, similar trends were observed before the pandemic, suggesting that the pandemic was not solely responsible for this increase in non-compliance (Pieracci et al. 2021; Zucca et al. 2020).

2.11.4 Increasing non-compliance and anomalies in certification

Non-compliance and certification anomalies are frequently being reported internationally in association with movement of dogs and cats. Missing microchips, no proof of rabies vaccination, or very young dogs that would be unable to have met manufacturer's recommendations or waiting periods if they received a rabies vaccination have been reported as common reasons to deny entry for companion animals being imported (Pieracci et al. 2021; Zucca et al. 2020). A number of studies have looked at RNATT levels in recently imported dogs with documented pre-export rabies vaccination. Klevar et al. (2015) found that 53% of non-commercially imported rescue dogs, which had been certified to have been vaccinated at least 21 days before export, had titres less than 0.5 IU/ml. In Italy, higher rates of RNATT failure were found in dogs imported into Italy (13.15%) compared to dogs being prepared for export from Italy (5.89%) in a study of 21,001 dogs from 2006 to 2012 (Rota Nodari et al. 2017).

In companion animals denied entry due to non-compliance and certification anomalies, the rates of rabies vaccination failure were found to be very high. Zucca et al. (2020) reported a failure rate of 75% in companion animals denied entry at the Italian – Austrian border from December 2017 to July 2020. A similar study found a failure rate of 86% in three month old puppies seized at the Italian – Austrian border between January 2018 and December 2020 (Cocchi et al. 2021). Following diagnosis of rabies in a recently imported dog from Azerbaijan into the United States, the investigation of the consignment found only 7 of the 25 dogs had serological evidence of prior rabies vaccination despite vaccination certificates and RNATT results being provided with the consignment (ProMED 2020).

Internationally, dogs that developed clinical signs of rabies shortly after importation, were subsequently euthanased and diagnosed. During 2002 to 2013, there were 21 rabies cases in animals in Western Europe that were imported from Morocco and Eastern Europe (Ribadeau-Dumas et al. 2016). In France, 9 rabid dogs were imported from 2001 to 2011 (Mailles et al. 2011). Importation of dogs that were later found to be infected with exotic RABV variants has been reported in the United States four times since 2015 (OIE 2021b; Pieracci et al. 2021; ProMED 2020, 2021). Recently, two dogs incubating rabies were imported into Canada from Iran (OIE 2021d, 2022). These incidents have resulted in extensive public health investigations, PEP and quarantine of multiple animals. In addition, Spain and France lost (and later regained) their freedom from dog-mediated rabies following its introduction by a non-compliant imported pet (Allibert et al. 2008; Cliquet, Picard-Meyer & Robardet 2014; Perez de Diego et al. 2015). In mid-2022, the United States and Canada have made significant changes to their import conditions for dogs and cats following the increase in rabies biosecurity risk. Similarly in April 2022, the United Kingdom suspended commercial imports of dogs and cats from Ukraine, Belarus, Poland and Romania following an increase in rabies biosecurity risk

Intentional non-compliances and fraudulent documentation have been detected and suspected during the import permit application process or during PEQ in dogs and cats being imported into Australia. Evidence has emerged of the operation of networks in approved countries with the intention of circumventing Australia's existing risk management measures for rabies virus.

The methods detected or suspected include providing falsified or fraudulent laboratory reports and other pre-export preparation documentation (such as rabies vaccination certificates); collecting blood samples from animals not intended for export but known to be compliant with Australia’s import conditions; and replacing microchips to link animals to compliant documentation.

2.12 Current biosecurity measures

The department has categorised countries approved for importation of dogs and cats into Australia into three groups based on their health status. For each group, prescribed pre-export and post-arrival biosecurity measures may apply. All dogs and cats being prepared for export to Australia must also be permanently identified by an ISO compatible microchip. The criteria for each group under the current policy is listed below in Table 6.

Table 6: The approved countries groups under the current policy

Groups	1	2	3
Description	RABV-free, with dog and cat health status at least equivalent to Australia	Other RABV-free countries	All other approved countries
Countries/territories	Cocos (Keeling) Islands*, New Zealand and Norfolk Island	Bahrain, Barbados, Christmas Islands, Cook Islands, Falkland Island, Fiji, French Polynesia, Guam, Hawaiian Islands, Iceland, Japan, Kiribati, Mauritius, Federated States of Micronesia, Nauru, New Caledonia, Niue, Palau, Papua New Guinea, Samoa (American), Samoa (Western), Singapore, Solomon Islands, Tonga, Kingdom of Tuvalu, Vanuatu, Wallis and Futuna Islands.	Antigua and Barbuda, Argentina, Austria, Bahamas, Belgium, Bermuda, Brunei, Darussalam, Bulgaria, Canada, Cayman Islands, Chile, Croatia, Cyprus, Czechia (Czech Republic), Denmark, Estonia, Finland, France, Germany, Gibraltar, Greece, Greenland, Guernsey, Hong Kong, Hungary, Ireland, Isle of Man, Israel, Italy, Jamaica, Jersey, Korea (Republic of), Kuwait, Latvia, Lithuania, Luxembourg, Macao, Malta, Monaco, Montenegro, Netherlands, Northern Mariana Islands, Norway, Poland, Portugal, Puerto Rico, Qatar, South Africa, Reunion, Serbia, Seychelles, Slovakia, Slovenia, Spain, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Sweden, Switzerland, Taiwan, Trinidad and Tobago, United Arab Emirates, the United Kingdom, the United States (excluding the State of Hawaii), Uruguay, Virgin Islands (British), Virgin Islands (USA).

* Importation of dogs is not permitted from the Cocos (Keeling) Islands.

2.12.1 Current import conditions for dogs and cats to Australia

Group 1 countries

Importation of dogs and cats is permitted from these countries, which the department recognises as being free from RABV and with a similar status to mainland Australia. Group 1 countries include New Zealand, Norfolk Island and the Cocos (Keeling) Islands. Dogs and cats must have been resident in group 1 countries:

- since birth or import from Australia
- or for at least 90 days in New Zealand since import from another country, as New Zealand's import conditions require a minimum 90 day residency before export
- or since import from New Zealand for Norfolk Island
- or for 180 days before export to Australia for cats from Cocos (Keeling) Islands.

There is no requirement for pre-export rabies vaccination or serological confirmation of response by RNATT. In addition, dogs and cats must be examined within 5 days before export and found to have no signs of infectious or contagious disease.

Group 2 countries

Importation of dogs and cats is permitted from these countries, which the department recognises as being free from RABV. Group 2 countries include Singapore, Japan, Hawaii and several Pacific Island countries. The dog or cat must have been continuously resident in a group 1 or 2 country since birth or direct import from Australia, or for a minimum period of 180 days immediately before export to Australia.

There is no requirement for pre-export rabies vaccination or serological confirmation of response by RNATT. In addition, dogs and cats must be examined within 5 days before export and found to have no signs of infectious or contagious disease.

Group 3 countries

Importation of dogs and cats is permitted from these countries, which the department recognises as having well controlled RABV. Group 3 countries include the United States (excluding Hawaii), the United Kingdom, Hong Kong, South Africa and many European countries.

The dog or cat must have been vaccinated with an inactivated RABV vaccine when at least 90 days of age, and this vaccination must be current, in accordance with manufacturer's directions, at the date of export to Australia.

Following rabies vaccination, a blood sample must be collected from the dog or cat and tested with a positive RNATT result of at least 0.5 IU/mL using either a FAVN test or an RFFIT. The sample must arrive and be tested at the laboratory at least 180 days before export to Australia. Not more than 730 days (24 months) must elapse between the date of blood sample collection and the date of export to Australia.

In addition, dogs and cats must be examined within 5 days before export and found to have no signs of infectious or contagious disease.

Non-approved countries

There is a process for the importation of dogs or cats originally resident in a non-approved country. This process requires that the animal first be exported to any approved country and then on to Australia. PEQ measures remain the same as for other companion animal imports. However, additional RABV pre-export testing and vaccination is required. Dogs and cats must also comply with the import conditions for the approved country.

Stage 1 (in the country of origin)

The dog or cat must be vaccinated with an inactivated RABV vaccine when at least 90 days of age, and this vaccine must be current, in accordance with manufacturer's directions, at the date of export.

Following rabies vaccination, an initial blood sample must be collected from the dog or cat and tested with a positive RNATT result of at least 0.5 IU/mL using either a FAVN test or an RFFIT.

This blood sample must be tested at either the Australian Centre for Disease Preparedness (ACDP); or a WOAHA reference laboratory for rabies which are in China, France, Mexico, South Korea or the United Kingdom.

The blood sample must arrive and be tested at the laboratory at least 180 days before export to Australia. Not more than 730 days (24 months) must elapse between the date of blood sample collection and the date of export to Australia.

Stage 2 (in an approved country)

The dog or cat must then be imported into an approved country.

Another blood sample must be collected from the dog or cat in this approved country and tested with a positive RNATT result of at least 0.5 IU/mL using either a FAVN test or RFFIT. This test must be conducted at a laboratory within or recognised by this approved country.

If the second RNATT result is at least 0.5 IU/mL, the dog or cat will be eligible for export to Australia at least 180 days after the date the initial sample collected in the country of origin arrived at the laboratory.

The dog or cat must also be revaccinated with an approved inactivated RABV vaccine in this approved country before export to Australia.

The dogs and cats must be examined within 5 days before export and found to have no signs of infectious or contagious disease.

3 Risk assessment

This section reviews the risk of RABV introduction associated with importing dogs and cats under Australia's current import conditions and considers whether those risks have changed significantly since the introduction of the existing conditions in 2013. However, due to the detected operations of fraud networks, export only from an approved country may no longer provide the level of risk management intended in the 2013 review. Accordingly, this risk assessment has considered the likelihood of entry in a dog or cat being imported into Australia from any country.

There has been no further information supporting a role for dog or cat semen in RABV transmission since 2013. Risk management measures for RABV continue not to be warranted for dog or cat semen. Import conditions for dog and cat semen will not be considered further in this risk assessment.

Risk assessment is defined in the WOA Code as ‘... the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard’.

Chapter 2.1 of the WOA Code provides recommendations for conducting import risk analyses, describing the risk assessment steps in Article 2.1.4 as entry, exposure and consequence assessments and their integration into a risk estimation, producing overall outcome of the risks associated with the hazards identified at the outset. In this review the hazard identified is RABV.

This assessment was conducted using a qualitative approach. The likelihood that an event will occur was evaluated and reported qualitatively, using qualitative likelihood descriptors for the release and exposure assessment, and the outbreak scenario in Table 7.

Table 7: Nomenclature for qualitative likelihoods

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

3.1 Entry assessment

The entry assessment estimates the likelihood that RABV would be present in a dog or cat being imported into Australia in the absence of any risk management measures, other than standard practices such as pre-export inspection of animals.

The following factors were considered relevant to the estimate of the likelihood of RABV being present in imported dogs and cats imported:

RABV is found almost worldwide (WHO 2021a). (Notable exceptions include Australia, New Zealand, Singapore, Japan and Hawaii).

- RABV is endemic in wildlife maintenance hosts in Canada, United States, Europe, and most Central and South American countries.

From a species perspective, dogs and cats are commonly infected with RABV.

- Dogs are the main reservoir host in the urban RABV cycle (Singh et al. 2017; WHO 2018b).
- Most cases of human RABV infection are transmitted by dogs (Cliquet & Picard-Meyer 2004).
- Cats are effective vectors for transmission, although they are not usually maintenance hosts (Rupprecht, Hanlon & Hemachudha 2002).

Rabies can have a long incubation period and there is no reliable way to diagnose infection in a live animal so there is potentially a long time period during which an infected animal could appear clinically normal and the infection not be identified by regular veterinary examination.

- Rabies incubation period is from 10 days to six months (Greene 2013; Hampson et al. 2009; Sparkes et al. 2015).
- Serological tests cannot be used for the diagnosis of rabies (AHA 2021b; Greene 2013; Singh et al. 2018; WOA 2022c).
- The definitive diagnosis of rabies is from the isolation and identification of the RABV or its components usually in brain tissue (WOAH 2022c, b).
- RABV infections produce little or no virus neutralising antibody titre in serum (Gerber et al. 1985; Manickam, Basheer & Jayakumar 2008; Swanepoel 1994; WHO 2006).
- Serological tests are generally used for measuring vaccination response such as before international animal movement or trade (WOAH 2022c).

While vaccination is effective and widely practiced in much of the world, there are several situations that can lead to vaccine failure. On its own, a history of vaccination does not guarantee an animal will not develop rabies.

- In countries, including approved countries, where RABV is endemic, rabies vaccination is recommended as part of the routine vaccinations for dogs and cats (Day et al. 2016).
- Vaccination has been shown to induce an effective and relatively long-lasting (1 - 4 years) humoral immune response in dogs and cats (Bahloul et al. 2006; Coyne et al. 2001; Fooks 2001; Lakshmanan et al. 2006).
- RABV neutralising antibodies generally peak around four weeks following vaccination and then decline (Manickam, Basheer & Jayakumar 2008; Mansfield et al. 2004).
- Rabies vaccines should only be administered to animals 12 weeks of age or older (Day et al. 2016; Lakshmanan et al. 2006), otherwise maternal antibodies may render them ineffective.
- Young animals (less than one year of age) require two doses of vaccine to generate an appropriate serological response (Pimburage et al. 2017; Wera et al. 2021).
- Serological response to vaccine may be reduced in large breed dogs, purebred dogs (Berndtsson et al. 2011; Tasioudi et al. 2018; Wallace et al. 2017), and those with low body condition (Wera et al. 2021).
- The occurrence of rabies in vaccinated dogs and cats is rare (Clark et al. 1981; Clark & Wilson 1996; De Benedictis et al. 2009; Murray, Holmes & Hanlon 2009). However, animals infected before or at the time of vaccination can continue to incubate the disease despite developing an antibody titre (Blancou et al. 1989; De Benedictis et al. 2009).

In recent years, there have been changes to the international trade environment for companion animals.

- There has been a marked increase in the yearly number of dog and cat imports into Australia since the 2013 review.
- Internationally, there has been significant growth within the companion animals breeding industry, with large-scale commercial breeding organisations, increasing international trade and online sales (Maher & Wyatt 2021).

Concurrently with these changes to the international trade environment, there appears to have been an increase in the level of non-compliance around rabies vaccination and RNATT results. This may, in part, be the cause of an apparent spate of RABV-infected dogs being moved internationally in recent years.

- Non-compliance and certification anomalies for companion animals (regarding rabies vaccination status and RNATT results) are now frequently being reported internationally (Cocchi et al. 2021; Klevar et al. 2015; Pieracci et al. 2021; Rota Nodari et al. 2017; Zucca et al. 2020).
- Increases in falsified, incomplete or inaccurate certification for rabies requirements has been found for dogs and cats being imported into the United States and the European Union (Pieracci et al. 2021; Zucca et al. 2020).
- In Europe, there is growing evidence that criminal networks are becoming involved in lucrative puppy imports (Maher & Wyatt 2019, 2021; Zucca et al. 2020).
- There are attempts to import young puppies, which could not have met rabies vaccination requirements, reported by many countries (Cocchi et al. 2021; Houle 2017; Pieracci et al. 2021; Zucca et al. 2020).
- Similar intentional non-compliances and fraudulent documentation have been detected or suspected during the import permit application process or during PEQ in dogs and cats being imported into Australia.
- Since 2001, there have been multiple cases of RABV-infected dogs imported into Western Europe and North America, notably France and Spain, the United States and Canada (Allibert et al. 2008; Cliquet, Picard-Meyer & Robardet 2014; Mailles et al. 2011; OIE 2021d; Perez de Diego et al. 2015; Pieracci et al. 2021; Ribadeau-Dumas et al. 2016).

Based on this information the likelihood that RABV would be present in a dog or cat imported into Australia was estimated to be **high**.

3.2 Exposure assessment

The exposure assessment estimates the likelihood that susceptible animals in Australia will be exposed to RABV via an imported dog or cat. It considers the exposure groups most likely to be affected as well as the possible pathways by which exposure of these groups could occur. For RABV, the exposure group is all mammals (including humans, wildlife and feral mammals). The most likely exposure pathway is via direct contact. This is based on the experience in other countries with incursions associated with the importation of dogs and cats. In these cases, animals in direct contact with the index case were exposed to, and in some cases infected with RABV.

The following factors were considered relevant to the estimate of the likelihood that susceptible animals would be exposed to RABV via an infected dog or cat:

There is a very large, diverse and widespread group of susceptible animals in Australia and transmission is readily achieved through regular behavioural interaction (for example grooming or fighting) with an infected dog or cat. While the specific degree of susceptibility to RABV of some Australian species has not been quantified, it is reasonable to assume they will not have any particular resistance. Humans and any other in-contact mammals are at risk of exposure.

- Transmission of RABV usually occurs via bites (but can also occur through grooming behaviour) of rabid animals. RABV in saliva then enters the body via skin lesions or mucous membranes (WHO 2021a).
- RABV transmission by aerosols has also been reported but is limited to environments with high concentrations of virus such as bat caves with large groups of bats or in laboratories (Bowen-Davies & Lowings 2000; Fisher, Streicker & Schnell 2018).
- The susceptibility of Australian native animals to rabies is unknown (AHA 2021b).
- Rare cases of RABV have been documented in American marsupials (Virginia opossum) (Diana, Mitchell & Feldman 2015). This supports the view that Australian marsupials (of which there are several species) may be susceptible to infection.

There is a moderate to long time-period during which an imported dog or cat infected with RABV could become infectious. This provides opportunity for interaction with susceptible animals, including humans, in Australia and the potential for virus transmission.

- The incubation period for rabies can range from 10 days to 6 months, with most cases apparent after 2 to 24 weeks (Greene 2013; Hampson et al. 2009; Sparkes et al. 2015).
- The majority of animals infected with RABV will develop clinical disease within six months (the incubation period for rabies defined by the WOA) (WOAH 2022b).
- Cases of rabies in dogs and cats with incubation periods over six months are rare (AHA 2021b).
- Dogs, cats and ferrets can excrete RABV up to ten days before the onset of any clinical signs.
- Infected animals may appear healthy but still transmit RABV to other animals (WOAH 2022b).

Dog and cat ownership in Australia is relatively high by world standards. Imported dogs and cats are very likely to encounter other susceptible species in Australia.

- A national survey estimated that there were approximately 5.1 million pet dogs and 3.8 million pet cats in Australia in 2019 (Animal Medicines Australia 2019).
- It has been estimated that almost 48% of the Australian population own a least one dog, and 37% own at least one cat (Wilkins et al. 2020).

While dog and cat populations in Australia are generally concentrated in urban areas and well managed, there are some notable exceptions that mean the level of domestic animal management cannot be relied on as a risk mitigation measure.

- Only 11.6% of dog owners and 8.5% of cat owners live outside urban areas (Wilkins et al. 2020).
- Local governments (councils) in urban Australia generally have effective animal control programs to minimise the stray dog population. This would reduce uncontrolled contacts that a RABV-infected animal may have with stray animals.
- There are less effective controls on community dogs in some rural areas which may increase RABV transmission to other susceptible species.
- There are large populations of free-roaming community dogs in communities in central and northern Australia.
- There are an estimated 2.8 million feral cats, of which only 0.7 million are located in urban landscapes (House of Representatives Standing Committee on the Environment and Energy 2020).

Based on this information the likelihood of susceptible species in exposure groups being exposed to RABV associated with imported dogs and cats was estimated to be **high**.

3.3 Estimation of the likelihood of entry and exposure

Using the matrix in Figure 1, the overall likelihood of entry and exposure is estimated by combining the likelihood of entry and the corresponding likelihood of exposure.

Figure 1 Matrix for combining likelihood of entry and exposure

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

With the likelihood of entry estimated to be high and combined with the likelihood of exposure estimated to be high, the likelihood of entry and exposure for RABV in imported dogs or cats was estimated to be **high**.

3.4 Consequence assessment

The consequence assessment describes the potential consequences associated with RABV entry and exposure and estimates the likelihood of these consequences occurring. This involves estimating the likelihood of establishment and/or spread of RABV for the most likely outbreak scenario, and determining the direct and indirect effects (health, environmental and

socioeconomic) should this outbreak scenario occur. Combining the likelihood of establishment and/or spread for this outbreak scenario with the corresponding overall effect of establishment and/or spread gives an estimation of likely consequences.

3.4.1 Likelihood of establishment and/or spread associated with the outbreak scenario

Once exposure of susceptible animals has occurred, a number of possible outbreak scenarios could follow, ranging from no spread to widespread establishment of the virus and, consequently, disease.

In determining the most likely outbreak scenario, consideration was given to the experience with RABV incursions associated with the importation of dogs and cats in other countries. Based on this experience, the likely extent of establishment and / or spread at detection is assumed to be limited to direct contacts of infected animals.

The most likely outbreak scenario following exposure to RABV was considered to be a regional outbreak where RABV establishes in directly exposed susceptible animals, and spreads through direct contact to other populations of susceptible animals within a region or state/territory. Because of the movement patterns of susceptible species and the almost inevitable fatal outcome, an incursion is likely to be detected before wider inter-state or national spread occurs.

The following factors were considered relevant to the estimate of the likelihood of establishment and/or spread associated with the outbreak scenario:

There is a very large, diverse and widespread group of susceptible animals in Australia and transmission is readily achieved through regular behavioural interaction (for example grooming or fighting) with an infected dog or cat. While the specific degree of susceptibility to RABV of some Australian species has not been quantified, it is reasonable to assume they will not have any particular resistance.

- RABV is transmissible to all mammals.
- Cats are effective for transmission; however, there are no known RABV strains adapted to felids (Rupprecht, Hanlon & Slate 2006).
- Spill over into non-native canid and felid species (foxes, wild canids and feral cats) may lead to the establishment and spread of RABV infection in feral and wild animal populations.
- The degree of susceptibility of RABV in Australian native animals is unknown (AHA 2021b).
- Rare cases of RABV have been documented in American marsupials (Virginia opossum) (Diana, Mitchell & Feldman 2015). This supports the view that Australian marsupials (of which there are several species) would be susceptible to infection.
- Australian native mammals in the orders Chiroptera (bats), Carnivora (dingoes) and Dasyuromorphia (antechinuses, dunnarts, quolls, Tasmanian devils) could contribute to the maintenance of a wildlife cycle of RABV (AHA 2021b).
- Transmission of RABV usually occurs via bites (but can also occur through grooming behaviour) of rabid animals. RABV in saliva then enters the body via skin lesions or mucous membranes (WHO 2021a).

- Some species of native animals regularly engage in fighting and might contribute to the maintenance of a wildlife cycle.
- Native wildlife on which canid species occasionally prey (possums, wombats, wallabies, kangaroos) may also be infected but are unlikely to maintain a wildlife RABV cycle.

Susceptible animals are widely distributed across Australia, thus favouring the spread of RABV if it were to establish.

- A national survey estimated that there were approximately 5.1 million pet dogs and 3.8 million pet cats in Australia in 2019 (Animal Medicines Australia 2019).
- It has been estimated that almost 48% of the Australian population own a least one dog, and 37% own at least one cat (Wilkins et al. 2020).
- The companion animal population is concentrated in urban areas in Australia. Only 11.6% of dog owners and 8.5% of cat owners live outside urban areas (Wilkins et al. 2020).
- Local governments (councils) in urban Australia generally have animal control programs to control and minimise the stray dog population. This reduces uncontrolled contacts that a RABV-infected animal may have with stray animals.
- There are large populations of free-roaming community dogs in communities in Northern Australia.
- There are an estimated 2.8 million feral cats, of which only 0.7 million are located in urban landscapes (House of Representatives Standing Committee on the Environment and Energy 2020).
- There are less effective controls on community dogs in some rural areas which may have implications for ongoing RABV transmission to both other dogs and humans.

There is a moderate to long time-period during which a dog or cat infected with RABV could become infectious. This provides opportunity for interaction with susceptible animals and the potential for transmission.

- The incubation period for RABV can range from 10 days to 6 months, with most cases apparent after 2 to 24 weeks (Greene 2013; Hampson et al. 2009; Sparkes et al. 2015).
- While the RABV incubation period is defined by the WOAHP as six months, the majority of animals infected with RABV will develop clinical disease within this time period (WOAHP 2022b).
- Dogs, cats and ferrets can excrete RABV up to ten days before the onset of any clinical signs.
- Infected animals may appear healthy but still transmit RABV to other animals (WOAHP 2022b).
- Pending confirmation of a diagnosis of RABV infection, the control and eradication policy outlined in the lyssaviruses response strategy would be implemented to reduce the risk of establishment or spread (AHA 2021b).

Australia's susceptible mammalian population is largely immunologically naïve due to restrictions on the use of rabies vaccines domestically. This means there are unlikely to be any

immunological barriers to establishment and spread in the event that RABV were to be introduced.

- Due to Australia’s rabies free status, there is no requirement for dogs and cats born and resident here to be vaccinated against rabies. Therefore, aside from some imported animals vaccinated overseas, the great majority of the population is immunologically naïve to RABV.
- A rabies vaccine is available in Australia on a limited use permit which allows it to be used only in special circumstances. For example, the vaccine can be used to prepare companion animals for export to countries that require pre-export rabies vaccination or as part of an emergency disease response to a rabies incursion.
- The high proportion of immunologically naïve and susceptible animals should not delay detection of primary cases in this population.

Based on this information the likelihood of establishment and / or spread of RABV in Australian domestic and wildlife mammalian populations was estimated to be **moderate**.

3.4.2 Effects of establishment and/or spread

Determination of the effects resulting from the outbreak scenario

Following estimation of the likelihood of establishment and / or spread of RABV is the determination of the effects (health, environmental and socioeconomic) resulting from the outbreak scenario. Adverse effects are evaluated in terms of seven (two direct and five indirect) criteria. Further details on the method for determining the effects resulting from the outbreak scenario can be found in the department’s previous import risk assessments (Biosecurity Australia 2010).

The following descriptors were applied to estimate the effects of the establishment and/or spread of RABV for each criterion. The magnitude of effects and geographic levels are described in Table 8 and Table 9 respectively. A national effect score was then determined for each effect criterion according to the corresponding level and magnitude outlined in Figure 2.

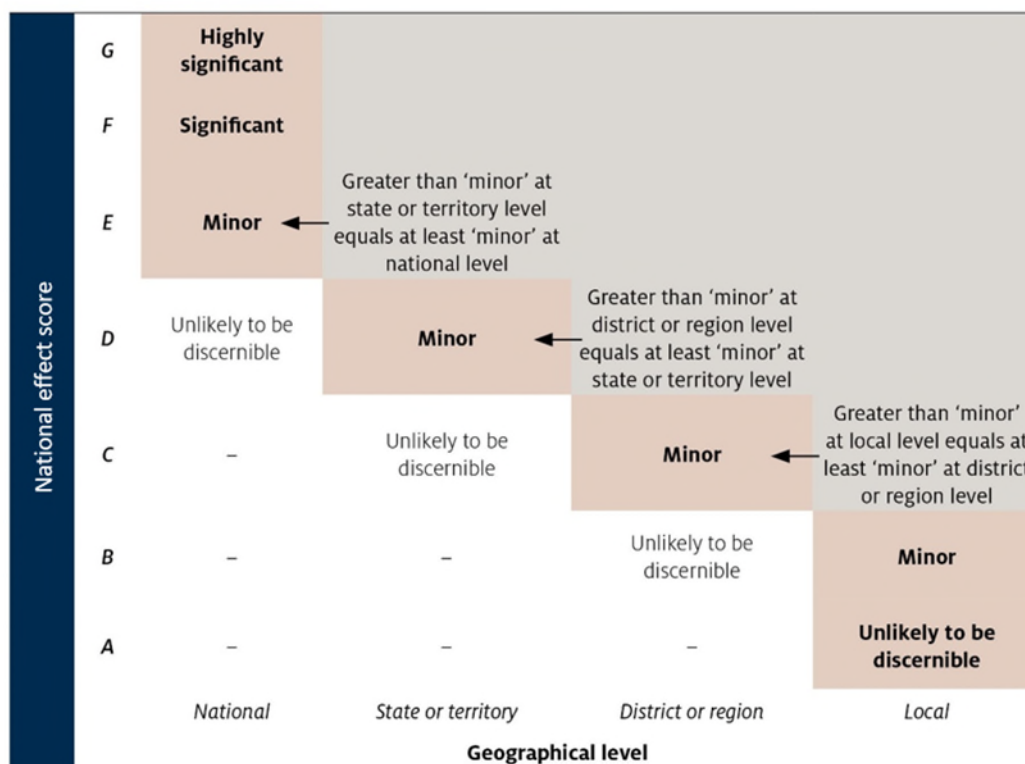
Table 8: Nomenclature for magnitude of effect

Effect	Descriptive definition
Highly significant	The effect is extremely serious and irreversible and likely to disturb either economic viability or the intrinsic value of the criterion.
Significant	The effect is serious and substantive but reversible and unlikely to disturb either economic viability or the intrinsic value of the criterion.
Minor significance	The effect is recognisable but minor and reversible.
Unlikely to be discernible	The effect is not unusually distinguishable from normal day to day variation in the criterion.

Table 9: Definition of geographic levels

Geographic levels	Description
Local	an aggregate of households or enterprises (a rural community, a town or a local government area).
District or region	a geographically or geopolitically associated collection of aggregates (generally a recognised section of a state or territory, such as 'Far North Queensland').
State or territory	a geographically or geopolitically associated collection of districts in a geographic area (generally a state or territory, although there may be exceptions with larger states such as Western Australia).
National	Australia wide (Australian mainland states and territories and Tasmania).

Figure 2 Assessment of direct or indirect effects on a national scale



Direct effects

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

- Rabies is a significant zoonosis with a long incubation period that may affect all mammals. Once clinical signs develop it is almost inevitably fatal (Singh et al. 2018; Sparkes et al. 2015).
- The incubation period for rabies can range from 10 days to 6 months (Greene 2013; Hampson et al. 2009; Sparkes et al. 2015).
- Death occurs within ten days of clinical signs appearing in dogs (Niezgoda, Hanlon & Rupprecht 2002; Tepsumethanon et al. 2004).
- There are rare instances of human and animal survival of clinical rabies, usually with severe neurological complications.

- Animals within the Carnivora and Chiroptera orders can act as natural reservoir hosts for RABV.

Based on these considerations, the effect of the establishment and/or spread of RABV for this criterion was estimated to be highly significant at the state level. The effect on the national economy or the Australian community as a whole and not just on directly affected parties, corresponds to **significant** at the national level (national effect score of **F** in Figure 2).

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

- The susceptibility of Australian native animals to RABV infection is unknown (AHA 2021b).
- Australian native mammals in the orders Chiroptera, Carnivora (dingoes) and Dasyuromorphia (antechinus, dunnart, quoll, Tasmanian devil) could contribute to the maintenance of a wildlife cycle of RABV.
- Rare cases of RABV have been documented in American marsupials (Virginia opossum) (Diana, Mitchell & Feldman 2015).

For this criterion, the effect of the establishment and / or spread of RABV in Australia was estimated to be significant at the state level. The effect on the national economy or the Australian community as a whole and not just on directly affected parties, corresponds to **minor** at the national level (national effect score of **E** in Figure 2).

Indirect effects

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

Australia would enact robust emergency animal disease measures in response to a RABV incursion, which are outlined in the lyssavirus AUSVETPLAN (AHA 2021b).

- Due to the serious public health implications, infection with RABV is listed in Australia's EADRA as a Category 1 disease. The government would provide 100% of the funding necessary for an emergency response to an outbreak (AHA 2021b).
- Australia's control and eradication programs for lyssaviruses include quarantine and movement controls, surveillance, euthanasia and testing of animals with clinical signs consistent with RABV, vaccination and public awareness campaigns (AHA 2021b).
- Emergency responses would need to be tailored to suit the location of the detection, for example urban compared to rural settings.
- The control area for an emergency disease response would be limited as transmission is predominantly to direct contacts.
- Compensation may be paid following an emergency animal disease response based on the relevant legislation in each state and territory.
- There may be limited suitable facilities for quarantine and monitoring of suspect or exposed animals (AHA 2021b).
- Community norms about pet management, such as with community dogs, may affect control measures such as movement restrictions.

Australia's emergency response would initially aim to eradicate RABV. However re-establishment of Australia's freedom from RABV would require an extensive surveillance program.

- The WOAHA Code recommends an ongoing surveillance for the 24 months; and an appropriate recording and reporting system for animal diseases, and investigations carried out for all susceptible animals showing clinical signs suggestive of rabies (WOAHA 2022b).

RABV vaccination in companion animals may be effectively used as part of an emergency response or long-term management. The efficacy of RABV vaccination is likely to limit an incursion to the affected state or territory and mitigate potential negative consequences to the life and health of susceptible species.

- RABV vaccination may be recommended for exposed domestic dog and cat populations as a preventative animal health measure or as part of long term control strategies.
- Currently only one rabies vaccine for companion animals is available in Australia and is restricted to limited uses such as for pre-export preparation or emergency disease responses.
- No oral rabies vaccines are currently available in Australia.

Should eradication not be feasible, resource intensive ongoing management and control programs would be necessary to manage the threats to public and animal health, associated with endemic RABV infection in feral and wild animals.

- Oral vaccination campaigns are not always feasible or effective, such as with bats (AHA 2021b).
- Trap, vaccinate and release programs for wildlife are time consuming and expensive (WHA 2018).
- The efficacy and safety of rabies vaccines in Australian native animals is unknown.
- Indiscriminate culling of maintenance hosts is generally ineffective in controlling RABV infections (AHA 2021b).

Based on these considerations, the effect of the establishment and / or spread of rabies in Australia for this criterion was estimated to be significant at the state level. The effect on the national economy or the Australian community as a whole and not just on directly affected parties, corresponds to **minor** at the national level (national effect score of **E** in Figure 2).

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

Depending on the location, the emergency response may impact local industries, especially those associated with animals and animal products.

- During the emergency response, quarantine and movement restrictions may be imposed on infected or potentially infected animals (AHA 2021b).
- Movement controls may also be applied for carcasses and animal products and by products from susceptible species showing clinical signs, waste products, effluent, vehicles and equipment (AHA 2021b).
- Restrictions may also be applied to sales and shows for dogs and cats, and other susceptible species during any emergency response (AHA 2021b).
- Following detection or RABV within one state / territory of Australia, the other states / territories may impose movement restrictions until the extent of the outbreak is known.
- The impacts on domestic industries of an emergency response to a RABV incursion would differ in urban and rural areas.

Rabies vaccination may be required as part of the emergency response or long term management.

- Currently only one rabies vaccine for companion animals is available in Australia and is restricted to limited uses such as for pre-export preparation or emergency disease responses.
- No oral rabies vaccines are currently available in Australia.

Based on these considerations, the effect of the establishment and / or spread of rabies in Australia for this criterion was estimated to be significant at the state level. The effect on the national economy or the Australian community as a whole and not just on directly affected parties, corresponds to **minor** at the national level (national effect score of **E** in Figure 2).

The effect on international trade, including loss of and restriction of markets, meeting new technical requirements to enter or maintain markets, and changes in international consumer demand
Australia's freedom from RABV is recognised by most trading partners. A change in Australia's status would result in disruption to these markets. However, there are well established international protocols for managing the biosecurity risk which could be readily adopted.

- In the event of a detection, pre-export or post-arrival quarantine may be required for companion animals being exported to RABV free markets.
- There would be significant costs for owners associated with any additional measures such as vaccination, RNATT and quarantine.
- In the event of a detection, there may be significant disruption to movement of dogs and cats to New Zealand and other RABV free countries.
- If RABV was to establish, renegotiation of some export protocols would be required.

Some export markets currently require rabies risk management measures for companion animals before export from Australia. No effect would be expected for these markets should RABV be detected in Australia.

- Rabies vaccination and subsequent RNATT is already required for the export of companion animals to some markets.

Based on these considerations, the effect of the establishment and / or spread of rabies in Australia for this criterion was estimated to be significant at the regional level. The effect on the national economy or the Australian community as a whole and not just on directly affected parties, corresponds to **minor** at the state level (national effect score of **D** in Figure 2).

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

Several potential wildlife reservoirs for RABV in Australia are vulnerable or endangered. This status would be further impacted by control programs should RABV establish in Australia.

- The grey-headed flying-fox (*Pteropus poliocephalus*) is listed as a vulnerable species under the Environment Protection and Biodiversity Conservation Act 1999.
- Several species of Australian carnivorous marsupials (order Dasyuromorphia) are also listed as endangered or vulnerable under the *Environment Protection and Biodiversity Conservation Act 1999*.
- Control programs including culling or vaccination of potential wildlife reservoirs hosts may have significant impacts on biodiversity.

Based on these considerations, the effect of the establishment and / or spread of rabies in Australia for this criterion was estimated to be significant at the state level. The effect on the national economy or the Australian community as a whole and not just on directly affected parties, corresponds to **minor** at the national level (national effect score of **E** in Figure 2).

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

Depending on the location, the emergency response may impact local economies and their ongoing viability.

- Emergency responses to a detection, including animal and animal product movement restrictions and culling programs, may have significant impacts on regional economies.
- Restrictions may also be applied to sales and shows for dogs, cats and other susceptible species during any emergency response (AHA 2021b).
- Following detection or RABV within one state / territory of Australia, the other states / territories may impose movement restrictions until the extent of the outbreak is known.
- Should disease establish within an area, the costs of vaccination of companion animals and serological tests to confirm vaccination would be borne by pet owners.

Local communities would be expected to have concerns regarding the emergency animal disease response. In particular, quarantine and euthanasia of pets, livestock and wildlife may not be well supported.

- Culling programs may raise public concerns for wildlife and feral animals, and negatively impact community support for disease control programs (AHA 2021b).
- There would likely be community concern regarding orders to quarantine and or euthanase animals during an emergency response.

Public health responses to a detection of RABV within a region would cause significant social impacts to the community and may be costly based on estimates from other countries.

- There would be significant social impacts should there be human deaths and the need for PEP for members of the public that had contact with suspected infected animals.
- Preventative immunisation would likely be recommended for those in certain high-risk occupations such as laboratory workers, and people who may have direct contact with susceptible mammals especially bats and carnivores (WHO 2018a).
- Preventative immunisation may also be recommended for people travelling to RABV-affected remote areas (WHO 2018a).
- The Centers for Disease Control and Prevention (CDC) estimates that post-exposure treatments for rabies in the United States typically exceeds USD \$3,000 per patient (CDC 2019).
- In the United States, the cost per human life saved ranges from USD \$10,000 to \$100 million depending on the nature of the exposure and the probability of RABV in a region (CDC 2019).
- The CDC estimates that the United States public health costs relating to rabies range from USD \$245 million to \$510 million annually (CDC 2019). This does not include healthcare costs, animal control measures and time lost from work.

Based on these considerations, the effect of the establishment and / or spread of rabies in Australia for this criterion was estimated to be significant at the state level. The effect on the national economy or the Australian community as a whole and not just on directly affected parties, corresponds to **minor** at the national level (national effect score of **E** in Figure 2).

3.5 Estimation of the likely consequences

The effect scores (A-G) obtained for each direct and indirect criterion were combined to give the overall effect by applying the rules outlined in Table 10 in numerical order until one applies.

Table 10: Rules used for combining direct and indirect effects

Rule	Effect scores for each direct and indirect criterion	Overall effect
1	Any criterion has an impact of 'G'; or more than one criterion has an impact of 'F'; or a single criterion has an impact of 'F' and each remaining criterion an 'E'.	Extreme
2	A single criterion has an impact of 'F'; or all criteria have an impact of 'E'.	High
3	One or more criteria have an impact of 'E'; or all criteria have an impact of 'D'.	Moderate
4	One or more criteria have an impact of 'D'; or all criteria have an impact of 'C'.	Low
5	One or more criteria have an impact of 'C'; or all criteria have an impact of 'B'.	Very Low
6	One or more but not all criteria have an impact of 'B'; or all criteria have an effect of 'A'.	Negligible

By using these rules, the overall effect of establishment and / or spread associated with the outbreak scenario was estimated to be **high**. The estimate of the overall effect associated with the outbreak scenario was combined with the likelihood of establishment and / or spread for the scenario using Figure 3 to obtain an estimation of likely consequences.

The likelihood of establishment and/or spread (**moderate**) was combined with the estimate of the overall effect of establishment and/or spread (**high**), to result in a rating of **high** likely consequences.

Figure 3 Matrix for determining likely consequences: combining the likelihood and overall effect of establishment and / or spread

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

Overall effect of establishment and spread

3.6 Risk estimation

Risk estimation is the integration of the likelihood of entry and exposure and the likely consequences of establishment and/or spread to derive the risk associated with the entry, exposure, establishment and/or spread of rabies introduced by the importation of dogs and cats into Australia. Using Figure 4, the likelihood of entry and exposure (**high**) is combined with the likely consequences of establishment and/or spread (**high**), resulting in a risk estimation of **high**.

Figure 4 Risk estimation matrix

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

Likely consequences

The unrestricted risk associated with rabies is determined to be **high**. The unrestricted risk exceeds Australia’s ALOP and therefore risk management is deemed necessary.

Table 11: Summary of risk assessment

Commodity	Likelihood of entry	Likelihood of exposure	Likelihood of entry and exposure	Likelihood of establishment and/or spread	Overall effect of establishment and/or spread	Likely consequences	Unrestricted risk
Dogs and cats	High	High	High	Moderate	High	High	High

4 Risk management measures

4.1 Pre-export risk management

After consideration of the available technical information presented in Section 2, the following pre-export conditions are recommended to manage the risk of RABV presented by imported dogs and cats.

4.1.1 Pre-export risk management considerations

Identification

Identification of an individual cat or dog for import into Australia is critical to link the animal to its pre-export preparation. Non-compliance and certification anomalies for rabies vaccination status and RNATT results requires a stringent means of ensuring these correspond to the animal that arrives in Australia.

Microchip implants are internationally recognised as an acceptable form of individual identification in animals. Microchips use passive radio-frequency identification (RFID) technology. International standards promote compatibility between chips and scanners.

Dogs or cats for import into Australia must be implanted with an International Organisation for Standardisation (ISO) compliant microchip. This review recommends that the microchip must be implanted before commencing pre-export preparation.

To ensure the microchip relates to the animal being exported, before pre-export preparation commences (and before blood is collected for an RNATT), a declaration by an official veterinarian, should accompany the import permit application. This should certify that the official has scanned the animal's microchip, that the animal is microchipped with the stated microchip number and the location of the microchip.

The risk management measures proposed in the 2013 review can no longer be considered effective due to the level of detected and suspected non-compliance and fraudulent documentation relating to the animal's identification. This proposed identification check by a official veterinarian will provide additional assurance that the individual cat or dog for import into Australia has been correctly linked to accurate pre-export preparation.

The review also considered alternative options for animal identification ranging from simple documentation or photographs to DNA testing, but all such options have significant limitations that make them currently unsuitable for international movement or trade purposes. No other form of animal identification was identified that is as easily verifiable and internationally standardised to be appropriate accurately identifying an individual animal for the purpose of import into Australia. Identification measures must be able to be applied to both dogs and cats.

In addition, the identification measure must be able to be easily verified by veterinarians and official veterinarians preparing animals for export to Australia and during biosecurity checks post entry.

Approved and non-approved countries

Dogs and cats can only be imported directly into Australia from approved countries. Dogs and cats must have resided in approved countries for 180 days immediately before export to Australia. Any changes to the current list of approved countries in Table 6 is outside the scope of this review.

However, given the increasing rate of detected and suspected non-compliance and certification anomalies, the list of approved countries should be reviewed as needed. Changes in trade volume, post border compliance verification reports, and changes in animal health status, competent authority or official veterinary services, should be considered when determining the need to review a country's approval status.

Australia's current process of approving countries is based on an assessment of the animal health status and the official controls, which underpin this status, to determine if imports from that country can reliably meet Australia's import conditions. Historically, countries were approved mainly on their RABV status but this has changed as other diseases were added to the list of hazards to be considered. Other diseases of concern for the importation of dogs and cats are listed in the 2013 review (Department of Agriculture 2013).

Approved countries, through their competent authorities, provide confidence to Australia that all companion animals intended for export are prepared and compliant with current import conditions before export to Australia. Veterinary health certificates are used by approved countries as documentary evidence for pre-export preparation.

Non-approved countries have not been determined to reliably meet Australia's import conditions. Direct importation of companion animals from these countries is not permitted. However, dogs and cats from non-approved countries are currently permitted entry via an approved country (the non-approved country pathway). This pathway includes some pre-export preparation in the non-approved country. In many instances it has not been possible to reliably verify these preparations.

This review recommends that the non-approved country pathway no longer be available. Dog and cats from non-approved countries must reside in an approved country for at least 180 days immediately before export to Australia. After this residency period, the dog and cat can be exported to Australia provided it meets all import conditions required for the approved country.

Transit or transshipments en route to Australia via non-approved countries is not considered to be part of an animal's residency as long as the animal does not leave the international side of the airport or is held in an approved equivalent quarantine arrangement.

Country or zone freedom

The department assesses whether a country or zone is free from RABV. As part of this assessment, consideration of whether a country or zone is free from RABV in all species and not just RABV in domestic dogs. It should be noted that the country or zone freedom is for RABV only and does not include other lyssaviruses. Australia will also consider any WOA self-

declarations of RABV freedom as part of the assessment. The competent authority's import conditions, border controls, laboratory and surveillance systems for RABV would also be considered.

Dogs and cats currently imported directly into Australia from approved countries, which Australia considers free from RABV, do not require additional risk management measures for rabies. Dogs and cats imported from group 1 and group 2 approved countries, must have resided solely in group 1 or 2 countries or Australia for 180 days immediately or since birth before export to Australia.

For Australian origin animals where the microchip was implanted in Australia before export, and which were exported less than 180 days before return to Australia, residency within Australia can be considered as part of the 180 days residency requirement.

This review recommends that certification of this residency period in a rabies-free country or zone be required on the veterinary health certificate to reduce the risk associated with potential fraudulent residency records.

Vaccination

Vaccination against rabies is an essential risk management measure for dogs and cats being exported from countries where RABV is present in the domestic and/or wildlife mammal population. Vaccination has been shown to induce an effective and relatively long-lasting (from 1 to 3 years) humoral immune response in dogs and cats.

This review does not recommend any changes to the current import condition for rabies vaccination for dogs and cats from approved countries where RABV is present. All dogs and cats imported from group 3 approved countries must be vaccinated against rabies, according to manufacturer's recommendations, before export to Australia with an inactivated RABV vaccine.

Rabies vaccines should only be administered to animals at least 12 weeks of age due to maternal antibody interference in the development of active immunity. Further boosters are required to maintain immunity and should follow manufacturer's instructions.

Vaccination should be with an inactivated RABV vaccine approved for use by the competent authority of the country of export and their development and manufacturing meeting WOAHS Manual recommendations.

An official government veterinarian must certify when a rabies vaccination is administered for the purpose of export to Australia. Certification must also include the recommended booster date based on manufacturer's instructions. Vaccination must not have lapsed and be current at the date of export to Australia and at all times during the preceding 180 days.

Pre-export confirmatory testing

The presence of RABV specific virus-neutralising antibodies, as detected by an RNATT, is considered a reliable indicator of effective vaccination. The WOAHS Code has set the standard for demonstration of an adequate serological response to rabies vaccination before international animal movement at 0.5 IU/mL (WOAHS 2022b).

The competent authority's systems for oversight of approved veterinarians collecting samples for pre-export testing are essential for ensuring Australia has confidence in the integrity of

samples and the chain of custody. Certification anomalies have been detected where samples are not directly transferred to the laboratory by the veterinarian but by the owners, pet agents or commercial couriers. There have also been considerable delays between sample collection and arrival at the laboratory.

This review found that the validity period of the RNATT should be aligned with the current WOAHA manual of testing guidelines. Therefore, it should be reduced from 24 months (in the current conditions) to 12 months. This review also found that the date samples arrive at the laboratory must continue to be at least 180 days before export to Australia to prevent suspected fraudulent sample batch testing.

All dogs and cats being imported from approved countries where RABV is present (group 3) must return a post-vaccination RNATT of at least 0.5 IU/mL at least 180 days before export to Australia. This blood sample must arrive at the laboratory for testing at least 180 days and not more than 12 months before the date of the export to Australia.

If animals have not been exported within 12 months of the date of arrival of the sample at the laboratory, a second RNATT (of at least 0.5 IU/mL) can demonstrate ongoing serological protection. In this case the sample should arrive at the laboratory within 12 months of the date of the original sample.

Preventive treatment

No treatment is currently available for animals after the exposure to RABV. There are few studies on PEP in animals, and the efficacy is unclear.

Pre-export inspection

The current import conditions for dogs and cats requires that the animal be inspected within 5 days of export and must be found to be free from ticks, fleas and clinical signs of infectious or contagious disease. This requirement is similar to the WOAHA Code, which recommends animals should show no clinical signs of rabies on the day before or on the day of export (WOAHA 2022b). No changes are proposed to this requirement for pre-export inspection.

4.2 Post-entry risk management

After reviewing the available technical literature on RABV in section 2, the following post-entry conditions are recommended to manage the risk of RABV presented by imported dogs and cats.

4.2.1 Post-entry risk management considerations

Since the 2013 review, there have been significant changes to the trade in companion animals. More companion animals are now being purchased online from overseas or imported into Australia for commercial purposes. This is also the experience in other countries, where an increased RABV biosecurity risk has been associated with these imports. The importation of rescue dogs for rehoming resulted in importation of rabid animals into the United States four times since 2015 (OIE 2021b; Pieracci et al. 2021; ProMED 2020, 2021).

The incidence of falsified or incomplete documentation related to rabies vaccination and serological testing accompanying imports into the United States from high RABV risk countries increased from 2018 to 2020 (Pieracci et al. 2021). Similar issues with missing or fraudulent documentation for rabies vaccination have been found in the European Union (Ribadeau-Dumas et al. 2016; Zucca et al. 2020). These increasing anomalies mean that no single pre-export RABV

risk management measure, other than 180 days residency in a RABV free country, adequately manage the biosecurity risk. Additional post-entry risk management measures are required for approved countries where RABV is well controlled to achieve Australia's ALOP.

Differential post-entry import conditions must be applied for companion animals depending on if they are imported from group 1 and 2 (RABV free) or group 3 (RABV well controlled) countries/ jurisdictions into Australia. These risk management options are outlined below.

Post-entry quarantine (PEQ)

Since the 2013 review when the PEQ period was reduced to at least 10 days, there have been no cases of rabies in PEQ or following released from PEQ. However, there have been imports of companion animals incubating RAB in other countries (Table 12). From 2002 to 2013, there were 21 rabies cases in animals in western Europe after importation from Morocco and eastern Europe (Perez de Diego et al. 2015; Ribadeau-Dumas et al. 2016). Nine rabid dogs were imported into France between 2001 and 2011 (Mailles et al. 2011), four into the United States between 2015 and 2021 (OIE 2021b; Pieracci et al. 2021; ProMED 2020, 2021; Raybern et al. 2020) and two into Canada in 2021-2022 (OIE 2021d, 2022). No PEQ period is applied to imports in these countries and these cases were associated with illegal movements, smuggling or commercial imports.

Table 12: Imports of companion animals incubating RABV since 2011

Year	Country	Details	Time to clinical signs / death after import	Reference
2011	France	Illegal importation of dog from Morocco via Spain to France	1 day	Mailles et al. (2011)
2013	Spain	Illegal movement of dog from Morocco	50 days	Perez de Diego et al. (2015)
2016	Western Europe	Study of imported cases in western Europe between 2001 and 2013. The majority of these were non-compliant with import conditions.	14 days (average infectious period).	Ribadeau-Dumas et al. (2016)
2019	The United States	Import of dogs from Egypt via Canada	23 days	Raybern et al. (2020)
2021	Germany	Illegal import of 8-week-old puppy from Turkey via Bulgaria to Germany	7 days	OIE (2021c)
2021	Canada	Import from Iran	10 days	OIE (2021d)
2021	The United States	Rescue import from Azerbaijan	3 days	OIE (2021b)
2022	Canada	Import from Iran	197 days	OIE (2022)

Based on the experience in other countries, most cases associated with fraudulent documentation or illegal importation showed clinical signs of rabies within 30 days of entry. Smith et al. (2021) suggested a 30-day waiting period would have reduced the likelihood of entry of rabid animals into the European Union and the United States in most recent cases associated with fraudulent certification. In experimental RABV infection studies, dogs displayed

clinical signs and/or died from 11 to 28 days post infection (Cho & Lawson 1989; Fekadu et al. 1992; Manickam, Basheer & Jayakumar 2008). The recent incident in Canada, which did not develop signs for 197 days post importation (OIE 2022), is extremely rare. These incidents in these countries where rabies is present but well controlled, resulted in extensive public health investigations and loss of animal health status in some cases.

For dog and cat imports from group 1 and 2 approved countries, the biosecurity risk of RABV is managed entirely offshore and no change is recommended to the PEQ period of at least 10 days.

Dog and cat imports from group 3 approved countries should undertake a PEQ period of at least 30 days if they have been prepared in compliance with the pre-export measures. In some cases, animals may need to be held longer than 30 days to verify compliance with the pre-export measures, in which case, the period should not exceed 180 days. This increase in PEQ period is required due to the significant risks due to commercialisation of the companion animals trade, and the increase in detected and suspected fraudulent certification for pre-export measures.

Post-entry verification

Due to the increases in detected and suspected non-compliance and fraudulent certification, additional verification may be required for imports from approved countries to ensure the RABV biosecurity risks were managed in line with Australia's import conditions. In instances where it is required, this verification at a minimum should ensure that the animal's veterinary health certificate and associated documentation is true and correct, and compliant with the import conditions. Imported dogs and cats must be held in PEQ pending this verification for no longer than 180 days.

Verification could include the following:

- Confirming authenticity of paperwork and microchip details with the competent authority of the exporting country.
- Confirming the validity and accuracy of test results and associated information with the testing laboratory.
- Confirming the vaccine lot numbers and expiry dates used in that geographical area.
- Veterinary examination findings, testing or imaging; for example, confirming age by dentition.

Additional tests, such as RNATT, have limited use for post-entry verification for individual animals, as they do not exclude or diagnose RABV infection. However, they could provide further evidence for compliance patterns for frequent importers, entities or countries. The use of rabies vaccination post-entry has limited usefulness as post-exposure prophylaxis.

Measures to verify compliance with Australia's import conditions will be implemented as required based on routine documentation checks, intelligence or changes in the usual pattern of trade.

4.3 Recommended pre-export measures

Based on the preceding, it was concluded that, for importation of dogs and cats from approved countries the following combination of pre-export measures is recommended to achieve Australia's ALOP.

For imports from all approved countries:

- The animal must be implanted with an ISO compatible microchip before commencing pre-export preparation.
- The animal has been examined within 5 days of export and showed no clinical signs of rabies.

For imports from group 1 approved countries:

- The animal must have resided in group 1 approved countries or Australia for 180 days (or since birth) before export to Australia.

For imports from group 2 approved countries:

- The animal must have resided in group 1 or 2 approved countries or Australia for 180 days (or since birth) before export to Australia.
- The animal's microchip must have been scanned by an official veterinarian of the exporting approved country at least 180 days prior to export to Australia, or before commencing pre-export preparation for animals less than 6 months. The official veterinarian must provide a declaration which includes that the animal is microchipped with the stated microchip number and the location of the microchip as part of the import permit application.

Imports from group 3 approved countries:

- The animal must have resided in approved countries or Australia for 180 days before export to Australia.
- The animal's microchip must have been scanned by an official veterinarian of the exporting approved country at least 180 days prior to export to Australia. The official veterinarian must provide a declaration which includes that the animal is microchipped with the stated microchip number and the location of the microchip as part of the import permit application.
- The animal was vaccinated with an inactivated RABV vaccine approved by the competent authority in the country of export (produced in accordance with the methods prescribed in the WOAHA Manual), in accordance with the manufacturer's recommendations. Rabies vaccination must be current according to the manufacturer's recommendations at all times between when blood was taken for RNATT and up to the time of export.
- The blood sample collected from the animal for an RNATT must arrive at the laboratory at least 180 days and not more than 12 months (365 days) before the date of export to Australia.
- The blood sample collected from the animal returned an RNATT result of at least 0.5 IU/mL within 12 months (365 days) immediately before export.

Note: If animals are not exported within 12 months of the date of arrival of the sample at the laboratory, a second RNATT (of at least 0.5 IU/mL) can demonstrate an ongoing serological protection. In this case, the sample must arrive at the laboratory within 12 months of the original sample. In addition, the blood sample must be collected within 12 months of the original blood sample date.

Note: Dogs and cats from non-approved countries must be legally moved to, and reside in, an approved country for at least 180 days immediately before export to Australia. After which, the dog and cat can be imported into Australia provided it meets all relevant import conditions for that approved country.

4.4 Recommended post-entry measures

Based on the preceding considerations it is concluded that, as the specified combination of pre-export measures achieves Australia's ALOP for animals from group 1 and group 2 approved countries, specific post-entry measures for RABV are not required. Animals from group 1 approved countries do not require PEQ. In addition, no change is recommended to the current PEQ period for animals from group 2 approved countries and they will continue to require a PEQ period of 10 days.

For imports from group 3 countries:

- For animals prepared in compliance with the pre-export measures, a PEQ of at least 30 days is required.
- Where considered relevant by the department based on document assessment and/or analysis of trade patterns and intelligence data, additional post-entry verification activities to verify compliance with the pre-export measures may be required. In such cases, animals may be held in PEQ for up to 180 days.

5 Biosecurity measures for rabies virus

Dogs and cats can only be imported into Australia directly from an approved country.

5.1 Importation of dogs or cats from group 1 approved countries

To achieve Australia's ALOP it is recommended that the following biosecurity measures should apply to dogs and cats imported from group 1 approved countries:

- 1) The dog or cat must have been implanted with an ISO compatible microchip before commencing pre-export preparation.

AND

- 2) The dog or cat must be continuously resident for at least 180 days immediately before export, or since birth, in group 1 approved countries or Australia.

AND

- 3) The dog or cat must be examined and found free from clinical signs of rabies within 5 days of export to Australia.

5.2 Importation of dogs or cats from group 2 approved countries

To achieve Australia's ALOP it is recommended that the following biosecurity measures should apply to dogs and cats imported from group 2 approved countries:

- 1) The dog or cat must have been implanted with an ISO compatible microchip before commencing pre-export preparation.

AND

- 2) The dog or cat must be continuously resident for at least 180 days immediately before export, or since birth, in group 1 or 2 approved countries or Australia.

AND

- 3) At least 180 days before export to Australia, the dog or cat's microchip must be scanned by an official veterinarian, and the stated microchip number, the location of the microchip and date of scanning must be included in a declaration as part of the import permit application. For animals less than six months of age, this scan must be completed prior to commencing pre-export preparation.

AND

- 4) The dog or cat must be examined and found free from clinical signs of rabies within 5 days of export to Australia.

5.3 Importation of dogs or cats from group 3 approved countries

To achieve Australia's ALOP it is recommended that the following biosecurity measures should apply to dogs and cats imported from a group 3 approved country:

- 1) The dog or cat must have been implanted with an ISO compatible microchip before commencing pre-export preparation.

AND

- 2) The dog or cat must be continuously resident for at least 180 days immediately before export, or since birth, in approved countries or Australia.

AND

- 3) At least 180 days before export to Australia, the dog or cat's microchip must be scanned by an official veterinarian, and the stated microchip number, the location of the microchip and date of scanning must be included in a declaration as part of the import permit application.

AND

- 4) At least 180 days before export to Australia, the dog or cat must have been vaccinated with an approved inactivated rabies vaccine (produced in accordance with the methods prescribed in the WOAHP Manual), in accordance with the manufacturer's recommendations and which is current up to the time of export to Australia.

AND

- 5) A blood sample must be collected from the animal at least 180 days before export to Australia and tested using a rabies neutralising antibody titre test (RNATT) – either fluorescent antibody virus neutralisation (FAVN) test or rapid fluorescent focus inhibition test (RFFIT) – with a positive result of at least 0.5 IU/ml.

AND

- 6) The date the sample collected for the RNATT arrives at the laboratory must be between 180 days and 12 months (365 days) before the date of export to Australia.

AND

- 7) The dog or cat must be examined and found free from clinical signs of rabies within 5 days of export to Australia.

AND

- 8) The dog or cat must undertake a PEQ period of at least 30 days (if prepared in compliance with the pre-export measures) at a government quarantine facility and not exceeding 180 days.

Glossary

Term	Definition
2013 review	2013 Importation of dogs, cats and their semen from approved countries: final policy review
ACDP	Australian Centre for Disease Preparedness
ABLV	Australian bat lyssavirus
ALOP	Appropriate level of protection
appropriate level of protection (ALOP) for Australia	The <i>Biosecurity Act 2015</i> defines the appropriate level of protection (or ALOP) for Australia as a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to very low, but not to zero.
approved countries	Countries, including jurisdictions and territories that are approved to directly export dogs and cats to Australia
AUSVETPLAN	Australian Veterinary Emergency Plan
Australian territory	Australian territory as referenced in the <i>Biosecurity Act 2015</i> refers to Australia, Christmas Island and Cocos (Keeling) Islands.
BA	Biosecurity advice
BICON	Australia's Biosecurity Import Condition System
biosecurity	The prevention of the entry, establishment or spread of unwanted pests and infectious disease agents to protect human, animal or plant health or life, and the environment
biosecurity measures	The <i>Biosecurity Act 2015</i> defines biosecurity measures as measures to manage any of the following: biosecurity risk, the risk of contagion of a listed human disease, the risk of listed human diseases entering, emerging, establishing themselves or spreading in Australian territory, and biosecurity emergencies and human biosecurity emergencies.
biosecurity risk	The <i>Biosecurity Act 2015</i> refers to biosecurity risk as the likelihood of a disease or pest entering, establishing or spreading in Australian territory, and the potential for the disease or pest causing harm to human, animal or plant health, the environment, economic or community activities.
Carnivora	Order of placental mammals that have specialised in primarily eating flesh, including canids and felids
CDC	Centers for Disease Control and Prevention
Chiroptera	Mammalian order for bats
CNS	Central nervous system
Dasyuromorphia	Mammalian order which includes Australian carnivorous marsupials such as antechinus, dunnart, quoll, and Tasmanian devil
DAFF	The Department of Agriculture, Fisheries and Forestry
DFA test / dFAT	Direct fluorescent antibody test
DOI	Duration of immunity
dRIT	Direct rapid immunohistochemical test
EADRA	Emergency animal disease response agreement
EBLV	European bat lyssavirus
ELISA	Enzyme-linked immunosorbent assay

Review of the rabies virus risk in imported dogs, cats and canine semen from approved countries

Term	Definition
Endemic/ enzootic	Belonging to, native to, or prevalent in a particular geography, area or environment
FAO	Food and Agriculture Organization of the United Nations
FAVN test	Fluorescent antibody virus neutralisation test
host	An organism that harbours a parasite, mutual partner, or commensal partner, typically providing nourishment and shelter
ICTV	International Committee on Taxonomy of Viruses
import permit	Official document authorising a person to bring or import particular goods into Australian territory in accordance with specified import conditions
IRA	Import risk analysis
ISO	International Organisation for Standardisation
IU	International units
Lyssavirus	A group of RNA viruses that includes rabies virus and bat lyssavirus
non-approved countries	countries that have not been approved to directly export dogs and cats to Australia
non-regulated risk analysis	Refers to the process for conducting a risk analysis that is not regulated under legislation (<i>Biosecurity import risk analysis guidelines 2016</i>)
ORV	Oral rabies vaccines
PAHO	Pan American Health Organization
pathogen	Biological agent that can cause disease to its host
pathognomonic	Disease specific, distinctive characteristic of a disease
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PEQ	Post-entry quarantine
quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing or treatment
RABV	Rabies virus
reservoir host	Animal that serves as a source of infection
RFFIT	Rapid fluorescent focus inhibition test
RFID	Radio-frequency identification
risk analysis	Refers to the technical or scientific process for assessing the level of biosecurity risk associated with the goods, or the class of goods, and if necessary, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or class of goods to a level that achieves the ALOP for Australia
RNATT	Rabies neutralising antibody titre test
spill over infection	The ability of a virus to infect a member of a new host species
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
stakeholders	Government agencies, individuals, community or industry groups or organisations, in Australia or overseas, including the proponent/applicant for a specific proposal, that have an interest in the policy issues

Review of the rabies virus risk in imported dogs, cats and canine semen from approved countries

Term	Definition
surveillance	An official process that collects and analyses information related to animal health.
sylvatic cycle	The transmission of RABV in wildlife and it is the predominant cycle in the North and South America and Europe
unrestricted risk	Unrestricted risk estimates apply in the absence of risk mitigation measures.
urban cycle	The transmission of RABV in urban area with dogs as the main reservoir host
vector	An organism that does not cause disease itself, but which causes infection by conveying pathogens from one host to another
WHA	Wildlife Health Australia
WHO	World Health Organization
WOAH	World Organisation for Animal Health, previously abbreviated to the OIE
WOAH Code	WOAH Terrestrial Animal Health Code 2022
WOAH Manual	WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2022
WTO	World Trade Organization
zoonotic disease	Disease that is transmittable between animals to human

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