



Australian Government
Department of Agriculture,
Fisheries and Forestry

Review of the biosecurity risks associated with veterinary immunobiologicals

Issues Paper

4 April 2024



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Stakeholder submissions on Issues Papers

This Issues Paper allows interested parties to comment on relevant biosecurity issues. Draft and final reports will consider any comments received.

Submissions should be sent to the Department of Agriculture, Fisheries and Forestry through the relevant [Have Your Say](#) channel.

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Acronyms and abbreviations

Term or abbreviation	Definition
9CFR	United States Code of Federal Regulations, Title 9
ALOP	Appropriate level of protection
APVMA	Australian Pesticides and Veterinary Medicines Authority
Ph Eur	European Pharmacopoeia
SPS Agreement	WTO agreement on the Application of Sanitary and Phytosanitary Measures
SPF	Specific pathogen free
TSE	Transmissible spongiform encephalopathy
WOAH	World Organisation for Animal Health
WOAH Code	WOAH Terrestrial Animal Health Code
WTO	World Trade Organization

Summary

The Australian Government Department of Agriculture, Fisheries and Forestry (the department) has prepared this Issues Paper to explore issues raised by importers and domestic stakeholders that will inform a review into the biosecurity risks associated with importing veterinary immunobiologicals into Australia.

This review will consider relevant peer-reviewed scientific information, advice from scientific experts, as well as industry practices.

The department currently permits the importation of veterinary immunobiologicals into Australia subject to the requirements of long-standing policy and guideline documents.

A review of Australia's policy for imports of veterinary immunobiologicals is needed to ensure that import requirements and conditions:

- align with current legislation (i.e., *Biosecurity Act 2015*),
- manage the contemporary biosecurity risk profile of veterinary immunobiologicals,
- reflect current industry best-practice and international standards, and
- address inherent biosecurity risks associated with new immunobiological technologies (e.g., genetic immunogens).

The department invites industry and government stakeholders to [provide preliminary submissions](#) in anticipation of the policy review. Submissions should be made within the initial consultation period.

1 Introduction

1.1 Australia's biosecurity policy framework

Australia's biosecurity system consists of three focus areas for preventing or responding to the incursion of pests and diseases: overseas, at our border, and within Australia. Across these three focus areas, the department undertakes a range of policy, operational, and compliance functions and implements various education, awareness, and communication campaigns.

The risk assessment process is an important function of Australia's biosecurity system. It enables the department to consider the level of biosecurity risk that may be associated with imports of specific goods into Australia. If the biosecurity risks exceed the appropriate level of protection (ALOP) for Australia, risk management measures are proposed to reduce the risks to an acceptable level. If the risks cannot be reduced to an acceptable level, the goods will not be imported into Australia, until suitable measures are identified.

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

Australia's risk assessments are undertaken by the department using technical and scientific experts in relevant fields and involve opportunities for consultation with stakeholders at various stages during the process.

The 'Review of the biosecurity risks associated with veterinary immunobiologicals' will be a scientific review of existing policy, import conditions, and scientific advice relating to veterinary immunobiologicals. Immunobiologicals include, but are not limited to,:

- Antigenic substances (e.g., vaccines and toxoids)
- Antibody-containing preparations (e.g., globulins and antitoxins) from human or animal donors
- Recombinantly derived immunoglobulins, and
- Nucleic acids that are translated *in vivo* into antigenic substances.

Publication of this Issues Paper represents the start of the formal risk review process.

1.2 Background

The department regulates imports of immunobiological products into Australia under established conditions which mitigate biosecurity risks to a level consistent with Australia's ALOP. These conditions are derived from long-standing policies which are now subject to review by the department.

Veterinary immunobiological products, such as animal vaccines, are classified as **conditionally non-prohibited goods** under the *Biosecurity (Conditionally Non-prohibited Goods) Determination 2021*. This means that they can only be brought into Australia once a satisfactory

biosecurity risk assessment is done and an import permit for the specific product has been issued by the relevant delegate of the Director of Biosecurity.

The following are examples of factors which may impact on the level of biosecurity risk associated with imports of immunobiological products into Australia:

- Veterinary vaccines frequently contain an immunogen which is derived directly from or is an infectious agent. The infectious agent may or may not have been modified to be inactivated or attenuated whilst still stimulating an immune response in a target animal.
- Immunobiologicals are often produced using biological components taken from large numbers of animals (e.g., sera, animal enzymes). These biological components support the growth and harvesting of cell cultures and are a known source of contamination of the final product.
- There are varying degrees of processing applied to these biological components which may or may not attenuate the infectiousness of contaminating disease agents.
- If an imported product is contaminated with a disease agent or the product is not appropriately inactivated, Australian animals will be exposed to that agent based on the intended end use of the product.
- A contaminated product is also likely to be distributed across a large geographical area of Australia, ensuring that large numbers of animals are exposed to the disease agent in a short period of time. It is unlikely that Adverse Experience Reporting mechanisms or disease surveillance programs would identify the contaminated product before large numbers of animals had been exposed.

2 Scope of the risk review

The policies the department is reviewing are relevant to an assessment of the biosecurity risk associated with imports of veterinary immunobiologicals. The primary policies subject to review are:

- [Specific Quarantine Requirements for the Importation of Inactivated Veterinary Vaccines, December 1997](#) (the Inactivated Vet Vaccine policy)
- [Australian Quarantine Policy and Requirements for the Importation of Live and Novel Veterinary Bulk and Finished Vaccines, November 1999](#) (the Live Vet Vaccine policy)

These policies outline the conditions that must be met to ensure biosecurity risks to Australia, which arise from the import of veterinary immunobiologicals, are managed to a level consistent with Australia's ALOP.

The following subordinate documents are also subject to review. Whilst content of the following guideline documents may not be directly affected, specific risk management measures referenced therein may be incorporated into new policy documents for veterinary immunobiologicals:

- [Contingency Import Policy for Specific Pathogen Free \(SPF\) Chicken Eggs, January 2006](#)
- [Guidelines for managing the risk of transmitting transmissible spongiform encephalopathies \(TSEs\) via veterinary vaccines and other in vivo veterinary products, October 2012](#)
- [Gamma irradiation as a treatment to address pathogens of animal biosecurity concern - Final policy review, November 2014](#)
- [Assessment of genetic recombination and reassortment of imported veterinary vaccines, July 2018](#)

The scope of the policy review includes biosecurity risk management measures only and does not include other factors, such as conditions related to product efficiency or safety issues (where those safety issues are not related to biosecurity risk). Product efficacy and safety are requirements within the purview of the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The scope of the review also does not include biosecurity risks associated with the importation of vaccines for human use.

3 Import risk analysis methodology

3.1 WOAHP Terrestrial Animal Health Code

The World Organisation for Animal Health (WOAH), in its Terrestrial Animal Health Code (the Terrestrial Code), describes the components of risk analysis in Chapter 2.1. The components of risk analysis are:

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

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

Given the key objective of this Issues Paper is to document the approach and results of the hazard identification, only this step of the risk analysis process is discussed in further detail. Full details of the risk analysis methodology will accompany the draft policy when it is released.

3.2 Risk review

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

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

Australia applies a process of risk review to the biosecurity risks associated with the importation of a good which presents an animal biosecurity risk for which current biosecurity measures exist.

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

3.3 Hazard identification

A hazard is a disease agent with the potential for harm. Article 2.1.2 of the WOA Code describes the hazard identification process as:

‘The hazard identification involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a commodity.

The hazards identified would be those appropriate to the species being imported, or from which the commodity is derived, and which may be present in the exporting country.’

The diverse range of animal-derived materials used to produce veterinary immunobiologicals justifies an inclusive list of hazardous infectious agents for these commodities.

In accordance with the WOA Code, a disease agent is considered a potential hazard if it was:

- 1) an exotic disease on Australia’s [National list of notifiable animal diseases](#)
- 2) WOA listed, an emerging disease, or if it can produce adverse consequences in Australia
- 3) a [Pathogen of animal biosecurity concern for biological products](#)
- 4) not known to be present in Australia, or
- 5) present in Australia and a notifiable disease and subject to an official control or eradication program.

Tables 1 to 9 in [Appendix A](#) lists the pathogen species identified as hazards associated with imports of veterinary immunobiologicals into Australia.

4 Veterinary immunobiological risk review

Current import policies for inactivated and live veterinary vaccines were published in December 1997 and November 1999 respectively. They have supported the department's biosecurity risk assessments for immunobiologicals since this time.

Australia needs a contemporary biosecurity policy for immunobiologicals which serves the country by ensuring biosecurity risk control settings are appropriate in the context of modern manufacturing systems in the biotechnology sector.

The department has identified the following elements that will also be considered as part of the review:

4.1 Responding to the threat of animal diseases

Australia's agricultural sector maintains its competitive trade advantage only through a strong biosecurity system. An incursion into Australia of an exotic disease or emerging pathogen would have a major impact on our livestock industries and our rural and regional communities.

The level of risk to Australia from the emergence of animal pathogens of biosecurity concern has increased over the last two decades. Disease outbreaks are more likely to spread across a wider geographical area, and more rapidly due to the growth in trade and transboundary movement of biological goods.

Outbreaks of significant animal pathogens are also close to Australia's border with lumpy skin disease virus, foot-and-mouth disease virus, and African swine fever virus examples of pathogens that have entered Australia's near region in recent years.

Policies and contemporary risk assessments are required to facilitate safe access to veterinary vaccines that assist in efforts to control both endemic and any potential emergency disease outbreaks in Australian territory.

4.2 New technologies

There have been major advancements in vaccine technologies over the last 20 years. Traditional vaccine technologies, like live attenuated and inactivated vaccines, require manufacturers to culture infectious agents in large volumes. These culture systems may have specific physical containment and/or work health & safety requirements.

Many new vaccine technologies forego the requirement to handle infectious agents at any stage of production. They may also rely less on animal-derived inputs.

Recombinant subunit vaccines, viral vectored vaccines, and messenger RNA (mRNA) vaccines are examples of new vaccine technologies. Existing policies do not adequately reflect conditions associated with these new technologies.

4.3 New legislation

Current biosecurity policies for veterinary vaccines were published under a superseded legislative framework (i.e., the *Quarantine Act 1908*). With the introduction of the *Biosecurity Act 2015*, the vaccine policies need to be reviewed so they are in line with this new legislative framework.

4.4 International standards

Production and regulatory standards applicable to the manufacture of immunobiologicals have matured significantly in the more than 20 years since publication of the current policies. Effective principles of quality assurance and codes of good manufacturing practice may provide high levels of confidence in the quality and safety of goods when they are manufactured to an appropriate standard.

Australia's existing import policies reflect manufacturing standards that were contemporary in the United States of America (Code of Federal Regulations, Title 9) and the European Union (European Pharmacopoeia) at the time of publication. Some of the specific standards referenced in Australia's policies are outdated or no longer in use. A review of Australia's import policy will include an assessment of contemporary United States Code of Federal Regulations, Title 9 (9CFR) and European Pharmacopoeia (Ph. Eur.) standards to determine their value in the department meeting its biosecurity objectives.

4.5 Aquaculture vaccines

The aquaculture industry in Australia is growing with consumer demand for seafood exceeding the supply from domestic production. The world now consumes more seafood sourced from farmed aquaculture than wild-caught fisheries and Australia's aquaculture sector is set to benefit from this trend.

Immunobiologicals play an integral role in disease management for intensive aquaculture systems. Current import policies for immunobiologicals do not recognise the biosecurity risks unique to the Australian aquaculture sector.

4.6 Harmonisation of Australian regulatory requirements

Australian importers and manufacturers of veterinary immunobiologicals are subject to the regulatory requirements of multiple agencies. The department's biosecurity regulations and the assessments of the APVMA for chemistry, efficacy and safety are examples of these. In reviewing existing biosecurity policies for immunobiologicals, the department will consider opportunities to harmonise regulations across these frameworks where processes are appropriate to manage biosecurity risks.

5 Stakeholder consultation

This Issues Paper gives stakeholders an opportunity to put forward preliminary submissions to the department in anticipation of the policy review. The following is a list of questions that respondents may wish to consider as part of their submission to the department:

- What has been your experience in working with the department on importing veterinary immunobiologicals into Australia?
- Australia's biosecurity policies impact the availability of veterinary immunobiological products in Australia. Are there products marketed offshore that would be useful to you that are not currently available in Australia?
- How can the department's biosecurity policies better support Australia's immunobiological production sector?
- As a domestic producer of veterinary immunobiologicals, what challenges do you face when importing biological goods that are produced offshore?
- What new manufacturing technologies for veterinary immunobiologicals need to be recognised in Australia's biosecurity policies?
- As a manufacturer of immunobiologicals, what production standards are relevant to the biosecurity risks posed by the importation of veterinary immunobiologicals.
- Are there any pathogen species associated with imports of veterinary immunobiologicals that have not been listed by the department (see [Attachment A – Hazard Identification](#) below)?
- What changes have you seen in demand for immunobiological products in Australia or overseas? What are the drivers for this change in demand?

Please lodge any comments or submissions through our Have Your Say Page. The department welcomes industry submissions received by **close of business Thursday, 6 June 2024**. The department will carefully consider all submissions as part of the policy review.

Updated policy content will be published for public consultation during which time stakeholders will have the opportunity to provide further comment.

The department will provide information about the next consultation period. This information will be available at www.agriculture.gov.au/biosecurity-trade/policy/risk-analysis/animal or to receive updates on this process, [Register as a stakeholder](#). To receive notices about animal biosecurity policy and biosecurity risk analysis subscribe to [Biosecurity Risk Analysis Animal](#). Additional information on how the department conducts [risk analyses and our international obligations](#) is also available.

Glossary

Term or abbreviation	Definition
Appropriate level of protection (ALOP) for Australia	The <i>Biosecurity Act 2015</i> defines the appropriate level of protection (or ALOP) for Australia as a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to very low, but not to zero.
Australian territory	Australian territory as referenced in the <i>Biosecurity Act 2015</i> refers to Australia, Christmas Island and Cocos (Keeling) Islands.
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 control	Goods imported into an Australian territory are subject to biosecurity control, as outlined in the <i>Biosecurity Act 2015</i> .
Biosecurity measure	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.
The department	The Australian Government Department of Agriculture, Fisheries and Forestry.
Goods	The <i>Biosecurity Act 2015</i> defines goods as an animal, a plant (whether moveable or not), a sample or specimen of a disease agent, a pest, mail or any other article, substance or thing (including, but not limited to, any kind of moveable property).
Good manufacturing practice	Is the part of quality assurance that ensures that products are consistently manufactured to the quality standards appropriate for their intended veterinary use and in accordance with their registration particulars and specifications.
Host	An organism that harbours a parasite, mutual partner, or commensal partner, typically providing nourishment and shelter.
Immunobiologicals	Antigenic substances (e.g., vaccines and toxoids) or antibody-containing preparations (e.g., globulins and antitoxins from human or animal donors, recombinantly derived immunoglobulins). These products are used for active or passive immunisation or therapy. Immunobiologicals may or may not be capable of replication in a recipient animal.
Immunogen	A stimulus that produces a humoral or cell-mediated immune response.
Import permit	Official document authorising a person to bring or import particular goods into Australian territory in accordance with specified import requirements.
Infectious agent	The <i>Biosecurity (Conditionally Non-prohibited Goods) Determination 2021</i> defines this as any of the following (whether naturally occurring or synthetically created): (a) a virus; (b) a prion; (c) a plasmid; (d) a viroid; (e) a thing that is a part of an infectious agent. Examples: For the purposes of paragraph (e), capsids, envelopes, enzymes, genetic material coding for an infectious agent, proteins.
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>).

Term or abbreviation	Definition
Pathogen	A biological agent that can cause disease.
Quality Assurance	The wide-ranging concept covering all aspects of the manufacturing process that individually or collectively influence the quality of a manufactured product. It is the sum total of the arrangements made to ensure that veterinary chemical products are consistently manufactured in an appropriate manner to the quality standards required for their intended use.
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.
Stakeholders	Government agencies, individuals, community or industry groups or organizations, whether in Australia or overseas, including the proponent/applicant for a specific proposal, who have an interest in the policy issues.

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Appendix A – Hazard Identification: Pathogen species associated with imports of veterinary immunobiologicals

Table 1 Hazardous disease agents – Multiple species

<i>Alphainfluenzavirus influenzae</i> (influenza, avian influenza, equine influenza, swine influenza)	<i>Anaplasma phagocytophilum</i> (tick borne fever, granulocytic anaplasmosis)	<i>Bacillus anthracis</i> (Anthrax)
<i>Bluetongue virus</i> (Bluetongue)	<i>Bordetella bronchiseptica</i> (Infectious bronchitis)	<i>Borrelia burgdorferi</i> (Lyme disease)
<i>Borrelia theileri</i> (bovine borreliosis)	<i>Brachyspira</i> spp.	<i>Brucella abortus</i> , <i>B. melitensis</i> , <i>B. ovis</i> , <i>B. suis</i> (Brucellosis)
<i>Burkholderia pseudomallei</i> (melioidosis)	<i>Campylobacter coli</i> (campylobacteriosis)	<i>Campylobacter jejuni</i> (campylobacteriosis)
<i>Chlamydia abortus</i> , <i>C. pecorum</i> (chlamydiosis)	<i>Chlamydia psittaci</i> (psittacosis, ornithosis)	<i>Clostridium</i> spp.
<i>Corynebacterium pseudotuberculosis</i> (caseous lymphadenitis)	<i>Coxiella burnetii</i> (Q fever)	<i>Cryptosporidium parvum</i> (cryptosporidiosis)
<i>Eastern equine encephalitis virus</i> (eastern equine encephalitis)	<i>Ehrlichia ruminantium</i> (heartwater)	<i>Epizootic hemorrhagic disease virus</i> (epizootic haemorrhagic disease)
<i>Erysipelothrix rhusiopathiae</i> (erysipelas)	<i>Escherichia coli</i>	<i>Foot-and-mouth disease virus</i> (foot-and-mouth disease)
<i>Francisella tularensis</i> (tularemia)	<i>Getah virus</i>	<i>Henipavirus hendraense</i> (Hendra virus disease)
<i>Histophilus somni</i> (histophilosis)	<i>Leptospira</i> spp. (leptospirosis)	<i>Listeria</i> spp. (listeriosis)
<i>Lyssavirus rabies</i> (rabies)	<i>Mammalian orthoreovirus</i>	<i>Mycobacterium avium</i> subsp. <i>paratuberculosis</i> / (Paratuberculosis, Johne's disease)
<i>Mycobacterium tuberculosis</i> (bovine tuberculosis)	<i>Mycoplasma capricolum</i> (contagious caprine pleuropneumonia)	<i>Orthobornavirus bornaense</i> (Borna disease)
<i>Orthobunyavirus akabaneense</i> (Akabane disease)	<i>Orthobunyavirus cacheense</i> (Cache Valley fever)	<i>Orthobunyavirus schmallenbergense</i>
<i>Orthobunyavirus shuniense</i>	<i>Orthoflavivirus encephalitis</i> (tick-borne encephalitis)	<i>Orthoflavivirus japonicum</i> (Japanese encephalitis)

<i>Orthoflavivirus loupingi</i> (louping ill, ovine encephalomyelitis)	<i>Orthoflavivirus nilense</i> (West Nile fever)	<i>Orthoflavivirus wesselsbronense</i> (Wesselsbron disease)
<i>Orthonairovirus haemorrhagiae</i> (Crimean-Congo haemorrhagic fever)	<i>Pasteurella</i> spp. (fowl cholera, atrophic rhinitis, bovine haemorrhagic septicaemia)	<i>Phlebovirus riftense</i> (Rift Valley fever)
<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar Typhimurium DT104	<i>Staphylococcus</i> spp.	<i>Streptococcus</i> spp.
<i>Toxoplasma gondii</i> (toxoplasmosis)	<i>Trypanosoma brucei</i> , <i>T. congolense</i> , <i>T. vivax</i> [trypanosomosis (tsetse-transmitted)]	<i>Trypanosoma evansi</i> (surra)
<i>Varicellovirus suidalphal</i> (Aujeszky's disease, pseudorabies)	<i>Vesicular exanthema of swine virus</i> (vesicular exanthema of swine)	<i>Vesiculovirus alagoas</i> , <i>Vesiculovirus cocal</i> , <i>Vesiculovirus indiana</i> , <i>Vesiculovirus newjersey</i> (vesicular stomatitis)
<i>Yersinia enterocolitica</i> (yersiniosis)	<i>Yersinia pestis</i> (plague)	

Table 2 Hazardous disease agents – Avian species

<i>Avastrovirus 2</i> (avian nephritis, infectious stunting syndrome, baby chick nephritis)	<i>Avian coronavirus</i> (Avian infectious bronchitis)	<i>Avian leukosis virus</i> (lymphoid leukosis)
<i>Avian orthoreovirus</i>	<i>Avian paraavulavirus 3</i>	<i>Avibacterium paragallinarum</i> (infectious coryza)
<i>Avibirnavirus gumboroense</i> (infectious bursal disease, Gumboro disease)	<i>Bordetella avium</i> (avian bordetellosis)	<i>Borrelia anserina</i> (avian spirochetosis)
<i>Clostridium colinum</i> (ulcerative enteritis)	<i>Fowl aviadenovirus A</i> (adenoviral gizzard erosion)	<i>Fowl aviadenovirus B</i>
<i>Fowl aviadenovirus C</i> (hepatitis hydropericardium syndrome)	<i>Fowl aviadenovirus D</i> , <i>Fowl aviadenovirus E</i> (inclusion body hepatitis)	<i>Fowlpox virus</i> (fowlpox)
<i>Gyrovirus chickenanemia</i> (chicken infectious anemia)	<i>Iltovirus gallidalphal</i> (infectious laryngotracheitis)	Lymphoproliferative disease virus (lymphoproliferative disease)
<i>Malacoplasma iowae</i>	<i>Mardivirus gallidalphal2</i>	<i>Metaavulavirus yucaipaense</i>

	(Marek's disease, fowl paralysis)	
<i>Metapneumovirus avis</i> (turkey rhinotracheitis, swollen head syndrome)	<i>Mycoplasma gallisepticum</i> (avian mycoplasmosis)	<i>Mycoplasma synoviae</i> (avian mycoplasmosis)
<i>Ornithobacterium rhinotracheale</i>	<i>Orthoavulavirus javanese</i> (Newcastle disease)	<i>Reticuloendotheliosis virus</i>
<i>Riemerella anatipestifer</i>	<i>Salmonella enterica</i> subsp. <i>arizonae</i> (Arizonosis)	<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar Enteritidis
<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar Gallinarum biovar Gallinarum (fowl typhoid)	<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar Gallinarum biovar Pullorum (pullorum disease)	<i>Tremovirus A</i> (avian encephalomyelitis)

Table 3 Hazardous disease agents – Bovine species

<i>Actinomyces bovis</i> (Lumpy jaw)	<i>Aichivirus B</i>	<i>Anaplasma bovis</i> , <i>Anaplasma marginale</i> (Bovine anaplasmosis)
<i>Babesia bigemina</i> , <i>B. bovis</i> , <i>B. divergens</i> (Bovine babesiosis)	<i>Besnoitia besnoiti</i> (Bovine besnoitiosis)	<i>Bocaparvovirus ungulate1</i> (bovine parvovirus infection)
<i>Bovine atadenovirus D</i> / <i>Bovine mastadenovirus A, B, C</i> [Bovine respiratory disease (infectious bovine rhinotracheitis, infectious pustular vulvovaginitis, bovine reproductive disease)]	<i>Bovine immunodeficiency virus</i>	<i>Bovine leukemia virus</i> (enzootic bovine leukosis)
<i>Campylobacter fetus</i> subsp. <i>venerealis</i> (bovine genital campylobacteriosis)	<i>Enterovirus E</i> , <i>Enterovirus F</i> (bovine enterovirus infection)	<i>Ephemerovirus febris</i> (bovine ephemeral fever)
<i>Epsilonpolyomavirus bovis</i>	<i>Jembrana disease virus</i> (Jembrana disease)	<i>Lumpy skin disease virus</i> (lumpy skin disease)
<i>Macavirus alcelaphinegamma1</i> (Malignant catarrhal fever)	<i>Morbillivirus pecoris</i> (Rinderpest)	<i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> small colony (SC) type (contagious bovine pleuropneumonia)
<i>Mycoplasma bovis</i> (bovine mycoplasmosis)	<i>Orthobunyavirus ainoense</i> (Aino disease)	<i>Orthopneumovirus bovis</i> (Bovine respiratory syncytial)

		disease, bovine respiratory disease complex)
<i>Pestivirus bovis</i> , <i>Pestivirus tauri</i> , <i>Pestivirus brazilense</i> (bovine viral diarrhoea)	<i>Respirovirus bovis</i>	<i>Rhadinovirus bovinegamma4</i>
<i>Theileria</i> spp. (East Coast fever, oriental theileriosis, tropical theileriosis)	<i>Tritrichomonas foetus</i> (trichomoniasis)	<i>Varicellovirus bovinealpha1</i>

Table 4 Hazardous disease agents – Equine species

<i>Actinobacillus equuli</i> (sleepy foal disease)	<i>African horse sickness virus</i> (African horse sickness)	<i>Alphaarterivirus equid</i> (equine viral arteritis)
<i>Babesia caballi</i> (equine babesiosis)	<i>Betacoronavirus 1</i>	<i>Burkholderia mallei</i> (glanders)
<i>Ehrlichia risticii</i> (Potomac horse fever)	<i>Equine encephalosis virus</i> (equine encephalosis)	<i>Equine infectious anaemia virus</i> (equine infectious anaemia)
<i>Equine mastadenovirus A</i>	<i>Equine mastadenovirus B</i>	<i>Equine rhinitis A virus</i>
<i>Equine torovirus</i>	<i>Erbovirus A</i>	<i>Histoplasma capsulatum</i> (histoplasmosis, epizootic lymphangitis)
Horsepox virus (horsepox)	<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar Abortusequi	<i>Taylorella equigenitalis</i> (contagious equine metritis)
<i>Theileria equi</i> (equine piroplasmosis)	<i>Trypanosoma equiperdum</i> (dourine)	<i>Varicellovirus equidalpha1</i> (equine rhinopneumonitis, equine herpes myeloencephalopathy)
<i>Varicellovirus equidalpha3</i> (equine coital exanthema)	<i>Varicellovirus equidalpha4</i> (equine rhinopneumonitis)	<i>Varicellovirus equidalpha8</i>
<i>Varicellovirus equidalpha9</i>	<i>Venezuelan equine encephalitis virus</i> (Venezuelan equine encephalitis)	<i>Western equine encephalitis virus</i> (western equine encephalitis)

Table 5 Hazardous disease agents – Ovine/caprine species

<i>Caprine arthritis encephalitis virus</i> (caprine arthritis encephalitis)	<i>Dichelobacter nodosus</i> (ovine footrot)	<i>Goatpox virus</i> (sheep and goat pox)
<i>Jaagsiekte sheep retrovirus</i> (ovine pulmonary adenocarcinoma)	<i>Morbillivirus caprinae</i> (peste-des-petits ruminants)	<i>Mycoplasma agalactiae</i> (contagious agalactia)
<i>Orf virus</i> (orf disease, scabby mouth)	<i>Orthonairovirus nairobiense</i> (Nairobi sheep disease)	<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar Abortusovis
<i>Sheeppox virus</i> (sheep and goat pox)	<i>Visna-maedi virus</i> (Maedi-visna)	

Table 6 Hazardous disease agents – Porcine species

<i>Actinobacillus pleuropneumoniae</i> (Porcine pleuropneumonia)	<i>Actinobacillus suis</i> (Actinobacillosis)	<i>Actinobaculum suis</i>
<i>African swine fever virus</i> (African swine fever)	<i>Alphacoronavirus 1</i> (transmissible gastroenteritis)	<i>Betaarterivirus suid 1 & 2</i> (porcine reproductive and respiratory syndrome)
<i>Betacoronavirus 1</i> (porcine hemagglutinating encephalomyelitis)	<i>Brachyspira hyodysenteriae</i> (swine dysentery)	<i>Cardiovirus A</i> (encephalomyocarditis)
<i>Enterovirus B</i> (swine vesicular disease)	<i>Glaesserella parasuis</i> (Glässer disease)	<i>Henipavirus nipahense</i>
<i>Lawsonia intracellularis</i> (porcine proliferative enteropathy)	<i>Mesomycoplasma hyopneumoniae</i> (porcine enzootic pneumonia)	<i>Mesomycoplasma hyorhinis</i> (fibrinous polyarthritis and polyserositis)
<i>Metamycoplasma hyosynoviae</i> (fibrinous polyarthritis)	<i>Mycoplasma suis</i> (infectious anaemia of pigs, porcine eperythrozoonosis)	<i>Orthorubulavirus suis</i> (blue eye disease)
<i>Pestivirus suis</i> (classical swine fever)	<i>Circovirus porcine 2</i>	<i>Porcine cytomegalovirus</i>
<i>Porcine epidemic diarrhea virus</i> (porcine epidemic diarrhoea)	<i>Porcine mastadenovirus A, B, C</i>	<i>Protoparvovirus ungulate1</i> (stillbirth, mummification, embryonic death, and infertility (SMEDI) syndrome)
<i>Rotavirus A, B, C, E</i>	<i>Schaalia hyovaginalis</i> (porcine actinomycosis)	<i>Streptococcus suis</i>
<i>Swinepox virus</i> / swine pox	<i>Teschovirus A</i>	

	(Teschovirus encephalomyelitis)	
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Table 7 Hazardous disease agents – Lagomorph species

<i>European brown hare syndrome virus</i>	<i>Myxoma virus</i> (myxomatosis)	<i>Rabbit fibroma virus</i>
<i>Rabbit haemorrhagic disease virus</i> (rabbit haemorrhagic disease)	<i>Treponema cuniculi</i> (rabbit syphilis)	

Table 8 Hazardous disease agents – Aquatic animal species

<i>Achlya</i> spp.	<i>Acineta</i> spp.	<i>Acinetobacter</i> spp.
<i>Aerococcus viridans</i> var. <i>homari</i> (<i>gaffkemia</i>)	<i>Aeromonas</i> spp.	<i>Ambystoma tigrinum virus</i>
<i>Aparavirus tauraense</i>	<i>Aphanomyces</i> spp.	<i>Apiosoma</i> spp.
Apostome ciliates, including <i>Ascophrys</i> spp., <i>Gymnodinioides</i> spp., <i>Synophrya</i> spp. and <i>Hyalophysa</i> spp.	Aquabirnaviruses (genus <i>Aquabirnavirus</i>)	Aquatic epicomensal bacteria, including <i>Cytophaga</i> spp., <i>Flavobacterium</i> spp., <i>Leucothrix</i> spp., and <i>Thiothrix</i> spp.
Aquatic megalocytiviruses (genus <i>Megalocytivirus</i>)	<i>Aspergillus awamori</i> (black gill infection)	<i>Atkinsiella dubia</i>
<i>Bacillus licheniformis</i>	<i>Bacillus mycoides</i>	Baculovirus penaei (BP) (tetrahedral baculovirus)
Beihai shrimp virus genotypes 1	Betanodaviruses (genus <i>Betanodavirus</i>) (viral encephalopathy and retinopathy, viral nervous necrosis)	<i>Brooklynella hostilis</i>
Candidatus <i>Hepatobacter penaei</i> (necrotising hepatopancreatitis)	<i>Carnobacterium</i> spp.	<i>Ceratonova shasta</i>
<i>Chlamydia</i> spp. (Epitheliocystis)	<i>Chryseobacterium joostei</i>	Ciliates (including <i>Ichthyophthirius multifiliis</i>)
<i>Citrobacter freundii</i>	<i>Cladosporium</i> spp.	<i>Clostridium perfringens</i>
Covert mortality nodavirus (viral covert mortality disease / covert mortality disease / 'bottom death' disease)	Crangon crangon flavivirus	Crustacea hepe-like virus 1 (CHEV1)
<i>Cryptobia</i> spp.	<i>Cryptocaryon irritans</i>	<i>Cyavirus cyprinidallo 3</i>

		(koi herpesvirus disease)
<i>Decapod iridescent virus 1</i>	<i>Dermocystidium</i> spp.	<i>Edwardsiella tarda</i>
<i>Eimeria</i> spp.	<i>Enterobacter cloacae</i>	<i>Enterococcus</i> spp.
<i>Enterocytozoon hepatopenaei</i> (hepatopancreatic microsporidiosis (HPM) and enterosporidiosis)	<i>Enteromyxum</i> spp.	<i>Ephelota</i> spp.
<i>Epizootic haematopoietic necrosis virus</i>	Erythrocytic necrosis virus	<i>Exophiala</i> spp.
Farfantepenaeus duorarum nodavirus	<i>Flavobacterium</i> spp.	<i>Flexibacter</i> spp.
<i>Fusarium</i> spp. (burn spot disease, black spot disease, black gill disease and fusariosis)	<i>Gammanudivirus cracrangonis</i>	<i>Gammanudivirus pemonodonis</i>
<i>Gilbertella persicaria</i>	<i>Glugea</i> spp.	<i>Goussia gadi</i>
Gregarines, including <i>Cephalolobus</i> spp., <i>Nematopsis</i> spp., and <i>Paraophioidina</i> spp.	<i>Haliphthoros</i> spp.	<i>Haplosporida</i> spp. (hepatopancreatic haplosporidiosis)
Haplosporidian-like parasite (red gill disease)	<i>Hematodinium</i> spp.	<i>Henneguya</i> spp.
<i>Hepanhamaparvovirus decapod1</i>	<i>Hexamita</i> spp.	<i>Ichthyophonus hoferi</i>
<i>Isavirus salaris</i> (infectious salmon anaemia)	Infectious myonecrosis virus	Infectious precocity virus (Infectious precocity virus disease, iron prawn syndrome)
<i>Inodosporus</i> spp.	<i>Kudoa</i> spp.	<i>Lactococcus</i> spp. (white muscle disease)
Laem Singh virus	<i>Lagenidium</i> spp.	<i>Leptolegnia</i> spp.
<i>Leptomitus</i> spp.	<i>Leptomonas</i> spp.	<i>Loma salmonae</i>
<i>Lymphocystis disease virus 1 and 2</i>	Macrobrachium nipponense reovirus	Macrobrachium rosenbergii Taihu virus (disease of seven days)
Macrobrachium rosenbergii nodavirus	<i>Metanophrys sinensis</i>	<i>Micrococcus</i> spp.
<i>Microsporidia</i> spp.	Mourilyan virus	<i>Mycobacterium</i> spp.
<i>Mycoplasma</i> spp.	<i>Myxobolus</i> spp.	<i>Neoparamoeba perurans</i> (Amoebic gill disease)
<i>Nimanivirus lahi</i>	<i>Nitzschia</i> spp.	<i>Nocardia</i> spp.
<i>Novirhabdovirus piscine</i> (viral haemorrhagic septicaemia)	<i>Novirhabdovirus salmonid</i> (infectious haematopoietic necrosis)	<i>Nucleospora salmonis</i>
<i>Okavirus flavicapitis</i> (yellowhead disease)	Oncorhynchus masou virus	<i>Ovipleistophora arlo</i>

<i>Piscine orthoreovirus</i> (erythrocytic inclusion body syndrome)	<i>Parauronema</i> spp.	<i>Parvicapsula</i> spp.
<i>Pasteurella</i> spp.	<i>Penaeus monodon</i> metallodensovirus	<i>Penaeus monodon</i> nucleopolyhedrovirus
<i>Penaeus vannamei</i> nodavirus (white tail disease, white muscle disease)	<i>Penstylhamaparvovirus</i> <i>decapod1</i>	Peritrichous and loricate ciliates, including <i>Cothurnia</i> spp., <i>Epistylis</i> spp., <i>Lagenophrys</i> spp., <i>Rhabdostyla</i> spp., <i>Vorticella</i> spp., <i>Zoothamnium</i> spp.
<i>Photobacterium</i> spp.	Pilchard herpesvirus	<i>Piscirickettsia salmonis</i>
<i>Pleistophora</i> spp.	<i>Proteus penneri</i>	<i>Providencia</i> spp.
<i>Pseudomonas</i> spp.	<i>Pythium</i> spp.	Ranaviruses (genus <i>Ranavirus</i>)
<i>Renibacterium salmoninarum</i>	<i>Salmon pancreas disease virus</i>	<i>Salmovirus salmonidallo1</i>
<i>Saprolegnia</i> spp. (Saprolegniosis)	<i>Sherwanella algae</i>	<i>Sirolopidium</i> spp.
Spawner-isolated mortality virus	<i>Sphaerospora</i> spp.	<i>Sphaerothecum destruens</i>
<i>Spirillum</i> spp.	<i>Spiroplasma</i> spp.	<i>Sprivirus cyprinus</i>
<i>Staphylococcus</i> spp.	<i>Streptococcus</i> spp.	<i>Tenacibaculum maritimum</i>
<i>Tetracapsuloides bryosalmonae</i>	<i>Thalassomyces</i> spp.	<i>Thelohanellus</i> spp.
<i>Trichodina</i> spp.	<i>Trichodinella</i> spp.	<i>Trypanosoma anura</i>
<i>Unicapsula</i> spp.	<i>Veronaea botryosa</i> (systemic phaeohyphomycosis)	<i>Vibrio</i> spp. (acute hepatopancreatic necrosis disease, glass post-larvae, translucent post-larvae disease, highly lethal <i>Vibrio</i> disease)
Wenzhou shrimp viruses	<i>White spot syndrome virus</i> (white spot disease)	<i>Yersinia ruckeri</i> – Hagerman strain (Enteric redmouth disease, Yersiniosis)

Table 9 Hazardous disease agents – Transmissible spongiform encephalopathies

Bovine spongiform encephalopathy	Chronic wasting disease of deer	Feline spongiform encephalopathy
Scrapie		