



December 2022

Factsheet

Importation of live infectious agents

Animal Division – standard process for risk assessment

As defined in the 'Biosecurity (Conditionally Non-prohibited Goods) Determination 2021'; infectious agent includes any of the following (whether naturally occurring or synthetically created): a virus, a prion, a plasmid, a viroid, or a thing that is a part of an infectious agent.

Importation of infectious agents into Australia may be permitted under specific circumstances. Before the import of any infectious agent is permitted, a risk assessment must be carried out. This assessment will determine the potential consequences and the appropriate risk management to prevent the establishment of the agent in Australia, in accordance with our appropriate level of protection (ALOP).

When undertaking these risk assessments, it is important to note that when an infectious agent is imported as a commodity (as opposed to a potential contamination risk for other commodities) there is a 100% likelihood of entry of the agent into Australia.

Import applications for non-live (or inactivated) infectious agents, or a part of an infectious agent also require a risk assessment to be undertaken to determine whether the inactivation technique will be sufficient to manage biosecurity risks.

The level of biosecurity risk associated with importing a live infectious agent will vary depending on the nature of the agent. These risks are classified from minimal risk e.g., microorganisms for use in food preparation starter cultures, to infectious agents assessed as high risk e.g., African swine fever virus.

There are several steps that must be completed before a live infectious agent is permitted import into Australia. Generally, the following steps are triggered when an importer applies for a biosecurity import permit to import an infectious agent (note, the process may, in some instances, be completed before an import application is received).

Risk assessment process

- 1) For live infectious agents which have not been previously assessed by the department, the application is considered on a case-by-case basis, following established procedures.
 - a) Infectious agents are routinely assessed at the genus level; however, for infectious agents considered to be potentially significant pathogens, assessment is done at the species, strain, or serotype level, depending on the potential consequences and level of risk assessment and management required.
 - b) Considerations include:
 - Whether the infectious agent has been isolated in Australia or is endemic to Australia or parts of Australia
 - biological factors
 - epidemiology; including vectors and survival in the environment

- pathogenicity
 - any modifications either through genetic manipulation or otherwise
 - classification (where available) by other agencies, groups, and standards.
- c) The assessment will determine the risk management measures required to ensure mitigation of the risk of the imported infectious agents being introduced into species or the environment where they may be either opportunist or significant pathogens or pests.
- d) Risk management measures that may be applied include:
- **End use restriction** – all infectious agents have end use restrictions applied to them to limit the inadvertent use in the environment or in susceptible species. Commonly, this limits the use of infectious agents only for use:
 - (1) *in vitro* – use in a laboratory without exposure to animals, plants, or the environment
 - (2) *in vivo* – use in a laboratory, allowing use in specified laboratory animals (or humans) in a controlled setting, without exposure to other animals, plants, or the environment. Use in non-laboratory animals is not permitted outside biosecurity containment.
 - **Biosecurity/Biosafety Containment** – Containment of infectious agents involves a combination of buildings, engineering function, equipment, and worker practices to handle microorganisms safely (AS/NZS 2243.3:2019, Safety in laboratories, Part 3: Microbiological safety and containment).

Where containment is required for risk management, the considerations around the level of containment are directly related to the biological characteristics of the infectious agent and the consequences of escape. Where the risk of an infectious agent is significant, the department utilises approved arrangements (www.agriculture.gov.au/biosecurity-trade/import/arrival/arrangements) to ensure the laboratories have adequate measures in place and that they comply with the required containment standards.
 - **Restriction of the organism to a specific institution** with specific types of containment or expertise – official laboratories such as reference laboratories and those belonging to state and territory governments, may provide additional risk management assurance through their governance processes, operating procedures, enhanced facilities, and availability of specific scientific expertise, over and above the established physical containment standards.
- 2) Where additional risk management (over and above standard containment) is determined to be required to manage potentially significant infectious agents (e.g., lumpy skin disease virus), the department conducts a specific risk assessment of the laboratory facility to obtain adequate assurance that the biosecurity risks can be managed. This risk assessment is based upon the World Health Organisation Laboratory Biosafety Manual guidelines.

This includes a detailed assessment of:

- Potential pathways of escape by an infectious agent.
- The physical containment facility features.
- The institution's standard operating procedures and established risk management policies (such as for transport, internal movement, and disposal of infectious agents) as well as training standards and record keeping.
- Internal governance and oversight of operations, such as institutional biosafety committee findings.

- Controls put in place by other regulatory agencies such as the Office of the Gene Technology Regulator and Department of Health (Security Sensitive Biological Agents).
- 3) For infectious agents the department considers significant or emerging exotic animal pathogens or pests, the department consults with states and territories through the Animal Health Committee (AHC) as well as environmental experts within the department. Where required, the department also consults with industry and appropriate scientific experts on the risk classification of the organism and the effectiveness of the proposed risk management.
 - 4) All exotic animal disease agents previously restricted to ACDP will be assessed using a standardised, risk-based approach. It is expected that only laboratories with a high level of external regulatory oversight will have the necessary biosecurity systems in place to receive permission to import exotic animal disease agents currently restricted to ACDP.

Permit application assessment and assurance

- 5) Once effective biosecurity risk management measures (protocols and recommended guidelines) are determined, an import permit application can be assessed. Assessment of an import permit application involves consideration of a range of factors that demonstrate a prospective importer's ability and capacity to safely manage the specific agent to be imported.
- 6) An import permit may be granted if the applicant is able to satisfy the delegate that they can meet all import requirements and conditions that may be applied.

The importer may be required to provide:

- Information about the infectious agent for import – genus/species/strain or serovar and any genetic modifications to the organism that alter the risk profile.
- Purpose of import and the proposed end use of the agent.
- Evidence that the facility and its staff have the appropriate containment and expertise to assure the department that biosecurity risks are understood and can be managed appropriately by the permit holder (e.g., standard operating procedures (SOPs), training material, follow-up site audits).
- Details of their approved arrangement facilities.
- Evidence of appropriate record keeping and reporting procedures for handling of the organism in the facility and ensuring adherence to conditions of import.

All information may be subject to verification prior to a decision as to whether the permit is issued or refused.

- 7) The importer must be able to provide ongoing assurance that they continue to adhere to the appropriate risk management set in permit conditions and any conditions of the relevant approved arrangement.

The department applies various import permit conditions, to obtain this assurance:

- Manufacturer/supplier declarations and/or certification from the competent authority of the country of export of the commodity – to ensure each consignment is exactly as assessed at the time of application (e.g., sourcing, manufacturing, exclusion of modification).
- End use restrictions (e.g., not permitted for use in animals or humans).
- Restriction to a particular approved arrangement or specified institution assessed in accordance with 1.d above.
- Protocols for goods determined on arrival to not meet conditions or be as described in import documentation.

- Conditions restricting work with the organism to be in accordance with SOPs or procedures provided at the time of application.
- 8) The department conducts ongoing verification to ensure import conditions are adhered to:
- a) **Document assessment** – for each imported consignment.
 - b) **Audits** – where containment within an approved arrangement is required, audits verify that the facility continues to effectively manage the biosecurity risk associated with each imported infectious agent.
 - c) **Provision of records** – for each new permit application the applicant must provide records maintained during the life of any previous permit to demonstrate conditions were adhered to and risks managed appropriately.

More information

If you have questions or would like to discuss, please contact:

email – animalbiosecurity@agriculture.gov.au

Acknowledgement of Country

We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

© Commonwealth of Australia 2022

Unless otherwise noted, copyright (and any other intellectual property rights) in this publication is owned by the Commonwealth of Australia (referred to as the Commonwealth).

All material in this publication is licensed under a [Creative Commons Attribution 4.0 International Licence](#) except content supplied by third parties, logos and the Commonwealth Coat of Arms.

The Australian Government acting through the Department of Agriculture, Fisheries and Forestry has exercised due care and skill in preparing and compiling the information and data in this publication. Notwithstanding, the Department of Agriculture, Fisheries and Forestry, its employees and advisers disclaim all liability, including liability for negligence and for any loss, damage, injury, expense or cost incurred by any person as a result of accessing, using or relying on any of the information or data in this publication to the maximum extent permitted by law.