# DECLARATION REGARDING INFORMATION REQUIRED FOR REASSESSMENT OF VETERINARY VACCINES



## Application Information

The Department of Agriculture, Fisheries and Forestry (the department) assesses import permit applications for veterinary vaccines considering the requirements of the following policies:

a) [Australian Quarantine Policy and Requirements for the Importation of Live and Novel Veterinary Bulk and Finished Vaccines, November 1999](https://www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/ba/memos/1999/animal/99-085acleaned.pdf)

b) [Specific Quarantine Requirements for the Importation of Inactivated Veterinary Vaccines (an addendum to the guidelines for submissions to import veterinary vaccines), December 1997](https://www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/ba/memos/2001/97-105A.pdf)

c) [Guidelines for managing the risk of transmitting transmissible spongiform encephalopathies (TSEs) via veterinary vaccines and other in vivo veterinary products, October 2012](https://www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/ba/animal/tse/Guidelines_TSE_vaccines.pdf).

These policies describe specific biosecurity requirements that relate to the production and testing of veterinary vaccines products. These biosecurity requirements, or an equivalent measure, must be met before veterinary immunobiological products can be imported into Australian territory. Please refer to the relevant policy for further information.

To lodge an application for a vaccine previously assessed by the department, applicants must:

* Complete an application in [BICON](https://bicon.agriculture.gov.au/BiconWeb4.0) to import a veterinary vaccine and pay the correct fees. Please note: Vaccines are classified as a Permit Category 5 (Non-standard goods). The department’s charging guidelines are available at: <https://www.agriculture.gov.au/fees/charging-guidelines>
* Have the manufacturer, or a regulatory associate of the manufacturer in Australia who is an authorised officer of the same company, complete and sign this document.
* Submit this document with the application to import a veterinary vaccine. The document must be submitted electronically.
* Provide relevant supporting information in a dossier. Dossiers must be submitted electronically.

The department may at any time require applicants to subject a vaccine product to a full risk assessment requiring complete dossiers detailing compliance with the relevant vaccine policies. Standard fees will apply for this full risk assessment.

## Introduction

The objective of Australia’s national biosecurity system is to protect the health of Australia’s animals, plants, and the environment, whilst facilitating the movement of safe goods in a global trade network. The continued growth of Australian animal industries, in terms of viability, productivity and sustainability, relies upon participants having access to safe vaccines for disease prevention and therapy.

Biosecurity requirements are designed to prevent product that is contaminated with an exotic pathogen or an exotic strain of an endemic pathogen from entering Australian territory. The establishment or spread of that pathogen in Australian territory and the harm and economic consequences arising from the entry of that pathogen are factors directly impacting on the level of biosecurity risk associated with imported goods.

The decision to reissue an import permit for a specific veterinary therapeutic product can only be made following a comprehensive technical assessment, including a review of the following aspects of production and use:

* Quality standards of manufacturing.
* Sourcing, treatment and testing of animal-derived materials used during production.
* Adverse outcomes arising from genetic recombination or re-assortment between imported replicative antigen and other strains already circulating in Australia [as an assessment of adverse experiences reported to the Australian Pesticides and Veterinary Medicines Authority (APVMA)].
* Production processes, including the management of cross contamination risks during production.
* Seed lot systems.
* Antigen inactivation (for immunobiologicals that do not contain replicative antigen).
* Product testing requirements.
* History of use

## Information Requirements

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|  | **Manufacturer’s response** |
| Import permit application reference number OR name of importer: |  |
| Name of vaccine and target species: |  |
| Is the product exported to Australia as a bulk antigen, vaccine excipient, brite stock, or fully finished vaccine? |  |
| Is the product exported to Australia registered with the APVMA[[1]](#footnote-2)? If not, why not? |  |
| Manufacturer’s details (name, address): |  |
| Name all antigens in the vaccine: |  |
| Previous import permit number(s): |  |
| Standards of manufacture |  |
| 3.8.1 Is the manufacturing facility currently licensed to produce veterinary vaccines by the country of export? | YES or NO  If YES, please provide a copy of the licence as supporting information. |
| 3.8.2. Please provide a copy of the certificate demonstrating compliance of the manufacturing facility with Good Manufacturing Practice (GMP) requirements. | ATTACHED |
| 3.8.3 Please provide a table listing the species name for all infectious agents currently held at the manufacturing facility[[2]](#footnote-3).  Within the table, please also:  - identify the location of each infectious agent at the manufacturing facility (e.g., production, QC, R&D), and  - highlight any infectious agents that are included on the department’s list of “Pathogens of **Highest** Animal Biosecurity Concern”[[3]](#footnote-4) | ATTACHED |
| 3.8.4 Have there been any changes to the list of infectious agents referenced in 3.8.3 above since it was last provided to the department? | YES or NO  If YES, please provide details of the changes and highlight any new infectious agents held at the manufacturing facility. |
| Production process |  |
| 3.9.1 Please provide a copy of the **current** Outline of Production, Special Outlines, or equivalent quality assurance (QA) document provided to overseas regulators which describes production steps for:  - individual bulk antigen(s) contained in the vaccine, and  - the final vaccine product. | ATTACHED |
| 3.9.2 Have there been any changes to the process of production outlined in this document since it was last provided to the department? | CHANGES or NO CHANGES have been made to the process of production outlined in the document specified in 3.9.1 since it was last provided to the department. |
| 3.9.3 If CHANGES have been made, please identify:  - the version number of the document last provided to the department, and  - the changes made to the process of production. | ATTACHED or NOT REQUIRED |
| Materials of animal origin including excipients and adjuvants |  |
| 3.10.1 Please provide a copy of the manufacturer’s current raw material specification for each material of animal origin (e.g., serums, enzymes, microbiological media) used during production of the vaccine from master seed to final product. | ATTACHED |
| 3.10.2 Please provide a copy of the Certificate of Analysis, the Certificate of Origin, or equivalent quality system document for each material of animal origin used during production of a batch of vaccine recently released for export to Australia.  This document will identify the source of the batch of material (species and country of origin) and any testing for extraneous agents performed on the material prior to its release. | ATTACHED |
| 3.10.3 Are any of the materials of animal origin treated with ionising radiation (e.g., gamma radiation)? | YES or NO |
| 3.10.4 If YES, please provide a copy of a Certificate of Irradiation for a batch of material used during production of a batch of vaccine recently released for export to Australia. | ATTACHED or NOT REQUIRED |
| 3.10.5 Please provide a copy of the export health certificate issued for batches of nutritive factors[[4]](#footnote-5) or animal enzymes used during production of a batch of vaccine recently released for export to Australia.  This certificate will be issued by the government competent authority in the country of export when the materials are being imported into the country of vaccine manufacture[[5]](#footnote-6).  This document will identify the source of the material (species and country of origin). |  |
| Final product testing |  |
| 3.11.1 Please provide a batch release record or equivalent QA document for a batch of vaccine recently released for commercial distribution in Australia. | ATTACHED |
| 3.11.2 Have there been changes to the final product test methods used since the last import permit was issued? | YES or NO |
| 3.11.3 If YES, please provide details of the changes. | ATTACHED or NOT REQUIRED |
| History of use |  |
| 3.12.1 Please provide data on the number of doses of vaccine sold in Australia since the last import permit was issued. | ATTACHED |
| 3.12.2 Please provide a pharmacovigilance report for the vaccine for the period since the last import permit was issued. | ATTACHED |

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| Manufacturer’s declaration |  |
| I declare that the information provided in this document and in supporting dossiers is accurate and that the Department of Agriculture, Fisheries and Forestry (the department) will be advised of any changes to the production process that affect the content of these documents.  I authorise the department to share information in this document with the Australian Pesticides and Veterinary Medicines Authority (APVMA). I understand that this information will be used to ensure compliance of the vaccine product with the regulatory requirements of each agency. | |
| **Signature:** |  |
| **Name:** |  |
| **Position:** |  |
| **Date:** |  |
| **Company name and address:** |  |

## Privacy notice

Personal information means any information or opinion about an identified, or reasonably identifiable, individual. Personal information that is collected under or in accordance with the *Biosecurity Act 2015* is also ‘protected information’ under the Biosecurity Act.

The Department of Agriculture, Fisheries and Forestry is authorised under the Biosecurity Act to collect your personal information for the purposes of determining import conditions for your veterinary vaccine product and for other related purposes. If you fail to provide some or all of the relevant personal information requested in this form, the department may be unable to process the import permit application that relates to this form.

Information collected by the department will only be used or disclosed under the Biosecurity Act. The department may disclose your personal information to the Department of Health and the Australian Pesticides and Veterinary Medicines Authority, and other Australian Government agencies, persons or organisations where necessary for these purposes. It will not usually be disclosed overseas. It will only be disclosed if authorised under the Biosecurity Act.

See our [Privacy Policy](https://www.agriculture.gov.au/about/commitment/privacy/privacy-policy) to learn more about accessing or correcting personal information or making a complaint.

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| **Document version control revision history** | | | |
| **Version no.** | **Date revised** | **Section revised** | **Revision** |
| 1 | 13 October 2011 | N/A | N/A |
| 2 | 5 May 2013 | All | * ‘AQIS’ to ‘DAFF’ * Update TSE policy reference |
| 3 | 24 June 2015 | All | * Replaced ‘DAFF’ with Department of Agriculture * Made compliant with online accessibility requirements |
| 4 | 4 July 2018 | Annex 1 | * Add ‘Lumpy skin disease virus’ as an Annex 1 pathogen |
| 5 | 1 February 2021 | All | * Replaced ‘Department of Agriculture’ and ‘Department of Agriculture and Water Resources’ with ‘Department of Agriculture, Water and the Environment’ * Updated the Privacy Notice * Replaced references to ‘Annex 1 diseases’ with references to ‘diseases of highest animal biosecurity concern’ * Added a link to the web location of the department’s veterinary vaccine policies * Amended the ‘Information required’ section |
| 6 | 8 May 2023 | All | * Update name of department to ‘Department of Agriculture, Fisheries, Forestry.’ * Update department contact email address. |
| 7 | 5 September 2025 | All | * Added history of use, raw material specification, and final product test method requirements. * Requirement for provenance and treatment documents added. * Revised ‘Introduction.’ * Title page image added. * Update Privacy Policy link. * Removed ‘changes to seed lots’ section. |

1. Australian Pesticides and Veterinary Medicines Authority (www.apvma.gov.au) [↑](#footnote-ref-2)
2. ‘Manufacturing facility’ includes all buildings on site including production buildings, QC and R&D areas. [↑](#footnote-ref-3)
3. The department’s list of “Pathogens of highest animal biosecurity concern” (formerly referred to as Annex 1 pathogens) can be accessed [here](https://www.agriculture.gov.au/sites/default/files/documents/pathogens-of-highest-biosecurity-concern.pdf). [↑](#footnote-ref-4)
4. Includes serum, foetal serum, serum albumins and other serum products used for cell line maintenance and growth. [↑](#footnote-ref-5)
5. Government export health certificates will be available for materials of animal origin (or their precursors) that have crossed an international border at any stage of their chain of production and supply. [↑](#footnote-ref-6)