



Australian Government
Department of Agriculture,
Fisheries and Forestry

DECLARATION REGARDING INFORMATION REQUIRED FOR REASSESSMENT OF VETERINARY VACCINES

1 Introduction

The Department of Agriculture, Fisheries and Forestry (the department) assesses import permit applications for veterinary vaccines against 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](#)
- b) [Specific Quarantine Requirements for the Importation of Inactivated Veterinary Vaccines \(an addendum to the guidelines for submissions to import veterinary vaccines\), December 1997](#)
- c) [Guidelines for managing the risk of transmitting transmissible spongiform encephalopathies \(TSEs\) via veterinary vaccines and other in vivo veterinary products, October 2012.](#)

Please refer to the relevant policy for further information on requirements.

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

- Complete an application in [BICON](#) 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.

2 Information Requirements

	Manufacturer's response
2.1 Import permit application reference number OR name of importer:	
2.2 Name of vaccine and target species:	
2.3 Is the product exported to Australia a bulk antigen, vaccine excipient or fully finished vaccine?	
2.4 Is the product exported to Australia registered with the APVMA¹? If not, why not?	
2.5 Manufacturer and address of plant:	
2.6 Name all antigens in vaccine:	
2.7 Previous import permit number:	

¹ Australian Pesticides and Veterinary Medicines Authority (www.apvma.gov.au)

2.8 Standards of manufacture	
2.8.1 Is the manufacturing facility currently licensed for production of veterinary vaccines by the country of export?	YES or NO If YES, please provide a copy of the licence as supporting information.
2.8.2. Please provide a copy of the certificate demonstrating compliance of the manufacturing facility with Good Manufacturing Practice (GMP) requirements.	ATTACHED
2.8.3 Does the manufacturing facility hold any pathogens that are included on the department's list of "Pathogens of highest animal biosecurity concern" (formerly referred to as Annex 1 pathogens) ² ? 'Manufacturing facility' includes all buildings on site including the production buildings, QC and R&D areas.	YES or NO If YES, please provide a list of these pathogens and where they are held at the facility.
2.8.4 Have there been any changes to the pathogens held or vaccines produced at the manufacturing facility since the last import permit was issued? 'Manufacturing facility' includes all buildings on site including the production buildings, QC and R&D areas.	YES or NO If YES, please provide details of the changes and highlight any new vaccines or pathogens at the facility compared with the last list that was provided to the department.
2.9 Production process	
2.9.1 What is the outline of production or equivalent quality assurance (QA) document used to manufacture each bulk antigen and the final product?	
2.9.2 Has a copy of this document previously been provided to the department?	YES or NO

² The department's list of "Pathogens of highest animal biosecurity concern" (formerly referred to as Annex 1 pathogens) can be accessed at <https://www.agriculture.gov.au/sites/default/files/documents/pathogens-of-highest-biosecurity-concern.pdf>.

2.9.3 If NO, please submit a copy with this application.	ATTACHED or NOT REQUIRED
2.9.4 If YES, have there been any changes to the process of production outlined in this document since the document was provided to the department?	CHANGES or NO CHANGES have been made to the process of production outlined in the document specified in 2.9.1 since this document was provided to the department.
2.9.5 If CHANGES have been made, outline all changes and provide updated document.	ATTACHED or NOT REQUIRED
2.10 Ingredients of animal, microbial and viral origin including excipients and adjuvants	
2.10.1 Have there been any changes to the tissues, source species, country of origin, treatment and testing of any of the materials of animal origin used during production of the vaccine from all stages from master seed to final product since the last permit was issued?	YES or NO
2.10.2 If YES please summarise all changes and provide updated raw material specifications or equivalent QA documents for all ingredients of animal origin used in production.	ATTACHED or NOT REQUIRED
2.10.1.3 Have there been changes to any of the master seed lots used during production of the vaccine since the last permit was issued?	YES or NO
2.10.4 If YES, please provide details of the master seed lot changes.	ATTACHED or NOT REQUIRED
2.11 Final product testing	
2.11.1 Please provide a batch release record or equivalent QA document for a current or recent batch (specify batch number).	ATTACHED

2.12 Manufacturer's declaration	
<p>I declare that the information provided in this document and in supporting dossiers is accurate and that the Department of Agriculture, Fisheries and Forestry will be advised of any changes to the production process that affect the content of these documents.</p> <p>I authorise the exchange of information relating to the vaccine product outlined in this Summary of information document between the Department of Agriculture, Water and the Environment and the Australian Pesticides and Veterinary Medicines Authority (APVMA). I understand that this information will be used by the agencies for the purpose of ensuring compliance of the vaccine product with the regulatory requirements of each agency.</p>	
Signature:	
Name:	
Date:	
Position:	
Company name and address:	

3 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 \(https://www.awe.gov.au/about/commitment/privacy\)](https://www.awe.gov.au/about/commitment/privacy) to learn more about accessing or correcting personal information or making a complaint. Alternatively, telephone the department on +61 2 6272 3933 (or +61 3 8318 6700 outside Australia).

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	<ul style="list-style-type: none"> • 'AQIS' to 'DAFF' • Update TSE policy reference
3	24 June 2015	All	<ul style="list-style-type: none"> • Replaced 'DAFF' with Department of Agriculture • Made compliant with online accessibility requirements
4	4 July 2018	Annex 1	<ul style="list-style-type: none"> • Add 'Lumpy skin disease virus' as an Annex 1 pathogen
5	1 February 2021	All	<ul style="list-style-type: none"> • 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	<p>Update name of department to 'Department of Agriculture, Fisheries, Forestry'.</p> <p>Update department contact email address.</p>