



## **DECLARATION REGARDING INFORMATION REQUIRED FOR REASSESSMENT OF VETERINARY VACCINES**

### **Introduction**

AQIS assesses import permit applications for veterinary vaccines according to 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'; or
- b) 'Specific Quarantine Requirements for the Importation of Inactivated Veterinary Vaccines (an addendum to the guidelines for submissions to import veterinary vaccines), December 1997'

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

The risk of contamination of vaccines with transmissible spongiform encephalopathies (TSE) is currently assessed on a case by case basis.

To lodge an application for a vaccine previously approved by AQIS applicants must:

- Complete an Application to Import Biological Material and pay the appropriate fees. Please note: Vaccines are classified as a Category 5 (Non-standard good);
- Complete and sign this document and submit it with the Application to Import Biological Material. The document may be submitted in electronic or hard copy format;
- Provide relevant supporting information in dossier format. Dossiers may be supplied in hard or electronic copy format.

AQIS may at any time require applicants to subject any 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.

### **Information Requirements**

	<b>Applicant response</b>
<b>1. AQIS import permit application reference number OR name of importer:</b>	
<b>2. Name of vaccine and target species:</b>	
<b>3. Manufacturer and address of plant:</b>	
<b>4. Name all antigens in vaccine:</b>	
<b>5. Previous AQIS Import Permit number:</b>	

<b>6. Standards of Manufacture</b>	
6.1 Is the manufacturing plant currently licensed for the production of veterinary vaccines by the country of export?	YES or NO
6.2. Please provide a copy of the certificate demonstrating compliance of the manufacturing facility with Good Manufacturing Practice (GMP) requirements.	Copy of GMP certificate to be provided as supporting information.
6.3 Are any Annex 1 pathogens held at the plant?	YES or NO
6.4 Have there been any changes to the pathogens held or vaccines produced at the manufacturing facility since the previous AQIS Import Permit was issued?	If YES provide details OR NO
<b>7. Production process</b>	
7.1 What is the Outline of Production or equivalent Quality Assurance (QA) document used to manufacture each bulk antigen and the final product?	
7.2 Has a copy of this document been provided to AQIS?	YES or NO
7.3 If NO, please submit a copy with application.	ATTACHED or NOT REQUIRED
7.4 If YES, have there been any changes to the process of production outlined in this document since the document was provided to AQIS?	CHANGES or NO CHANGES have been made to the process of production outlined in the document specified in 7.1 since this document was provided to AQIS.
7.5 If CHANGES have been made, outline all changes and provide updated document.	ATTACHED or NOT REQUIRED
<b>8. Ingredients of animal, microbial and fungal origin including excipients and adjuvants</b>	
8.1 Since the previous AQIS import permit was issued have there been any changes to the tissues, source species, country of origin, treatment and testing of any of the ingredients of animal origin used in production of the vaccine from all stages from master seed to final product.	YES or NO
8.2 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
8.3 Since previous AQIS import permit, have there been any changes to any ingredients of microbial and/or fungal origin.	YES or NO
8.4 If YES, please summarise all changes and	ATTACHED or NOT REQUIRED

provide updated Raw Material Specifications or equivalent QA documents for all ingredients of microbial and/or fungal origin used in production.	
<b>9. Final product testing</b>	
9.1 Please supply Batch Release Record or equivalent QA document for current or recent batch. (Specify batch number)	ATTACHED
<b>10. Applicant declaration</b>	
<p>I declare that the information provided in this document and in supporting dossiers is accurate and that AQIS will be advised of any changes to the production process which affect the content of these documents.</p> <p>I authorise the exchange of information, in relation to the vaccine product outlined in this Summary of Information document, between AQIS and the Australian Pesticides and Veterinary Medicines Authority (APVMA). I understand that this information will be used by AQIS and the APVMA for the purpose of ensuring compliance of the vaccine product with the regulatory requirements of each agency.</p>	
<b>Signature:</b>	
<b>Name:</b>	
<b>Date:</b>	
<b>Position:</b>	
<b>Company name and address</b>	

<b>Document Version Control Revision History</b>			
<b>Version No.</b>	<b>Date Revised</b>	<b>Section Revised</b>	<b>Revision</b>
1	13 October 2011	N/A	N/A

**ANNEX 1 -Exotic animal diseases of major economic and social concern**

<b>SPECIES</b>	<b>PATHOGEN/DISEASE</b>
<b>Bovine</b>	Foot and mouth disease virus Rinderpest virus
<b>Equine</b>	African horse sickness virus
<b>Ovine/Caprine</b>	Foot and mouth disease virus Rinderpest virus Peste des petits ruminants virus Ovine/caprine pox virus Pulmonary adenomatosis
<b>Porcine</b>	Foot and mouth disease virus Swine vesicular disease virus African swine fever virus Classical swine fever virus
<b>Avian</b>	Clinical avian influenza virus Virulent Newcastle disease virus <i>Note: Use of eggs from SPF flocks in affected country may be allowed subject to additional testing for ND and AI</i>
<b>Other species</b>	As determined by AQIS on application