



## **GUIDELINES TO FEES FOR VETERINARY VACCINES**

### **Fee schedule implemented 1 July 2009 for the assessment of veterinary vaccines**

Application Fee	\$85 for electronic application via AQIS website \$150 for non-electronic application eg fax and mail
Initial Assessment Fee	\$320 per assessable item (equivalent to 4 hours assessment time)
Additional Assessment Fee	\$40 for every additional 15 minutes assessment time

### **Introduction**

1. All applications must be accompanied by an application fee plus \$320 assessment fee per assessable item.
2. Each antigen in a multivalent product is considered an assessable item.
3. Importers will be notified as part of the initial assessment if additional fees will be involved.
4. Importers can submit the full estimate of costs at the time of application.
5. If this is an over-estimate, AQIS will refund over payment at the completion of assessment. Alternatively, an invoice will be sent following 8 hours of assessment time.
6. AQIS will maintain all assessment records for invoicing purposes. These can be made available to the applicant if requested.
7. Final costs can only be provided as an estimate as assessment times are variable.
8. "Renewals" refers to applications to import vaccines for which previous import permits have been issued. A new permit will only be issued after a fully documented risk assessment by AQIS.

### **Vaccine Renewals**

A guide to the fees payable for assessing applications for vaccine renewals is as follows:

- Monovalent vaccines will incur the minimal assessment fee of \$320.
- Multivalent vaccines will incur an assessment fee of \$320 for each antigen.
- Master seeds will incur an assessment fee of \$320 for each seed.

AQIS may charge additional fees at the rate of \$40/15 min taking into account:

- Significant changes in manufacture
- Changes to relevant policy advice
- Inadequate documentation provided by importer
- AQIS determines a full assessment is required.

There are four categories of vaccine renewals as follows:

1. Batch Specific Live Vaccine Renewals

Note: These products will require a full reassessment every two years or as advised by AQIS.

2. Non Batch Specific Selected Live Companion Animal Renewals

Note: These products will require a full reassessment every two years or as advised by AQIS.

3. Inactivated Viral Vaccine Renewals

Note: These products are fully reassessed every four years or as advised by AQIS.

4. Inactivated Bacterial Vaccines Renewals

Note: These products are fully reassessed every six years or as advised by AQIS.

### **New Vaccines or Master Seeds**

Initial applications should be accompanied by payment of \$470. During this initial four hours AQIS will:

- Review application to check completed information summary and supporting dossiers have been submitted; and
- Scan documentation for obvious deficiencies or omissions; and
- Determine probability of need for public consultation or site inspection; and
- Set up and commence risk assessment document; and
- Determine additional fees required to progress assessment. Note that each master seed organism and each master cell line is regarded as one assessable item and an assessment fee of \$320 applies per assessable item.

As a guide it is envisaged that new products will also require approximately four hours additional assessment time for the following:

- assessment of raw materials; and
- assessment of overall production process; and
- assessment of in-process and end-product testing; and
- correspondence and meetings with importer/manufacturer; and
- consultation with Biosecurity Australia.

Further charges would apply for prolonged consultation with Biosecurity Australia, public consultations or site inspections.