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Biosecurity

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ANIMAL BIOSECURITY POLICY MEMORANDUM 2000/48

LIVE AND NOVEL VETERINARY VACCINES INTERIM GUIDELINES FOR THE PUBLIC CONSULTATIVE PROCESS AND EXPERT REVIEW PANEL ON IMPORT APPLICATIONS

This Animal Biosecurity Policy Memorandum (ABPM) provides interim guidelines for the processes of public consultation on and expert review of applications for the importation of higher risk live and novel veterinary vaccines.

The "Australian Quarantine Policy and Requirements for the Importation of Live and Novel Veterinary Bulk and Finished Vaccines" was adopted in December 1999 (AQPM 1999/85). An important component of the policy is the requirement for public consultation on applications to import higher risk veterinary vaccines such as live viral vaccines for livestock use. The policy also requires that an expert working group review the application and public comments received in cases where stakeholders raise significant new scientific issues. Interim guidelines for the processes of public consultation on and the expert review of such applications (Attachment 1) are now available.

AQIS is concerned to ensure that the confidentiality of commercially sensitive information regarding the manufacture of vaccines is preserved. These guidelines should effectively address this issue. If appropriate and in consultation with the applicant, AQIS will endeavour to coordinate the public consultation process with the National Registration Authority (NRA).

Stakeholders are encouraged to provide comment on the guidelines for consideration.

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Confidentiality

Respondents are advised that, subject to the *Freedom of Information Act 1982* and the *Privacy Act 1982*, all submissions received in response to Animal Quarantine Policy Memoranda will be publicly available and may be listed or referred to in any papers or reports prepared on the subject matter of the Memoranda.

The Commonwealth reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. Where a request for anonymity does not accompany the submission the respondent will be taken to have consented to the disclosure of his or her identity for the purposes of Information Privacy Principle 11 of the Privacy Act.

The contents of the submission will not be treated as confidential unless they are marked 'confidential' and they are capable of being classified as such in accordance with the Freedom of Information Act.

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