



24 February 2004

ANIMAL BIOSECURITY POLICY MEMORANDUM 2004/03

DEVELOPMENT OF IMPORT POLICY FOR SPECIFIC PATHOGEN FREE (SPF) EGGS

This Animal Biosecurity Policy Memorandum (ABPM) provides stakeholders with the draft review on the importation and/or use of overseas SPF eggs for vaccine production and other uses. Included as part of the review are a draft policy and draft conditions. We would welcome comments on these documents by 26 March 2004.

Biosecurity Australia has reviewed its quarantine policy for SPF eggs following requests from three vaccine manufacturers in Australia to remove the contingency clause from the current policy on the importation of SPF eggs for vaccine production, and permit the use of SPF eggs of overseas origin in live avian vaccines.

SPF eggs are essential for certain veterinary and human vaccines, quarantine monitoring and sentinel programs, disease diagnostic work and biomedical research and development. Recent shortfalls in the Australian production of SPF eggs have raised further concern that the current contingency policy is unable to meet the needs of essential human and animal disease control programs should shortfalls continue.

The attached draft review, policy and conditions recognise that European Pharmacopoeia requirements are adequate to address quarantine concerns with the use of the eggs for *in vitro* purposes, inactivated avian vaccines and human vaccines. However, a continued history of live avian vaccine contamination highlights the need for additional control on these vaccines. Increased sampling and testing of the source SPF flock or the use of more sensitive extraneous agent testing of the final live avian vaccine will be required. A further review is necessary to determine the most appropriate additional extraneous agent tests. Biosecurity Australia is seeking expressions of interest from independent experts in the field of avian diagnostics to assist us in undertaking this review on a consultancy basis.

Until that review is finalised, source SPF flocks used for live avian vaccine manufacture should be tested for specific exotic diseases at a sample rate sufficient to provide a 99% confidence in detecting the disease agent if it occurs at a 0.5% prevalence. However, an option of using more sensitive testing on the final live avian vaccine may be available following case-by-case assessment. This would require detailed justification based on the sensitivity of tests used to detect very low titres of extraneous agent. Applications are also subject to individual public consultation. Also note that the list of exotic avian pathogens requiring additional sampling and/or testing may be revisited when the ongoing table egg and egg products IRA is finalised.

Because of the high quarantine risks involved with the use of SPF eggs of non-Australian origin, especially with live avian vaccines, the use of these eggs in live avian vaccines will be contingent on demonstration of a critical national need for the vaccine. However, it is anticipated that this contingency clause will be removed in 12 months allowing time for issues such as additional extraneous agent testing of live avian vaccines to be resolved.

Your comments are invited

You are invited to comment on the draft review, policy and conditions. We would appreciate your response, including supporting comments, by 26 March 2004. We will take your comments into consideration prior to finalising the documents.

Please pass this notice to other interested parties. If those parties wish to be included in future communications on this matter they should get in touch with the contact officer (details below).

Confidentiality

Respondents are advised that, subject to the Freedom of Information Act 1982 and the Privacy Act 1988, all submissions received in response to ABPMs 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.

DAVID BANKS
General Manager
Animal Biosecurity

Contact Officer:	Warren Vant
Telephone no:	(02) 6272 4436
Facsimile no:	(02) 6272 3399
E-mail:	warren.vant@daff.gov.au

ATTACHMENTS:

- A. "Review of the import policy on SPF eggs"
- B. Draft "Quarantine Policy for the importation and/or use of fertile specific pathogen free eggs (*Gallus gallus*) of non-Australian origin"