Department of
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FISHERIES &
FORESTRY -
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ANIMAL BIOSECURITY POLICY MEMORANDUM 2002/05

MEASURES TO ADDRESS ADDITIONAL TSE CONCERNS WITH VETERINARY VACCINES AND OTHER HIGH-RISK BIOLOGICALS

DECISION ON QUARANTINE CONDITIONS

This Animal Biosecurity Policy Memorandum (ABPM) provides final quarantine measures to address additional Transmissible Spongiform Encephalopathy (TSE) concerns with veterinary vaccines and other high-risk biologicals (Attachment A).

Animal Biosecurity proposed quarantine measures to address additional concerns with veterinary vaccines and other high-risk biologicals in ABPM 2001/32 of 14 November 2001. Six responses were received.

In response to comments received, the review has been amended to include:

. Further consideration of TSE risks associated with products used in dogs and cats;

. Clarification that PrP^{sc} replication has only been reported in neural cell lines to date despite expression having been demonstrated in a wide range of tissues;

. That PrP^{sc} may be detected at between one-third and a half of the scrapie incubation period, using tonsillar biopsy and immunohistochemistry, in sheep fully susceptible to scrapie (VRQ-homozygous) but not in sheep with a semi-resistant genotype;

. Linking the summary of country TSE risk factors to Article 2.3.13.1 of the Office Internationale des Epizootes (OIE) Animal Health Code;

. Removing the proposed restriction on the use of feline cell lines from Feline Spongiform Encephalopathy (FSE) or high Bovine Spongiform Encephalopathy (BSE) risk countries if created at least 6 years prior to the first reported case in the country of origin;

. Removing the proposed restriction on the use of certain feline or mink cell lines in vaccines destined for use in species not known to be susceptible to TSEs, naturally or experimentally, subject to a demonstrated safety record and individual risk assessment providing additional assurances of safety;

. Inclusion of controls on other TSEs (eg chronic wasting disease);

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. Inclusion of a section on gelatin clarifying existing requirements and flagging possible future additional restrictions; and

. Various editorial changes.

Biosecurity Australia will give further consideration to the risk associated with the use of neurological material from all other species. Risk represented by the use of meat extracts derived from other mammalian livestock species typically fed meat and bone meal (eg pigs) is considered to be relatively low compared with the other products addressed above. However, Biosecurity Australia will continue to closely monitor the issue of cross species infectivity and may need to consider additional restrictions at a later date. Cross species infectivity may also impact on future requirements for feline and mink cell lines. The requirements for gelatin and other excipients of animal origin will be reviewed and amended as appropriate, for consistency with the final Therapeutic Goods Administration (TGA) requirements, when available.

Next Steps

Biosecurity Australia greatly appreciates the comments received and advises that the recommendations of the final review, as attached, take effect immediately. As outlined in the previous ABPM, importers with existing permits that may be affected are advised to contact the Australian Quarantine Inspection Service (AQIS) to discuss how to achieve compliance with these additional measures.

I would be grateful if you would pass details of this advice to other interested parties, who should advise Biosecurity Australia if they wish to be included in future communications on this matter.

Confidentiality

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