Department of
AGRICULTURE
FISHERIES &
FORESTRY -
AUSTRALIA

14 November 2001

# ANIMAL BIOSECURITY POLICY MEMORANDUM 2001/32

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

This Animal Biosecurity Policy Memorandum (ABPM) clarifies and expands existing veterinary vaccine and biologicals policies, consistent with the Department's bovine spongiform encephalopathy (BSE) policy, to address additional concerns with transmissible spongiform encephalopathies (TSEs). Comment is sought on certain aspects.

Quarantine policies were developed in 1994 for the importation of biologicals (ie products for the purpose of research, laboratories, medical, environmental, industrial, etc) and for inactivated veterinary vaccines. This was followed by additional specific requirements for inactivated vaccines released as an addendum in 1997. In December 1999, quarantine policy and specific requirements were released for the importation of live veterinary vaccines.

The specific requirements of the above policies relating to TSEs are as follows:

. Importation of vaccines is not permitted for those which incorporate cell lines, serum, meat extracts and other materials derived from bovines that were born or lived in BSE-affected countries or derived from sheep or goats that were born or lived in scrapie-affected countries

  - however, cell lines created at least 6 years prior to the first reported case of BSE or scrapie in the country of origin are acceptable providing all other quarantine requirements are met.

. Similar restrictions are applied to high risk biologicals such as veterinary therapeutics, catgut, other *in vivo* products, cell lines and *in vitro* products imported in sufficient quantities to have the potential to be diverted to *in vivo* use.

. Importation is also not permitted of live vaccines that incorporate material derived from the neurological material (eg brain infusion) of any species that are susceptible to TSE regardless of the country of origin of such neurological materials.

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To clarify and expand the existing policies to address more recent TSE concerns, Biosecurity Australia is providing recommendations to the Australian Quarantine and Inspection Service (AQIS) as attached. A summary of the major recommendations follows. Biosecurity Australia strongly encourages importers to read the attached document and seek clarification, where required, rather than rely on this summary.

These recommendations are consistent with the Department's BSE policy and risk assessments conducted in relation to the 1994 guidelines on the importation of biological products and the veterinary vaccine policies. Biosecurity Australia considers these recommendations to be appropriate risk measures necessary to address additional concerns as detailed in the attachment.

A. Biosecurity Australia considers the following restrictions to be critical, are within the scope of existing policies and is recommending immediate implementation by AQIS:

. Extending restrictions on country of origin from countries which have reported BSE to all "BSE risk countries" as defined in the attachment.

. Extending the prohibition on the use of neurological material from TSE susceptible species, as detailed in the live vaccine policy, to all veterinary vaccines and all other *in vivo* veterinary therapeutics

  - due to the ineffectiveness of inactivating agents against prions, the TSE risk is the same for inactivated vaccines as for live vaccines This is compounded by reports of possible potentiation of infectivity by inactivants such as formalin.

B. Biosecurity Australia also proposes the following measures to address the risks identified in the attached document. However, while consistent with the general principles of existing policies, these may extend beyond their scope and technical comment is therefore sought on:

. Extending the prohibition on the use of neurological material to include neurological material derived from other livestock species from BSE risk countries.

. Applying additional restrictions to feline and mink derived cell lines where there is a risk of feline spongiform encephalopathy or transmissible mink encephalopathy respectively.

. Extending the current restriction on the use of bovine cell lines or bovine isolated master seeds to prohibit these from the UK (regardless of date of creation) or from any other "BSE risk country" if created after 1984

  - There is still considerable debate as to when the first (index) case of BSE occurred in the UK

  - Because of under reporting in many countries and imports of meat and bone meal (MBM), bovine cell lines and master seeds from other BSE risk countries, if created around or after the time of the first case in the UK, may also be a risk.

Biosecurity Australia seeks technical comments on the recommendations in B above by 9 December 2001 (because of the importance and potential risks associated with these products, extensions for comment will not be provided). Until then, Biosecurity Australia has asked to AQIS that new permits be put on hold for product which do not meet these recommendations.

Importers with existing permits which may be affected are advised to contact AQIS to discuss how to achieve compliance with these additional measures.

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 MBM (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 consider additional restrictions at a later date.

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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