Australian Government

Department of Agriculture, Fisheries and Forestry

12 July 2004

ANIMAL BIOSECURITY POLICY MEMORANDUM 2004/10

REVISED BIOSECURITY REQUIREMENTS FOR MINIMISING THE RISK OF TRANSMITTING TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (TSEs) VIA VETERINARY VACCINES AND OTHER *IN VIVO* VETERINARY PRODUCTS

This Animal Biosecurity Policy Memorandum (ABPM) provides stakeholders with a draft policy (Attachment A) revising the 2002 policy document 'Measures to Address Additional TSE Concerns with Veterinary Vaccines and Other High Risk Biologicals'. The policy has been reviewed and amended to be consistent with the Therapeutic Goods Administration (TGA) policy on TSEs and also to better complement existing domestic and international bovine spongiform encephalopathy (BSE) policies. Comments on the document are sought by 6 August 2004.

Following a review of its biosecurity policies for veterinary vaccines and other high-risk biologicals, Biosecurity Australia released the policy document 'Measures to Address Additional TSE Concerns with Veterinary Vaccines and Other High Risk Biologicals' in February 2002 (ABPM 2002/05). That policy identified several areas where control measures were considered essential to guarantee the safety of these products. Biosecurity Australia has again reviewed the policy in light of the larger number of BSE affected countries, further TSE research and the release of a TSE policy by Australia's Therapeutic Goods Administration (TGA). The TGA is a unit of the Australian Government Department of Health and Ageing and is responsible for ensuring the safety of human medicines and other therapeutic goods.

Major changes to the policy include:

1. consistency with TGA requirements;
2. clarifying the differences in risk between:
    a. BSE status, as defined by the OIE, of the country of origin;
    b. country of origin;
    c. tissue of origin;
    d. method of administration (i.e. oral vs injection);
    e. susceptible and non-susceptible target species; and
3. a greater range of control options for the use of serum, peptones, cell lines and master seed organisms from minimal risk countries.

The rigorous controls of the previous policy would continue to apply, including restrictions on the use of:

1. neurological tissue from TSE susceptible species, regardless of country of origin;
2. bovine tissue from moderate and high BSE risk countries;
3. higher TSE risk tissues from minimal BSE risk countries; and
4. tissues sourced from species susceptible to TSEs, other than BSE, from affected countries.

Your comments are invited

You are invited to comment on the revised policy (at Attachment A). We would appreciate your response, including supporting comments, by 6 August 2004. We will take your comments into consideration in finalising the revision of the draft policy.

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). Alternatively, if you wish to be removed from the distribution list, please advise the contact officer.

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.

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