Policy for the Transfer of Biological Specimens to Overseas Laboratories for Infectious and Parasitic Disease Testing

(Endorsed by Animal Health Committee in September 2010)

BACKGROUND

Based on past experiences, the risk to Australia's animal trade and animal health status associated with the transfer of biological specimens overseas for infectious and parasitic disease testing or analyses is real and can have a significant socio-economic impact in Australia. Major issues of concern include:

1. The possibility of inappropriate overseas reporting of test result(s) that suggests the presence of an infectious or parasitic agent not previously known to occur in Australia.

2. When the standard of testing (the validity of test results) is beyond Australian control, it can be difficult to refute any test results and to ensure that only true and valid results are reported internationally.

PURPOSE

This policy provides guidelines for the submission of biological specimens to overseas laboratories for testing that may lead to or suggest a diagnosis of infectious or parasitic disease.

SCOPE

This policy applies to all testing laboratories, research institutions and persons sending biological specimens from Australian animals to overseas laboratories or other agencies for laboratory or consultative procedures that may lead to or suggest a diagnosis of infectious or parasitic disease. Senders are encouraged to select, wherever possible, overseas laboratories or other agencies that operate under an appropriate quality system such as that which applies in NATA-accredited laboratories in Australia (i.e. ISO/IEC 17025). The selected overseas laboratories or agencies should be accredited by one of NATA's Mutual Recognition Arrangement partners.

NOTE: *ALL specimens to be tested for suspicion or possibility of a disease not known to be present in Australia must be sent to AAHL for testing or subsequent despatch to an overseas laboratory for testing [see AHC Protocols – Procedures for transmission of diagnostic specimens for suspect emergency animal diseases (October 2006)].*

DEFINITIONS

"AAHL" means the Commonwealth Scientific and Industrial Research Organisation Australian Animal Health Laboratory at Geelong, Victoria.

"Australian animals" means all terrestrial animals, aquatic animals, avian species and bees.

"Australian CVO" means the Chief Veterinary Officer of the Australian Government.

"Biological specimens" or "specimens" means all specimens from, or derived from, Australian animals, regardless of whether they were collected from field or laboratory situations and whether they are fresh, fixed or processed.

"State CVO" means the Chief Veterinary Officer of the State or Territory in which the sending institution resides.

"NATA" means the National Association of Testing Authorities.

"Recipient" means any laboratory person or laboratory — including university, government, industry and private sector laboratories — receiving specimens from senders, for laboratory testing.

"Sender" means any laboratory person or laboratory — including university, government, industry and private sector laboratories — sending specimens to recipients for laboratory testing.

"Testing" means detection of infectious or parasitic diseases or their aetiological agents, including identification of infectious or parasitic agents, detection of immune responses to infectious or parasitic agents, interpretation of tissue lesions, and any other laboratory or consultative procedures that may lead to or suggest an aetiological diagnosis.

"Test" means any form of procedure used to conduct testing.

PROCESS

1. The sender should first ensure that the testing cannot be done in Australia. If the testing could be done in Australia, it should only be done overseas instead if there is a compelling reason to do so.

2. Before any biological specimens are sent overseas for testing, the sender is required to ensure that the relevant State CVO is satisfied with the reason(s) for having the testing conducted overseas rather than in Australia and has approved the transfer in writing (clearance). Subject to the State CVO's decision, a Material Transfer Agreement between the sender and recipient should be in place before despatch, stating:

    2.1 the intended purpose of the submission, including a list of the specimens and the tests to be conducted on each;

    2.2 that the only tests conducted will be those specified for each of the specimens listed;

    2.3 that the test results will be released only to the sender;

    2.4 that none of the specimens will be transferred to another party without the sender's prior consent and until a Material Transfer Agreement between the new recipient and the original sender is in place;

    2.5 that the specimens will be destroyed after a specified holding period or, if practical, returned to the sender, and will not be used for any other purpose without prior approval. (Note that this requirement will not apply when the intended purpose is submission to a "type culture collection" or some other library or database, or for taxonomic identification of an agent that has already been tentatively identified and subsequently reported to the State CVO.)

2.6 that unless specified otherwise, all aforementioned requirements can be fulfilled without breaching regulations and other legal obligations pertinent to the recipient's Government.

3. The State CVO will advise the sender in writing of the decision on clearance within a reasonable timeframe that is clearly understood by the sender at the time of lodging a request for clearance. The consignment must be accompanied by copies of the clearance and if applicable, the signed Material Transfer Agreement.

4. The sender will notify the State CVO in writing, immediately following the despatch of specimens to the overseas recipient, of the details of the specimens despatched.

5. It is the responsibility of the sender to notify the State CVO of any test result that identifies or suggests the presence of an infectious or parasitic disease or agent not known to occur in Australia. In the event that such a result is obtained, the release of the result by the sender is subject to approval by the State CVO.