file no: T97/3146

17 December 1997

ANIMAL QUARANTINE POLICY MEMORANDUM 1997/105

Chief Veterinary Officers, all States and the NT
Director, Animal and Plant Health Branch, BRS
Chief, CSIRO Division of Animal Health
Principal VOs (Quarantine), all States, ACT & the NT
National Farmers' Federation
National Meat Association of Australia
Australian Alpaca Association
Australian Dairy Industry Council
Australian Horse Council
National Registration Authority for Agricultural and Veterinary Chemicals
CSL
Virbac
Intervet (Australia) Pty Ltd
Boehringer Ingelheim
Pfizer Animal Health
Veterinary Counsellors, Washington, Brussels and Seoul
Agricultural Counsellor, Australian Embassy, Tokyo
Office of the Australian CVO
Manager, Animal Programs Section, AQIS Operations
Head, Foreign Diseases Unit, DPIE
Australian Veterinary Association
Quarantine and Animal Health Task Force, NFF
Australian Livestock Exporters' Council
Australian Registered Cattle Breeders' Association
Deer Industry Association of Australia
Mallinckrodt
Veterinary Manufacturers and Distributors Association

Cyanamid Websters
AUSVAC
Rhone Meriuex
Bayer Australia

Chief Veterinary Officer, MAF RA, NZ

FINALISED SPECIFIC QUARANTINE REQUIREMENTS FOR THE IMPORTATION OF INACTIVATED VETERINARY VACCINES

Animal Quarantine Policy Memoranda 1997/33 was circulated on 12 May 1997 requesting your comments on draft specific requirements for the importation of inactivated veterinary vaccines. Comments received have been taken into consideration when finalising these requirements. They form an addendum to the AQIS "Guidelines for the Production and Control of Inactivated Veterinary Vaccines in Australia" and "Guidelines for Submissions to Import Veterinary Vaccines" which were released in November 1994.

The 1994 guidelines are generalised and do not provide sufficient specific information for importers preparing import applications. This addendum provides advice, consistent with the existing guidelines and assessment procedures, on the specific requirements for the quarantine assessment of inactivated vaccines.

The requirements are generally consistent with the European Pharmacopoeia and the E.U. requirements for veterinary medicinal products. These requirements specify controls on sourcing, sterilisation and testing and are largely QA and GMP based. In general, these requirements are considered the minimum standard by AQIS with additional controls and procedures in the addendum to address specific Australian quarantine concerns. The US Code

of Federal Regulations 9CFR 113 provides more detail on many specific test procedures and are used as an enhancement to the Eu.Pharm. requirements as appropriate.

Although the standards and requirements of both the 9CFRs and European Pharmacopoeia are referred to in the addendum, duplication of procedures is avoided where possible. Importers will have a choice between the 9CFR or Eu. Pharm. for most test procedures however the addendum may specify one or the other, both or an additional requirement to address additional Australian quarantine concerns.

Generally respondents accepted the draft specific requirements. The importance was also accepted of a quality assurance approach, from sourcing of safe substrates and the need for audit trails confirming country and species of origin through to demonstration of a safe finished product. While based primarily on the European Pharmacopoeia and E.U. requirements, the requirements are flexible enough to allow for the assessment of product based on other codes. The sourcing and certification requirements for substrates are also generally consistent with the current AQIS "Guidelines for the importation of biological material".

While many changes have been made to the original draft document, the following are the most significant:

. Provides greater flexibility for AQIS officers in the interpretation of these requirements.
. A more detailed section on inactivation.
. Greater emphasis placed on the risks of cross-contamination.
. The need for approximate date of collection of substrates to allow more accurate determination of diseases present in the country of origin at the time of collection.
. The range of pathogens listed in Annex 3 has been increased, however freedom can usually be demonstrated on the basis of country or species of origin, processing, treatment or testing.

A discussion paper on the importation of live and novel veterinary vaccines is being finalised and will be released for public comment soon. It summaries comments on the 1996 draft policy on live vaccines and provides a detailed discussion on the various types of vaccines, their advantages, safety and quarantine concerns. It will also make recommendations on an import policy for live and novel vaccines. The requirements for inactivated vaccines may be subject to revision pending the outcome of consultation on proposed import requirements for live and novel vaccines.

DAVID WILSON
A/g Assistant Director
Animal Quarantine Policy Branch

Contact Officer: Peter Hewitt
Telephone no: (06) 271 6682
Facsimile no: (06) 272 3399