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ANIMAL QUARANTINE POLICY MEMORANDUM 1999/85

Chief Veterinary Officers, all States and the NT
Animal Programs Section, AQIS Operations
Office of the Australian CVO
Animal Health Branch, NOAPFH
Veterinary Counsellors, Washington, Brussels & Seoul
Agricultural Counsellor, Tokyo
Australian Alpaca Association
Australian Dairy Industry Council
Australian Egg Industry Association
Australian Horse Council
Australian Ostrich Association
EU Delegation, Canberra
Australian Pharmaceutical Manufacturers Association
Medical Industry Association of Australia
National Registration Authority for Agricultural and Veterinary Chemicals
AVCARE
CSIRO Division of Animal Health
National Farmers' Federation
Quarantine and Animal Health Task Force, NFF
Australian Animal Health Council
Australian Veterinary Association
Australian Livestock Exporters' Council
National Meat Association of Australia
Chief Veterinary Officer, MAF RA, NZ
Pork Council of Australia
Australian Registered Cattle Breeders' Association
Deer Industry Association of Australia
National Poultry Association
Australian Poultry Industries' Association
Therapeutic Goods Administration
Veterinary Manufacturers and Distributors Association

IMPORT RISK ANALYSIS: LIVE AND NOVEL VETERINARY VACCINES

ADOPTION OF QUARANTINE POLICY

This Animal Quarantine Policy Memorandum (AQPM) advises adoption of quarantine import policy and requirements for the importation of live and novel veterinary bulk and finished vaccines.

In February 1999, AQPM 1999/011 was issued setting out quarantine import policy and requirements for the importation of live and novel veterinary bulk and finished vaccines. One stakeholder drew to AQIS's attention that paragraph 2.2.1(e) of the new policy was potentially inconsistent with Australia's obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). This paragraph effectively prohibited imports of live viral livestock vaccines unless the livestock industry demonstrated a need due to increased occurrence or virulence of a disease and the absence of effective inactivated vaccine available locally or overseas. AQIS obtained legal advice which confirmed that the paragraph potentially breached the requirements of Article 2.3 of the SPS Agreement.

To maintain an equivalent level of quarantine confidence, AQIS has replaced the relevant paragraphs with the restriction that livestock vaccines have a demonstrated and well-documented safety record. Legal advice supports the view that this amendment is consistent with the SPS Agreement. Similar requirements for live bacterial vaccines (2.3.1(f)) and live avian vaccines (5.9.1) have also been amended.

This safety record of the imported vaccine will be based on use, in a significantly large number of animals, in countries with appropriate veterinary services, diagnostic capabilities and adverse

reaction reporting mechanisms. What constitutes a significantly large number will be determined by AQIS on a case-by-case basis taking into consideration factors such as vaccine type, target species, contamination history of similar vaccines, reporting mechanisms, how widespread a vaccine has been used, etc.

There have also been several editorial amendments to reduce repetition within the document and to better reflect AQIS responsibilities. Changes include:

Paragraph	**Purpose of amendment**
2.1.2 inserted	Justification of requirement for established safety record
2.1.7 inserted	Replaces 2.1.9 - improve consistency
2.1.17-19	Amended to clarify requirements and reduce repetition (new 2.1.18-20)
2.2.1	Amended as detailed above to address SPS obligations
2.3.1	Amended as detailed above to address SPS obligations
3.3.2.3 deleted	AQIS does not require a specific monograph to perform a quarantine risk assessment of a product.
3.4.2 deleted	Repetitive
4.8.2-4 deleted	Repetitive
4.9.3 deleted	Repetitive
5.1.4 , 5.3.10, 5.4.4, 5.6.8	Amended to avoid repetition. Methods consolidated into Appendix 2
5.4.3	Amended to clarify requirements to demonstrate freedom from bacterial contaminants in master seed bacteria.
5.9.1	Amended to address SPS obligations
5.9.2-10	Consolidated for clarity and remove redundancies.

The new conditions fully reflect Australia's highly conservative approach to quarantine risk management. Unrestricted importation of live vaccines would present an inherently high risk due to direct exposure of live animals to these products. The process of risk management in this case involves case-by-case assessment of all applications and, if required, public consultation and review by an expert working panel. Further requirements include good management practice, audit trails, detailed information on certification and test results, and, if necessary, additional testing on the finished product by the Australian Animal Health Laboratory or another AQIS-approved laboratory.

Next Steps

The conditions attached to this AQPM will be adopted today, 15 December 1999.

AQIS expresses its appreciation to all who assisted with the development of this import policy. Further information on this matter may be obtained from the contact officer listed below.

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