This is a joint response from the Australian Quarantine and Inspection Service (AQIS) and Biosecurity Australia in relation to the claims made by Animal Health Alliance (Australia) Ltd to the Productivity Commission on the assessment of applications to import veterinary vaccines.

Roles

AQIS Biologicals Programme administers Australian quarantine conditions for the importation of biological products. These include animal or microbial derived products such as foods, therapeutics, laboratory materials, and vaccines.

Biosecurity Australia provides science based quarantine assessments and policy advice that protects Australia's favourable pest and disease status and enhances Australia's access to international animal and plant related markets.

Vaccine policies

The veterinary vaccine policies were developed following considerable consultation with stakeholders which included the vaccine manufacturers.

The policies for the importation of live and inactivated veterinary vaccines are highly prescriptive and consistent with Australia's conservative approach to quarantine risk. Vaccines are potentially a very high disease (exotic and endemic) risk due to the potential for contamination from the ingredients and culture media used to produce them (e.g. bovine serum, meat, offal and blood products). Contaminated vaccines can spread disease over large parts of Australia before being detected and Australia's livestock based export industries rely on safe vaccines to provide Australian producers with a competitive advantage in overseas markets through having a disease free status for many of the serious livestock diseases.

Included in the policies, are measures to ensure that the final product is not contaminated with extraneous disease agents (exotic, endemic and exotic strains of endemic pathogens). Whilst the APVMA generally ensure that domestically manufactured vaccines are not contaminated with extraneous disease agents, APVMA, AQIS and Biosecurity Australia agreed that AQIS would take responsibility for ensuring that imported vaccines are not contaminated with extraneous disease agents. This was largely due to concerns about contamination with exotic strains of endemic pathogens. This reduced the duplication that would occur if AQIS were only to look at contamination with exotic strains of endemic pathogens and APVMA were to look at contamination with endemic strains. Therefore the concerns raised by Animal Health Alliance (Australia) Ltd in regard to duplication and the assessment of vaccines for contamination with endemic extraneous agents are unfounded.

Assessment of applications

AQIS has undertaken considerable effort responding to industry demands in 2007 by employing qualified staff (including veterinary officers and microbiologists) to assess vaccine applications and working with the industry to improve response times. This includes arranging for AQIS assessment staff to visit vaccine production facilities when vaccine applications are received. This includes frequent one on one meeting's with the Animal Health Alliance (Australia) Ltd and individual vaccine importers. The major issues on assessment response time have always been applicants not

providing all the relevant information available for AQIS to assess against the import policies for live and inactivated veterinary vaccines.

Where relevant information has not been provided or the applicant has claimed that alternate measures are equivalent to the requirements of the policies, AQIS generally refers these claims to Biosecurity Australia for advice. Assessing equivalence is complex and needs to be carefully considered. The applicants may provide insufficient scientific information to support their claims and therefore literature searches and consultation with experts are required and are time consuming. This places considerable pressure on resources in both AQIS and Biosecurity Australia. This pressure could be reduced if all applicants ensured that all the required relevant information was provided up front at the time of submitting an application. It is in the interests of the members of the Animal Health Alliance (Australia) Ltd to encourage the submission of complete applications that meet the policy.

AQIS and Biosecurity Australia have attempted to improve the standard of applications by running a one day workshop in February 2007 with the vaccine industry, undertaking overseas audits of vaccine manufacturing facilities and setting up a specific vaccine sub committee in July 2007 to work through assessment issues with industry. Greater cooperation with the APVMA on vaccine assessments has been made a priority by AQIS and this is reflected in the 2007-2008 AQIS business plan to ensure that duplication of regulatory requirements for vaccine applications are minimised, where respective legislation allows.