



Animal Health Alliance  
SOLUTIONS FOR THE FUTURE

Animal Health Alliance (Australia) Ltd  
ABN: 76 116 948 344  
Address: Level 2 AMP Building  
1 Hobart Place  
Canberra ACT 2601  

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Locked Bag 916  
Phone: 02 6257 9022  
Fax: 02 6257 9055  
[www.animalhealthalliance.org.au](http://www.animalhealthalliance.org.au)

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Committee Secretary  
Senate Rural Affairs and Transport Legislation Committee  
PO Box 6100  
PARLIAMENT HOUSE ACT 2600

[rat.sen@aph.gov.au](mailto:rat.sen@aph.gov.au)

### **Inquiry into the Quarantine Amendment (Disallowing Permits) Bill 2011**

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment.

The Alliance supports the principle intent of Australia's quarantine and biosecurity policies and risk assessment measures that manage the risk of entry, establishment or spread of pests and diseases not present in Australia that could cause significant harm to people, animals, plants and other aspects of the environment. Alliance members are significant importers of veterinary vaccines and animal/plant/microbial ingredients for vaccine manufacture in Australia and therefore welcomes the opportunity to provide input into the *Inquiry into the Quarantine Amendment (Disallowing Permits) Bill 2011*.

Australia's general public and production farming stakeholders rely on veterinary vaccines to prevent and control diseases in companion and production animals, to minimise death and debilitation, reduce antibiotic use and maximise animal production. Vaccines are made overseas and in Australia. Both Australian and overseas sourced animal, plant and microbial components are used, which require assessment by AQIS.

All imported veterinary vaccines and animal, plant and microbial ingredients are assessed at an interval of not more than every 2 years by the Biologicals Import Program (BIP) against the relevant veterinary vaccine policies and in many cases applications reviewed are only relevant to individual batches of vaccine. [i.e. AQIS Guidelines for Submissions to Import Veterinary Vaccines (1995); Specific Quarantine Requirements for the Importation of Inactivated Bulk and Finished Veterinary Vaccines (1997); and Australian Quarantine Policy and Requirements for the Importation of Live and Novel Bulk and Finished Veterinary Vaccines (1999)].

Our support for Australia's quarantine and biosecurity system is contingent upon the adoption of 'sound science' and conformity with Australia's international obligations under the WTO and SPS agreements. As such, the Alliance opposes the Bill in its entirety and strongly recommends its withdrawal by the sponsor, Senator Nick Xenaphon, for the following reasons:

1. Political interference in the current AQIS import approval process (as suggested by the Bill) would almost certainly result in international retaliation from our major trading partners and detract from Australia's ability to continue to negotiate free trade agreements;
2. Historically, Australia already has a reputation internationally of being a difficult country to import into due to its 'strict' quarantine requirements – including a political step in the quarantine assessment


process would further erode our international credibility and may result in legal challenge at WTO level;

3. The BIP of AQIS issues maximal 2 year import permits for veterinary vaccines and animal/plant/microbial ingredients for vaccine manufacture in Australia. The veterinary vaccine and pharmaceutical industry (“Industry”) is strongly of the opinion that for many years the AQIS vaccine assessment timelines have been unacceptably long. Disruption to existing markets, delayed availability of goods and of new, contemporary vaccines to end-users is a direct result of AQIS’ long and unpredictable timelines and highly conservative approach to risk assessment. The Bill will only serve to lengthen the already unacceptable timeline for the issuance of import permits;
4. The renewal process at the end of the current 2 year cycle is a relatively efficient one. Since the Bill also captures import permit renewals, which as part of the process, are subject to a new import risk analysis being undertaken every 2 years, it could mean that a company’s ability to conduct business in Australia could unreasonably be stopped completely and without warning. Manufacturers require lengthy lead times. Companies would not accept the risk caused by political interference and would almost certainly reconsider their Australian operations. Some biological permits have taken years to obtain and the data provided for these permits is exhaustive. Lack of science behind any decision to remove the approval may cost the country’s producers significantly if products are no longer available, especially in some of the niche biological areas;
5. Permits for live vaccines for food producing species are issued permits on a batch by batch basis and even though these may be valid for up to 2 years it is only for that particular batch. Any delays to issue of a permit can easily result in lack of availability of vaccines and result in animals not receiving vital vaccinations. This can result in serious outbreaks of disease and/or producer stock losses;
6. Having permits passed through parliament would be at odds with having products registered by the APVMA as this does not have any political input. Political input already seems to be in place with policies that are drafted by DAFF, so surely having these in place means that no further political input is required?
7. Interference by the Federal Parliament may result in one vaccine permit being refused for 1 company but approval for another company with a vaccine treating the same disease.

**Based on the above, the Alliance strongly opposes the Bill in its entirety and recommends its withdrawal from the political process.**

If you have any enquiries regarding the Alliance submission please contact me on 02 6257 9022.

Yours sincerely



Dr Peter Holdsworth AM FAICD  
Chief Executive Officer  
Animal Health Alliance (Australia) Ltd