



Department of
**AGRICULTURE
FISHERIES &
FORESTRY -
AUSTRALIA**



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ANIMAL BIOSECURITY POLICY MEMORANDUM 2002/38

DEVELOPMENT OF POLICY FOR THE IMPORTATION OF SPECIFIC PATHOGEN FREE (SPF) EGGS

This Animal Biosecurity Policy Memorandum (ABPM) provides stakeholders with a discussion paper on the options for the development of quarantine policy for the routine importation of specific pathogen free (SPF) eggs for vaccine production and other uses. Comments are sought by 14 October 2002 on the approach Biosecurity Australia should follow in developing the policy.

Biosecurity Australia has received requests from 3 vaccine manufacturers in Australia to

- a) remove the contingency clause from the current policy on the importation of specific pathogen free (SPF) eggs for vaccine production and
- b) permit the use of SPF eggs in live avian vaccines.

The manufacturers main concern is continuity of supply. Their requests raise a number of complex issues that have potential to impact on various industry and disease control programs.

The current policy, established in June 1998, for the importation of SPF eggs for vaccine production is only to be used on a 'contingency basis', that is in the event of a failure in domestic SPF egg supply and subsequent adverse effect on vaccine availability for disease control purposes. Their use in live avian vaccines is not permitted.

The SPF egg industry in Australia is small due to limited domestic demand: there are few major users and significant fluctuations in demand. SPF egg producers require considerable prior notice for production to meet demand.

Biosecurity Australia considers it desirable that all Australian users continue to have access to SPF eggs for vaccine production and human and animal disease control programs.

The purpose of this ABPM and discussion paper (Attachment A) is to provide stakeholders with relevant information on the issue and to seek comments on the way forward. Two options are presented: an internal review by Biosecurity Australia or a formal import risk analysis. More detail on the steps involved and the estimated time is included in the attachment.

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Your comments are invited

You are invited to comment on the proposed options. We would appreciate your response, including supporting comments, by 14 October 2002. We will take your comments into consideration in making a decision on the way to progress this development of policy.

Please pass this notice to other interested parties. If those parties wish to be included in future communications on this matter they should get in touch with the contact officer (details below).

Confidentiality

Respondents are advised that, subject to the Freedom of Information Act 1982 and the Privacy Act 1988, all submissions received in response to Animal Biosecurity Policy Memoranda will be publicly available and may be listed or referred to in any papers or reports prepared on the subject matter of the Memoranda.

The Commonwealth reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. Where a request for anonymity does not accompany the submission the respondent will be taken to have consented to the disclosure of his or her identity for the purposes of Information Privacy Principle 11 of the Privacy Act.

The contents of the submission will not be treated as confidential unless they are marked 'confidential' and they are capable of being classified as such in accordance with the Freedom of Information Act.

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DISCUSSION PAPER

THE IMPORTATION OF SPECIFIC PATHOGEN FREE (SPF) EGGS FOR VACCINE PRODUCTION

BACKGROUND

Current policies

Veterinary vaccines are considered high quarantine risk products because of their direct exposure to animals

- . despite modern manufacturing methods and quality assurance procedures, reports of vaccines contaminated with extraneous pathogens still occur overseas although in recent years these reports have primarily been associated with mammalian vaccines
- . prior to December 1994, the only veterinary vaccines permitted into Australia were a few dog and cat vaccines from New Zealand and livestock vaccines for use, under State Chief Veterinary Officer control, only in animals destined for export.

Due to increasing demand and globalisation of the pharmaceutical and vaccine industry, a general policy for the importation of **inactivated (killed) veterinary vaccines** was developed in 1994. In 1997, specific requirements for these vaccines were released as an addendum to the policy.

In 1998, Biosecurity Australia received an access request for the importation of **SPF eggs for vaccine production**. The request centred on concerns that domestic SPF egg production in Australia was concentrated around two producers and, in the event of a disease outbreak in one of the flocks, vaccine production using SPF eggs would be adversely effected.

Following considerable consultation, the policy was finalised in June 1998. Because of the inherent risks associated with vaccines, and substrates used in vaccine production, including SPF eggs, the policy restricted importation to 'contingency use' only and did not permit use in live avian vaccines, being the highest risk. The SPF egg contingency policy requires the following:

- . that expected losses from disease attributable to a lack of vaccine availability be compared to the quarantine risk from using imported eggs and taken into account prior to invoking the contingency clause
- . preference to be given to the use of the imported eggs in the production of inactivated vaccines rather than live vaccines, mammalian vaccines in preference to avian vaccines and in vaccines for use in exports only in preference to vaccines for domestic use
- . use of imported SPF eggs in live avian vaccines is not permitted
- . import permits will be limited to the period necessary to meet the contingency need

- . the foreign SPF flock and eggs must meet all relevant requirements in relation to testing and disease freedom of the European Pharmacopoeia, the Australian Therapeutic Goods Orders (TGO21) and the imported hatching eggs protocol
- . additional controls are required for the transport, storage, handling and testing of eggs and subsequent vaccines in Australia including the need for compliance agreements, quality assurance manuals and standard operating procedures.

In December 1999, a policy for the **importation of live veterinary vaccines** was established following a formal import risk analysis process. Certain clauses were amended following an appeal and subsequent legal advice that the clauses were not fully compliant with our WTO SPS obligations. As a result, the policy requires that the imported vaccine be either manufactured from Australian SPF eggs or have a documented and demonstrated history of safe use and that the application undergo an additional level of public consultation prior to approval.

Australian production

Most SPF eggs produced in Australia are used for veterinary vaccine production by three manufacturers

- . one vaccine manufacturer now produces viral vaccines for Australian use in the United States; however, all SPF eggs used in the production of live avian vaccines are of Australian origin, imported specifically for these vaccines.
- . the other two major veterinary vaccine manufacturers produce vaccines on a campaign basis (ie for a production run which may last several weeks, one or two times a year).

A small proportion of the total domestic SPF egg production is used in laboratories for research and disease diagnostic and surveillance work. A proportion is also used for several commercial and experimental human vaccines.

Due to the few major users and campaign manufacturing, demand for SPF eggs varies markedly throughout the year. Biosecurity Australia is aware that local manufacturers can meet demand provided they have sufficient notice, preferably at least nine months. Unfortunately, that level of notice is often not available.

SPF policy review request

Because of supply problems, an Australian vaccine manufacturer has approached the Australian Quarantine and Inspection Service (AQIS) and Biosecurity Australia to invoke the contingency clause of the SPF egg policy. Apart from the contingency aspect, the current policy does not allow use of foreign SPF eggs in live avian vaccines.

Continuity of supply

In accordance with our WTO obligations and responsibilities under the *Quarantine Act 1908*, in considering this request to change the policy, Biosecurity Australia can only take into consideration economic effects which relate directly or indirectly to disease control, and not the economic impact associated with competition. While the economic viability of the Australian SPF eggs industry can not be considered, the continuity of supply for all users is a key consideration.

It is desirable that all Australian users continue to have access to safe SPF eggs, imported or domestic, for the purpose of ongoing vaccine production and human and animal disease control programs. An absence of domestic SPF egg producers would primarily affect the many small users of SPF eggs as it might be impractical and/or very difficult for small vaccine production units and research and diagnostic facilities to import their eggs and/or meet quarantine import conditions. This could result in an adverse effect on both human or animal disease control programs.

To this end, Biosecurity Australia convened a meeting in February 2002 with the relevant major industries and regulatory authorities, in an endeavour to encourage the vaccine manufacturers and SPF egg producers to resolve the issue of continuity of supply of SPF eggs without disruption to other users. As a result of that meeting, it was decided to initiate a review process, the first step is this discussion paper advising stakeholders of the issues, and seeking input on the most appropriate review method.

OPTIONS

Two options are proposed below that would follow further clarification of Australia's international obligations under the SPS Agreement regarding the use of contingency measures.

1. Biosecurity Australia to undertake an internal review, involving the following steps:

- . review the existing contingency SPF egg policy, taking into consideration current quarantine policies on veterinary vaccine and hatching eggs and relevant technical issues already identified by the on-going IRAs (ie the generic import risk analyses of uncooked chicken meat and non-viable eggs and products containing egg).
- . consider any additional quarantine concerns identified by either Biosecurity Australia or through the consultative process.
- . peer review of amended policy by the expert risk analysis panels for the uncooked chicken meat and non-viable eggs and products containing egg, and participants from the February 2002 meeting
- . policy document revised by Biosecurity Australia taking into consideration relevant comment from peer review
- . policy document released for public consultation
- . document revised and finalised by Biosecurity Australia taking into consideration relevant comment from stakeholders

The estimated time frame for this process is 12-18 months.

2. A formal import risk analysis (IRA)

Biosecurity Australia conducts IRAs according to a structured and transparent process. Interested parties are consulted throughout the process including on

- . the proposed approach to the IRA, including the scope, indicative timetable and the IRA team
- . the issues paper that identifies the main pest and disease hazards. It is circulated for 60 days public comment
- . the draft import risk analysis report that develops from the issues paper and stakeholder comment. It assesses the pest and disease risks and proposes risk management measures and is also circulated for 60 days public comment
- . The final IRA report that takes into account stakeholder comments on the draft report. It is subject to a 30 day appeal period for those who consider the proper process has not been followed.

The IRA would follow the revised process, the final documentation is to be released later this year. A revised draft IRA framework document was circulated in September 2001 (ABPM 2001/26). It can be accessed on the internet at:

http://www.affa.gov.au/corporate_docs/publications/pdf/market_access/biosecurity/IRA_framework.pdf.

Similar to the internal review, the IRA would review existing policies and, as appropriate, draw on the expert risk analysis panels for the uncooked chicken meat and non-viable eggs and products containing egg.

The estimated time frame for this process is 2-3 years.

For further information on the IRA process please contact:

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