Market
Access
and
Biosecurity

**LIVE AND NOVEL VETERINARY
BULK AND FINISHED
VACCINES**

INTERIM
GUIDELINES FOR
PUBLIC CONSULTATION
&
EXPERT REVIEW PANEL

Department of **AGRICULTURE, FISHERIES AND FORESTRY - AUSTRALIA**

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INTERIM
GUIDELINES FOR PUBLIC CONSULTATION & EXPERT REVIEW PANEL
ON
QUARANTINE RISK ANALYSIS OF LIVE VETERINARY VACCINES

1. GENERAL

1.1 The importation of live veterinary vaccines, especially live viral vaccines destined for use in livestock species, represents a potentially high quarantine risk to Australia. Access to these vaccines may however be necessary for the continued viability of Australian livestock industries. Accordingly, AQIS has established a mechanism that will ensure thorough assessment of these vaccines. For the higher risk vaccines, the process includes both public consultation and, where required, an expert working group.

1.2 Public consultation will be conducted for live viral vaccines for use in livestock and others considered by AQIS to represent a significant potential risk to agricultural industries or the environment. Such vaccines are defined in the AQIS "Policy and Requirements for live and novel bulk and finished veterinary vaccines" hereafter referred to as the "AQIS Policy".

1.3 As much of the information presented to AQIS for assessment is considered commercial-in-confidence, only summarised information relevant to the quarantine assessment will be made available for public consultation.

1.4 The public consultative process will only be applied to the initial application for each vaccine unless there are significant changes to the production process or any other factor that impacts on the quarantine risk. Vaccines produced using master seed and master cell lines that have been previously used in Australian vaccines will only be referred for public consultation if AQIS considers the potential risk represented by the vaccine justifies such action.

1.5 The decision to refer an application to public consultation will be made by the Assistant Director, Animal and Plant Programs Branch of AQIS (AQIS-APPB) who will take into consideration, on a case by case basis, the live vaccine policy requirements as well as factors such as contamination history of similar vaccines, potential for contamination to have a significant impact on the agricultural industry and/or the environment or have a high risk of reversion to virulence or genetic reassortment.

1.6 AQIS-APPB will consider comments received from the public consultation process. Where appropriate, all relevant queries and other issues arising from the public consultation will be referred by AQIS to the applicant for response. If appropriate, the applicant's response and/or quarantine advice from AQIS will be forwarded to whoever raised the query or issue.

1.7 If the public consultative process generates sufficient concern on quarantine issues which cannot be resolved between AQIS, the applicant and respondent, AQIS-APPB will make a recommendation to the Director, Quarantine and Exports Operations Division of AQIS for determination on whether to refer the application to an expert review panel. The panel will review the public comments received, the initial quarantine risk analysis conducted by AQIS and any import conditions proposed by AQIS.

1.8 Irrespective of any review by the expert panel, AQIS may choose to seek external expert advice on an application at any time during the assessment process.

1.9 The responsibility for the final decision on importation and conditions to be applied to the subsequent import permit rests with the Director of Quarantine (or delegate).

1.10 Applications will not be approved or referred for public consultation until AQIS is satisfied that all of the relevant requirements specified by the AQIS Policy will be met.

1.11 These guidelines for public consultation and expert review panel are interim only and are expected to be amended in response to practical considerations identified during implementation of the process. Anticipated time frames associated with each stage of the assessment, consultation and review process may be determined after implementation.

2. ASSESSMENT AND PUBLIC CONSULTATIVE PROCESS

2.1 The importer shall submit an "Application to Import Biological Material" to AQIS for the vaccine along with all prescribed fees payable.

2.2 The importer shall also supply all relevant information, documentation and certification as detailed in the AQIS Policy.

2.3 AQIS-APPB will conduct an initial review of the application and information submitted. The assessment will be conducted and documented in a systematic and consistent manner.

2.4 Any deficiencies occurring in either information presented or process shall be documented in the Assessment Report. The AQIS assessor will inform the importer of any such deficiencies.

2.5 Any such deficiencies must be corrected to enable the completion of the initial assessment and any subsequent public consultation process.

2.6 AQIS will reject applications that fail to address any identified deficiencies including those that fail to meet the appropriate requirements in the AQIS policy. In situations where the information presented is insufficient and unlikely to be available in the future, the application will be rejected. The importer will be informed of the reason(s) for rejection.

2.7 For vaccines that do not require referral to public consultation, an import permit with appropriate conditions for importation may be issued if the AQIS assessment indicates that use of the vaccine within Australia does not represent a significant quarantine risk and that it meets the requirements of the AQIS Policy.

2.8 For vaccines to be referred to public consultation in accordance with the AQIS Policy, AQIS will prepare a summary risk analysis document using the Assessment Report as the basis.

2.9 The summary assessment document will:

- describe the vaccine and vaccine organism
- describe the location of the production facility
- either list species and country of origin of all materials of biological origin used or provide confirmation of country freedom from the relevant diseases
- describe tests carried out to demonstrate freedom from pathogens
- describe any treatments which would eliminate potential contaminants
- state the good manufacturing practice (GMP) and other standards applied
- provide an overview of quarantine confidence in sourcing, testing, treatments, documentation, audits
- provide an overview of relevant quarantine issues and concerns which might be necessary for the public to provide considered comment of a technical nature
- detail proposed AQIS import conditions for the vaccine.

2.10 To preserve the confidentiality of the application, the summary document may only specify general details concerning production such as: "bovine serum of NZ origin was used in pig cell line of 1978 US origin". It will avoid the use of specific commercial information such as the cell line ATCC reference number.

2.11 The summary document will be provided to the importer for comment prior to release for public consultation. All commercial-in-confidence issues must be resolved and written acceptance of the document obtained from the importer prior to release.

2.12 Notification of the proposed importation and availability of the summary document will be made to the peak agricultural industry bodies and also placed on the AQIS web page (www.aqis.gov.au).

2.13 The notification will state that AQIS's role is to assess the quarantine risks associated with importation and use. AQIS will not consider other issues such as efficacy or labelling. Only comments on technical quarantine issues will be taken into consideration.

2.14 Respondents will be advised that, subject to the *Freedom of Information Act 1982* and the *Privacy Act 1982*, all comments received will be publicly available and may be listed or referred to in any papers or reports prepared on the application.

2.15 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.

2.16 The contents of the respondent's 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.

2.17 The public consultative period will be 30 days.

2.18 AQIS will take all relevant technical comments into consideration in finalising the risk analysis and import permit conditions. Minor issues may be resolved by AQIS in liaison with the applicant and respondents. If the consultative process identifies inadequately addressed yet valid quarantine safety issues, the application may be referred to an expert review panel as detailed in 1.6 and 1.7.

3. EXPERT REVIEW PANEL PROCESS

3.1 The role of the expert review panel is to review the scientific aspects of the AQIS assessment, public comments, the quarantine risks associated with the application and any import conditions proposed by AQIS. Its role is not to represent the commercial interests of any particular industry group.

3.2 The expert review panel of 5 members will be selected by the Director, Quarantine and Exports Operations Division, AQIS. A representative from Animal and Plant Programs, AQIS, will chair the panel. The following organisations will be invited to nominate representatives for the panel:

- Australian Veterinary Association
- National Registration Authority for Agricultural and Veterinary Chemicals
- Quarantine Animal Health Task Force of the National Farmers' Federation

. National Office of Animal and Plant Health or CSIRO Animal Health Division *(rotational or on an availability basis)*.

3.3 A representative will also be invited from the following as appropriate:

. Therapeutic Goods Administration *(vaccines for zoonotic diseases)*
. Office of Gene Technology Regulator *(recombinant vaccines)*
. Environment Australia *(vaccines which may have a significant environmental impact)*.

3.4 Secretariat functions will be provided by Animal and Plant Programs Branch of AQIS.

3.5 All information provided to the panel will be treated as commercial-in-confidence. Each representative will be required to declare any commercial interest or association with vaccine manufacture, importation or distribution. AQIS may reject any nomination on the basis of commercial conflict of interest.

3.6 All members, other than from government regulatory bodies (ie AQIS, NRA), will be required to sign contracts agreeing to maintain the confidentiality of commercial material.

3.7 The primary selection criteria for representatives to the panel will be knowledge and understanding of quarantine principles and the ability to apply these principles to an analysis of the quarantine risks of importing vaccines.

3.8 Other selection criteria include understanding and knowledge of vaccine production methodology, microbiology, diagnostic procedures, pathogen inactivation, auditing and GMP.

3.9 Individual members of the panel will be provided by AQIS with copies of the Assessment Report, the summary risk analysis document, and comments received.

3.10 Panel members may request additional information for review. This would include relevant parts of the application dossier and any subsequent information provided by the importer.

3.11 If required, it will be the applicant's responsibility to make available copies of such information to each panel member. All such information should be sent to the secretariat who will distribute it to panel members.

3.12 Panel members may seek clarification from the reviewing AQIS officer of the initial risk assessment or may ask AQIS to obtain additional information from the importer.

3.13 The initial and subsequent meetings may either be held in person at a location of overall least inconvenience and cost or, subject to agreement by all members, by tele-conference. Privacy during meetings and tele-conferences will be maintained.

3.14 Additional meetings may be required until all issues are resolved and/or the panel can present a recommendation to the Executive Director of AQIS. Unresolved issues will be referred by AQIS to the applicant for a response within 30 days.

3.15 The panel may unanimously recommend one of the following:

- Approval without restriction
- Approval subject to certain conditions
- Rejection because of unacceptable, unmanageable quarantine risk
- Rejection because of insufficient information presented by the importer and that sufficient information is unlikely to be obtained to address quarantine concerns
- Additional information or documentation to be provided or further testing or treatment to be conducted and verified before the panel finalises its decision.

3.16 If a unanimous decision can not be reached even after additional information or documentation has been provided or further testing and treatment conducted, the issues in dispute along with the opinions of the individual panel members shall be referred to the Executive Director of AQIS for decision.

4. AUDITING

4.1 Prior to final import approval, the facility manufacturing the vaccine will be audited by an AQIS representative to ensure the facility, production and the product meets requirements specified in the AQIS Policy and that product destined for export to Australia can be produced consistently in accordance with the policy and specified import conditions.

4.2 Auditing would not usually be undertaken until after the risk analysis, including public consultation and review by the expert panel, has been completed. The expert panel may however decide to reserve a decision pending the outcome of an audit if it considers there are sufficient concerns with the ability of the facility to meet the policy requirements.

5. COSTS

5.1 The importer must pay all prescribed fees associated with their application to import quarantine material including costs of audits.

5.2 The importer will also pay for costs associated with the public consultative process and the expert review panel. These costs will be determined in consultation with the Biologicals Industry Consultative Committee.

5.3 Prior to submitting an application to public consultation, AQIS will advise applicants of the estimated costs and time frames associated with public consultation and the likelihood, estimated costs and time frames associated with a possible review by an expert panel.