Present systems and future needs for risk assessment of veterinary biologicals in Australia: the perspective of the regulator

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Summary: The increasing range and complexity of biologicals, and the greater demand for these products, have resulted in a greater volume of trade in animal-based biological material. This has given rise, in turn, to many approaches to the regulation of importation of these materials, as countries seek protection against the introduction of disease. Harmonisation of these regulatory approaches would contribute significantly to the availability of veterinary biologicals, to their manufacture and trade, and to disease security.

Australia has developed systems for the categorisation and evaluation of biologicals, control by import permits, and specific procedures at point-of-entry and in institutions where these products are used. Computerised records and precedents assist in evaluation and in the issuing of permits. Recognition that some materials must be subject to further control has led to a system of registration of institutions based on levels of biosecurity, and approved use and disposal programmes. Institutions vary from high-security animal health laboratories to human in vitro fertilisation clinics, which use animal-derived media and materials. Such institutions are regulated through quality assurance contracts.

Quarantine authorities have linkages with other agencies which have an interest in these products. These linkages reflect the administrative structures of government in Australia, and provide for management of all forms of risk. The author describes these systems and overviews their biological basis.


INTRODUCTION

Authorities in Australia have sought to address all potential means of introduction of animal disease, as the preservation of animal health status in this country is a matter of great public concern. The relatively small population of Australia (17 million people) combined with a large volume of agricultural production (derived, for example, from 25 million cattle and 165 million sheep) means that much of this production must be exported. In view of the ease with which animals and their products can spread disease,
continuing access of Australian exports of these products to world markets is dependent on the animal health status in the country. The presence of large numbers of feral animals, insect species which are related to vectors of disease overseas, and a wide range of climates and types of agricultural production means that disease control and eradication can present a formidable and costly challenge.

The completion of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT; now World Trade Organisation: WTO) – and with it the conclusion of an Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) – has introduced new disciplines in quarantine measures.

For many years, studies have been conducted to assess the potential introduction of exotic diseases through the importation of biological substances for research, commerce, diagnostic work or environmental release. A mechanism for controlling the importation, registration and use of such substances has evolved over a number of years. Simultaneously, a method for structured risk assessment has been developed.

Most countries recognise the magnitude and complexity of this task, and the risk assessment methods developed in Australia, based on categories of biologicals, may be of use to other nations.

Electronic systems for handling risk assessment and scanning cargo manifests in co-operation with Customs authorities facilitate this process.

**RISK**

The capacity for immunobiologicals and therapeutic substances to cause or introduce disease is well documented. Contamination with adventitious agents, reversion to virulence of attenuated organisms and failure of inactivation are all well-documented as means of transmitting disease. Less easy to assess and less well-documented is the capacity of other substances – known to be contaminated or potentially contaminated with disease agents – to spread disease through contact with the domestic population (9, 16).

The normal process of manufacture of many animal-based products inactivates many potential contaminating agents, while other agents (if present) will survive, as organisms differ in their response to inactivation/sterilisation procedures.

For these reasons, and due to the large number of applications being assessed each week, a structured form of risk assessment must be employed (3, 4, 8, 9, 10, 16). For commercial stability and quarantine security, and for probity and equity, it is important that a consistent method be employed for the assessment and handling of these products (7, 8, 11). So many applications are received that resources must be directed towards the areas of greatest risk, and the complex nature of the substances means that even these areas of risk cannot be necessarily identified or assessed at the point of entry. This tends to lead to pre-approval systems and to the use of permits to allow importation.

Low-risk substances are allowed free entry and freedom of use. Some substances, following detailed assessment, will be allowed entry on presentation of a permit accompanied by adequate certification from either the manufacturer or the government of the exporting country. Other substances will be allowed entry by a permit which restricts their use and distribution.
Trade

Advances in diagnostic technology increase demands for biologicals of all kinds. The increasing use of biologically-based processes in commerce (e.g. the manufacture of fermented antibiotics) and the increasing cost of development of each product, together with limitations through patents, have created an increasing demand for international trade in biologicals. Similarly, it is becoming increasingly difficult for countries to meet their own needs for many kinds of substances through domestic manufacture and production. At the same time, new attitudes to world trade following the Uruguay Round of GATT, the establishment of the WTO, and the conclusion of the SPS Agreement (5, 6) are leading to restrictions which prevent quarantine being used as a non-tariff barrier to trade.

The SPS Agreement demands harmonisation of quarantine requirements (i.e. the use of international rules) as far as possible. Where animals and animal products are concerned, the stipulations of the *International Animal Health Code* of the Office International des Epizooties (OIE) (13) are recognised as constituting the international rules. The SPS Agreement requires scientific justification of variations from the OIE Code, or of quarantine measures for commodities for which codes have not yet been developed.

The OIE *International Animal Health Code* (13) now includes a section on 'Import risk analysis', and the processes described can be incorporated into methods used for risk assessments of veterinary biologicals. Nevertheless, these stipulations are of a general nature and do not address the specifics of the wide variety of categories of veterinary biologicals. Against this background, most countries have developed their own approach to the subject; this, in itself, has the potential to complicate trade in such items.

The development of a detailed international code would improve national quarantine security and ensure the wider availability of the veterinary biologicals which are needed throughout the world. This is especially important in developing countries, which have less capacity to undertake their own risk assessments (12). Such an international code would also establish a basis for stable trade in these items.

The Australian approach to the regulatory handling of biologicals through risk assessment, and through quarantine procedures before and after arrival in Australia, and at the port of entry, may contribute to the development of such an international code.

**QUARANTINE PROCEDURES**

The following sections describe the process of assessment and granting of permits, the inspection of products on arrival at the point of entry, and a number of mechanisms for controlling post-importation use of biologicals (15). Certain biologicals can be used only *in vitro* and only in the institution for which they are imported. These products must be employed for the specified purpose, kept under appropriate conditions of security and subjected to a use and disposal programme which will guarantee continued quarantine security until final disposal.

Modern management principles – which include quality assurance mechanisms – are used (1, 2). The quarantine authorities enter into quality assurance agreements with the users and importers of these products. Use and disposal programmes are built into the
operating procedures and quality control arrangements of the institution where the imported products will be used, and quarantine authorities follow up with audits of these control mechanisms. This enables inspection resources and regulatory procedures to be targeted towards the areas of greatest need, and engenders responsibility among importers and users.

Categorisation of biologicals

A system of categorisation has been developed to ensure consistency of assessment, regulatory procedures and stability in the industry, as well as establishing precedents which minimise variation in risk assessments.

The international movement of many biologicals (e.g. microorganisms, cell-lines, animal serum, blood proteins, enzymes, hormones, tissue extracts and other animal products) represents a potentially high quarantine risk. These products are essential, however, for a variety of purposes (e.g. research, therapeutics, analysis, environmental use). To enable continued importation of these products, assurances are required either that they are safe for unrestricted use and distribution, or that adequate controls exist to ensure products are handled safely, are not exposed either directly or indirectly to animals, and are disposed of safely.

Australian guidelines on assessment and importation requirements were developed to provide these assurances. There are many categories of product, presenting various degrees of quarantine risk, and these risks are detailed in the guidelines, together with assessment procedures, and application and import requirements. Typical categories of biologicals are listed in Table I.

POLICY OUTLINE

Import protocols should be as simple as possible. Products may be imported into Australia for in vitro or in vivo use, provided that they meet specific standards designed to eliminate contamination by disease-causing organisms. When these specifications cannot be met, additional restrictions should apply, depending on the intended use and regulatory controls over the higher-risk product.

Low-risk products

Many low-risk products may be imported without an import permit, provided that they are declared on quarantine entry, are accurately and adequately described, and meet specific conditions on importation.

Catalogues containing thousands of substances are offered for assessment. Most low-risk products are currently approved as items within these biologicals catalogues under the ‘AQIS Policy on the Importation of In Vitro Biologicals’. Supply of products in the catalogues is restricted to institutions registered with the Australian Quarantine and Inspection Service (AQIS). Biologicals may be imported for unrestricted distribution if certain requirements are met (e.g. appropriate certification of health and origin of the products).

In addition to the security provided by AQIS-registered institutions, importation of products from certain countries is prohibited due to the presence of diseases which could result in massive economic or social cost to Australia. The importation of bovine,
<table>
<thead>
<tr>
<th>Category No.</th>
<th>Description/use/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Synthetic material</td>
</tr>
<tr>
<td>2.</td>
<td>Amino acids, alcohols, esters, sugars and vitamins</td>
</tr>
<tr>
<td>3.</td>
<td>Cosmetics</td>
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<td>4.</td>
<td>Plant extracts and processed biochemicals of plant origin</td>
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<td>5.</td>
<td>Products derived by microbial fermentation</td>
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<tr>
<td>6.</td>
<td>Diagnostic, analytical and immunochemical <em>in vitro</em> kits</td>
</tr>
<tr>
<td>7.</td>
<td>Material of human origin</td>
</tr>
<tr>
<td>8.</td>
<td>Therapeutics</td>
</tr>
<tr>
<td>9.</td>
<td>Implantables of animal origin</td>
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<tr>
<td>10.</td>
<td>Antibodies and immunoglobulins</td>
</tr>
<tr>
<td>11.</td>
<td>DNA, RNA, restriction enzymes and other molecular biology products</td>
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<tr>
<td>12.</td>
<td>Cell-lines and hybridomas</td>
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<tr>
<td>12.1.</td>
<td>Human cell-lines</td>
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<td>12.2.</td>
<td>Rodent cell-lines</td>
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<td>12.3.</td>
<td>Rabbit cell-lines</td>
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<td>12.4.</td>
<td>Hybridomas</td>
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<td>12.5.</td>
<td>Insect cell-lines</td>
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<tr>
<td>12.6.</td>
<td>Cell-lines from other species</td>
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<tr>
<td>13.</td>
<td>Animal proteins, hormones, enzymes, albumins, tissue extracts and culture media containing animal material</td>
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<tr>
<td>13.1.</td>
<td>Biochemicals of animal origin (≤ 20 g) – <em>in vitro</em> use only</td>
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<tr>
<td>13.2.</td>
<td><em>In vitro</em> use only</td>
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<tr>
<td>13.3.</td>
<td>Irradiation</td>
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<tr>
<td>13.4.</td>
<td>Industrial, environmental, food, veterinary or pharmaceutical uses</td>
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<tr>
<td>14.</td>
<td>Animal serum</td>
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<tr>
<td>14.1.</td>
<td>Serum in <em>in vitro</em> kits or used to transport antibodies</td>
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<tr>
<td>14.2.</td>
<td>Animal serum – <em>in vitro</em> use and restricted distribution</td>
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<tr>
<td>14.3.</td>
<td>Animal serum (unrestricted) – irradiation</td>
</tr>
<tr>
<td>14.4.</td>
<td>Animal serum (unrestricted) – certification and/or testing</td>
</tr>
<tr>
<td>15.</td>
<td>Microorganisms</td>
</tr>
<tr>
<td>15.1.</td>
<td>Starter cultures used in food/beverage manufacture</td>
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<tr>
<td>15.2.</td>
<td>Microorganisms for environmental use</td>
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<tr>
<td>15.3.</td>
<td>Microorganisms for <em>in vitro</em> laboratory use only</td>
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<tr>
<td>15.4.</td>
<td>Vaccines and vaccine seed cultures</td>
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<tr>
<td>16.</td>
<td>Probiotics</td>
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<tr>
<td>17.</td>
<td>Preserved specimens, microscope slides and smears</td>
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</tbody>
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DNA: deoxyribonucleic acid  
RNA: ribonucleic acid
ovine, porcine or caprine serum from countries affected with foot and mouth disease or rinderpest is prohibited.

Some *in vitro* products may be approved on the basis that if the product is to be used *in vivo*, inactivant chemicals or other security measures are used.

Commercial importation (i.e. by importers who are not users of the products) can be streamlined through the use of Approved Quarantine Directives (AQDs). AQDs are made under the provisions of the Quarantine Act and, through these directives, documented quality management systems ensure compliance with the conditions applicable to the products.

**Higher-risk products**

Import permits are required for higher-risk products. When a high-risk product is to be imported in commercial quantities, or for agricultural or *in vivo* use in non-laboratory animal species, appropriate guarantees must be provided of freedom from exotic pathogens and from exotic strains of endemic pathogens of concern. If considered necessary, the supply and use of such products are restricted to AQIS-registered institutions (for *in vitro* use only), or to non-agricultural/veterinary purposes. Distribution beyond AQIS-registered institutions is necessary for many products (e.g. culture media); minimum standards have therefore been established for high-risk products, even when supply and use is restricted. These include controls over source, treatment, testing and end-use.

**PROCEDURES**

The users of veterinary biologicals are provided with information regarding applications, and departmental policies and attitudes regarding various products.

The sequence of events for approval of imports of biologicals is described below.

**Application to AQIS**

Applications to AQIS must be submitted on the appropriate form, provided by AQIS, and must specify certain criteria.

On receipt of the form in the AQIS office, the details are entered in the PIMS (permit information management system) computer. The computer program has the following characteristics:

- a tracking mechanism to enable ready access to information on the progress of the application, and the name and location of the AQIS assessor
- an information system involving the name, address and identification number of the applicant
- a database, maintaining records of applications by the same institution or researcher/user, and with the capacity to retrieve records on a user or product basis
- a record of the conditions applied to previous importations of the same product
- when the computer program is complete, it will include categorisation of the product and a database of precedents to enable the application to be considered in relation to applications for similar products
- capacity to print permits, including conditions of importation (the permit must be presented at the point of entry).
Action at the point of entry into Australia

Quarantine officers are trained to determine the nature of the product and to examine certification documentation regarding pre-export treatment and restrictions on the ultimate destination of the product.

Items of quarantine interest are identified by declarations from the importers for Customs and quarantine entry. This is now undertaken electronically. Customs agents have computer links with Customs and AQIS. The Quarantine Entry Management System (QEMS) allows input and examination of documentation by computer. This is now conducted jointly with Customs under the Joint Entry Management System (JEMS). This system has largely replaced manual examination of manifests and declarations.

Officers check the product against the requirements of the permit. If necessary, officers may order treatments or despatch of the product to an approved institution.

Post-importation treatment

The product may enter Australia with certain restrictions (e.g. location, inactivation). AQIS can arrange for irradiation of certain products before release to the importer. The user or importer may have an agreement with AQIS, as part of a quality assurance programme regulated by AQDs, which enables the importer to collect items directly from the airport, subject to further treatment or labelling for distribution from storage. Some products may be restricted to particular institutions. The importers are subjected to audit to ensure compliance.

Registered institutions/approved premises

AQIS has developed a ‘Register of Scientific Institutions Approved to Handle Imported Biological Material’ on the basis of biocontainment, approved quality assurance systems, use and disposal programmes, and other criteria. The five categories of institutions, each having different requirements, are described below.

Independent analytical or diagnostic pathology laboratories accredited by the National Association of Testing Authorities

National Association of Testing Authorities (NATA) accreditation and statutory declaration concern the safe use and proper disposal of imported biological material.

Institutions involved with in vitro work only

Such institutions are expected to produce a Biologicals Use and Disposal Programme (BUDP), which should detail record-keeping, waste disposal, proper handling procedures, etc.

Institutions involved in in vivo work in laboratory animals

For in vivo work with laboratory animals, the BUDP must also demonstrate adequate animal housing and adequate record-keeping.

Institutions involved with in vivo work in non-laboratory animals

The BUDP requirements here are similar to those for institutions working with laboratory animals, but the initial use of restricted material on non-laboratory animals also requires independent AQIS approval.
In vitro fertilisation clinics

NATA and the Fertility Society provide accreditation of in vitro fertilisation clinics, safety manuals and waste disposal strategies. AQIS approval is also required for the initial use of restricted material on humans (e.g. embryo washing prior to implantation).

(The Communicable Diseases Section of the Department of Human Services and Health is also involved in the approval of material.)

Products imported by the end-user

If the importer of a high-risk product is also the end-user, detailed records (e.g. dates of importation, batch numbers, amounts) of the imported product must be maintained, and an officer must be nominated who will be responsible for the use and disposal of the product. An import permit may not be issued for some high-risk products unless the importer is certified under the Quarantine Act as an ‘Approved Premises’ for the appropriate function, or is listed on the AQIS register of institutions.

Products imported by a commercial distributor

Records (product, dates, batch numbers, amounts, testing and certification) of the imported product and end-user must be maintained. If the product is approved for restricted use and distribution only, the end-user must be an AQIS-registered institution/laboratory. For certain high-risk products, commercial importers may be required to conclude an agreement with AQIS, under an AQD, prior to being granted an import permit.

Audits

Audits of importers – on a ‘fee-for-service’ basis – are conducted by AQIS to ensure compliance with import conditions and AQDs. Due to resource limitations and the need to minimise costs, AQIS uses a structured approach to direct resources to areas of greatest need.

Post-importation testing and treatment

Treatment and testing of the product in the country of origin is encouraged, although it may be possible to test and/or treat a product on arrival, prior to release from quarantine. Importers wishing to make use of this option are required to conclude an agreement with AQIS for this purpose, under an additional AQD.

When post-importation surveillance testing is conducted in Australia, testing for the presence of exotic pathogens is usually conducted by the Australian Animal Health Laboratory (AAHL) in Geelong. Testing for the presence of endemic pathogens is usually performed by laboratories which participate in and meet the standards required by the Australian National Quality Assurance Programme (Veterinary Serology and Virology) (6).

Pathogen testing requirements

Some products require testing for freedom from certain pathogens. Where pathogen testing is required, the testing procedure must be approved for the product concerned by AQIS prior to permit issue. The following documents are used as a guide to testing procedures, but procedures still require prior AQIS approval, as they may need to be adapted to conform with quarantine requirements in Australia:

- the OIE Manual of standards for diagnostic tests and vaccines (14)
- the Australian Standard Diagnostic Techniques for Animal Diseases (6)

- the European Pharmacopoeia.

Approved overseas laboratories

Where pathogen testing is conducted overseas, the testing laboratory must be approved by the appropriate official government authority in the country. In addition, the testing procedures must be approved by AQIS for the particular product, prior to the issue of the import permit.

Where institutions have been inspected or evaluated by a recognised authority in one country, this can obviate the need for other countries to do the same. Inspection of facilities by the Veterinary Medicines Directorate of the United Kingdom, for example, is acceptable to most countries.

Certification

Many products are imported into Australia on the basis that the country and species of origin of raw material, and the processing and/or testing of the product, provide an assurance that it is safe. In most cases, Australia must rely on overseas certification to guarantee origin, processing or testing. The section on 'Import risk analysis' in the OIE International Animal Health Code (13) includes a chapter on 'Evaluation of Veterinary Services'. This provision gives state Veterinary Services in the importing country greater confidence in certification by the exporting country.

Special facilities

Facilities of particular types – such as the AAHL, which is the only facility approved for the handling of most exotic animal disease agents and certain zoonotic agents – require special conditions. This high-security laboratory is authorised to handle exotic agents on an individual basis and with an approved operating procedure for each agent. Such operating procedures might include the use of the following:

- particular precautions in the laboratory (e.g. half suits with supplied air)
- work in Class 1, 2 or 3 biosafety cabinets
- in laboratories with either batch flow or continuous flow, treatment of the liquid effluent specified (batch treatment enables the use of higher temperatures and a longer duration of exposure to heat)
- for some agents, facilities are currently required to have facilities for incineration of exhaust air and double or triple HEPA (high-efficiency particulate air) filtration of exhaust air
- for some agents, the operators must be vaccinated against the agent of concern.

Special procedures have been evolved for the delivery of specimens to the AAHL, their handling at the laboratory, and the disposal of materials. At the AAHL, a Security Assessment Group has been appointed, which conducts an external review of microbiological security at the laboratory.

The external Security Assessment Group works with the microbiological group from the laboratory to review all incidents and the continuing function of the air-pressure differentials within the laboratory, the effluent treatment systems, and other security devices, including autoclaves and decontamination procedures.
Escapes of organisms from high-security laboratories in various parts of the world have demonstrated the need for special surveillance of these laboratories. At the same time, the diagnostic capability of these laboratories is essential for efficient animal disease control.

**COORDINATION WITH OTHER REGULATORY AGENCIES**

AQIS is responsible for quarantine procedures to prevent the introduction of exotic disease. Other features of the use of biologicals require consultation with environmental authorities, authorities governing the use of genetically-manipulated organisms (GMOs), and authorities responsible for the registration of materials for diagnosis or immunobiological use. The principal agencies and their areas of responsibility are described below.

**Department of Human Services and Health**

AQIS consults with the Department of Human Services and Health (DHSH) on materials imported for human use or with implications for human health. This avoids a dual permit system. For example, some human diagnostic kits have constituents derived from animals. The Therapeutic Goods Administration Laboratories (TGAL) of DHSH are responsible for the approval of human therapeutic substances. There is necessary consultation with TGAL on various materials, including speciality (e.g. homeopathic) medicines.

**Australian Nature Conservation Agency**

Formerly the Australian National Parks and Wildlife Service, the Australian Nature Conservation Agency (ANCA) has responsibility for endangered species and certain environmental issues. ANCA is consulted when considering applications for imports of relevant veterinary biologicals.

**Genetic Manipulation Advisory Committee**

The Genetic Manipulation Advisory Committee (GMAC) has responsibility for the release of GMOs and related products. Imported organisms are aligned with Australian requirements by reference to GMAC. This again avoids duplication in permit issuance. The major developments in biotechnology which have occurred in recent years have made it necessary for quarantine risk assessors to be trained in and to understand this discipline.

In practice, once a precedent has been established, GMAC authorises AQIS to handle applications for GMOs and related products.

**Customs Australia (the Australian Customs Service)**

In Australian practice, Customs and quarantine authorities coordinate actions, especially at the point of entry. Imports have to meet both Customs and quarantine requirements. Initially, Customs and quarantine authorities both scanned manifests manually for items of significance. This coordinated action has been preserved in the electronic processing (JEMS) described above.

Coordination of regulatory agencies is also critical in legal action, especially the prosecution of offenders, and in intuitive and covert actions designed to minimise the smuggling of items which present a risk.
The Joint Passenger Declaration at the time of entry is a product of this liaison, and coordinates action against offenders who contravene both Customs and Quarantine Acts.

**Commonwealth Environmental Protection Agency**

The Commonwealth Environmental Protection Agency (CEPA) has responsibility for materials which may affect the environment within the Australian Commonwealth. CEPA requires that regulatory agencies considering materials of significance to the environment make an assessment on behalf of CEPA and report the outcome. This avoids duplication and ensures that the agency with appropriate skills undertakes the primary assessment.

**National Registration Authority**

The National Registration Authority (NRA) has responsibility for the registration of agricultural chemicals and veterinary drugs. AQIS has close contacts with the NRA, particularly in relation to vaccines. The linkage between quarantine risk assessment and 'good manufacturing practice' can be used to ensure continuing innocuity and safety.

**CONCLUSIONS**

It is recognised that not all quarantine procedures for veterinary biologicals can be undertaken at the point of entry (also known as 'the barrier') into Australia. Many modern diagnostic materials require the inclusion of reference antisera raised in animals, even in diagnostic kits for human disease. The development of conditions with which the importer and user must comply, and of the agreement to use the product under the appropriate levels of biocontainment, enables these materials to be imported into Australia to serve essential needs, but also minimises risk of exposure to animals and thus the risk of introduction of exotic disease.

This level of security may not be appropriate for all countries, particularly those which share land borders with neighbouring countries. Some of the procedures described above might be used by regions (i.e. groups of countries) for regional security rather than by individual countries. This approach maximises opportunities for trade with the region.

The elements of the Australian programme form the basis of a regime for quarantine handling of imported biological products and for control of the use of such products within the country. As such, this programme may serve as a model for the development of minimum rules for the harmonisation of international practice in this field.

Acceptance of results of inspections and evaluations of facilities conducted by other countries would minimise costs and facilitate the importation of products into countries which do not have resources for such inspection and evaluation. As many products are prepared by following standard procedures, universal acceptance of the capacity of these products to transmit (or to be free from) specific pathogens would streamline assessment and improve harmonisation.

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SYSTÈMES ACTUELS ET BESOINS À VENIR EN MATIÈRE D'ÉVALUATION DES RISQUES APPLIQUÉE AUX PRODUITS BIOLOGIQUES À USAGE VÉTÉRINAIRE EN AUSTRALIE : PERSPECTIVES OFFICIELLES. - K.A. Doyle.

Résumé : La diversité et la complexité croissantes des produits biologiques, ainsi que l'accroissement de la demande dans ce domaine, ont abouti à une intensification des échanges de matériel biologique d'origine animale. Cette situation a également entraîné une multiplication des approches concernant la réglementation des importations de ce type de matériels, chaque pays cherchant à se protéger contre l'introduction de maladies. L'harmonisation de ces approches réglementaires favoriserait sensiblement la fabrication et la commercialisation de produits biologiques à usage vétérinaire plus nombreux et sûrs.

L'Australie a mis au point des systèmes permettant la classification et l'évaluation des produits biologiques et leur contrôle à l'aide d'autorisations d'importation ; des procédures spécifiques ont également été prévues aux frontières et dans les établissements où ces produits sont utilisés. La tenue de registres et d'historiques informatisés constitue une aide précieuse pour l'évaluation et la délivrance de permis. Comme certains matériels doivent être soumis à des contrôles ultérieurs, un système d'enregistrement des établissements en fonction du niveau requis de sécurité biologique, ainsi que des programmes approuvés d'utilisation et d'élimination, ont été institués. Les établissements impliqués sont variés, allant du laboratoire vétérinaire de haute sécurité à la clinique de fécondation humaine in vitro qui utilise des supports et matériels d'origine animale. Ils sont régis par des contrats de garantie de qualité.

Les autorités chargées des mesures de quarantaine sont en contact avec les autres services intéressés par ces produits. Ce mode de fonctionnement, calqué sur le modèle des administrations australiennes, permet de gérer tous les types de risques. L'auteur décrit ces systèmes et donne un aperçu de leurs fondements biologiques.


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Resumen: La diversidad y complejidad crecientes de los productos biológicos, junto a la mayor demanda de los mismos, se han traducido en un incremento del volumen de intercambios de materiales biológicos de origen animal. Ello, a su vez, y porque los países buscan protegerse contra la introducción de enfermedades, ha dado origen a muchos enfoques distintos sobre la reglamentación de las importaciones de dichos materiales. La armonización de todas estas modalidades reglamentarias contribuiría de modo significativo a la disponibilidad de productos biológicos veterinarios, a su fabricación y comercialización, y a la seguridad sanitaria.
Australia ha desarrollado sistemas que permiten la evaluación y definición de categorías para los productos biológicos, así como su control mediante licencias de importación y la aplicación de procedimientos específicos en los puestos fronterizos y en las instituciones en que tales productos son utilizados. El empleo de registros y procedentes informatizados interviene en la práctica de evaluaciones y en la concesión de licencias. El reconocimiento de que ciertos materiales deben ser objeto de un control posterior ha llevado a la creación de un sistema de registro de instituciones (basado en el nivel de seguridad biológica que ofrecen) y de programas de utilización y eliminación aprobados. Las instituciones consideradas son diversas, desde laboratorios de sanidad animal de alta seguridad hasta clínicas de fertilización in vitro humana, en las que se emplean medios y materiales de origen animal. Tales instituciones son objeto de reglamentación a través de contratos de garantía de calidad.

Las autoridades competentes en materia de cuarentena mantienen vínculos con otras agencias gubernamentales interesadas en estos productos. Estos cuerpos de enlace son reflejo de las estructuras administrativas del gobierno australiano, y aseguran el manejo de todas las formas de riesgo. El autor describe estos sistemas y expone sus fundamentos biológicos generales.


REFERENCES


