
8 THE INTEGRITY OF THE SYSTEM

8.1 Introduction

Demonstrable integrity in the measures and activities taken to meet Australia's biosecurity requirements is vital. This is true whether the National Biosecurity Authority is relying on (and then auditing) actions taken by others or applying the measures itself.

This is not a new insight. The Nairn Report recommended adoption of a total quality management approach to the development and implementation of biosecurity policies and programs. Total quality management is recognised as fundamental to successful business practice throughout the economy.

Commissioner Callinan made specific recommendations in relation to auditing and verification. While his Inquiry was limited to the equine influenza outbreak, a number of his comments pointed to more systemic failures. His findings were referred to the Panel by the Minister for Agriculture, Fisheries and Forestry.

8.2 Current arrangements

8.2.1 Auditing

Ensuring that Australia's biosecurity activities are managed effectively is a complex task. There are many risks to be controlled at different sites, by different jurisdictions, both within Australia and offshore. Inherent risks change, patterns of trade change, and so therefore do the appropriate risk management measures. To ensure these risks are being managed or controlled, inspection activities are placed at appropriate points along the continuum.

An effective risk management system should also include formal auditing activities. Auditing provides a structured process of checking the inspection system to obtain the evidence needed to verify the extent to which the biosecurity measures are being met. It also provides a mechanism to detect and respond to changes more effectively. Auditing improves the overall confidence in the system and can be conducted internally by AQIS or externally by an independent agent. Both inspection and audit functions are verification activities. The definitions for these terms are in Box 27.

BOX 27 Definitions

Inspection – Examination of product or systems for biosecurity control of animal, plant, food and human health including in-process and finished product testing, in order to verify that they conform to requirements.

Audit – Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which the criteria are fulfilled. The *audit* process includes a desk assessment of documentary material and where necessary, on-site verification through an examination of the systems in place.

Verification – Confirmation through the provision of objective evidence that specified requirements have been fulfilled. Includes *Inspection* and *Audit* activities.

Audit activities can be categorised as follows.

- Internal audits are carried out by an internal group which is independent of line management and can report directly to the chief executive officer (for example, compliance programs or national verification systems).
- External audits are conducted by independent bodies such as the Australian National Audit Office or an importing country's authorities. Some other countries have specialist external audit functions concerned with biosecurity. In Europe this role is played by the Food and Veterinary Office, and in the United States by specialists within the office of the Inspector General for the Department of Agriculture.

Internal audits are designed to improve the operations of an organisation. They provide a systematic approach to evaluating the internal control environment as well as assessing broader management processes. Internal audit programs should review:

- program implementation to assess compliance with objectives and whether operations are being carried out as stipulated;
- compliance with policies, procedures and legal obligations, including international treaties;
- the effectiveness of management systems; and
- financial management and the efficiency and effectiveness with which resources are used.

External audit provides additional verification that systems are achieving objectives. It also provides independent and public assurance that the system, including the internal audit process, is performing and has the ability to respond appropriately to changing patterns of risk.

8.2.2 Internal audit systems

AQIS audit activities include verifying import and export inspection and certification programs and compliance agreements with businesses. AQIS also audits private or other government agencies that perform regulatory activities on its behalf, such as privately run Quarantine Approved Premises and food export inspection functions conducted by state authorities.

Auditing activities for imports

The auditing activities for imports can be separated into pre-, border and post-border systems. In general, current audit arrangements focus on requirements for import permits. For example, import requirements often include evidence of inspection by an overseas authority or some form of treatment such as fumigation. This evidence is usually in the form of a certificate. There has been little systematic audit of the controls or systems that underpin certification, except in relation to fumigation.

Offshore systems audits are an example of **pre-border** audit and verification. They are occasionally conducted by AQIS and Biosecurity Australia and can take a number of forms, from a desk audit of information supplied by individual facilities to an extensive *in situ* audit of official controls over whole supply chains. These audits improve confidence that Australia's import requirements are being met.

A **border** example is the auditing by AQIS of effectiveness measures associated with Increased Quarantine Intervention targets. This is to ensure the pre-determined inspection targets are being met consistently and are effective in detecting items of biosecurity concern.

For imported foods, AQIS accepts certification from competent authorities of exporting countries in lieu of routine border testing. In most cases the foreign government's certification has been accepted primarily on the basis of desk audits by AQIS of the relevant foreign export inspection and certification system. This is supplemented by randomly inspecting 5 per cent of imported product at the border to audit the validity of the system that underpins the certification. As noted in Chapter 7, AQIS does not have the legal ability to audit the food safety management systems implemented by Australian import businesses.

Border audit activities also include arrangements for Quarantine Approved Premises and compliance agreements with importers.

AQIS categorises Quarantine Approved Premises according to the activities they undertake. AQIS determines the appropriate level of biosecurity containment that is needed and then specifies their auditing requirements.

A failure to comply with AQIS requirements results in a corrective action request. This may lead to a follow-up audit visit to validate resolution of the issue, greater audit frequency, or in cases of significant non-compliance, a suspension of the agreement with AQIS until the corrective action is undertaken.

Similarly, AQIS has compliance agreements with registered importers and conducts audits based on an assessment of risk (see Chapter 4).

An example of **post-border** audit arrangements is the Animal Health Performance Standards, a self-assessment arrangement developed by government and business organisations. The Animal Health Performance Standards ensure that contributors to Australia's animal health system perform to appropriate standards in all activities that affect Australia's animal health status.

In addition, a number of national exotic pest and disease preparedness exercises have tested the effectiveness of Australia's response strategies. The best known recent examples are Exercise Minotaur, which was conducted in 2002 for foot and mouth disease, and Exercise Eleusis, conducted in 2005 for avian influenza.

Auditing activities for exports

AQIS has relatively well-developed inspection and auditing activities to verify export risk management systems. Export establishments are registered on the basis that AQIS will conduct:

- inspections to verify that export products meet importing country requirements; and
- regular audits to confirm that establishments remain compliant with their approved arrangements and legislative requirements.

Arrangements for the export meat program are outlined in Box 28. Audits are not always conducted by AQIS itself, for example, dairy export establishments are audited by state regulatory authorities. Organic/biodynamic products are audited by AQIS-accredited certifying organisations.

Internal compliance investigations

The AQIS Compliance and Investigations Branch is responsible for detecting, investigating and prosecuting breaches of quarantine and imported food legislation. Its role includes the application of product integrity standards under export legislation, working with businesses to reduce non-compliant behaviour and identifying and reporting regulatory risks to AQIS management. This Branch is the only regulatory area within AQIS that has achieved full certification to ISO 9000 Quality Management Systems.

BOX 28 Export Meat Program – inspection and audit activities

Industry and third party verification: registered export meat establishments have a quality system that is monitored via an AQIS internal audit and systems review. AQIS verification occurs on a daily basis at abattoirs and most boning rooms, but only annually in the case of meat freight forwarders. Audit frequency also depends on the importing country requirements and the history of a company's compliance.

Supervisory verification: AQIS Area Technical Managers conduct monthly performance evaluations of AQIS on-plant inspection activities.

Program verification: AQIS Field Operations Managers undertake critical analysis and audit of registered meat establishments. They also oversee the implementation of any corrective actions that resulted from overseas audits.

In addition to routine verification audits, a systematic check of specific aspects of an export meat establishment's Approved Arrangement is undertaken according to the AQIS National Establishment Verification System. Different activities are the focus of monthly checks (for example, pest control and good hygienic practices). This ensures that over a twelve month period there is a comprehensive check of a range of specified activities across the establishment's approved meat inspection program.

Internal verification: AQIS has a National Verification Unit to ensure that the meat inspection program has control systems in place (documented and implemented) to manage legislation, importing country requirements and certification. The National Verification Unit audits the National Establishment Verification System each year and includes some site visits.

External verification: The main form of external verification comes from trading partners auditing Australia's export meat program. In 2007, external systems audits were conducted by Taiwan, the European Union, the United States of America, Russia and Malaysia.

8.2.3 External systems

External audits and reviews are undertaken on various elements of Australia's biosecurity system. Some specific examples include:

- reviews by the Quarantine and Exports Advisory Council of the Northern Australia Quarantine Strategy, the Import Clearance Program and regular advice on AQIS quarantine and exports programs;
- Australian National Audit Office performance audits, such as *Managing for Quarantine Effectiveness* (2001a and 2005) and *Export Certification: Australian Quarantine and Inspection Service* (2006); and
- the *Review of Australia's Quarantine Function* conducted by the Australian Parliament's Joint Committee of Public Accounts and Audit (2003) focused on Increased Quarantine Intervention funding.

AQIS has also contracted private consultants to audit specific areas of its quarantine programs. For example, Ernst & Young has conducted a number of reviews of AQIS systems including *A Review of Lapsing Quarantine Funding* (2004) and *A Review of Quarantine Border Security Strategy and Policies* (2007).

Australian export programs are also subject to regular external assessment and evaluations by trading partners (see Box 28). The purpose of these evaluations is to provide the importing country with confidence that AQIS is competent to act as its agent in ensuring that export requirements are met. For example, the European Commission has conducted five audits since 2005 of various aspects of Australia's export system.

8.2.4 International auditing standards

The International Organization for Standardization has developed auditing standards and guidelines for conformity assessment, such as ISO/IEC 17021: 2006 – *Conformity assessment - Requirements for bodies providing audit and certification of management systems* and ISO 19011: 2002 – *Guideline for quality and/or environmental management systems auditing*. The ISO standards form the basis of complementary work undertaken by the OIE, the International Plant Protection Convention and the Codex Alimentarius Commission.

These international bodies are now also directing effort to develop auditing standards to cover the assessment of food safety and animal and plant health. The OIE has recently developed a tool for assessing countries' veterinary services—the Performance of Veterinary Services tool. The OIE is carrying out a program of training assessors in the use of this tool, and conducting assessments mainly on developing countries. The assessments include country visits or audits by teams of assessors, including some from Australia. Over 50 countries have already been assessed and audited with a similar number being assessed over the next two years. It is possible that this tool will be accepted as a *de facto* standard in the future and countries, including Australia, will expect to see the results of a Performance of Veterinary Services assessment as part of normal trade negotiations.

The Codex Alimentarius Commission has guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1999). These guidelines include procedures enabling an importing country to assess and verify the inspection and certification systems of an exporting country. The Codex Alimentarius Commission also recently approved new work on the development of *Principles and Guidelines for the Conduct of Foreign On-site Audits*.

The International Plant Protection Convention has a Phytosanitary Capacity Evaluation tool that can be applied to identify gaps in a biosecurity system. It is essentially a technical assistance tool for developing countries and has not yet been applied to the Australian phytosanitary system. The tool does not define acceptable levels of capacity—it is up to the country to determine what level of phytosanitary systems it needs.

Like Australia, many countries have developed official auditing systems to verify that their domestic produce and imported goods meet specified standards. The European Commission's Food and Veterinary Office has developed a significant auditing program that is applied to imported food and agricultural products (see Box 29).

BOX 29 The European Commission's Food and Veterinary Office

The Food and Veterinary Office, based in Grange, Ireland, conducts assessments to ensure compliance with European Commission's import requirements by both domestic producers and those countries that export to the European Union. Its mission is to:

- promote effective control systems in the food safety and quality, veterinary and plant health sectors;
- check on compliance with the requirements of European Union food safety and quality, veterinary and plant health legislation within the European Union and in third countries exporting to the European Union;
- contribute to the development of European Union policy in the food safety and quality, veterinary and plant health sectors; and
- to inform stakeholders of the outcome of evaluations.

The Food and Veterinary Office develops an annual inspection program that is published on its website. The program focuses on priority areas and countries for inspection. Each inspection results in a report, together with conclusions and recommendations that are published (at the draft stage) on its website. The relevant competent authority may comment before a final report is published.

Australia is subject to periodic audits conducted by the Food and Veterinary Office for a number of commodities. In 2007, the Office conducted audits to assess fisheries products including aquaculture products and live bi-valve molluscs; milk and milk-based products, bovine semen for artificial insemination, programs covering public health and animal health related to red meat production.

Source: http://ec.europa.eu/food/fvo/index_en.htm

The United States Department of Agriculture's Office of the Inspector General was established in 1978 to perform independent audits of the Department's programs and operations. Its responsibilities are outlined below (see Box 30).

BOX 30 United States Department of Agriculture’s Office of the Inspector General

The *Inspector General Act of 1978* requires the Inspector General to independently and objectively:

- perform audits and investigations of the United States Department of Agriculture’s programs and operations;
- work with the United States Department of Agriculture’s management team in activities that promote economy, efficiency, and effectiveness or that prevent and detect fraud and abuse in programs and operations, both within the United States Department of Agriculture and in non-Federal entities that receive United States Department of Agriculture assistance; and
- report its activities to the Secretary of the Department and the United States Congress every six months.

Source: <http://www.usda.gov/oig>

8.3 Current debates and views in submissions

It was put to the Panel that there are significant shortcomings in the current approach to auditing and verifying the integrity of Australia’s biosecurity systems across the continuum. The need for a more strategic approach has been emphasised, in particular through:

- improved pre-border audit systems to ensure that Australian import requirements are being met;
- improved auditing and review of border inspection arrangements; and
- auditing the appropriateness of post-border emergency preparedness and pest and disease surveillance activities.

Examples of criticisms made in submissions to the Panel include:

‘While it is understood that some breaches are to be expected, the current system has no independent auditing of the delivery of the quarantine service by AQIS.’ (Western Australian Government submission, p. 14)

‘To ensure that the AQIS facilities are effective in managing the substantial risks, a system of independent audit should be introduced.’ (Peter Lawrence and David Spence submission, p. 4)

This issue was also examined by Commissioner Callinan who made a number of recommendations in relation to internal and external audit arrangements for the importation of horses. He found that:

‘... policies current at August 2007 did not provide for premises to be approved and inspected by AQIS, Biosecurity Australia or another qualified person before they could be used for pre-export quarantine. Nor did they require that such premises have fully documented procedures drawn up in accordance with a Hazard Analysis Critical Control Point system. Nor were there any arrangements for implementation of those procedures to be audited from time to time by AQIS, Biosecurity Australia or another qualified person. Introduction of those measures would reduce risk of infection of horses during pre-export quarantine.’ (Callinan 2008, p. xxiv)

Commissioner Callinan formed the view that there were three areas where implementation of biosecurity measures needed to be checked regularly. These were:

‘... the proposed written procedures for pre-export quarantine facilities; the other requirements imposed by the import conditions before a horse is transported to Australia; and the operating procedures for the clearance and quarantine of horses once they arrive in Australia.’ (Callinan 2008, p. xxvii)

Commissioner Callinan argued that compliance in these areas should be subject to regular checking and reporting to the Minister. In Commissioner Callinan’s view, past shortcomings were such that this role should not be undertaken by AQIS or Biosecurity Australia, to ensure an appropriate level of independence. He therefore recommended that an external auditor be appointed for this function (the Inspector General of Horse Importation). In addition, he recommended that a senior person within AQIS be appointed to take responsibility and accountability for the oversight of horse importation. Commissioner Callinan pointed out that these positions were required because:

‘... of the number of different AQIS national programs and regions engaged in the formation or implementation of policy for the importation of horses and the position and role of Biosecurity Australia.’ (Callinan 2008, p. xxvii)

8.3.1 Lack of consistency and a systematic approach

The Panel noted discrepancies in the approach to quality management procedures used across AQIS programs. This was particularly evident in comparing systems for export and import programs. As mentioned earlier, an auditing approach is used in export programs, with exporting businesses required to have business management systems in place based on elements of ISO 9000 Quality Management Systems. The ISO system includes internal review,

training, corrective action and incorporates food safety controls such as Hazard Analysis and Critical Control Points. Requirements for importing businesses are less prescribed, hence system auditing is more problematic.

The differences between the audit systems for exports and imports may be attributed at least in part, to the incentives that drive compliant behaviour of stakeholders. For exporters there are powerful incentives to ‘get it right’, with inspection rates linked to performance, sanctions for non-compliance and the ever present threat of the loss of priority overseas markets. For imports, specific inspection rates are driven by mandated and rigid Increased Quarantine Intervention targets that do not provide clear incentives or reward compliance with import requirements.

Differences in approaches taken at the Eastern Creek and Sandown Quarantine Stations were also found by Commissioner Callinan. He noted that the use of systems such as Hazard Analysis and Critical Control Points, and a review or audit of procedures had not occurred at the Eastern Creek quarantine station, observing that:

‘For the purposes of overcoming biosecurity deficiencies, the documented procedures applying at the privately operated quarantine facility for horses at Sandown in Victoria provide a useful and obvious point of comparison.’ (Callinan 2008, p. 250)

Some submissions to the Panel linked program-level differences to AQIS management arrangements. For example, the Community and Public Sector Union claimed inconsistent work practices from region to region, despite the fact that regional programs are supposed to operate as a national program (Community and Public Sector Union submission). Other observations included:

‘Existing monitoring and review mechanisms for biosecurity and quarantine are not always effective. Areas of potential weakness include validation, verification and sanctions polices for operational areas.’ (Western Australian Government submission, p. 14)

‘One of the essential bases of third party certification is independent auditing of the certifying agencies. This principle needs to be extended to program delivery within AQIS to ensure consistency of delivery, continual correction of shortcomings and continual improvement in the standards.’ (Quarantine and Exports Advisory Council submission, p. 18)

A number of stakeholders expressed the view that improved business management systems would identify and correct these inconsistencies, leading to more reliable delivery of services. For example, the New South Wales Department of Primary Industry submission recommended a quality assurance approach.

‘There is a need for a Quality Assurance system to be implemented within the pre-border and border quarantine system to ensure consistency of operations and to instil an ongoing commitment to continual improvement.’ (NSW Department of Primary Industry submission, p. 5)

8.3.2 Lack of clear internal auditing procedures

There does not appear to be a clearly defined, consistent or systematic policy for auditing the various programs and controls along the biosecurity continuum. Moreover, without effective data from routine audits, it is more difficult to make improvements to risk control systems based on data analysis.

This shortcoming appears especially acute for pre-border import systems. The current pre-border evaluation system is variable in terms of scope, auditor competency standards, reporting and subsequent approval processes. Several submissions proposed the establishment of a dedicated audit unit within AQIS.

‘It is QEAC’s view that the delivery of all quarantine and market access programs within AQIS should be subject to audit by a dedicated audit unit.’ (Quarantine and Exports Advisory Council submission, p. 18)

‘Consideration should be given to having a dedicated group within the department that provides an internal audit function of operations. I am aware that some Programs in AQIS have gone down this path (e.g. Verification Unit in Import Clearance) however this should be expanded across all Programs that deliver Quarantine functions.’ (Greg Hankins submission, p. 1)

Lack of a clear policy has the potential to expose Australia to domestic and international criticism regarding consistency in audit application. Australian Pork Limited argued that audits must be able to be defended as being equivalent to those applied to similar goods produced within Australia to avoid substantive criticism.

‘APL believes that in the interests of equivalency, standards the same as, or procedures shown to be in practice equivalent to current Australian standards, must be in place in establishments approved to export to Australia.’ (Australian Pork Limited submission, p. 32)

8.3.3 Enhanced use of pre-border audit and inspection

The need for a regular pre-border audit and inspection program was discussed in a number of submissions, particularly in relation to the certifications provided by foreign governments or manufacturer declarations.

‘Regular inspection or audit of exporting country regulation of pre-border activity is needed.’ (Australian Veterinary Association submission, p. 18)

‘APL has sought verification from both BA (during the IRA process) and AQIS as to how it satisfies itself that overseas abattoirs and processing plants conform to Australian standards, that audits by Australian authorities are of an equivalence and intensity expected of Australia by its competitors and how it intends to address the issues of identification and segregation.’ (Australian Pork Limited submission, p. 32)

The approach to auditing pork producing establishments, following the pigmeat Import Risk Analysis in 2004, provides a useful case study. Audits were undertaken by AQIS in a number of countries, including the United States, Finland, Denmark, Italy, Spain and the United Kingdom, over the period 2004 to 2007. While these assessments were conducted professionally, they lacked transparent policy guidelines or clearly defined audit management programs. Pigmeat products can now be imported providing the mandatory animal health certification is attached. However, there is no strategic program to monitor compliance in these countries on a risk assessed basis. Ensuring compliance relies on the border inspection process.

A more comprehensive approach is applied under the Australian Fumigation Accreditation Scheme where a pre-border audit program identifies off-shore control points that need to be targeted to ensure compliance with Australia’s fumigation requirements. The Scheme is unique in that it educates fumigators and the government certification authorities on Australia’s requirements as well as having a follow-up audit system to ensure compliance. Several submissions pointed to the Australian Fumigation Accreditation Scheme as an example of how effective auditing combined with education awareness programs can help mitigate pre-border risks.

Following the outbreak of equine influenza, AQIS introduced a systematic approach to the supervision of pre-export quarantine facilities for horses, including inspecting all consignments and facilities prior to shipment. To date, it has been on a consignment by consignment basis rather than system-wide.

8.3.4 Lack of independent external systems audit

As mentioned previously, external audits are conducted by various importing countries (for example, the European Commission’s Food and Veterinary

Office) or by the Australian Government. These audits have provided useful recommendations that have been acted upon by AQIS. However, in general, independent audits conducted by the Australian Government have focused on AQIS business performance, including its financial and legal functions, rather than an assessment of systematic risk management efforts.

Commissioner Callinan recommended the establishment of an Inspector General of Horse Importation with a high, statutorily guaranteed, level of independence. The Australian Veterinary Association supported the broadening of this position to cover all commodities.

‘The Callinan Inquiry has directed discussion toward an independent Inspector General for horses. This person could monitor/ audit such activities and for all commodities.’ (Australian Veterinary Association submission, p. 18)

8.4 Panel’s consideration

Improvement in the performance of biosecurity functions across the continuum is imperative. There is evidence that the lack of a rigorous auditing and verification system identified by Commissioner Callinan in the horse context is systemic. The Panel has concluded that there is a real need to improve the management of policies and programs and to verify the effectiveness of risk management activities. There is a need for quality assurance processes for biosecurity systems, including those that are shared between the Commonwealth and the states and those that are managed by the private sector to meet Commonwealth requirements.

8.4.1 A uniform business approach to risk management

Functions carried out by AQIS need to be comprehensive and uniform. The Panel considers that the National Biosecurity Authority needs a rigorous system incorporating clear specifications and standards, backed by objective assurances provided via internal and external audit. These are fundamental to good business management. They need to contain a commitment to continuous planning, sufficient information technology support and review processes that lead to routine corrective adjustments. Specific elements that the Panel considers critical for reliable implementation of biosecurity functions include:

- adoption and maintenance of a quality management approach;
- validation procedures to ensure that risk management measures and service delivery models applied address identified risks in the most effective way;

- verification that the activities implemented to deal with risk are appropriate to the task;
- documentation control, particularly where requirements may be varied following review, and clear status of the documentation available to staff, businesses and other stakeholders;
- program planning that includes measureable performance indicators;
- implementation of a staff training policy for auditing;
- a sanctions policy to deal with non-compliant implementation of requirements;
- a reward and penalty policy to enable recognition of consistent compliance;
- legislative capacity to effectively trace goods beyond the border; and
- good business practices in the spheres of communication, complaints handling, and document control.

The Panel acknowledges that within AQIS programs, there is a range of quality assurance systems. The ISO 9000 certification of the Compliance and Investigation Branch and the procedures and systematic approach of the Australian Fumigation Accreditation Scheme show the benefits of defined documented systems that include internal audit programs. Other programs have elements of quality management approaches, such as the recent (post-Callinan) development of Standard Operating Procedures and work plans. However, these alone will not achieve better assurance systems with inbuilt feedback loops. Existing elements should be recognised with the objective being to upgrade the organisation's management systems and capability.

Recommendation

- 65 The National Biosecurity Authority should develop quality management systems that:
- incorporate consistent quality management approaches across its programs;
 - include periodic audit of external assurances such as official certification provided by overseas authorities and accredited third-party systems; and
 - include, where relevant, ISO 9000 and other quality standards in introducing these quality management strategies and systems.

8.4.2 Improving internal auditing systems

As part of effective risk management systems, the National Biosecurity Authority should have a strong internal audit capability. Similarly, sufficient

resources and information technology support to enable data collection and analysis are essential. Fundamental requirements for auditing systems include consistency with World Trade Organization Members' obligations, with particular reference to the SPS Agreement and relevant international guidelines and standards.

The audit activities should cover the biosecurity continuum as follows:

- pre-border assessments and audits that include competent authority evaluations; animal and plant pest and disease status (including recognition of regions or compartments as free of pests and diseases); individual commodity evaluations (for example, pigmeat and citrus); risk pathway evaluations (mail and shipping containers); and treatment evaluations (for example, the effectiveness of fumigation and irradiation treatments);
- assessments and auditing of border inspection control points to verify their effectiveness, including imported goods and transport (ships, aircraft, and containers) and passengers; Quarantine Approved Premises and Pre- and Post-Entry quarantine stations; and
- post-border assessments and auditing of government and business biosecurity plans; emergency preparedness plans; animal and plant health performance standards; monitoring and surveillance activities for national priority exotic pests and diseases; and product integrity systems.

The Panel considers that to achieve a consistent risk-based systems approach to auditing, a unit should be established within the National Biosecurity Authority to undertake these tasks. The unit should work closely with the pest and disease intelligence gathering and assessment group (see Chapter 7). It should also audit across the continuum by examining pathways, especially for linkages between pre-border and border control systems. There also needs to be greater accountability and responsibility for auditing post-border biosecurity arrangements.

The program of audits and their reports should be provided to the Director of Biosecurity and the National Biosecurity Commission. The Panel recommends that the National Biosecurity Commission should determine the audit activities to be conducted by the National Biosecurity Authority in relation to Biosecurity Import Policy Determinations. The Commission should also review the overall audit program of the Authority and advise the Director of Biosecurity on its appropriateness.

The Panel also recommends that the National Biosecurity Authority recognise and adequately resource and train enforcement officers with a

remit to cover biosecurity issues along the continuum. Enforcement officers should have the ability to conduct investigations, to support prosecutions for offences against all the legislation the Authority administers and, subject to agreement with the Director of Public Prosecutions, carry out prosecutions for minor offences.

AQIS uses ‘on-the-spot’ fines (infringement notices) for quarantine offences by travellers, administered within the Airports Program. The Panel’s view is that the biosecurity legislation should widen the range of pecuniary penalties for misdemeanours and the use of infringement notices should be expanded beyond the airports environment to include other quarantine breaches that are high in volume with minimal complexity.

The new infringement notice scheme should be consistent with Commonwealth guidelines on infringement notice schemes (such as Australian Law Reform Commission report number 95, *Principled Regulation: Federal Civil and Administrative Penalties in Australia*) and match other ‘best practice’ infringement notice schemes such as the *Customs Act 1901* model.

The issuing of an infringement notice should be consistently applied and administered for all undeclared and misdeclared quarantinable items (see Chapter 4). The Panel believes that consideration should be given to making them non-discretionary. This would require a prior public awareness program and very clear warning to inbound passengers, customs brokers and others engaged in trade or tourism. This would act as a quick and visible deterrent. New Zealand has operated such a scheme and reports considerable success in reducing the incidence of undeclared biosecurity risk items.

The National Biosecurity Authority should make arrangements with the Director of Public Prosecutions to cover proceedings for all prosecutions including pecuniary penalties. These arrangements should be agreed under a memorandum of understanding, or similar agreement, such as those between the Director of Public Prosecutions and the Australian Tax Office and Australian Securities and Investments Commission. The Director of Public Prosecutions will maintain its role in relation to all prosecutions:

- for minor offences, the National Biosecurity Authority would issue pecuniary penalties under the broad supervision of the Director of Public Prosecutions to ensure consistency with the prosecution policy of the Commonwealth; and
- for all other offences, the National Biosecurity Authority would investigate and refer matters to the Director of Public Prosecutions to determine whether a prosecution should be instituted.

Recommendations

- 66 The National Biosecurity Authority should establish an internal audit group to inquire and report on the adherence by the Authority to its policies and their adequacy to deal with risks across the biosecurity continuum.
- a The responsibilities of this group should include both financial and performance audits of the Authority's programs.
 - b The internal audit program should cover the National Biosecurity Authority's activities over an audit cycle.
 - c The audit reports should be provided to the National Biosecurity Commission and the Director of Biosecurity.
- 67 In relation to the National Biosecurity Authority's internal audit program, the National Biosecurity Commission should have:
- a a determinative role for audit activities that relate to Biosecurity Import Policy Determinations; and
 - b an advisory role in relation to the overall internal audit program.
- 68 The National Biosecurity Authority should maintain an enforcement branch with the resources and expertise to investigate breaches of the biosecurity legislation, with this function being afforded a high priority. Arrangements should be made with the Director of Public Prosecutions in relation to the conduct of prosecution of offences against the biosecurity legislation including to provide:
- a protocols to facilitate the commencement of proceedings by the Authority in cases involving the non-payment of infringement notices which cover high-volume matters of minimal complexity; and
 - b for the recovery of pecuniary penalties by the Authority.

8.4.3 Improving independent audit systems

The Panel considers that independent audits provide indispensable assistance in verifying the performance of individual programs and providing an objective overview of the organisation. As indicated in Chapter 3, the Panel recommends an independent audit function to assess activities along the biosecurity continuum through the establishment of the position of the Inspector General of Biosecurity. The Panel noted that the United States Department of Agriculture has a somewhat similar Office of the Inspector General.

The Inspector General of Biosecurity should be located within the Department of Agriculture, Fisheries and Forestry. The Minister should be able to refer matters to it and commission it to investigate matters and report to him/her. The Inspector General's powers should include the ability to obtain access to

premises and documents sufficient to ensure that all parts of the biosecurity continuum are comprehensively assessed. This task would include the audit of biosecurity programs related to health and environment responsibilities that are currently undertaken by AQIS on behalf of the Department of Health and Ageing and the Department of the Environment, Water, Heritage and the Arts.

The time periods for audits will be determined by the Inspector General of Biosecurity on a systematic risk-based approach, for example, every five years, annually, or on an *ad hoc* or even random basis, depending on the component to be audited and its risk.

The Inspector General of Biosecurity would be required to provide regular independent reports to the Minister for Agriculture, Fisheries and Forestry on the performance of the risk management measures across the biosecurity continuum. These reports would be copied to the Director of Biosecurity and the National Biosecurity Commission to provide valuable feedback to improve biosecurity programs and systems. These reports would be publicly available (unless there were very specific reasons to the contrary) to improve accountability and therefore the public confidence in the process.

Regular communication between the Inspector General of Biosecurity and the Director of Biosecurity would be critical. The Inspector General of Biosecurity should be free to contract auditing to outside bodies that meet specified requirements. The Biosecurity Advisory Council should also provide advice to the Director of Biosecurity on inspection and audit activities.

The establishment of the Inspector General of Biosecurity will not preclude compliance and performance assessments and reviews conducted by the Australian National Audit Office. The Panel regards these audits and reviews as particularly useful in providing external accountability on the performance of biosecurity programs.

Audits are also conducted by the competent inspection authority of overseas governments. These audits provide an additional layer of accountability, particularly for our export certification systems. Their results need to be incorporated into the feedback loops to management.

It will be to Australia's advantage to create a specialist independent audit function. Its existence will provide trading partners with additional comfort about the effectiveness of Australia's biosecurity system. This can be important in negotiations concerning both market access and in relation to measures adopted or proposed by Australia with respect to imports.

Recommendations

- 69 The Minister for Agriculture, Fisheries and Forestry should be enabled under the legislation to require the Inspector General of Biosecurity to inquire into any matter which is the responsibility of the National Biosecurity Authority.
- 70 The Inspector General of Biosecurity should develop a program of audit on appropriate timescales (for example, five years, one year and to allow for *ad hoc* audits).
- 71 The Inspector General of Biosecurity should provide regular independent reports to the Minister with these reports copied to the Director of Biosecurity and the National Biosecurity Commission. These reports should be made public unless a strong contrary reason exists. The Director of Biosecurity and the National Biosecurity Commission, as relevant, should report to the Minister on actions taken on recommendations by the Inspector General. The reports and responses to them should be reflected in the National Biosecurity Authority's annual report to Parliament.
- 72 The Biosecurity Advisory Council should provide advice on inspection and audit activities to the Director of Biosecurity.