

Quarantine and Biosecurity Review

Issues Paper

Quarantine and Biosecurity Review Panel

14 March 2008

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PART A – INTRODUCTION

A1. Quarantine and Biosecurity Review

1. On 19 February 2008, the Minister for Agriculture, Fisheries and Forestry, the Hon. Tony Burke MP, announced a major, independent review of Australia's quarantine and biosecurity arrangements.
2. A Panel has been appointed to undertake the Review and provide recommendations to the government by 31 July 2008. The Panel members are:
 - Mr Roger Beale AO (Chairman);
 - Dr Jeff Fairbrother AM;
 - Mr Andrew Inglis AM; and
 - Mr David Trebeck.
3. The Panel has been asked to provide recommendations on the appropriateness, effectiveness and efficiency of:
 - current arrangements to achieve Australia's appropriate level of protection;
 - public communication, consultation and research and review processes;
 - resourcing levels and systems and their alignment with risk in delivering requisite services; and
 - governance and institutional arrangements to deliver biosecurity, quarantine and export certification services.
4. Information regarding the Review, including the full Terms of Reference and a brief biographical note on each of the Panel members, is available at www.quarantinebiosecurityreview.gov.au

Consultation during the Review

5. The Panel will consult widely during the Review and expects to receive submissions from domestic and international parties. The Panel will be meeting with interested international parties and also intends to travel to each state and territory to discuss submissions with key stakeholders.

Purpose of this issues paper

6. This paper is a guide for people preparing submissions to the Review. It sets the scene for the Review and highlights a number of issues that the Panel has identified for further consideration. The paper also poses specific questions to spark discussion. However, people should not feel constrained by the questions and are welcome to draw any relevant matters to the Panel's attention in their submission.

Making a submission

7. Submissions are due by close of business on **11 April 2008**.
8. All submissions will be lodged on the website after the Panel has authorised their publication. If you have concerns regarding the confidentiality of part of your submission, please discuss those concerns with the Quarantine and Biosecurity Review Secretariat on 1800 196 192. The requirements of the *Freedom of Information Act 1982* and the *Privacy Act 1988* will apply.
9. Submissions should be emailed to quarantinebiosecurityreview@daff.gov.au

10. If email is not possible, please send to:

Quarantine and Biosecurity Review Secretariat
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

or fax to: *from overseas* +61 2 6272 5825

from within Australia 02 6272 5825

11. Please include a coversheet (downloadable from the website) with your submission.

PART B – CONTEXT AND BOUNDARIES

B1. Quarantine and biosecurity

12. The terms “quarantine” and “biosecurity” have often been used interchangeably. Biosecurity is a relatively new term and its definition is significantly broader than the concern for exotic pests, weeds and infectious agents that is the traditional focus of quarantine. For the purposes of this Issues Paper, the following definitions have been adopted:
- **Biosecurity** is the protection of the economy, environment and human health from the negative impacts associated with entry, establishment or spread of exotic pests, diseases and weeds.
 - **Quarantine** is the system of measures which are used to manage risks of the entry and establishment of pests or diseases which threaten animal, plant or human health.

Scope of the Review

13. The objective of Australia’s quarantine and biosecurity policies and risk management measures is to enhance the national interest through a science-based process that manages the risk of the entry, establishment or spread of pests and diseases not present in Australia that could cause significant harm to people, animals, plants and other aspects of the environment.
14. This Review will focus on exotic pests and diseases and will not address the spread, within or between states, of endemic pests or diseases (see Box 1).

Box 1: Description of terms

Exotic pests and diseases are those pests and diseases which are not yet present in Australia, or which have yet to become established. Examples include equine influenza, citrus canker, bovine spongiform encephalopathy (BSE or “mad cow disease”) and Siam weed.

Endemic pests and diseases are those pests and diseases which are established in Australia. Examples include sugar cane smut, ovine Johne’s disease, bridal creeper and cane toads.

A pest or disease is considered to be **established** if it has survived and continued to spread within Australia’s animal populations or plant species for a sufficiently long enough period of time after its entry into Australia for it to be considered unlikely to be eradicated.

15. The risks posed to human health, agriculture, forestry, fisheries and the environment by exotic pests and diseases are all included.
16. The rapid growth and changing patterns in international trade (see Part B3) mean Australia faces increased risks that exotic pests and diseases can be accidentally introduced by passengers, imported commodities, packaging material and transport vessels (such as cargo containers). The Review will be examining these risk pathways. Australia has contributed to this growth in international trade as an exporter, and its pest and disease status and access to overseas markets is an important consideration.
17. The Review will also consider the possible arrival, establishment and spread of exotic pests and diseases through natural pathways (such as migratory birds) that may transmit exotic pests or diseases.

18. The Review will not be considering the level at which Australia has set its **appropriate level of protection (ALOP)** – which is at a level aimed at reducing risk to a very low level, but not to zero. Australia’s rights and obligations as a signatory to the World Trade Organization (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement) are also not under review.
19. In addition, gene technology issues (including Genetically Modified Organisms), chemical residue regulation or public health systems will not be considered, other than where services in relation to these matters are provided by the Australian Quarantine Inspection Service (AQIS), where there is apparent regulatory overlap, or where they illustrate alternative regulatory approaches worthy of consideration.

B2. Australia’s system

International obligations

20. Australia is fortunate to be relatively free of many of the serious animal and plant pests and diseases that exist in most other countries. This favourable situation provides Australia’s export-oriented agricultural industries with an advantage in global markets. It is also important for maintaining the unique characteristics of Australia’s natural environment. Managing threats is an essential function of the quarantine and biosecurity system.
21. WTO agreements are the legal foundation for the international trading system. The two main agreements that concern the technical conditions for trade in agricultural products are the *Agreement on Technical Barriers to Trade* (the TBT Agreement) and the SPS Agreement.
 - The TBT Agreement is not as directly relevant to the Review. It aims to ensure that technical regulations, voluntary standards, testing and certification procedures do not create unnecessary obstacles to trade.
22. The SPS Agreement sets out the rules for food safety and animal and plant health standards (sanitary and phytosanitary measures) that may, directly or indirectly, affect international trade. It allows countries to set their own standards provided their regulations are science-based. SPS measures should be applied only to the extent necessary to protect human, animal or plant life or health. They should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail. Further detail on the SPS Agreement is provided in Box 2.

Box 2: The SPS Agreement

Member countries are encouraged to use international standards, guidelines and recommendations where they exist. The standards are developed by leading scientists and government experts on health protection and are subject to international scrutiny and review. This process is often referred to as **harmonisation**.

Members may use measures which result in higher standards based on appropriate **assessment of risks**, provided they describe the factors they took into consideration, the assessment procedures used and the level of risk they determined to be acceptable.

The SPS Agreement encourages **consistent** decision making. Measures should be based as far as possible on the analysis and assessment of objective and accurate scientific data.

Governments are required to notify other countries of any new or changed SPS requirements which affect trade. They must also be open to scrutiny in how they apply their food safety and animal and plant health regulations. Such increased **transparency** protects consumers, as well as trading partners, from hidden protectionism through unnecessary technical requirements.

An acceptable level of risk can often be achieved by using alternative risk controls measures. If another country can show that the measures it applies provide the same level of health protection, these should be accepted as **equivalent**. Alternatives must be technically and economically feasible and provide the same level of food safety or animal and plant health. Governments should select measures that are **not more trade restrictive** than required to meet their health objective.

Appropriate Level of Protection

23. Annex A of the SPS Agreement defines the concept of an ALOP. Like other countries, Australia's ALOP is expressed qualitatively – as being a high level of sanitary and phytosanitary protection, aimed at reducing risk to a very low level, but not to zero. Successive Australian Governments have adopted this conservative approach to manage quarantine and biosecurity risks, reflecting community expectations about the importance of maintaining Australia's relative freedom from the more significant exotic pests and diseases.
24. It is not clear whether Australian policy makers, administrators and the broader community have always had a clear or common interpretation of this qualitative concept. This is an issue the Panel wishes to explore as part of the Review.
25. Under this approach, commodities may not be imported unless the quarantine and biosecurity risks are able to be reduced to a level consistent with Australia's ALOP. The Australian Government uses risk analyses to consider the level of quarantine and biosecurity risk that may be associated with the importation or proposed importation of animals, plants or other goods. The process used is consistent with Australia's obligations under the SPS Agreement. It takes into account relevant international standards on risk assessment and the technical standards that have been developed by international bodies as follows:
 - animal health standards developed by the World Animal Health Organisation, also known as the Office International des Epizootics;
 - plant health standards developed by the International Plant Protection Convention; and
 - food safety standards developed by the Food and Agriculture Organization of the United Nations/World Health Organization Joint Codex Alimentarius Commission (known as Codex).
26. If the risks associated with the importation of a commodity are found by the Director of Animal and Plant Quarantine (refer paragraph 33) to exceed the level of risk acceptable to Australia, risk management measures are proposed to reduce them to that level. If quarantine and biosecurity risks cannot be reduced to an acceptable level, imports will not be allowed. More information on import risk analysis can be found in the *Import Risk Analysis Handbook 2007*.
27. The application of Australia's SPS measures is subject to review by the WTO and its member countries. Australia's import risk analyses have occasionally been or are being challenged through the WTO dispute settlement process. Dispute proceedings

have recently been initiated by New Zealand concerning phytosanitary measures proposed by Australia on the prospective importation of apples from New Zealand.

28. It is important to note that Australia exports approximately two-thirds of its agricultural production. Compliance with the SPS rules and obligations allows Australia to expect similar compliance from its trading partners. This provides Australian exporters with significant benefits of access to overseas markets.

The Quarantine and Biosecurity Continuum

29. Australia's quarantine and biosecurity system is a continuum, from pre-border to border and post-border activities.
30. At the **pre-border** level, Australia:
 - participates in international standard-setting bodies;
 - undertakes risk analyses in relation to animals, plants and/or other goods proposed for import;
 - maintains, including through bilateral and multilateral cooperation, intelligence on the disease and pest status of its trading partners;
 - develops offshore quarantine and biosecurity arrangements where appropriate; and
 - works with its neighbours to build capacity to counter the spread of exotic pests and diseases.
31. At the **border**, Australia screens vessels (ships and aircraft), people and goods (such as cargo and mail) entering the country to detect potential threats to Australian human, animal and plant health.
32. The Australian Government also undertakes targeted **post-border** measures (that is, within Australia), including working with state and territory governments and industry to coordinate emergency responses to pest and disease incursions. The movement of goods of quarantine and biosecurity concern within Australia is primarily the responsibility of relevant state and territory authorities. They undertake inter- and intra-state quarantine operations reflecting regional differences in pest and disease status, as a part of their wider plant and animal health responsibilities.

Commonwealth arrangements

33. Within the Australian Government, the key plant and animal quarantine and biosecurity functions are located in the Department of Agriculture, Fisheries and Forestry.
 - The Secretary of the Department of Agriculture, Fisheries and Forestry is appointed as the **Director of Animal and Plant Quarantine** under the *Quarantine Act 1908*. The Director, or the Director's delegate, is responsible for determining whether or not an importation can be permitted, and if so, under what conditions.
 - **Biosecurity Australia** undertakes risk analyses, develops recommendations on biosecurity policy and provides quarantine advice to the Director of Animal and Plant Quarantine and AQIS.
 - **AQIS** develops operational procedures, delivers quarantine services and makes a range of quarantine decisions (including import permit decisions under

delegation from the Director of Animal and Plant Quarantine). AQIS also works with agricultural food exporters by providing information, inspection and certification to meet the importing requirements of overseas countries.

- **Product Integrity, Animal and Plant Health Division** works with Australia’s state and territory governments to coordinate pest and disease preparedness, emergency responses and intra-state quarantine and biosecurity arrangements.
 - **International Division** works with industry and trading partners to open new markets, maintain existing ones, reduce trade distortions, reduce plant and animal disease risks and develop international trade standards.
34. The **Eminent Scientists Group** is a high level review group independent of Biosecurity Australia that is tasked with providing external scientific scrutiny of import risk analyses. The key purpose of the Eminent Scientists Group is to review drafts of import risk analysis reports.
35. The Department of Agriculture, Fisheries and Forestry also works closely with a range of Commonwealth agencies including the Australian Customs Service and the Department of the Environment, Water, Heritage and the Arts. The Department of Health and Ageing is responsible for developing Australia’s human quarantine policy, which is implemented at the border by AQIS on its behalf. Australian Government quarantine and biosecurity agencies also interact with Commonwealth, state and territory public health agencies, including Food Standards Australia New Zealand, the Office of the Gene Technology Regulator, state and territory health departments and local government public health officers.
36. Examples of activities and responsibilities across the continuum are shown in Figure 1.

Figure 1: Responsibilities and activities across the quarantine and biosecurity continuum

The Continuum	Pre-border	Border	Post-border
Activity	Import risk analyses (covering risk assessment, management and communication) Offshore assessment, audit and verification International standard setting Capacity building in overseas countries Gathering global pest and disease intelligence	Implementation of risk management systems Judgement and interpretation of policy Education and awareness Inspection Monitoring Enforcement and Compliance	Emergency preparedness Practice / simulations Education and awareness Monitoring and surveillance National coordination and response to pest and disease incursions
Agency Responsible	Biosecurity Australia, plus AQIS and Product Integrity Animal and Plant Health Division (also supported by International Division)	AQIS	Product Integrity Animal and Plant Health Division and state and territory governments (plus Animal Health Australia Ltd, Plant Health Australia Ltd)

Shared responsibility

37. Australia's current quarantine and biosecurity system is based on cooperation and shared responsibility between governments, industry and the public. This cooperative approach has seen:
- the development of some co-regulatory arrangements under which industry and third party bodies deliver services under government supervision;
 - cost sharing deeds for animal and plant pest and disease incursions;
 - consultative decision making committees; and
 - cost recovery systems for funding of inspection and certification activities for imports and exports.
38. Ministerial Councils are forums for the national development and implementation of proposals which would not otherwise be possible because of the limitations imposed by the division of constitutional powers between the Commonwealth, state and territory governments. The **Primary Industries Ministerial Council** (described in Box 3 below) and the **Natural Resource Management Ministerial Council** both have a role in relation to quarantine and biosecurity issues. The Natural Resource Management Ministerial Council comprises Commonwealth, state, territory and New Zealand government ministers responsible for primary industries, natural resources, environment and water policy.
39. Each of these Ministerial Councils is supported by committees, working groups and consultative forums, as illustrated in Figure 2 representing the management of animal diseases. Similar arrangements are in place for the management of plant health and aquatic animal health.

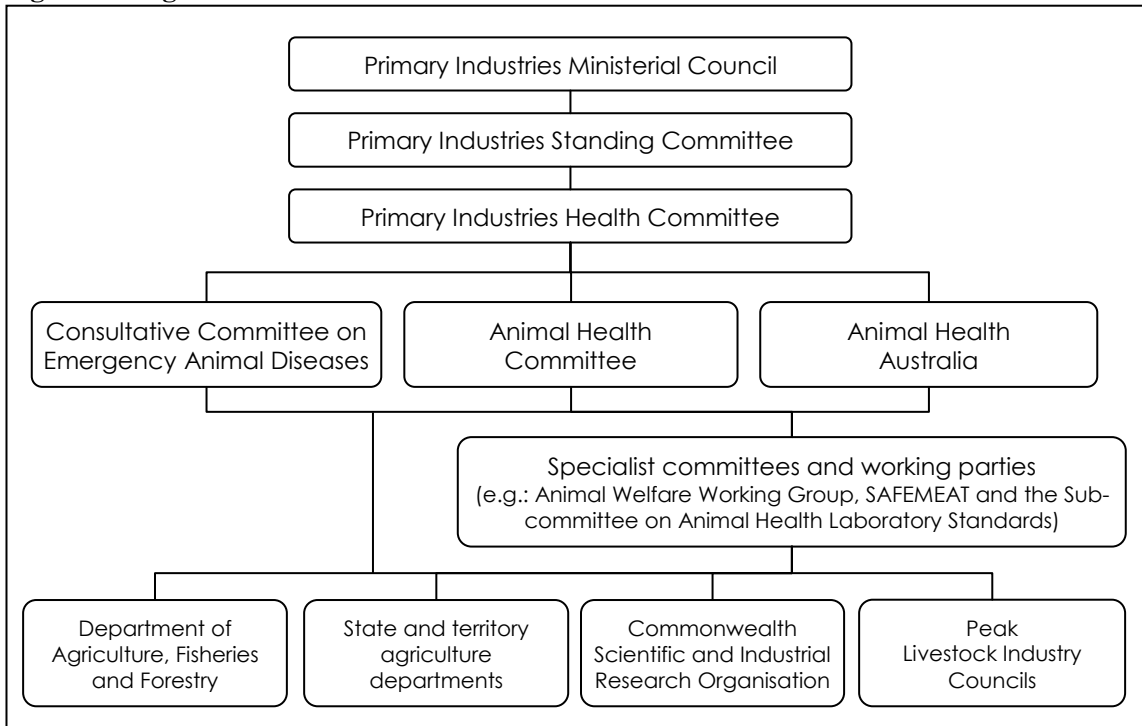
Box 3: Description of Primary Industries Ministerial Council and associated committees

The Primary Industries Ministerial Council (comprising ministers for agriculture, food, fibre, forestry, fisheries and aquaculture industries/ production, and rural adjustment policy from Australian national, state and territory governments and the New Zealand Government) is the peak government forum for consulting, coordinating and integrating government action on national primary industries issues.

The **Primary Industries Ministerial Council** is supported by a permanent committee - the **Primary Industries Standing Committee** - which comprises the heads of the Australian, state, territory, and New Zealand departments of agriculture, and representatives of the Bureau of Meteorology and CSIRO.

The Standing Committee is in turn supported by the **Primary Industries Health Committee**, which manages the Standing Committee's agenda on health issues and provides direction to its supporting committees. The Primary Industries Health Committee comprises deputy heads of primary industries departments and representatives from the CSIRO.

Figure 2: Organisation of animal health in Australia



40. This approach of co-ordinated systems is reinforced by the companies that the Australian Government, state and territory governments and key industry groups have jointly formed to support the national quarantine and biosecurity system. **Animal Health Australia** manages national programs to maintain animal health and support response systems. Similarly, **Plant Health Australia** manages projects and coordinates development of national plant health policy and capability in Australia. Both organisations have a role in coordinating and prioritising research.

B3. Changing operating environment

41. Australia is part of an expanding international trade and travel environment. More goods and people move across Australia's borders each year. The originating sources of Australia's imports and international travellers are changing, in some cases coming from areas of greater pest and disease risk. A number of other developments have also added to the complexity of managing quarantine and biosecurity risks, including:
- increased consumer demand for evidence of product integrity (food that is what the label says it is, and that is safe, e.g. traceback);
 - a number of high-profile disease outbreaks overseas (for example, BSE and foot and mouth disease);
 - new and emerging diseases, many with the potential to affect animals and humans (zoonosis). Examples include diseases such as highly pathogenic avian influenza, Nipah virus, BSE and SARS;
 - the emerging influence of climate change on the spread and establishment of exotic pests and diseases; and
 - an increased focus on security matters in response to terrorism incidents and the potential threats to food safety and agricultural production systems.

42. Although the quarantine and biosecurity threat to primary production from exotic pests and diseases has long been recognised, contemporary risk management systems are now expanding to include the management of threats to the natural environment, including fisheries.
43. Another aspect of the changing operating environment is new technologies and developments in the tools and approaches to risk management used for quarantine and biosecurity control measures. New technologies, such as rapid diagnostic tests, have allowed quarantine and biosecurity agencies to better detect, diagnose and manage risks. Adopting new strategies or technologies potentially provides more effective risk management.

B4. Parallel and previous reviews

Parallel reviews

44. Two parallel reviews are in progress which are relevant to Australia's quarantine and biosecurity arrangements.
45. The *Equine Influenza Inquiry* (announced on 2 September 2007) is undertaking a full, independent inquiry into the outbreak of equine influenza in Australia in August 2007, especially:
 - the circumstances that contributed to the outbreak; and
 - the need for any strengthened biosecurity procedures for quarantine management of imported horses.
46. The report of the Equine Influenza Inquiry is to be provided no later than 25 April 2008.
47. The *Homeland and Border Security Review* is to consider the roles, responsibilities and functions of departments and agencies involved in homeland and border security. It will also consider possible changes to optimise the coordination and effectiveness of Australia's homeland and border security efforts, and will report by 30 June 2008.
48. The Panel will be monitoring progress with these reviews and will consider any relevant recommendations.

Previous reviews

49. The Panel will also assess findings from previous reviews of Australia's quarantine and biosecurity policies, as well as the operation of the agencies tasked with implementing those policies. These reviews include:
 - the 1988 Quarantine Review Committee report, *Australian Quarantine Requirements for the Future* (the Lindsay review);
 - the 1996 review, *Australian Quarantine: A Shared Responsibility* (the Nairn review);
 - the 1998 Quarantine and Exports Advisory Council report, *Review of the Northern Australian Quarantine Strategy*;
 - performance audits on quarantine effectiveness by the Australian National Audit Office in 2000-01 and 2005-06;
 - relevant Productivity Commission reports such as the 2002 report, *Impact of a Foot and Mouth Disease Outbreak on Australia*;

- the 2003 Joint Committee of Public Accounts and Audit Report, *Review of Australia's Quarantine Function*; and
- the 2007 report by the Agriculture and Food Policy Reference Group, *Creating our Future: Agriculture and Food Policy for the Next Generation* (the Corish Report).

PART C – ISSUES FOR CONSIDERATION

50. This section outlines the Panel’s initial thoughts on issues arising from the Terms of Reference and poses specific questions to spark discussion and input from stakeholders.
51. As mentioned previously, those making submissions should not feel constrained by the issues or questions raised and are welcome to draw any other relevant matters to the Panel’s attention. Nor do the questions posed imply any conclusions yet adopted by the Panel.
52. Respondents may also wish to comment on what the Panel considers to be the boundaries for the Review as identified in Part B of the issues paper.

C1. Risk across the quarantine and biosecurity continuum

53. In the quarantine and biosecurity context, risk analysis comprises three parts: risk assessment; risk management; and risk communication.

Risk assessment is the process of identifying and estimating the risks associated with a proposed import and evaluating the consequences of taking those risks.

Risk management is the process of identifying, documenting and implementing measures to reduce risk and its consequences.

Risk communication is the process of interactive exchange of information and opinions concerning risk between risk managers, trading partners, industry participants and the general community.

54. Each pest and disease, and its mode of transmission, presents a different mix of risks and uncertainties to be assessed and managed. Australia’s quarantine and biosecurity agencies use risk analysis along the quarantine and biosecurity continuum to minimise the chance of pest and diseases establishing in Australia and its waters (refer Part B for further information).

Questions:

- Are Australia’s quarantine and biosecurity systems appropriate to maintain its ALOP (very low risk, but not zero)?
- Is ALOP understood and applied in a consistent way? Is it achieved in a way that is not more trade restrictive than required?
- Should the wider implications – for exporters, consumers and the economy – be taken into account when developing quarantine and biosecurity arrangements, and if so, how?
- What are the benefits of Australia’s current approach to quarantine and biosecurity?
- Is it well understood in the Australian community that quarantine measures can only be applied to the extent that they are necessary to protect human, animal or plant life or health that they are the not more trade restrictive than required, and that they may not be used as an industry protection mechanism?
- Do Australia’s risk assessments (including import risk analyses) competently and comprehensively assess risk and risk management issues when providing advice on market access requests and import applications? Are they sufficiently timely?
- Is the role of the Eminent Scientists Group in the import risk analysis process

understood and appropriate?

- Is the quarantine and biosecurity framework adequate to analyse and manage risks to the environment? Does Biosecurity Australia have the skills/ability to assess any such risks?
- Are threats to Australia's marine environment and fisheries arising from bio-fouling on ships' hulls and organisms in ballast water best handled in a quarantine and biosecurity framework, or some other framework?
- Are risk analyses, import policy determinations and permit conditions sufficiently updated through monitoring of actual experience in the application of risk management measures? Do the appropriate feedback loops exist and are they effective?
- Does AQIS implement risk management in a manner consistent with the advice/recommendations provided by Biosecurity Australia and the Director of Animal and Plant Quarantine (as outlined in the Import Risk Analysis Handbook)?
- Is there adequate auditing and verification of pre-border, border and post-border measures to ensure that policy determinations and permit conditions, including arrangements for co-regulation with industry, are in fact meeting the appropriate standard?
- How should the quarantine and biosecurity continuum (pre-border, border and post-border) be monitored to ensure that the system functions (to prevent and respond to pest and disease incursions)?
- Are the arrangements for sharing pest and disease information between the Commonwealth, the states and territories and industries working adequately?
- Are Australia's emergency response plans for exotic pest and disease outbreaks adequate?
- Are the current cost-sharing arrangements between Commonwealth, state and territory governments and affected industries, that apply in the event of a pest or disease incursion, appropriate? Should they be broadened to cover other exotic pests such as exotic weeds?
- Are the arrangements for incursions with a principally environmental impact appropriate?
- Are the arrangements for export inspection and certification effective? Are they consistent with Australia's international obligations?

C2. The legislative framework

55. The Australian quarantine and biosecurity system is supported by Commonwealth, state and territory laws and regulations. Local government also plays an important role in the delivery of some aspects of quarantine and biosecurity regulation, such as food safety and public health.
56. State and territory laws and arrangements for matters covered under the SPS Agreement are subject to an over-riding Commonwealth obligation under its WTO treaty obligations to ensure that state and local governments are in compliance. Section 109 of the Constitution, together with the range of powers conferred on the Commonwealth including the quarantine power, the foreign affairs power, the corporations power and the trade powers, provides a framework within which relevant Commonwealth legislation will prevail over any inconsistent state law.

57. The Commonwealth quarantine and biosecurity laws are contained in the *Quarantine Act 1908* (the Act) and subordinate legislation including the *Quarantine Regulations 2000*, the *Quarantine Proclamation 1998*, the *Quarantine (Cocos Islands) Proclamation 2004* and the *Quarantine (Christmas Island) Proclamation 2004*.
58. While the Act was amended significantly in response to the 1996 Nairn review, its core was drafted over a century ago. Some commentators have suggested that a comprehensive modernisation of the Act would be beneficial, although the costs, risks and disruption of a reform on this scale cannot be ignored.
59. The Commonwealth has not attempted, as it probably could, to cover the quarantine and biosecurity field comprehensively in its legislation so as to exclude the application of state law, to “internationally traded things of quarantine relevance”. It has preferred to work by cooperation with state, territory and local governments to implement its international obligations and national policies. Several states have acted to control the import to that state of a commodity permitted to enter Australia under the Act.

Questions:

- Are the current roles and responsibilities of the Commonwealth and the states and territories well understood and operating effectively?
- Does the current legislative framework provide the Commonwealth, states and territories with the authority and powers needed to undertake quarantine and biosecurity functions effectively?
- Is the *Quarantine Act 1908*, as amended, relevant and effective to meet Australia’s current quarantine and biosecurity needs? Should it be rewritten and modernised?
- Should the human health aspects of the Act be removed and placed into a separate (new) Act administered by the Department of Health and Ageing?
- Are Australia’s legislative arrangements designed to manage relevant environmental and marine threats effectively?
- Are the different elements of legislative systems (both different Commonwealth legislation, and the state and territory statutes) operating in an effective and complementary manner?
- Does the Commonwealth need to consider drafting its legislation and framing its subordinate legislation in such a way as to ensure that any state, territory or local government action, which would have the effect of frustrating a Commonwealth decision or its actions to implement the SPS Agreement, would be over-ridden?
- Should an import permit be used to restrict a product from a particular region in Australia if it is determined on a scientific basis to be regionally free of a pest or disease, while still allowing general access to the Australian market?
- Are there other models (either domestic or international) for jurisdictional or legislative arrangements which could be more effective?

C3. Jurisdictional and institutional arrangements

60. Australia's current quarantine and biosecurity system is based on cooperation and shared responsibility between governments, industry and the public. Governments work together to implement the overlapping jurisdictional arrangements set out in Part B.

Questions:

- Is the division of roles and responsibilities between government, industry and individuals appropriate? Are they working well in practice?
- What measures should be used to ensure their effectiveness?
- What other administrative models could be considered to implement quarantine and biosecurity policy?
- Is there appropriate interaction between Biosecurity Australia, AQIS and the Product Integrity, Animal and Plant Health Division and other relevant Commonwealth and state and territory agencies?

61. The Australian Government approach of having AQIS, Biosecurity Australia and the Product Integrity, Animal and Plant Health Division as partially separated agencies/entities contrasts with structures used elsewhere.
62. The creation of Biosecurity Australia as a "prescribed agency" in 2004 within the Department of Agriculture, Fisheries and Forestry gives it a degree of financial independence and was intended to underline its role of providing science-based advice independent of export interests or domestic industry pressures. Biosecurity Australia remains under the Secretary of the Department of Agriculture, Fisheries and Forestry for more general management and policy oversight purposes.
63. While there are a variety of approaches taken around the world, a number of countries, including New Zealand and the United Kingdom, have a more formally integrated structure. The 1996 Nairn review recommended an independent statutory authority which would subsume the roles currently undertaken by Biosecurity Australia, AQIS and elements of the functions undertaken by the Product Integrity, Animal and Plant Health Division of the Department of Agriculture, Fisheries and Forestry, as well as the Director of Animal and Plant Quarantine.
64. Australian arrangements have on occasion been subject to claims by trading partners that they give the appearance of being subject to political pressure relating to considerations precluded under the SPS Agreement. This could include matters of industry protection, or of approaches to import risk that are not consistent with Australia's ALOP or scientific evidence. This perception has presumably been heightened by public statements by some members of parliament in the past.
65. Some governance experts argue that where decisions are being made which could affect the health of Australians, important agricultural commodities or damage the environment, and where those decisions inevitably are matters for judgement balancing a broad range of factors, it is best they are taken by a democratically elected Minister acting on advice and subject to Administrative Decisions Judicial Review in relation to the legality of the decision. This is the approach taken in some legislation governing broadly analogous areas, such as the *Environment*

Protection and Biodiversity Conservation Act 1999 and the Foreign Investment Review Board.

66. Others argue that Ministers are inevitably subject to direct political pressures from peers and interest groups, particularly those who stand to be negatively affected by a decision. They argue that, no matter how appropriately the Minister may behave, it is difficult to avoid the perception that decisions are tainted by matters not relevant under Australia's treaty obligations and domestic legislation. This school of thought favours an approach which places the decision in the hands of either a public servant, or a Tribunal/authority with appropriate security of tenure, and similarly subject to judicial review. This mirrors the approach taken in a number of other policy areas – such as the regulation of competition, corporations and essential services (electricity, gas, water) at the Commonwealth and state levels, or the determination and oversight of air safety requirements.

Questions:

- Should the current approach, which separates the roles and responsibilities of AQIS, Biosecurity Australia and the Product Integrity Animal and Plant Health Division, be integrated?
- Should the quarantine and biosecurity function be integrated within the Department of Agriculture, Fisheries and Forestry, or exist as a separate agency (statutory authority)?
- Should the same regulatory agency deal with both exports and imports?
- Is the current decision making role of the Director of Animal and Plant Quarantine appropriate?
- Is it appropriate for the Director of Animal and Plant Quarantine to also be the Secretary of the Department of Agriculture, Fisheries and Forestry?
- Who should have the ultimate decision making power on risk policy and import permits – a Minister or an independent public servant or statutory authority?
- How should wider consumer and economy interests (a national interest test) be incorporated into such decisions (subject to consistency with international obligations)?

67. As a key border regulatory agency, AQIS has a vital role in implementing and administering strict quarantine and biosecurity controls at Australia's borders to minimise the risk of exotic pest and disease incursions. AQIS also helps to facilitate trade for both imports and exports of agriculture products by providing inspection, auditing, verification and certification services to the meat, horticulture, grain, fish, dairy, live animal and food production industries.

Questions:

- Do any conflicts result from AQIS' joint responsibilities of facilitation and regulation?
- Should the regulator also be a facilitator?

C4. Culture, efficiency and resourcing

68. Currently, Australia's quarantine and biosecurity system, including its export operations, is funded through a mixture of government funding, cost-recovery, and cost sharing mechanisms. This approach reflects the shared responsibility adopted in Australia's quarantine and biosecurity system.

69. Cost-recovery was first introduced for AQIS in 1979. Initially AQIS was required to recover 50 per cent of the cost of providing services. This figure has changed over time and can be different depending on the particular program. Currently, AQIS is required to recover 60 per cent of export program costs. The funding mechanism for import programs can vary considerably. Some are required to fully recover costs, while other programs, for example the Northern Australia Quarantine Strategy, are government funded. Cost recovery is undertaken in line with the *Australian Government Cost Recovery Guidelines* and in consultation with industry consultative committees.
70. Australia approves some private facilities for use in the management of quarantine and biosecurity risk. These include approved premises, privately operated post-entry quarantine facilities and private research and diagnostic laboratories.
71. Cost-recovery and risk control measurements, such as intervention targets (see below), are used mainly in border operations. They are not widely used pre-border or post-border. Some pre-border inspections have been cost-recovered, however most are funded by the Australian Government. Post-border operational activities are primarily conducted by state and territory governments. The effectiveness and resourcing of these activities are not usually compared between jurisdictions. For a number of exotic pest and disease outbreaks there are cost sharing deeds or agreements where the eradication costs are shared between governments and the affected industry.

Intervention targets

72. At the border, AQIS performs its functions alongside, and in some cases as an agent for, other agencies, particularly the Australian Customs Service, Department of Health and Ageing, Department of Immigration and Citizenship, and Food Standards Australia New Zealand.
73. In the May 2001 Budget, primarily in response to a foot and mouth disease outbreak in the United Kingdom, the Australian Government announced *Increased Quarantine Intervention* – a funding package to strengthen border agencies, with the following policy aims:
 - international airports – at least 81 per cent of arriving international passengers to have baggage inspected or x-rayed, with a number of new detector dog teams in support;
 - international air cargo – all aircraft containers to be externally inspected;
 - seaports – all ships, passengers and baggage of arriving from overseas to be inspected;
 - sea cargo containers – all containers (external surfaces) to be inspected; and
 - international mail exchanges – all articles arriving by post to be inspected by x-ray or detector dog.
74. The Government introduced intervention and effectiveness targets to measure the success of the Increased Quarantine Initiative funding. **Intervention** refers to the application of a specified set of quarantine activities to determine the status of goods of quarantine interest. **Effectiveness** refers to the success rate of the intervention procedure.
75. As a result, and unlike Customs and Immigration agencies, AQIS has limited freedom to determine its intervention strategies on the basis of managed risk. For

example, it is required by directive of Government to screen 81 per cent of incoming air passengers. This consumes considerable resources.

76. It is arguable whether the current level of passenger screening is required for risk management purposes. More importantly, there is considerable doubt whether it will be logistically possible to maintain this screening level given anticipated increases in international passenger numbers. This raises the question of whether resources are being optimally deployed to enable AQIS to best manage risk.
77. If fewer AQIS staff were required at the airport arrival area, greater opportunity may exist to rationalise 'front line services' (as is done by Australian Customs Service for immigration purposes) and allow AQIS staff to better focus resources in areas where there are known to be greater risks.

Questions:

- Are resources available to Australia's quarantine and biosecurity authorities deployed across the continuum to the areas of highest risk/return?
- Is the emphasis on screening international air passenger arrivals, air cargo, sea cargo, ships/passengers/baggage at seaports from overseas and international mail consistent with risks and returns?
- Is there sufficient development of, and reliance on, pre-border intelligence?
- Are there opportunities for greater alignment between pre-border application and information requirements for quarantine, customs and immigration to streamline processes and enhance risk management? Could there be opportunities for greater rationalisation of staff, IT systems and screening investments?
- Is there sufficient priority given to monitoring and surveillance post-border? Who should provide these functions and resources?
- Do the arrangements to recover costs of aspects of the quarantine and biosecurity system appropriately reflect the balance between public interests and private benefits? Are there alternatives which would provide improved incentives and resources to better reflect the balance of national interests?
- Does cost-recovery have an impact on the ability of AQIS staff to deliver public good outcomes?
- Does cost-recovery limit monitoring of pests and diseases at the border, for example where the product is treated or destroyed to minimise the costs to the importer?
- To what extent and under what conditions is it appropriate to use private facilities in the quarantine and biosecurity system? Are the current monitoring, auditing and supervision arrangements for public and private quarantine facilities effective?
- Are the current import and export certification processes, the auditing of those processes in their application, and the surveillance of their operation, appropriate? Can the administration of import and export certification arrangements be streamlined?
- Are the requisite skills and disciplines available to deliver optimal quarantine and biosecurity systems? If not, what are the highest priority areas? Is the education and training of personnel with these skills adequate? If not what are the highest priority areas?
- Is infrastructure such as diagnostic laboratories and containment facilities adequate to meet quarantine and biosecurity needs? If not what are the highest priority areas?

C5. Communication and consultation

78. Emphasis is placed on engagement with industry representatives and the general public in the development and implementation of Australia's quarantine and biosecurity policies. Communication with interested parties is also highly important in the current process for Import Risk Analyses.
79. For example, Biosecurity Australia undertakes formal and informal consultations with domestic and international stakeholders when undertaking an import risk analysis. The importance of these consultations, which aim to increase the transparency and rigour of risk analyses, is reflected in the fact that they are built into the regulated process that Biosecurity Australia is required to follow (brought into effect in September 2007).
80. AQIS maintains contact with industry through consultative committees. Industry consultative committees help develop effective operational responses to government policy for AQIS import and export programs. At the broadest level the Quarantine and Exports Advisory Council provides advice to the Minister and the Director of Animal and Plant Quarantine on major quarantine and export certification policy issues.
81. AQIS also conducts community education and awareness campaigns designed to reduce risks by improving compliance with quarantine and biosecurity requirements. One example is *Quarantine Matters!*, which is a national campaign that encourages Australians to take responsibility for quarantine and biosecurity.
82. Animal Health Australia and Plant Health Australia also run campaigns with government and industry, such as *Spotted Anything Unusual?* and the new *Farm Biosecurity - secure your farm: secure your future*, to raise awareness about early reporting of suspected exotic pests and diseases.

Questions:

- Australia's ALOP is very low, but not zero. Is this understood in the relevant communities?
- What mechanisms could be adopted to improve communication of this policy setting? For example, are there opportunities that Australia should be pursuing with trading partners to improve the understanding of Australia's quarantine and biosecurity system?
- Are the various industry consultative arrangements with AQIS appropriate and effective?
- Is the Quarantine and Exports Advisory Council an effective forum for advising the Minister and Director of Animal and Plant Quarantine of quarantine and biosecurity issues?
- Are the consultative arrangements used during import risk analyses appropriate and effective? Are the outcomes of import risk analyses effectively communicated to domestic and international stakeholders?
- Are current quarantine and biosecurity education and awareness programs effective? What methods can be used to assess the effectiveness of quarantine and biosecurity communication?
- Are existing communication tools to encourage the reporting of suspected exotic pests and diseases, such as the *Spotted Anything Unusual?*, effective?

C6. Research

83. Australia has research programs in animal and plant health, pest and disease detection, diagnosis, treatment, containment and eradication. Research is undertaken by government, private and academic institutions, and may also involve collaboration with overseas research organisations. The spectrum of research activity includes activities across the quarantine and biosecurity continuum.
84. Research priorities are coordinated through various committees and working groups, such as the Animal Health Committee (refer Figure 2), the Plant Health Committee and the Aquatic Animal Health Committee. As mentioned previously, Animal Health Australia and Plant Health Australia also have a role in coordinating and prioritising research.
85. A feature of Australia's research effort is the role of the many Cooperative Research Centres - operated through the Department of Innovation, Industry, Science and Research. Several of these have a specific interest in quarantine and biosecurity matters, such as the Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease, the Cooperative Research Centre for National Plant Biosecurity, Invasive Animals Cooperative Research Centre and the Cooperative Research Centre for Sustainable Aquaculture of Finfish. Many of the commodity-specific Cooperative Research Centres are interested in the development of better technologies and tools to manage quarantine and biosecurity threats specific to their industries.
86. The CSIRO's Australian Animal Health Laboratory plays a vital role in maintaining Australia's capability to quickly diagnose exotic and emerging animal diseases. It develops diagnostic tests, vaccines and treatments. The CSIRO has a division of entomology that conducts relevant plant pest research but there is no separate division for plant diseases.
87. In many cases, research is jointly funded and managed by the Australian Government, states and territories and industry. For example, the Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease has coordinated projects to assist the detection of SARS along the quarantine and biosecurity continuum. This research was coordinated between Australian academic and government organisations (including CSIRO), and those in Canada and China.
88. Australia's various Research and Development Corporations are also important in the context of quarantine and biosecurity research, for example Meat and Livestock Australia, the Rural Industries Research and Development Corporation, the Grains Research and Development Corporation, Horticulture Australia Limited and Dairy Australia. Much of the funding collected by Research and Development Corporations is from levies on producers. As an example of research supported by a Research and Development Corporation, Australian Pork Limited has supported peri-urban regional surveillance for biosecurity for the pig industry in eastern Australia.
89. As part of the import risk analysis process, Biosecurity Australia occasionally commissions research where it has identified gaps in scientific knowledge regarding a specific exotic pest or disease and where it is practical to do so. For example in the pig meat import risk analysis, Biosecurity Australia commissioned

an experiment at a research laboratory in Lelystad, The Netherlands on the transmission of porcine reproductive and respiratory syndrome virus through oral uptake of infected pork. This work was important in understanding and assessing the quarantine risk associated with imported products.

90. Research on risk analysis methods has also begun to emerge. The Australian Government established a Centre of Excellence for Risk Analysis to strengthen the integrity of Australia's import risk analysis process. It operates out of the School of Botany at the University of Melbourne.

Questions:

- How should the effectiveness of research on quarantine and biosecurity issues be evaluated?
- Is research appropriately funded, coordinated and prioritised?
- Is the distribution of the research effort appropriate along the quarantine and biosecurity continuum?
- What methods could be used to set and review research priorities across the continuum?
- Who should establish and review research priorities?
- In the context of competing research priorities, is sufficient emphasis given to research on new technologies for use in quarantine and biosecurity, including as control measures, in product integrity, and certification systems?
- In the context of competing research priorities, is sufficient emphasis given to research on risk analysis methods?
- How effectively is new information from research activity incorporated into Australia's risk management measures?
- Are there any critical information or knowledge gaps that can be remedied to support better research and policy outcomes?
- Who should pay for quarantine and biosecurity research?

C7. Review

91. Australia's quarantine and biosecurity policies and systems are subject to a range of evaluation and review mechanisms. These include reviews of policy initiated by Government, judicial and non-judicial reviews, and reviews undertaken as part of Australia's international obligations as a member of the WTO. Operational matters are also subject to ongoing review.
92. Included in government review processes are periodic audits conducted by the Australian National Audit Office, Senate Inquiries and the ongoing Senate Estimates process where Commonwealth officials are questioned on programs they are responsible for administering (transcripts are available through Hansard).
93. Decisions made under the *Quarantine Act 1908* are not subject to merits review. However, they are subject to judicial review under the *Administrative Decisions (Judicial Review) Act 1977*. This includes a decision by the Director of Animal and Plant Quarantine to issue or not issue an import permit. An example was the case taken by Australian Pork Limited against the Director of Animal and Plant Quarantine (*Director of Animal and Plant Quarantine v Australian Pork Limited [2005] FCAFC 206 (16 September 2005)*).

94. Non-judicial reviews include the Import Risk Analysis Appeals Panel, to which stakeholders may appeal if they believe there has been a significant deviation from the required import risk analysis process. This appeals mechanism is independent of Biosecurity Australia. The Import Risk Analysis Appeals Panel considers any appeals and reports its findings to the appellant(s) and the Director of Animal and Plant Quarantine.
95. As a member of the WTO, Australia is subject to 'trade policy reviews' of its policies and administrative systems every five years. This includes Australia's compliance with the SPS Agreement. Reviews of compliance of specific SPS measures would normally be conducted directly with affected trading partners. However, where bilateral solutions cannot be agreed, members are ultimately able to utilise the WTO dispute settlement process.
96. A review of an existing import policy may be triggered in cases where the operational trade environment has changed, such as a disease outbreak or changes in the science regarding an exotic pest or disease in another country. This occurred recently in response to the foot and mouth disease outbreaks in the United Kingdom and Cyprus, resulting in additional import control measures being applied to imports from these countries.
97. Operational aspects of quarantine and biosecurity are periodically reviewed through monitoring. A range of audit, certification and verification systems are used to monitor the performance of, and ensure compliance with, the operational risk management systems for imported and exported products at the border and in some cases pre-border. Most post-border monitoring for exotic pests and disease is conducted by state and territory governments and private animal and plant health specialists.

Questions:

- Are existing monitoring and review mechanisms for quarantine and biosecurity policy and operations appropriate and effective? If not, what options should be considered, and why?
- Who should conduct reviews?
- Have the findings from recent reviews of policy and operations been adequately addressed and implemented?
- Is monitoring of the quarantine and biosecurity continuum targeted at the right areas (e.g. primarily at the border)? Is there a process to ensure that the results of monitoring are being used effectively to improve the operation of the system?