

Regulation Impact Statement

Biosecurity Legislation

Regulation Impact Statement

November 2012

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Abbreviations

Abbreviation	Description
AQIS	Australian Quarantine Inspection Service
DAFF	Department of Agriculture, Fisheries and Forestry
DoHA	Department of Health and Ageing
ICT	Information and communication technology
PwC	PricewaterhouseCoopers
QAP	Quarantine Approved Premises
RIS	Regulation Impact Statement

Executive summary

Biosecurity involves 'managing risks where there is a likelihood of a disease or pest entering Australia and establishing itself or spreading and potentially causing harm to human, animal, or plant health, the environment; or causing economic consequences.'

Managing the entry, establishment and spread of pests and diseases is vital, not only for the wellbeing of Australia's population and native environment but also for the viability of some of Australia's most important sectors.

In Australia, the management of biosecurity is achieved through collaboration between the Australian, state and territory governments, industry participants and other stakeholders. The Department of Agriculture, Fisheries and Forestry (DAFF) is the primary biosecurity agency at the national level. The *Quarantine Act* 1908 ('the Quarantine Act') provides the legislative basis for human, plant and animal quarantine activities in Australia and provides a national approach to protecting Australia from pests and diseases.

Biosecurity risks have changed significantly since the core of the Quarantine Act was drafted over a century ago. In addition, the last significant review of the system in 2008, *One Biosecurity: A Working Partnership* found that, while Australia operates a good biosecurity system, there are a number of opportunities for improvement.

In this context, the Australian Government has committed to reform its biosecurity legislation, and to address issues with – and replace – the Quarantine Act and its associated instruments. The proposed biosecurity legislation aims to manage biosecurity risks but in a more flexible manner than the current legislation.

The proposed legislation provides an overarching legislative framework. Much of this framework is common, in practical terms, to the existing situation or provides heads of power for more detailed regulations, and in isolation does not represent substantive change from current policy or practice. This Regulatory Impact Statement (RIS) is focussed on only those parts of the proposed legislation that could be expected to generate substantive costs or benefits for stakeholders relative to the current situation.

Three specific issues have been identified for analysis in this RIS and relate to:

- approved arrangements between government and industry participants
- introduction of a new policy for the approval of first points of entry
- use of biosecurity zones in prevention and control.

This RIS considers each of these issues in terms of the problem being addressed, potential alternatives to the proposed biosecurity legislation, and the associated costs and benefits. There is also a brief discussion of other changes with less significant impacts (such as those relating to human health).

In addition to the benefits associated with reforms in the three areas outlined above, there is also a broad, unquantified benefit of the proposed biosecurity legislation that relates to the value of improving the overall quality of the legislative framework by reducing the costs associated with interpreting complex, prescriptive, outdated legislation (a benefit to both government and business). The legislative reform will also assist the plans for broader reform in biosecurity primarily in the form of more flexible legislative mechanisms that will allow change.

Biosecurity Bill, section 9

Approved arrangements

The Quarantine Act states that quarantine related activities must be performed by DAFF officers or under their direct supervision. This has led to the department implementing partnership arrangements with industry participants that are formalised through various provisions of the Quarantine Act. In particular, section 46A of the Quarantine Act is used where arrangements apply to a physical premise whilst section 66B is used where the arrangement applies to a specific quarantine activity performed on behalf of DAFF. Under section 46A and 66B each premise or activity is subject to a separate approval or agreement.

As a result of the current legislative requirement, industry participants may be subject to multiple arrangements under one or both of the existing sections to ensure they are compliant. This leads to an increased regulatory burden on industry participants, and imposes a significant administrative burden on the department as well as creating inefficiency and duplication of process. More broadly, the current arrangements are seen as unduly restrictive and rigid, with insufficient flexibility to allow for partnerships between industry participants and government in respect of certain activities or types of premises.

The proposed biosecurity legislation will transition those that are currently on a QAP or compliance agreement to an approved arrangement, and broaden the scope of operations that may be brought under an approved arrangement. The model of approved arrangements, within the context of the proposed biosecurity legislation, provides a mechanism whereby government and industry participants are able to work together to achieve biosecurity objectives. These arrangements are most beneficial when they are focused on areas where industry participants have an advantage over government in providing a particular service or facility (such as on the basis of efficiency or technical expertise). In these cases, having industry participants provide a service can allow a more flexible and expedient process to occur, which has benefits to both industry participants and government (for example, where industry participants are able to include particular biosecurity requirements within their usual business process, thereby avoiding the need to defer to biosecurity officials at that stage).

There are three areas identified in this analysis where the proposed changes to approved arrangements are likely to have an impact (in terms of both costs and benefits to both industry participants and government).

- Broadening the scope and flexibility of approved arrangements between government and industry participants Where the changes influence the number and type of approved arrangements sought by industry participants with government. It is expected that in time, there would be an increase in the number of arrangements agreed between industry participants and government, primarily on the basis of the improved flexibility under the proposal, and the inclusion of 'end-to-end' systems within the proposed scope of approved arrangements. The increased number of parties subject to approved arrangements will allow for increased flexibility for those parties, providing more effective and efficient outcomes.
- Reducing administrative complexity for government and industry participants Where the changes
 allow approved arrangements to be established and managed at a lower administrative cost than
 previously. It is expected that government and industry participants will benefit from reduced
 administrative costs, where the new arrangements allow a much more flexible approach to
 management.
- *Costs to transition to approved arrangements* most notably in relation to the fit and proper person test.

First points of entry

The Quarantine Act provides that overseas vessels must enter Australia at a first port of entry, as listed in the *Quarantine Proclamation 1998*. While the *Quarantine Proclamation 1998* lists the 59 ports that are currently proclaimed as first ports of entry:

- there is no transparent process that sets out how ports come to be proclaimed, nor how ports may be removed from this list
- there are no requirements setting out how to identify suitable first ports (and associated infrastructure requirements) to ensure that the port can be serviced by biosecurity officials or that biosecurity risks can be managed
- there is little clarity around what area constitutes a port in terms of the geographical boundaries of a port (this is important when determining biosecurity risk).

A number of proclaimed first points of entry are no longer receiving a substantive volume of international vessels (for a variety of reasons). Some are not in use at all.

The current ambiguity surrounding the proclamation and management of first ports of entry has led to a number of vessels entering non-proclaimed ports (both with permission – which imposes a range of costs to process numerous 'one off' applications, and without permission – which raises concerns around the effective management of biosecurity risks).

The proposed biosecurity legislation will introduce clear requirements to provide certainty to port and landing place operators about the process to become a first point of entry, and the circumstances under which a first point of entry determination may be varied or revoked.

Port operators would be positively impacted by the greater transparency and certainty within the first point of entry process. In addition, the decision to apply for first point of entry status lies with port operators and enables operators to choose the option that best aligns with their business objectives. Costs include application costs as well as potential costs to upgrade facilities to meet specific requirements that would be set out in regulations. Some may choose to forego their first point of entry status, with potential impacts on profitability and port users.

DAFF would benefit from the proposed arrangements because the legislation will enable requirements for facilities for biosecurity officers to be set out in regulations. It would thereby help to ensure that officers have the necessary tools and facilities available to them at each port to carry out specific biosecurity duties relevant for that port.

Vessel masters would be able to work within a superior framework, resulting in greater transparency of port requirements, potentially fewer applications to land at non-proclaimed ports and greater flexibility to manage short term or seasonal use of ports. Vessel masters would also have greater certainty about the facilities available to them upon arriving at a first point of entry.

Declaration of biosecurity zones

The Australian Government currently assumes a relatively narrow biosecurity reach even though its constitutional powers allow for broader regulation. Specifically, the Australian Government has not yet exercised its absolute constitutional power but rather has focused on regulating border activities. Onshore activities have generally been the responsibility of state and territory governments, with assistance from the Australian Government in particular instances.

This relatively narrow focus has caused a range of issues, including:

- additional, and sometimes overlapping, biosecurity measures imposed by individual states and territories
- the non-traceability of animal and plant matter of greater biosecurity interest once it passes the border
- inefficient strategies and actions due to the uncertain roles and responsibilities of both individual states and territories and the Australian Government
- inadequate information sharing and coordination between governments.

The proposed biosecurity legislation provides additional powers to the Australian Government to manage biosecurity risks *post-border*. These powers include: biosecurity response zones, biosecurity zones, monitoring zones and biosecurity control orders. The potential impact of these changes on industry participants, and the community more broadly depend on:

- the extent to which they impose costs on business or individuals by restricting their normal operations (ie restricting access to property, restricting movement of people, vehicles or goods, requiring monitoring activities).
- the extent to which the new arrangements will improve the management of biosecurity risks, including reducing the potential spread of an introduced species or disease.
- the frequency with which the measures are used.

These powers complement rather than replace existing state powers. They may be used infrequently but provide a greater number of options for managing post border incursions in a timely and effective way, particularly if there are benefits in managing a response consistently across different jurisdictions.

The extent of costs and benefits from these powers will vary considerably from case to case, depending on how they are applied. The key benefit of these changes will be improved management of incidents post-border and the resulting reduction in costs to stakeholders who could be affected if the pest/disease spread further. The costs associated with these powers will primarily be incurred by those industry participants within a declared zone or affected by a notice which may include costs of restrictions to movement of persons, livestock or goods, costs of providing access to property for monitoring. Importantly, these costs would be similar to those incurred when existing powers are exercised by state and territories. The additional cost of sometimes using these powers is likely to be small and in some cases could result in cost savings relative to the alternative of managing a response using different powers in each state.

Conclusion

In most cases, the proposed biosecurity legislation provides the enabling powers for government, with additional details to be set in regulations. While key areas of costs and benefits can be identified, an estimate of the scale of costs and benefits cannot be provided in most cases without the detail that would be set in regulations. For instance, the potential compliance costs of meeting requirements for first points of entry would be determined based on the criteria and application process to be set in regulations. The impact analysis is, therefore, primarily qualitative. In that regard, the overall assessment is that the proposed biosecurity legislation is likely to generate a net benefit relative to the status quo, and is recommended for adoption.

This RIS has been prepared by PwC in consultation with the Department and in accordance with the Office of Best Practice Regulation requirements, this report has been written as a Departmental document from the point of view of the Department.

Introduction and context

Biosecurity involves 'managing risks where there is a likelihood of a disease or pest entering Australia and establishing itself or spreading and potentially causing harm to human, animal, or plant health, the environment; or causing economic consequences.'2

A number of factors mean that Australia is increasingly vulnerable to pests and diseases which threaten its biosecurity status. These include the increasing numbers of vessels, passengers and goods from higher risk origins entering Australia and the changing nature of trade and movement with a higher percentage arriving from higher risk countries. The work releated to managing the associated biosecurity risks is expected to double in the next 10 years.³

The number of incursions of pests and diseases is increasing and there are also increasing demand from international trading partners for greater levels of assurance in relation to exports.

If the existing approach to managing Australia's biosecurity system does not change, funding of the biosecurity system will need to grow proportionately with the increases in movements of vessels, people and goods to achieve the same level of biosecurity activity. It is questionable whether such an ongoing cost increase is sustainable.

The existing approach to funding and targeting resources is unsustainable if Australia is to maintain its favourable biosecurity status. Australia, particularly its agriculture, fisheries, forestry and food industries, gains significant economic benefits from this status which would be adversely affected if it was not maintained. Breaches of the biosecurity system can also have significant implications for human health and biodiversity.

The following sections provide an overview of recent events that provide an important context to the problems identified with the current legislation.

The current situation

Australia remains relatively free from many of the pests and diseases that affect primary industries, the environment and human health in other countries.⁴ However, in recent years Australia's borders have become increasingly vulnerable to pests and diseases. Australia's increased vulnerability is due to a number of factors including globalisation and the increased movement of goods and people across borders.

Australia's favourable pest and disease status is important as it underpins Australia's agricultural and food sector and its ability to export and it is integral to the unique status of Australia's natural environment. One indicator of the economic benefit to Australia is the contribution of Australia's agriculture, fisheries and forestry industries to gross domestic product (GDP). In 2010-11 these industries contributed \$36.2 billion in exports (or 3 per cent of GDP).⁵

The Department of Agriculture, Fisheries and Forestry (the Department) has primary responsibility for managing Australia's biosecurity system. In 2011-12, total funding for the Department's biosecurity programs

² Draft Biosecurity Bill, section 9

 $^{^{3}}$ Based on Department of Agriculture, Fisheries and Forestry information.

⁴ Lizzio, J and Jones, C. March 2010. 'Biosecurity and Australia's primary industries- the role of biotechnology,' Bureau of Rural Sciences.

⁵ Department of Agriculture, Fisheries and Forestry Annual Report 2010-11, Snapshot of agriculture, fisheries and forestry, Value of exports for agriculture, fisheries and forestry, 2010-11, www.daff.gov.au/about/annual-report/annual-report-2010-11/report-on-performance/quarantine-and-export-services.

is estimated at \$509.5 million; the majority of which is comprised of \$186 million from government appropriation and \$295 million from external revenues.

The need for new biosecurity legislation

There are various reasons that have been identified for a shift in the approach of managing biosecurity. These are:

- the existing primary focus on interception at the border is a narrow and resource intensive response to the biosecurity continuum
- resources are allocated inefficiently to address different risks
- several key components of the biosecurity system at that time were identified as inadequate, inefficient or ineffective.

The nature of biosecurity risks in Australia

Biosecurity risks have the potential to impose significant costs on Australian firms, government and individuals if they are not managed effectively.

One example of this is the discovery of red imported fire ants (non native species) in Queensland. The Australian Bureau of Agricultural and Resource Economics estimated the potential costs of this pest to Australia over a 30 year period to be nearly \$9 billion. Currently, under emergency response arrangements (these include the Emergency Animal Disease Response Agreement, the Emergency Plant Pest Response Deed and the draft National Environmental Biosecurity Response Agreement.), the Australian Government is contributing to pest and disease eradication and other management programs at a cost of over \$315 million; of which the Australian Government has or is committed to contribute half of all government costs.

In the case of Foot and Mouth Disease, the recent Matthew's review⁷ commissioned the Australian Bureau of Agricultural and Resource Economics and Sciences to revisit the Productivity Commission's 2002 report on the economic impact of hypothetical foot and mouth disease outbreaks on Australia.

The Australian Bureau of Agricultural and Resource Economics and Sciences estimated that over a ten year period there would be severe direct economic losses to the livestock and meat processing sector from an outbreak of foot and mouth disease. These losses ranged from \$7.1 billion for a small three month outbreak, to \$16.0 billion for a large 12 month outbreak (expressed in current dollar terms). Control and compensation costs were estimated to range between \$25 million for the small outbreak, and \$600 million for the large outbreak. Reflecting international experience, the economic impact of trade restrictions (export market closures) would be far greater than the cost of controlling the disease.

The Beale Review and, prior to that, the Nairn Review were significant investigations into Australia's current biosecurity management framework and the current level of biosecurity risk Australia faces. These reports illustrate the nature of biosecurity risks to Australia, the potentially severe consequences should an incursion occur, as well as the need for government intervention. Therefore, this Regulatory Impact State (RIS) does not 're-prosecute' the need for quarantine activities at Australia's border from first principles in extensive detail.

⁶ Beale, Fairbrother, Inglis, Trebeck, "One Biosecurity: A Working Partnership," pg 2.

 $^{7 \}quad \text{Matthews, Ken AO, ``A review of Australia's preparedness for the threat of foot-and-mouth disease,'' October 2011, pg 3.}$

The role for government in mitigating biosecurity risks

Government intervention or action is typically justified in instances of market 'failure'. In this case, to take one example, the presence of negative externalities (a form of market failure where one party imposes costs on others that are not compensated or benefits that are not paid for) in the context of biosecurity has been widely documented.

For example, the importer of a good containing a pest or disease does not usually bear the full costs of any resultant pest or disease outbreak. Rather, pests and diseases affect other producers through a loss of production and/or additional costs associated with the control of the pest and disease and consumers through the potential increase in price for affected goods or the unavailability of the affected good.

After completing research and assessing the impacts of invasions, Perrings, Dehnen, Touza, & Williamson (2005) state that "responsibility for environmental protection lies with national governments and takes the form of quarantine regulations." Further "one of the most striking consequences of globalisation is the increase in the problem of invasive species" and subsequently invasion costs, indicating the growing need for government intervention.⁸

In Australia, the management of biosecurity is achieved through collaboration between the Australian, state and territory governments and other stakeholders. DAFF is the primary biosecurity agency; however there are a number of other Australian government agencies with responsibilities for border security and which participate in biosecurity decision making. Examples of these agencies include:

- the Department of Health and Ageing (DoHA) collaborates with state and territory government health agencies and other relevant agencies to develop, maintain and provide direction for human health issues and strict human quarantine policies to protect Australia from the introduction of serious communicable diseases⁹
- the Department of Sustainability, Environment, Water, Population and Communities (DSEWPC) is involved in respect of matters about pests that affect Australia's unique environment and to ensure a strategic, effective and consistent approach is used to manage environmental threats
- the Australian Customs and Border Protection Service (Customs) has shared responsibility with DAFF
 to regulate and control movement into and out of Australia of people, cargo and vessels at airports,
 sea ports and mail centres
- the Department of Immigration and Citizenship (DIAC) manages the entry of travellers.

In addition, state and territory governments have an integral involvement in managing and implementing on shore biosecurity activities. 10

The core priority for DAFF in managing biosecurity risks is to focus resources on those areas of greatest risk and where government intervention is most needed. 11

Priorities also include:

Perrings, C., Dehnen, K., Touza, J., & Williamson, M. (2005). How to manage biological invasions under globalisation. Ecology and Evolution, Vol.20.

Department of Health and Ageing, 'Annual Report, Outcome 14 – Biosecurity and Emergency Response', http://www.health.gov.au/internet/annrpt/publishing.nsf/Content/annual-report-0809-toc~0809-2~3~0809-2-3~14

¹⁰ Department of Agriculture, Fisheries and Forestry, 'Biosecurity', http://www.daff.gov.au/bsg.

 $^{^{11} \ \} Department of Agriculture, Fisheries and Forestry, `About our Biosecurity System', http://www.daff.gov.au/bsg/system.$

- the continued partnerships between Australian departments, state and territory governments, industry participants, clients and stakeholders
- the delivery of biosecurity services to support access to overseas markets and protect the economy and the environment from the impacts of unwanted pests and diseases.

Australia focuses heavily on maintaining its biosecurity system across the continuum, applying measures to identify hazards and manage risks through preparedness, prevention, response and recovery strategies. This focus on the continuum supports consistent service delivery, provides effective biosecurity risk management, improves the efficiency and responsiveness of operations, and strengthens client relationships.

Biosecurity risks have changed significantly since the core of the Quarantine Act was drafted over a century ago. The information below sets out some activities currently undertaken at the key points along the biosecurity continuum.

Activities conducted across the biosecurity continuum include:

- gathering and exchange of information on intelligence and surveillance
- conducting import risk analyses and risk assessments
- completing import policy reveiws
- conducting offshore assessments, treatments and inspections
- screening and inspection of international passengers, cargo, mail, animals and plants
- assessing and managing the associated biosecurity risks through targeting goods and vessels arriving in Australia for intervention
- managing the high biosecurity risks of live animals and plants through containing, observing and/or treating at quarantine facilities
- ensuring that imported foods are fit and safe for human consumption by inspecting and controlling upon arrival in Australia
- eradicating or managing those pests and diseases that have established
- monitoring Australia's environment for new pests or diseases that may have emerged¹³

Currently the Australian Government predominantly focuses its resources on 'at the border' activities. It also conducts some offshore activities, while the responsibility of onshore activities generally rests with state and territory agencies.

Industry participants are able to participate in the management of biosecurity risks through the implementation of a partnership arrangement between DAFF and the industry participant whereby industry participants agree to meet biosecurity standards and/or perform a range of biosecurity functions. These are formalised through provisions under the Quarantine Act.

Problems associated with current legislation

There are several problems associated with the current legislation. It is not aligned to modern business realities, has been amended approximately 50 times resulting in poorly integrated provisions and is marked

¹² Lizzio, J and Jones, C. March 2010. 'Biosecurity and Australia's primary industries – the role of biotechnology', Bureau of Rural Sciences.

¹³ Department of Agriculture, Fisheries and Forestry, 'Biosecurity', http://www.daff.gov.au/bsg.

by inconsistent use of language, poor structure, a range of drafting styles and duplication or overlap of powers.

Specific problems that have been identified and which are the focus of this RIS, are:

- the need for greater shared responsibility between the Australian, state and territory governments, and between government, business and community
- poorly specified obligations related to first points of entry
- insufficient powers to achieve biosecurity objectives.

Objectives and options to achieve them Government objectives

The objectives of government action to address the problems evident in existing biosecurity legislation are to:

- manage Australian biosecurity risks to an acceptable level and subsequently manage the impact associated with biosecurity incidents (such as the introduction of pests and diseases into Australia).
- maximise the economic efficiency of the management of biosecurity risks.

Options to achieve objectives

This chapter sets out, at a high level, a range of options for meeting the government's objectives from no regulation through to the proposed biosecurity legislation. These are considered in more detail in the chapters that follow in relation to the specific areas that are the focus of this RIS. Components of the legislation that are not specifically considered in this RIS are also set out in **Error! Reference source not found.**, setting out the extent of any change to the relevant legislative arrangements and any impacts on stakeholders (if any).

The current legislation

The status quo involves maintaining the current regulatory approach, which is the Quarantine Act and associated subordinate instruments. For the purposes of analysis for this RIS, the status quo is assumed to maintain:

- the current approach to articulating the Acceptable Level of Protection
- the current approach to Import Risk Assessments and associated risk determinations
- industry participants partnership arrangements as administered under two separate sections in the Ouarantine Act (sections 46A and 66B)
- the current approach to designating first ports of entry, whereby overseas vessels must enter Australia at a first port of entry proclaimed under the Quarantine Act
- the current governance arrangements
- the current cost recovery arrangements
- limited powers in post-border space
- a rigid enforcement regime with only the ability to undertake criminal prosecution.

The proposed biosecurity legislation

The proposed biosecurity legislation will replace the century old Quarantine Act and aims to create a responsive and flexible operating environment. The reforms will allow for better management of the risks of animal and plant pests and diseases entering, establishing and spreading in Australia and potentially causing harm to people, the environment and the economy.

The proposed biosecurity legislation comprises two new Bills; the *Biosecurity Bill 2012* and the *Inspector-General of Biosecurity Bill 2012*. The *Biosecurity Bill 2012* consists of the following chapters:

Chapter 1 – Preliminary: This chapter sets out a number of administrative matters and includes commencement, the objects of the Act, Australia's appropriate level of protection, binding of the Crown, geographical coverage, as well as how the Act will interact with state and territory laws.

Chapter 2 – Managing biosecurity risks: human health: This chapter covers the continued management of human health risks at Australia's borders. It outlines the measures which may be used to respond to the threat of serious communicable diseases.

Chapter 3 – Managing biosecurity risks: goods: This chapter provides for the powers of biosecurity officers to evaluate the potential risks associated with the import or proposed import of goods, prohibit or conditionally allow goods to be imported into Australia and to manage risks associated with goods brought into Australia.

Chapter 4 – Managing biosecurity risks: conveyances: This chapter outlines the establishment and management of first points of entry and the management of biosecurity risks associated with conveyances (vessels, aircraft, etc) entering into Australia's jurisdiction from overseas and with offshore installations.

Chapter 5 – Ballast water and sediment: This chapter implements the International Convention for the Control and Management of Ships' Ballast Water and Sediments 2004 and creates a single, Australian-wide ballast water and sediment management regime.

Chapter 6 – Managing biosecurity risks: monitoring, control and response: This chapter outlines powers to monitor and, where necessary, manage biosecurity risks when they emerge on-shore.

Chapter 7 – Approved Arrangements: This chapter outlines the scope and principles of approved arrangements, the processes for application, approval and any subsequent changes to an arrangement with a biosecurity industry participant.

Chapter 8 – Biosecurity emergencies and humans biosecurity emergencies: This chapter outlines the powers and provisions relating to the declaration of a state of biosecurity emergency and the management of associated biosecurity risks.

Chapter 9 – Compliance: This chapter establishes the monitoring, investigation and audit provisions under the Bill.

Chapter 10 – Warrants: This chapter contains general provisions relating to the various types of warrants that may be issued under the Bill.

Chapter 11 – Enforcement: This chapter provides a modern regime of enforcement tools to respond to non-compliance including civil penalties and criminal offences as well as a range of administrative options such as an infringement notice scheme, enforceable undertakings and identity provisions.

Chapter 12 – Governance and officials: This chapter makes clear the powers and responsibilities of the Director of Biosecurity, the Director of Human Biosecurity, and biosecurity officers, biosecurity enforcement officers, chief human biosecurity officers and human biosecurity officers.

Chapter 13 – Miscellaneous: This chapter contains provisions on recovery of costs and protection from civil proceeding while also covering other provisions that do not fit under any of the other chapters.

In comparison to the current situation, the information below describes the differences of the proposed biosecurity legislation as well as comments on the extent of impacts on stakeholders. This Regulation Impact Statement focuses on those areas that represent the most significant changes (and therefore impacts) for stakeholders (as discussed below).

Comparison between Quarantine Act and the current situation

Chapter 1 Preliminary

Compared to current legislation

- Outlines constitutional heads of power.
- The Commonwealth will cover the field in relation to importation of goods into Australia.
- Australia's Appropriate Level of Protection will be enshrined in the new legislation.

Outcomes and impact

These changes provide clarity around heads of power but this does not have tangible implications for stakeholders.

The risk of inconsistent import conditions imposed by States and Territories where they are inconsistent with Commonwealth laws will be reduced but in practice, inconsistent conditions can already be challenged because of Australia's obligations under World Trade and Free Trade agreements.

Australia's Appropriate Level of Protection is already Government policy and in operation it will not be any different if it is included in legislation.

In isolation, these changes are not expected to result in substantive impacts on stakeholders.

Chapter 2 Managing biosecurity risks: human health

Compared to current legislation

- More powers to manage human biosecurity risks.
- Interventions tailored to accommodate an individual's circumstances.

Outcomes and impact

Consultation on the draft RIS revealed that the impact of these changes will be minor as there will be little practical change to current procedures despite greater clarity and flexibility in the legislation. Further, only a small number of people are likely to be affected. For example, the changes do not affect the list of human diseases for which interventions are applied.

Chapter 3 Managing biosecurity risks: goods

Compared to current legislation

- Goods can be unloaded unless directed not to unload.
- Reversal of onus of proof for illegally imported goods.
- Abandoned or forfeited goods will be able to be destroyed, sold, exported or otherwise disposed of.

Outcomes and impact

DAFF operations staff have advised that in practice, the direction not to unload will not impact current loading/unloading practices.

The reversal of onus of proof will transfer the evidence burden from Government to importers – overall it is expected it will be easier and less resource intensive for an importer to prove goods were imported legally than for Government to prove the reverse. This change may affect the outcomes of individual prosecutions.

Flexibility to manage abandoned goods would provide benefits to government eg. in reduced storage and administrative costs but the quantum of benefits is expected to be minor.

These changes were not subject to more detailed analysis because of their relatively minor overall impact.

Chapter 4 Managing biosecurity risks: conveyances

Compared to current legislation

- Greater transparency around first points of entry
- Vessel sanitation certification scheme.

Outcomes and impact

The changes to first points of entry represent a substantive change to existing policy and will impact existing first points of entry and potential new first points of entry. Although the extent of impacts will depend on the detail in the regulations, some analysis of the high level impacts on stakeholders has been undertaken.

Consultation revealed that the vessel sanitation certification scheme will not materially impact existing processes as these certificates are, in practice, already recognised.

Chapter 5 Ballast water and sediment

Compared to current legislation

- Manage ballast water via exchange or treatment systems.
- Ballast water record books required.
- Ballast water management certificate and management plan required.

Outcomes and impact

The ballast water changes reflect an international convention that will come into force 12 months after ratification by 30 counties representing 35 percent of the world's merchant shipping tonnage. As of October 2012, 36 countries have ratified the convention representing 29% of world tonnage. Extensive consultation occurred prior to Australia ratifying the convention which included the development of a regulatory impact statement in 2007. Analysis of these impacts is not repeated in this RIS.

Chapter 6 Managing biosecurity risks: monitoring, control and response

Compared to current legislation

- New post border powers.
- Information gathering powers.
- Biosecurity control orders.
- Biosecurity zones.

Outcomes and impact

These measures give the Commonwealth additional powers for managing biosecurity risks post border. Most states and territories already have similar powers. In practice, use of Commonwealth state or territory powers will be coordinated under existing national agreements. Some analysis of possible impacts is included in the RIS.

Chapter 7 Approved arrangements

Compared to current legislation

Improve approved arrangements with industry to cover:

- Broader range of operations.
- Less administration costs for industry and government in managing Approved Arrangements.
- Ability to vary, suspend or revoke an Approved Arrangements.

Outcomes and impact

These measures will provide greater flexibility for industry to manage the biosecurity risks associated with their operations. In practice, this is likely to have the greatest benefits for large importers. Arrangements for smaller operators are unlikely to change significantly. The potential impacts are analysed in this RIS.

Chapter 8 Biosecurity emergencies and humans biosecurity emergencies

Compared to current legislation

Broadens the scope of the powers to cover:

- Threats to human, plant and animal health.
- The environment.
- The economy.

Outcomes and impact

These provisions are similar to existing powers in the Quarantine Act that have never been invoked but are broadened to include acting when there are potential impacts on the environment or economy. The powers are designed to manage serious situations and those that are not able to be anticipated. Given the similarities to existing powers and that they may never be invoked, it is not possible to predict substantive impacts on stakeholders and these have not been analysed.

Chapter 9 Compliance

Compared to current legislation

• Establishes the monitoring, investigation and audit provisions under the Bill.

Allows the Director of Biosecurity or Director of Human Biosecurity to assess whether a person is fit and proper in relation to applications for things such as import permits or approved arrangements, and also allows the Director of Biosecurity to require personal information for applications.

Outcomes and impact

These provisions outline the monitoring, investigation and audit powers for ensuring compliance with the Bill, and are similar to existing provisions in the Quarantine Act. The introduction of a fit and proper person test, in conjunction with the power to require personal information for applications, is envisaged to increase the efficiency of the process by allowing the review of a complete application without needing to seek additional information. These requirements are designed to protect the integrity of the application process for importers and other stakeholders. In addition, the requirements assist in the management of biosecurity risk by ensuring that privileges such as import permits or approved arrangements are given only to those able to responsibly and appropriately handle them.

Chapter 10 Warrants

Compared to current legislation

- Contains general provisions relating to the various types of warrants that may be issued under the Bill.
- Allows for entry to premises and the taking of possession of conveyances or premises by consent, with a warrant, or in certain circumstances without a warrant or consent.

Outcomes and impact

The warrant provisions will allow for appropriate officials to enter premises or exercise other specific powers for ensuring compliance with the Bill, or managing biosecurity risk. These provisions provide for warrants to be issued and exercised in accordance with the Bill in circumstances that are consistent with the *Australian Government Commonwealth Guide to Framing Offences, Infringement Notices and Enforcement Powers.* It is not envisaged that in practice there will be a high number of warrants issued each year.

Chapter 11 Enforcement

Compared to current legislation

More flexible, modern regime of penalties and offences to include:

- Infringement notices.
- Enforceable undertakings.
- Civil penalties.
- Criminal sanctions.

Outcomes and impact

The introduction of a civil penalty regime in addition to existing criminal offences provides the department with greater opportunity to take action where non-compliance has been identified. This will provide more flexibility than criminal sanctions alone to encourage behavioural change. The changes are consistent with normal practice in other sectors and are briefly outlined in this RIS.

Chapter 12 Governance and Officials

Compared to current legislation

General administration power for Director of Biosecurity to provide transparency, certainty and consistency on how the legislation will be applied.

Outcomes and impact

This additional power will provide greater administrative transparency. It does not allow the Director to 'reinterpret' legislation but may provide some benefit for stakeholders where there is uncertainty. The impacts for stakeholders will depend on the aspect of legislation being interpreted and the outcome and analysis of possible impacts would be speculative.

Chapter 13 Miscellaneous

Compared to current legislation

- Increased ability to deny/stop services where fees are outstanding.
- Reporting timeframes.

Protection from civil proceedings for officers performing functions under the Act.

Outcomes and impact

These provisions are administrative in nature and details, particularly in relation to cost recovery, will be provided in regulations. The department may benefit from the increased incentive for service users to pay fees. The reporting timeframes are not substantially different to existing timeframes. The protection of officers performing functions under the Act is consistent with current practice. Possible impacts of these provisions are not analysed in this RIS.

Inspector-General of Biosecurity Bill

Compared to current legislation

Establishes the Inspector-General of Biosecurity as a separate statutory office:

- Statutory office reports to the Minister.
- Quality of Processes.
- Report on reviews and findings (publically available).

Outcomes and impact

An interim Inspector-General has already been appointed and the incremental cost of establishing the office in legislation is therefore expected to be minimal. However, this office is expected to avoid the need for future Beale and Nairn style reviews – avoiding the costs of conducting these reviews would to some extent offset the costs of this office. These impacts are minor in nature and not analysed in detail in this RIS.

No regulation

A 'no regulation' option would involve no biosecurity controls and no measures to mitigate biosecurity risks to Australia. This option was not considered feasible because it does not achieve the objective of seeking to manage biosecurity risks to an acceptable level. It also is not consistent with Australia's international obligations.

Self regulation

A 'self regulation' option would involve industry participants leading risk mitigation measures and taking responsibility for managing these risks. As self regulation measures can have no legal basis, their success relies on there being sufficient incentive to business to act in a way that mitigates risk (such as potential loss of revenue). These approaches are not effective in cases, such as in managing biosecurity risks, where the potential costs of an incident are high and wide ranging and may not fall on the party primarily responsible for managing those risks, and where it is difficult to identify the party that has not properly managed risks.

Direct supervision by government

Under a direct supervision option government takes full responsibility for biosecurity measures and industry participants have no role in mitigation measures. This approach was not progressed as it is not feasible from a resourcing perspective for governments and is not cost effective. It was also not consistent with the government's cost recovery policy or with the 'shared responsibility' approach as outlined and recommended in both the Nairn and Beale reviews.

Assessing impacts

In developing proposed biosecurity legislation, a number of problems with the existing arrangements are addressed, the most significant of which relate to:

- 1 Approved arrangements.
- 2 Management of first points of entry.
- Biosecurity zones that provide the Australian Government with additional powers to manage biosecurity risks post border.

These areas were considered to impose the most significant impact, in part because some are new provisions, but also because they have the most wide reaching impacts on stakeholders.

A fourth area, ballast water management also involves significant changes, however a RIS on ballast water proposals was prepared in 2007 and the proposals have already been subject to extensive consultation. ¹⁴ As the content in that RIS remains current, the changes to ballast water management are not considered in this RIS. The differences between the existing Quarantine Act or the current situation and the proposed legislation are summarised in **Error! Reference source not found.**. This table provides brief commentary on whether or not these differences are expected to have substantive impacts on stakeholders and therefore whether substantive analysis of the impacts in this RIS was warranted.

Other areas within the new legislation either currently exist under the *Quarantine Act 1908* or exist in state and territory legislation.

In most cases, the proposed biosecurity legislation provides the enabling powers for government, with specific details around implementation and compliance to be set in regulations. While key areas of costs and benefits can be identified, an estimate of the scale of costs and benefits cannot be provided in most cases. For instance, the potential compliance costs of meeting requirements for first points of entry would be determined based on the criteria and application process to be set in regulations. The impact analysis is, therefore, primarily qualitative.

The focus of the analysis is on those elements which represent the most significant change and are considered to have the greatest potential impact on business and consumers. Each of these elements or issues are considered in turn in a thematic manner, that is, the nature of the problem, options and assessment are considered for each issue, before moving onto the next. This approach has been taken to assist the reader in working through one issue before moving onto the complexities of the next. After consideration of the most significant elements, the other less significant aspects of the proposed biosecurity legislation are briefly considered, before the RIS talks about implementation and review.

¹⁴ CIE (2007) Ballast water management,. A regulation impact statement, prepared for Department of Agriculture, Forestry and Fisheries by the Centre for International Economics Canberra & Sydney.

Approved arrangements

Nature of the problem

Currently the responsibility for protecting Australia's international borders primarily falls on government, which may increase the risk of 'moral hazard'. Moral hazard occurs when an individual or organisation is insulated from a risk or does not bear the cost of a risk occurring. Consequently the individual or organisation behaves differently, with a tendency to act less carefully than they otherwise would to mitigate the risk (as they have less incentive to work to reduce the probability of the risk occurring). For example, a vessel's captain may not adequately ensure the vessel harbours no pests or disease on board before entering Australian waters given the burden of checking the vessel falls on the Australian Government.

This issue with the Quarantine Act was noted in a submission from the Quarantine and Exports Advisory Council to the Beale review, stating:

"The responsibility of managing risk should not be a sole AQIS responsibility but be spread across corporate Australia. There should be a legislative mechanism to ensure corporate Australia and importers take responsibility for managing the risk by ensuring appropriate systems and procedures are in place." 15

The burden on government will continue to increase moving forward given the expected increase in the volume of goods, vessels and people coming into and out of Australia. Further, the focus on government can ignore private sector expertise in risk management.

The Quarantine Act requires that quarantine related activities are performed by DAFF officers or under their direct supervision. Sections 46A and 66B of the Quarantine Act create an exemption where DAFF can enter into arrangements (partnership arrangements) with industry participants to perform some of these functions themselves.

- Section 46A: allows the Director of Quarantine to approve a premises for the purpose of receiving, storing and dealing with goods subject to quarantine, referred to as a Quarantine Approved Premises (QAP).
- Section 66B: allows the Director to enter into a Compliance Agreement with an industry participant, which requires the industry participant to perform specific tasks in relation to goods that are subject to quarantine in an agreed manner.

Under section 46A and 66B, each premise or activity is subject to a separate approval or agreement. As a result, industry participants may be subject to multiple arrangements under one or both of the existing sections to ensure they are compliant. This leads to increased regulatory burden on industry participants, and imposes a significant administrative burden on DAFF as well as creating inefficiency and duplication of process. More broadly, the current arrangements are seen as unduly restrictive and rigid, with insufficient flexibility to allow for partnerships between industry participants and government in respect of certain activities or types of premises.

 $^{^{15}}$ Quarantine and Exports Advisory Council submission to the Beale review, p.3.

Options to address the problem

No regulation

No government intervention is not considered to be a feasible option as there are strong public interest concerns and potentially high risk events in relation to approved arrangements. The risks should be managed to a specified level for the broad benefit of the community and industry.

Market forces are insufficient incentive for industry participants to appropriately manage biosecurity risks to Australia. They may limit their management activities to identifying and preventing harm to their own business rather than identifying and preventing harm to Australia. Some approved arrangement participants will also lack the expertise required to identify and manage biosecurity risks.

The current legislation

Under current legislation, QAP and compliance agreements are already in place that achieve, to some extent, the benefits of partnerships between industry participants and government. There are a number of aspects of current arrangements however which are not optimal, and therefore do not achieve all of the potential benefits of these types of arrangements.

For instance, under the current legislation, large importers with control of their end to end supply chain processes are not able to take advantage of partnership arrangements with DAFF. As a result, any expertise they might have in managing risks is not utilised, and there may be higher costs to those participants and to government as a result of quarantine related activities being performed by DAFF.

Continuing with the current legislation would lead to the continuation of the above mentioned problems and therefore this is not deemed to be a feasible option for the purposes of this RIS.

The proposed biosecurity legislation

The proposed approved arrangement provisions will allow for:

- consolidation of existing QAPs and compliance agreements into single approved arrangements
- a systems-based approach to managing biosecurity risks that will enable larger end to end importers to participate in an approved arrangement.

Under the proposed biosecurity legislation, the Director of Biosecurity and the Director of Human Biosecurity may, upon the application of a biosecurity industry participant, approve an arrangement for the performance of particular biosecurity functions, or the exercising of particular biosecurity powers to manage biosecurity risks. An arrangement must meet the requirements set out in the regulations. The legislation would be flexible enough to allow the Directors to consider any matter they determine to be relevant when approving an arrangement.

If a Director reasonably believes that due to a change in circumstances an arrangement no longer meets the requirements on which the arrangement was approved (such as a change in the acceptable level of biosecurity risk), the Director may vary the arrangement, or require the biosecurity industry participant to vary the arrangement. Similarly, a biosecurity industry participant can request a variation to the arrangement. If the Director refuses a biosecurity industry participant's request for a variation, the Director will have to provide the reasons for the refusal.

The Director would also be able to suspend or revoke an approved arrangement. If the Director requires a suspension or revokes an agreement, a show cause notice would be issued first, giving the biosecurity industry participant 14 days to respond. The Director would not be required to issue a show cause notice if the grounds for suspension or revocation are serious or urgent. If a biosecurity industry participant requests a suspension or revocation, the Director would be required to approve the request.

If an approved arrangement has been suspended or revoked by a Director, the Director may require a biosecurity industry participant to take actions to ensure that biosecurity risks are still being adequately managed.

Direct supervision

A more prescriptive approach and greater government intervention is not feasible from a resourcing perspective for governments, not cost effective and not consistent with the 'shared responsibility' concept.

Assessment

Approved arrangements are most beneficial where industry participants have an advantage over government in providing a particular service or facility (for example, where industry participants are able to include particular biosecurity requirements within their usual business process, thereby avoiding the need to defer to biosecurity officials at that stage). That said, not all organisations will necessarily experience net benefits from moving to approved arrangements, and the voluntary nature of the arrangements will mean that generally only those that received net benefits will transition to this type of arrangement. One submission highlighted that it is likely that small operations may not expect significant benefits from such a shift due to the upfront training and support costs required. The proposed legislation is likely to have an impact (in terms of both costs and benefits to both businesses and government):

- Broadening the scope and flexibility of approved arrangements between government and business —
 where the changes influence the number and type of approved arrangements sought by industry
 participants with government.
- Reducing administrative complexity for government and industry participants where the changes allow approved arrangements to be established and managed at a lower administrative cost than previously.
- *Impacts associated with transition to approved arrangements* transition of existing agreements to approved arrangements is expected to take place within 18 months of commencement.

Each of these factors is discussed in more detail in the following sections.

Potential costs and benefits for industry participants

Broadening scope and flexibility of approved arrangements between government and businesses

Industry stakeholders' participation in partnership type agreements is currently voluntary, and would continue to be so under approved arrangements in the proposed biosecurity legislation. Costs associated with these arrangements, therefore, are incurred voluntarily by participants. It is reasonable to assume that industry participants not currently under a partnership type agreement will apply for an approved arrangement with government in cases where they believe that there is a net benefit for them of entering into the arrangement (over a reasonable timeframe for investment).

A key element in the potential change in up-take of approved arrangements is the broadening in scope and flexibility of arrangements that can be agreed under the proposed biosecurity legislation. There are two main implications:

1. There is unlikely to be a significant impact on the scope or scale of businesses currently under QAPs or compliance agreements that have been agreed under the Quarantine Act. Those industry participants who have limited control over the supply chain of the commodity or product they are importing,

- would transition to an approved arrangement similar to the current model they are using, whether that be the procedural or premises based model.
- 2. Larger industry participants that control the whole of supply process for their commodity or product may move to an agreement under the new model if it lowers their net costs and they can effectively manage biosecurity risks using their own systems. This would not occur if an industry participant thought that moving to a broader arrangement under the new model would be too costly or not deliver the benefits in the long term to justify the implementation costs.

The net change in the number of partnership type agreements in place would therefore be determined by the extent to which there is growth in the number of industry participants that seek new approved arrangements for their 'end-to-end' business process and additional functions. The following information, provided by DAFF, provides a guide on the potential uptake of these new types of approved arrangements for larger industry participants:

- There are currently approximately 1000 industry participants that import what can be classified as 'large' quantities. ¹⁶ Of these large importers, it is expected that there would be approximately 100 that have the appropriate internal systems in place to satisfy the requirements of an approved arrangement, that is, there are 100 industry participants that would be able to complete an 'end to end' risk analysis of their goods.
- It is anticipated that there would be 30-40 of these large industry participants that, already within their business model, satisfy the requirements and would need to simply put together their risk analysis and business model for DAFF to review. This results in 60-70 importers (that is, the 100 industry participants minus the 30-40 that already satisfy these requirements) who may benefit from implementing an agreement under the new arrangement and who would incur some initial costs to ensure their business model and risk analysis adequately satisfies DAFF's requirements.
- The importers who are successful would need to undergo audit checks to verify their risk analysis and ensure they are adequately managing their biosecurity risks. It is expected that the majority of these industry participants would have a high degree of exposure to these types of audit processes under current arrangements. Therefore the audit process would most likely not deter these participants and would not affect uptake.

Based on this analysis, it is reasonable to expect that there would be a small increase in the extent of approved arrangements agreed with industry participants under the proposed biosecurity legislation, though the additional agreements would be amongst larger importers and would have broader scope than current arrangements (that is, they would cover more business processes).

Example of potential benefits from approved arrangements

To demonstrate the potential benefits due to the proposed approved arrangement framework, the following example provides an illustration of potential benefits for an industry participant that chooses to be brought under the scope of an approved arrangement.

Company A is a major importer of commodity X and has been importing this commodity into Australia for many years without any biosecurity breaches. The company has controls in place across the total supply chain for all products it imports into Australia. The company's owner is a diligent importer who understands the biosecurity risks associated with the products it imports and its systems are able to provide evidence to

 $^{^{16}}$ Large quanties, based on 2011/2012 departmental statistics, is an importer that has approximately one or more entries per week.

support this. On average, the company imports 10,000 containers of this commodity each year. Under current processes, all of these containers must be inspected by biosecurity officers regardless of the company's compliance history and biosecurity management controls in place.

Under the new approved arrangement framework, the systems that Company A has in place would be recognised by DAFF as appropriate for managing the biosecurity risks associated with the goods the company is importing. Further, the low risk of Commodity X would also be taken into account due to the risk return approach enabled by legislation. Consequently, Company A would experience less intervention from DAFF. Out of the 10 000 containers, a lower percentage would be selected for inspection to provide assurance, or verify, that the company's arrangements effectively manage risks across the continuum. For this example, Company A's inspection rate could be reduced to 50 per cent of containers. (Note: this is to illustrate the potential benefit and does not reflect the true reduction for intervention that may be applied by DAFF).

Table 1: Impact on 'Company A' each year

Activity/Item	Current	Future
Container Inspection		
Containers inspected	10 000	5 000(a)
Time cost/container	60 minutes (b)	60 minutes (b)
Total time cost	10 000 hours	5 000 hours
Monetary cost/container	\$180(c)	\$180(c)
Total monetary cost	\$1 800 000	\$900 000
Potential time saving to Company A		5 000 hours
Potential cost saving to Company A		\$900 000

Source: The numbers of containers for this example are fictional and represent no real industry participant. The new intervention rate and average time taken were assumed and the fee for service costs are using current (2011) fee for service rates DAFF currently enforces.

Notes: (a) Assumed a reduced intervention rate of 50 per cent under new arrangements. (b) Assumed an average time taken of 60 minutes per container under both scenarios. (c) As per DAFF's fee for service rates, a rate of \$90 per 30 minutes was used. Additional costs incurred outside quarantine fees are also incurred such as transport, container lifts and storage space at Quarantine Approved Premises (QAPs). However these have not been included as these would be charged by the QAP and not DAFF.

Reduced administrative complexity in establishing and managing approved arrangements

Most industry participants operate either as a QAP, or under compliance agreements, although:

- universities can operate a large number of OAPs
- some participants (such as waste providers) can operate as a QAP and also have a range of compliance agreements in place.

Administrative costs

The proposed biosecurity legislation could reduce the current administrative costs for both industry participants and government. Under the proposed biosecurity legislation, there could be one approved arrangement covering a range of activities of an industry participant rather than multiple arrangements as is the current process. Biosecurity officers would no longer be required to process multiple applications, assess

multiple arrangements and complete multiple audits for those industry participants that apply under the new approved arrangement model.

Application costs

The Department intends to move away from the yearly renewals to a model that sees renewals required less frequently.

Industry participants may benefit from reduced application costs (both time and money costs) because of the need for fewer agreements. Further, depending on their arrangement, product, supply chain or other detail, they may experience less disruption to their business processes. This is because an audit and compliance program could be aligned with a single approved arrangement rather than multiple audits for multiple existing arrangements.

Impacts associated with transition to approved arrangements

Existing QAPs and compliance agreements will remain valid on commencement of the Act (one year after Royal Assent). The intent is to transition these existing agreements to approved arrangements within 18 months of commencement and/or as existing QAPs and agreements expire (two and a half years after the legislation receives Royal Assent).

In transitioning across, participants will need to pass a fit and proper person test and there may be some time spent understanding the transition process and completing paperwork. The provisions under the proposed Biosecurity Legislation provide the Director of Biosecurity and the Director of Human Biosecurity with the ability to apply the fit and proper person test and gather personal information from applicants. Information to make a determination will comprise publically available information, information gathered in the course of conducting business with other government agencies and information provided by the person. This is to ensure that persons covered by approved arrangements or who have been granted import permits are persons that are able to appropriately manage biosecurity risks. This is important because such a person might be involved in the importation of high risk goods or be approved to undertake activities to manage their own biosecurity risks with oversight by the Commonwealth. An import permit or an approved arrangement is a privilege rather than a right and means that the person is allowed to do certain things the general public are not allowed to do. It is important that such persons are considered fit and proper to be able to conduct these activities and there is no reason to believe that the person will not operate within the scope of their approval or adhere to any conditions or requirements that are placed upon it. As per the *Acts Interpretation Act 1901*, person includes a corporation or an individual.

The operational detail of changes to application processes and required content and information are not available. However, it is unlikely substantive new costs would be incurred as existing agreements are rolled over to an approved arrangement if the applicant is seeking to continue a similar arrangement. That said, a number of submissions highlighted examples of costs that might be incurred such as the development of manuals and procedures. To provide some indication of the potential magnitude of costs, it is assumed that:

- Time to deal with paper work related to the transition to an approved arrangement assumed to be 30 minutes.
- Fit and proper person test processing fee: \$42¹⁷.

¹⁷ Estimated cost based on the fee for a National Police Check application from a non-government organisation (eg: commercial entities like brokers, migration agents etc) is \$42. Source: http://www.afp.gov.au/what-we-do/police-checks/national-police-checks.aspx#fees.

- Time required to comply with 'fit and proper person' test requirements: 30 mins¹⁸.
- Value of time: \$71 per hour (including on-costs and overheads)19.
- Reduction in number of parties subject to an approved arrangement (currently around 1433 compliance agreements and 2824 QAPs, assume for illustrative purposes a 40 per cent reduction from these figures in terms of likely number of approved arrangements although precise number may differ from this).

This equates to a total cost of around\$289,000 assuming the costs of transition are all incurred at the beginning of the first year.

Potential costs and benefits for Government

There will be costs to government to transition those that currently operate as a QAP or under compliance agreements. This will involve assessing material that is provided by those seeking to transition across, and assessing whether applicants are fit and proper persons. As with other impacts in this chapter, the precise cost to government will depend on the nature and extent of the information that must be assessed. More broadly, there will be potential costs to government of administering a greater number of approved arrangements with industry participants than is currently the case.

The regulatory impact statement for the proposed amendments to the Children's Services Regulations 1998-Anaphylaxis Management and Criminal History Check estimates that complying with a police check will take on average 30 minutes of time.

¹⁹ Based on ABS, Weekly Average Earnings, Australia, May 2012 (fulltime, adult, total earnings) and grossed up to account for on-costs and overheads of 16.5 per cent and 50 per cent respectively. These estimates are based on published guidance that was derived from a number of generic and plausible estimates to be used in the absence of more specific data. (Government of Victoria, 2007, Victorian Guide to Regulation, Department of Treasury and Finance, Melbourne). Please note that this per hour estimate is not a net present value calculation.

Summary of impacts

Impact	Industry participants	Government
Broader scope and flexibility of approved arrangements	Increased number of arrangements facilitated under new legislative settings	Potential cost of administering a greater number of approved arrangements with industry participants
Reduced administrative complexity in establishing and managing approved arrangements	Current arrangements can be managed more efficiently at a lower cost to business	Benefit through reduced costs of managing approved arrangements (higher efficiency)
Impacts associated with transition to approved arrangements	Cost of transitioning to approved arrangement for each business currently under QAP or compliance agreement.	Cost of transitioning businesses to approved arrangements.

Public consultation

Several submissions received during the consultation period stated that, in theory, approved arrangements are a cost effective and resource friendly option, however more information would be required to know whether they will in fact lead to savings. It was also stated that the approved arrangement provisions provides opportunities for regulatory burden reduction, decreased overall costs to industry and government and streamlining of systems.

Submissions also highlighted the need for appropriate accreditation, auditing and performance monitoring systems using appropriately qualified auditors, exemptions from providing securities or mandatory securities and the need for more specific information on what arrangements can be approved, as the current legislation is quite specific. While several of the issues raised in submissions and throughout the consultation were the result of misinterpretation of the proposed biosecurity legislation, many others will be addressed in the regulations and accompanying polices and documentation.

Importantly approved arrangements do not intend to significantly alter the existing QAP and compliance arrangement schemes. Rather the intention is to replace them with a single combined model that is more flexible and expands, rather than restricts, the circumstances in which an arrangement can be entered into with the Commonwealth. If current QAP arrangements with DAFF meet the requirements in the legislation for an approved arrangement (ie. operations adequately manage risk and applicant meets fit and proper person test), it is likely that they can continue unaltered as an approved arrangement under the new legislation. (Note: each arrangement will be considered on its individual merits, so approval cannot be guaranteed).

In terms of using appropriately qualified auditors for approved arrangements, the provisions allow for the appointment of third party auditors. The auditor does not necessarily have to be a biosecurity officer but an expert in a relevant field.

Comments were considered about the impact of requiring some organisations to provide a 'security' as a condition of an approved arrangement. Security is intended to be a compliance tool, so that if a Biosecurity Industry Participant does not manage biosecurity risks in accordance with its approved arrangement, the security may then be used by the Commonwealth to pay for managing that incident. This is not a mandatory provision within the legislation and is in fact a discretionary provision that may be used by the relevant Director. The financial capacity of an organisation to provide an amount of security and the level of biosecurity risk posed by the proposed arrangement will be considered by the Director.

Approved arrangement regulations will be released for public consultation.

First points of entry

The *Quarantine Act 1908* currently requires overseas vessels and aircraft entering Australia to arrive at a first port of entry, currently listed in the *Quarantine Proclamations 1998*. The Quarantine Act allows the Governor-General to proclaim a port or a landing place as a first port of entry, and may include conditions or restrictions, (eg a port may be limited to receiving a specific class of goods, vessels or aircraft). This is intended to ensure that a first port has the facilities to manage the quarantine risks associated with the people, goods, vessels and aircraft it receives. Vessels can be properly processed at these first ports and inspected (if required) by DAFF staff.

Nature of the problem

While the *Quarantine Proclamation 1998* lists the 59 ports that are proclaimed as first ports of entry, there is currently no transparent process which sets out how ports qualify to be proclaimed or any requirements (including associated infrastructure requirements) that a first port must meet to ensure it can be serviced by biosecurity officials. Further, there is little clarity around what area constitutes a port in terms of geographical boundaries which is important for determining biosecurity risk.

Likewise, there is no clear mechanism to remove a port or landing place's first port status, if the level of biosecurity risk is not being adequately managed, a condition of approval has been contravened or the first port of entry has been decommissioned. In fact there are a number of proclaimed first ports of entry listed in the *Quarantine Proclamation 1998* that no longer receive a substantive volume of international vessels (for a variety of reasons) or are not in use at all (dormant first ports of entry). For example, the Port of Yamba is rarely used as a first port of entry and in the event it is used, can only be used for the landing of timber products arriving from New Zealand or Norfolk Island. There are around four to five dormant first points.

There are also instances where investment and business needs (eg a new mine that commences operation) have led to some areas being used intensively over a short period of time however the closest port may not be a proclaimed first port of entry. To use such a port, each vessel applies for permission under section 20AA of the Quarantine Act each time they enter the port. The approval is only valid for entry at that time and may be subject to conditions, and so some locations can be the subject of many one-off applications in a given year. This imposes administrative costs on vessel operators. Under s20D of the Quarantine Act, permission can also be sought to land a good at a port not proclaimed to receive that good (which may also be subject to conditions).

Further, there is the potential that vessels can enter and leave a port which is not proclaimed without the knowledge of regulators. This particularly occurs in areas where there is new traffic and the port has not been proclaimed (ie where the system has not kept up to date with the most probable ports for vessel traffic, such as in new areas of industrial activity). These entries increase the biosecurity risks in the region where no biosecurity compliance is being undertaken.

Options to address the problem

No regulation

A 'no regulation' alternative would allow for anything to be imported through any port in Australia, irrespective of the level of biosecurity risk. This option is not feasible as it would unacceptably increase the risk of animal and plant pests and diseases entering, establishing, spreading and potentially causing harm to people, the environment and the economy.

Self regulation

Under 'self-regulation', those arriving at a first point of entry would regulate their own activities according to industry participant's-formulated rules and codes of conduct, with industry participants solely responsible for enforcement. This is not a feasible option for first points of entry as there are strong public interest concerns and potentially high risk events in relation to first points of entry, of which many of the costs are not internalised by those operating the vessel arriving in Australia.

In addition, market forces will not require industry participants to appropriately identify and manage biosecurity risks to Australia in relation to first points of entry. Those arriving at a first point of entry may limit their management activities to identifying and preventing harm to their own business rather than identifying and preventing harm to Australia. Some entering at a first point of entry will also lack the expertise required to identify and manage biosecurity risks. For example a commercial vessel arriving at a first port will not necessarily have a vested interest in any environmental impacts from any pests present on the vessel. As Biosecurity officers are experienced in regularly carrying out routine vessel inspections, they are more attuned to identifying obvious and (more importantly) potential biosecurity risks that aren't necessarily associated with immediate commercial impacts, such as mosquito larvae found in any receptacles. In a world of 'self regulation', vessel masters may not have the skill/equipment/motivation to thoroughly inspect their vessel for pests, and send them to an entomologist for identification; which is routine (if necessary) for Biosecurity officers.

The current legislation

Continuing with the current legislation would lead to the continuation of the above problems, and therefore this is not considered to be a feasible option going forward.

Proposed biosecurity legislation

Under the proposed biosecurity legislation, the Director of Biosecurity may determine a first point of entry for overseas aircraft or vessels.

In deciding whether to make a first point of entry determination, the Director of Biosecurity must be satisfied that the requirements set out in the regulations are met and that the level of biosecurity risk associated with the operations of the port or landing place is acceptable. This is to ensure that biosecurity risks associated with the people, goods, vessels and aircraft it receives are being managed. The Director of Biosecurity can consider any matter that they deem relevant when determining whether they are satisfied. A first point of entry can be determined subject to conditions, for example a first point of entry may only be authorised to receive timber.

All overseas vessels and aircraft subject to biosecurity control are required to go to a first point of entry when entering Australia. On entering a first point a master must ensure that the vessel or aircraft enters a biosecurity entry zone.

Similarly a vessel or aircraft that is subject to biosecurity control may seek permission from the Director of Biosecurity to travel to a place that is not a first point of entry. A vessel or aircraft may seek permission from the Director of Biosecurity to unload goods at a port or landing place not determined to receive those goods.

A biosecurity officer will have the power to direct a master of an overseas vessel or aircraft to enter a specific port or landing place, or to not enter one or more specific ports or landing places (these may or may not be first point of entry). The proposed biosecurity legislation will also give a biosecurity officer the ability to enter any landing place or port in Australia, to perform functions or exercise powers without the consent of the operator.

The proposed biosecurity legislation will provide the Director of Biosecurity with the ability to suspend or revoke a first point of entry determination if the level of biosecurity risk is not being adequately managed, a condition of approval has been contravened or requirements for approval change.

Assessment

The proposed biosecurity legislation will provide flexibility for DAFF to negotiate with first point of entry operators regarding how they can manage their biosecurity risks to an acceptable level in the most efficient way. It will also establish the minimum level of regulation required to effectively manage biosecurity risks at a first point of entry while providing DAFF with the capacity to enforce any requirements or conditions.

The proposed legislative approach effectively equates to direct supervision, as only government will have the ability to declare a first point of entry. This will ensure comprehensive powers for biosecurity officers to manage biosecurity risks at ports and landing places.

The remainder of this section sets out the costs and benefits of the proposed biosecurity legislation specifically on:

- businesses (port operators and vessel masters)
- government
- other stakeholders (consumers and the general public).

Potential costs and benefits for business (port operators)

Greater transparency and certainty

Setting out requirements for first points of entry in regulations would provide a more transparent framework and accountable decision making process than is currently in place. This would clarify the responsibilities for port operators to be designated as a first point of entry, providing greater certainty both in terms of the application process, and the requirements to maintain this status over time. It would also ensure port operators are aware of the circumstances under which a first point of entry status may be revoked.

While the benefits of improved transparency and certainty are difficult to quantify, they are important for business and strategic planning. The required investment in facilities for port operators to maintain first point of entry status is an important element in their forward investment planning – understanding what is required to maintain this status allows operators to determine the value of this status compared with the costs associated with maintaining the infrastructure over time. For some ports, this decision will make business sense, while for others it may not (as discussed in more detail below). For all of these decisions, certainty around government decision making helps to reduce risks associated with investment.

Compliance costs

Under the proposed biosecurity legislation, first point of entry port operators would be subject to a greater regulatory burden than is currently the case under the Quarantine Act. These compliance costs can be assessed across two broad categories:

- Costs associated with applying to become a first point of entry (including costs associated with demonstrating compliance, such as providing documentation, externally provided evidence, etc).
- Costs associated with upgrading current facilities to meet requirements (which may be achieved within a transition period).

Application costs

There would be a cost to industry participants associated with applying to become a first point of entry. There would be time costs associated with completing the application process and a possible monetary fee set by DAFF for submitting and assessing an application. In addition, this application process would involve a port operator demonstrating that it can manage the biosecurity risks associated with its operations in the

application process before it can be determined as a first point of entry. This demonstration of adequacy or providing of evidence to meet biosecurity risks may be done through submitting detailed documentation and/or hosting site visits. It is expected that port operators would incur a cost to undertake these activities of compiling evidence to demonstrate their capabilities. Where possible the intention is to build on or use information already provided to other regulatory agencies such as the Australian Customs and Border Protection Service.

Costs of upgrading facilities

The second type of compliance cost relates to the potential need for some port operators to upgrade current facilities to meet requirements in the regulations. Some ports may not currently meet the requirements set in regulations, and would be required to undertake upgrades to meet standards (where they have committed to do so when applying for first point of entry status). These upgrade costs may result from tasks such as delineating boundaries, providing for waste management and providing facilities for biosecurity officers.

New requirements for providing particular facilities for biosecurity officers would most likely cause some current port operators to incur a cost. The extent of these costs will depend on the required outcomes set out in regulations and case by case assessment of how these outcomes can be met and will vary significantly across operators. Specifications for required facilities would reflect the size of the port, the port environs, the type of operations at the port and the type of goods, vessels, aircraft and people the port would receive. Some large operators may already have in place the required structures/facilities and will not incur any costs at all. Other operators may require significant upgrades or entirely new infrastructure. It is reasonable to assume that for some operators, implementation costs could be significant, and some may choose to not continue to be proclaimed under new requirements or have a different basis of proclamation. Additional maintenance costs relating to the upgrading facilities might also be incurred (above and beyond those maintenance costs already incurred), but this would depend on the nature of the upgrade requirements, and extent of current maintenance activity and size of operations.

The transition time provided to operators to meet obligations will have an impact on the scale of implementation costs. This is because the length of transition time influences the costs associated with retiring existing infrastructure prematurely before normal upgrading schedules. The longer the transition time, the lower the implementation costs for ports. Conversely, the longer transition time will have an influence on the effectiveness of the plans, as this extends the period during which facilities have not been upgraded or extended as required. Under the proposed biosecurity legislation there will be a three year transition period once the Act commences which will be one year after Royal Assent, a total period of four years. Stakeholders considered three years to be an adequate period of time to allow a port or landing space to comply with the conditions required for approval.

These expected compliance or regulatory costs are in addition to the current regulatory burden already imposed on industry participants by other Australian Government regulatory schemes. The list below highlights key schemes that are already in place and make up part of the regulatory environment surrounding industry participants that are involved in activities relating to first points of entry.

- Customs Regulations 1926
- Maritime Transport and Offshore Facilities Security Regulations 2003
- Aviation Transport Security Regulations 2005
- Migration Regulations 1994
- Agricultural and Veterinary Chemicals Regulations 1995
- Imported Food Control Regulations 1993
- Hazardous Waste (Regulation of Exports and Imports) Regulations 1996
- Environment Protection and Biodiversity Conservation Regulations 2000.

Costs of compliance will vary depending on how consistent the proposed changes to first points of entry build on these existing regulatory requirements.

One consultation participant (a practising Customs Broker) stated that:

"[Most first points of entry are already] established and should not need a lot of work/cost to meet the new conditions that could be applied. It is more likely to be 'country' ports that would require more cost to meet the guidelines and conditions to operate as a first point. Correcting the current approved list and adjusting resources to suit should see cost reductions and thereby allow resources to be better used. Often ports have surplus or under used infrastructure so there should not be a need for a lot of new and expensive infrastructure to be built, rather upgrading what already existing – again a cost savings to port operators and DAFF."

Impact on ports that are not maintained as first points of entry

Under the proposed biosecurity legislation, DAFF would be able to suspend or revoke port/landing places' first point of entry status. Some currently proclaimed ports may not meet the new requirements unless they undertake significant facility upgrades. Consequently, some landing places may choose to not apply to become a first point of entry under the proposed biosecurity legislation and thus have their first point of entry status revoked. This would mean that port would no longer be able to receive international vessels (for their first entry to Australia).

There are currently 59 proclaimed First Sea Ports and 29 First Airports within Australia (a total of 92 first points of entry currently proclaimed).²⁰ To determine the potential impact on industry participants, an evaluation of the status of current first points of entry (ports only) was undertaken. Through consultation with industry participants²¹, it is believed a portion of these may not be able to meet the requirements of being deemed a first point of entry under the proposed biosecurity legislation unless significant upgrades were undertaken to their facilities.

Current first points of entry that may be unable to meet the requirements may be those ports which currently have restrictions in place as to whether or not animals, plants or goods can be landed there as the restrictions indicate that the port only undertakes a narrow or limited set of operations. This limitation in operations may in turn mean the port has a limited range of facilities available for biosecurity officers. Consequently, the port may decide that it would be inappropriate from a business perspective to maintain a first point of entry status given the potential significant cost of upgrading facilities and the benefit from maintaining first point status. Accordingly, a port under current restrictions may not apply under the new legislation resulting in the termination of their current first point of entry status.

Table 2 highlights the proportion of first points of entry (sea ports only) that have total, partial or no restrictions in place regarding animals, plants or goods. Restriction was defined to be where no animals, plants or goods could be landed at the port, partial restrictions was considered to be if one or two items could not be landed, and unrestricted is where all three components could be landed at the first point of entry. As Table 2 illustrates, approximately 25 per cent of ports currently have a restricted status. It is these ports that may decide to forgo applying under the proposed biosecurity legislation and have their first point of entry status terminated.

 $^{^{20}}$ Quarantine Proclamation 1998 as amended, made under section 13 of the *Quarantine Act* 1908. (Prepared 11 March 2005).

 $^{^{21}\,}$ Consultations were completed with DAFF employees and with Ports Australia.

Table 2: Restrictions in place on sea ports that are currently first points of entry

Туре	Number	Percentage
Restricted	16	25.4%
Partially restricted	40	63.5%
Unrestricted	7	11.1%
Total	63	100%

The requirements for first point of entry status are to be set in regulations. The extent to which these requirements may dissuade current first ports of entry from applying under the proposed biosecurity legislation is unclear, as the requirements are still to be determined. However, the requirements would include some flexibility to reflect port scale, environs, type of operations and type of good, vessel and people the port receives (ie smaller ports would not have the same requirements as larger ports).

The costs for those ports that choose to not apply for first point of entry status under the proposed biosecurity legislation would be the loss of any profitable activities forgone. These costs will vary considerably across ports. The ports most likely to have their first point status not maintained are expected to be those ports that are currently under utilised and do not have the required facilities/ infrastructure in place to effectively manage biosecurity risks given their current limited use by international vessels.

Potential costs and benefits for business (vessel masters)

Increased transparency of port requirements and fewer applications to land at non-proclaimed ports

The proposed changes to the legislation regarding first point of entry would also have an impact on vessel masters and pilots. Vessel masters and pilots seeking entry to Australia would have greater certainty as to what facilities would be afforded to them upon arriving at a first point of entry.

It is expected that vessel masters would be more impacted by the change to legislation than pilots. This is because current use of first ports of entry by international vessels and aircraft differs. Most international aircraft arrive at a major airport that is a proclaimed first point of entry and most likely has adequate facilities for managing biosecurity risks (such as Sydney, Melbourne and Perth).

Alternatively, due to passenger requirements, trade flows or new investment projects, vessels are sometimes required to land at a non-proclaimed first point of entry. Under current arrangements (s20AA and s20D), this requires individual vessel masters to seek permission to land from either the Health Minister or Director of Quarantine and (if sought under s20AA) the permission is valid for the specified entry only. This has resulted in multiple vessel masters incurring the cost of seeking permission to enter the same non-declared port that for a period of time may be under heavy use (for example for the commencement of a new mine).

Under the proposed biosecurity legislation, an improved framework would be in place to manage short term port usage. The new framework would potentially allow for the declaration of a first point of entry for a period of time when heavily used which could then be revoked when the port usage by international vessels reduces. The framework would also mean that vessel masters have a more transparent view of those ports proclaimed as a first point of entry and thus could plan accordingly, avoiding the cost of seeking permission to land at a non-declared first point of entry. The approach under the proposed biosecurity legislation would also reduce the frequency of one-off applications from vessel masters to land at a non-proclaimed first point of entry.

Potential costs and benefits for Government

The requirement for vessels and aircraft to enter at a first point of entry provides the ability to manage the department's resources appropriately and effectively. It would be inappropriate and costly for the department to service all Australian ports and it would be unsuitable to expect all port operators to provide the necessary facilities to manage biosecurity risks in case of a landing of a vessel or aircraft.

Adequate facilities

The requirements under the proposed biosecurity legislation would increase the efficiency and effectiveness of biosecurity officers by providing adequate facilities for officers to complete their biosecurity management objectives. It would mean that officers have the necessary tools and facilities available to them at each port to carry out specific biosecurity duties relevant for that port. That is, it would ensure that biosecurity risks are managed effectively as well as efficiently as the right facilities for each port would be available given each port has differing service needs and levels.

A result of the requirements is that all DAFF officers would have a better understanding of each port's characteristics (for example boundaries, infrastructure) and be aware of the facilities to expect at each port. Thus officers would be able to better prepare and plan for managing biosecurity risks at each port, potentially reducing the time required to undertake activities at the port.

Non-proclaimed ports

The approach under the proposed biosecurity legislation would reduce the frequency of one-off applications from vessel masters to land at a non-proclaimed first point of entry (currently around one per day). It is estimated that this could reduce one-off applications by around 50 per cent.

In turn, this would also increase the efficiency of biosecurity officers as it would lessen the frequency, time and associated monetary cost of sending a team of biosecurity officers to a non-proclaimed port to undertake appropriate biosecurity management tasks on the vessel who sought permission to land at a non-proclaimed port.

Potential costs and benefits for other stakeholders (consumers and the general public)

Consumers who use ports that do not continue as first points of entry

Those businesses or individuals that may rely on the use of a particular port, which does not continue on as a first point of entry under the proposed biosecurity legislation may incur additional costs associated with using a different port to received goods. The extent to which this occurs will depend on which ports no longer continue as first points of entry, and which industry participants rely on these ports. As noted above, the ports which are most likely to not continue as a first point of entry are those which currently have limited use and provide a narrow range of services. It may be that some industry participants still rely on these ports due to their remoteness to other ports (that is, the next nearest port is a substantive distance away).

Summary of impacts

Port operators

Impact - Greater transparency and certainty for port operators relating to the first point of entry process due to requirements being set in regulations.

Effect - Positive

Impact - Compliance costs and regulatory burden – There would be two additional compliance costs applicable to those port operators who choose to apply for first point of entry status: 1) application and demonstration costs and 2) upgrade of facilities costs to meet the requirements set in the regulations.

Effect - Negative

Impact - Change in first point of entry status as decided by port operator – If the cost associated with upgrading facilities to meet the requirements within regulations is greater than the expected revenue generated from undertaking first point of entry activities, ports may decide to forgo applying for first point of entry status under the proposed biosecurity legislation.

Effect - Negative

Vessel masters

Impact - Greater transparency of port requirements and potential reduced submissions to land at non-proclaimed ports. Superior framework to work within resulting in greater transparency of port requirements and potential reduced submissions to land at non-proclaimed ports.

Effect - Positive

DAFF

Impact - Greater efficiency and effectiveness in completing required operational task due to the greater provision of facilities by port operators and reduced visits to non-proclaimed ports.

Effect - Positive

Other stakeholders

Impact - Impacts on consumers who use ports that do not continue as first points of entry.

Public consultation

There were few references to first points of entry within the submissions received and where mentioned were generally supportive of changes from the current approach of declaring first ports and landing places in the *Quarantine Proclamation 1998* to a more streamlined and transparent process. It was stated that a key benefit would be more certainty for airport and port operators in the requirements to be a first point of entry operator.

It was noted that there may be additional costs for non-compliant first point of entry operators to become compliant under the new legislation and this may cause some port operators financial hardship to invest in the equipment and infrastructure required. It was suggested that assistance should be afforded so these operators can comply with the new arrangements.

Another submission supported the capacity for greater flexibility in defining first points of entry but made the point that the provision of infrastructure for quarantine purposes was now the responsibility of new owners/operators of ports seeking recognition as first points of entry.

A government submission supported the ability for the proposed process to determine what is an appropriate first point of entry based on level of risk and ability to manage risks, with ongoing requirements to maintain a specific biosecurity status. The submission also stated that there is clear benefit in being able to set an appropriate level of protection from biosecurity threats when determining first point of entry, and to then require this level of protection.

Compliance requirements for first points of entry will be provided in regulations and accompanying policies and guidelines to be released for public consultation. Assistance, monetary or otherwise, is not an issue considered for the draft primary legislation and is a matter for government during implementation.

Biosecurity zones

The Australian Government currently assumes a relatively narrow biosecurity reach even though its Constitutional powers allow for broader regulation. Specifically, the Australian Government has not yet exercised its full Constitutional power but rather has focused on regulating border activities.

The *Quarantine Act 1908* currently allows for the creation of a monitoring and control area within 400 meters of a point where goods and cargo are discharged (eg at a first port of entry). In this area quarantine officers can carry out vector monitoring and control activities, but these monitoring powers are currently limited to human health risks.

Onshore activities however have generally been the responsibility of state and territory governments, with the assistance from the Australian Government in particular instances.

Nature of the problem

This relatively narrow focus of the Australian Government has caused a range of issues, including:

- lack of powers for the Australian Government to manage incursions in Australia
- additional, and sometimes overlapping, biosecurity measures imposed by individual states and territories
- the non-traceability of animal and plant matter of greater biosecurity interest once it passes the border
- inefficient strategies and actions due to the uncertain roles and responsibilities of both individual states and territories and the Australian Government
- inadequate information sharing and coordination between the states and territories.

There is disagreement over specific roles and responsibilities which is leading to gaps in the continuum and is therefore detrimental to Australia's biosecurity. The capacity of the Australian Government, state and territory governments to respond in emergency situations also varies, which may impact on the ability to effectively prevent the incursion of pest and disease.

Options to address the problem

No regulation

A 'no regulation' option would have the Australian Government playing no part in the post-border management of pests and diseases. This would leave the states and territories to manage post-border incursions of pests and diseases. This is inconsistent with the Australian Government's leadership role in the post-border biosecurity space as recognised by Australian Government/state agreements, decision making and consultative forums. The 'shared responsibility' approach was also outlined and recommended in both the Nairn review and the Beale review.

Self regulation

Due to the involvement of the state and territories, it is not open to the Australian Government to initiate 'self-regulation' arrangements under which businesses would regulate their own activities in relation to biosecurity zones according to industry participant's formulated rules and codes of conduct, with industry participants taking sole responsibility for enforcement. 'Self-regulation' is also not feasible as there would be many industry participants and others (including members of the public) moving within, and in and out of, biosecurity zones. Coordinating the activity and movement of these people would be almost impossible and,

even if it were possible, it would be prohibitively burdensome from an administration perspective. Further, there are strong public interest concerns and high risks associated with biosecurity zones and market forces will not require industry participants to appropriately identify and manage biosecurity risks to Australia.

Direct supervision

Direct supervision would involve the Australian Government overriding state and territory laws in relation to biosecurity zones. This option is not feasible as the states and territories have important roles to play in the post-border biosecurity space as recognised by the Australian Government/state agreements, decision making and consultative forums. The 'shared responsibility' approach was also outlined and recommended in both the Nairn review and the Beale review.

The current legislation

Continuing with the current legislation would lead to the continuation of the above problems, and therefore this is not deemed to be a feasible option going forward.

The proposed biosecurity legislation

The proposed biosecurity legislation will provide the Australian Government with greater capacity to assist with responses to post-border incursion of pests and diseases. While the powers are currently available to the states and territories, the biosecurity legislation will allow a nationally consistent response to pests or diseases through the use of one set of powers when needed. The biosecurity legislation will also extend the scope of the Australian Government's post border powers to include plant and animal biosecurity risks. The Australian Government will continue to work with states and territories through arrangements such as the Emergency Plant Pest Response Deed, the National Environmental Biosecurity Response Agreement and the Emergency Animal Disease Response Agreement to jointly manage biosecurity risks.

The proposed biosecurity legislation will provide biosecurity officers with the power to order biosecurity measures in relation to goods, conveyances and fixed property, by issuing a biosecurity control order to manage biosecurity risks onshore. A biosecurity control order can only be issued where the biosecurity officer suspects on reasonable grounds that it is necessary to prevent or control the establishment or spread of a pest or disease.

In addition, the Director of Biosecurity would have the ability to declare biosecurity zones (as well as sub zones within a zone) and to apply post border biosecurity measures within these zones. The powers that may be used in zones to manage risks onshore will be listed in the legislation.

There will be three types of zones that can be declared by the Director of Biosecurity:

- Biosecurity zone (ongoing) Biosecurity zones which are established on an ongoing basis will be used
 for those areas where there is a requirement for an area of biosecurity control on an ongoing basis. A
 good example of this is around a port or airport, where there is continual need for management of
 biosecurity risks, with the arrival of goods or persons. The powers available in biosecurity zones
 would:
 - direct that biosecurity measures specified in the determination be taken in respect of goods, a conveyance or fixed property in the zone
 - direct specified persons, goods or conveyances to enter or leave the zone at a specified place or places or to submit to screening before entering or leaving the zone
 - direct that goods and conveyances not be moved into or out of the zone without permission (which may be subject to conditions)
 - allow biosecurity officers to enter and remain on private property in the zone for the purposes of performing powers and exercising powers under the Act (with an obligation to produce an identity card to a person in charge of the property) without consent

- direct that the zone be identified and marked
- require persons in charge of goods, conveyances or fixed property in the zone to answer questions and provide documents
- enter private property in the zone without consent to inspect goods
- enter private property in the zone to conduct pest and disease monitoring activities without consent
- stop a conveyance for the purposes of inspecting the conveyance or goods on the conveyance
- direct a person in the zone to
 - leave the zone
 - subject himself or herself to biosecurity measures specified in the determination on entering or leaving the zone
 - inform another person, or other people, of matters specified in the direction
- set up equipment or other structures in the zone, including on private property without consent
- direct a person in charge of property to carry out pest and disease monitoring activities.
- Monitoring zone (ongoing or temporary) A monitoring zone would allow a biosecurity officer to perform monitoring activities, to ensure that a pest or disease is not present at a location. It may be ongoing (such as around a first point of entry) or temporary (if declared around a biosecurity response zone). It is possible that a monitoring zone may be upgraded to a biosecurity response zone if a pest or disease is found in a monitoring zone, and affects multiple properties.
- Biosecurity response zone (temporary) The Director of Human Biosecurity would have the power to
 declare a human health response zone and to apply post border measures to deal with listed human
 pest and diseases within the zone. The Act will not compel the Australian Government to act, but
 allows it to, complementing rather than replacing existing powers used by state and territory
 governments.

Assessment

A number of submissions stated that there is merit in the proposals regarding biosecurity zones to manage the risk and help prevent the negative impacts from pests and diseases. The value of a national approach and the Commonwealth playing a role in the management of serious threats was also recognised.

Some state governments highlighted concerns around potential conflict between Commonwealth and state/territory regulation of zones. The intention is to consult closely with state and territory governments to ensure understanding and avoid any confusion.

It was emphasised during the consultation phase that the proposed powers provide another tool by which incursions could be managed and that they would operate within the exiting consensus arrangements.

The potential impact of the proposed biosecurity legislation on business, and other stakeholders more broadly, is dependent on the following factors.

- The extent to which these measures may impose costs on business or other stakeholders by restricting their normal operations (ie restricting access to property, restricting movement of people, vehicles or goods, requiring monitoring activities).
- The extent to which the proposed arrangements will improve the management of biosecurity risks, including reducing the potential spread of an introduced species or disease.

• The frequency with which the measures may be used by government (ie the three types of zones noted above).

Each of these factors is discussed in the following section.

Potential costs and benefits for businesses

The potential costs of new Biosecurity zone powers vary across the three types of zones that may be declared.

Biosecurity zone (on-going)

There are expected to be some transition costs for business at the time of establishment, although they are likely to be minor given the nature of the areas. The establishment of these zones is expected to have a relatively low impact, given existing arrangements in these areas (where there are already areas around ports and airports which manage biosecurity risks).

Monitoring zone (on-going or temporary)

The extent of costs to businesses and other stakeholders associated with a monitoring zone will vary considerably depending on the size of the area captured, and the monitoring activities that would take place in the zone. That said, given the nature of monitoring activities, the degree of cost associated with disruption and inconvenience is likely to be small (in particular in comparison to a biosecurity response zone).

Biosecurity response zone (temporary)

The declaration of a biosecurity response zone would involve the greatest degree of disruption and inconvenience for businesses and other stakeholders, and the highest potential cost. The likely costs of this measure depend on the extent of potential measures conducted within the response zone (such as restricting movement of people and goods into and out of the area, requiring use of property by biosecurity officials, requiring destruction of goods etc). In addition, costs are more likely to be incurred by business given the potential short lead time provided for business to adjust the changes (ie the zone can be declared at short notice with no opportunity for business to be prepared ahead of time). Under the base case, there are existing state and territory powers that can be used to impose a majority of these provisions and requirements. The costs associated with these measures, therefore, are only those that would not have otherwise been incurred by the use of similar powers at a state or territory level.

The extent of these costs would vary depending on the size of the area declared, the number of businesses operating within the zone, the measures taken by biosecurity officials and the length of time that the zone is declared. It is likely, therefore, that the costs associated with this measure would have wide variance (ie some may impose relatively low costs if they are applied to a small area, or the area does not include a large number of industry participants, while others may impose significantly higher costs).

Potential costs and benefits for government

The more significant costs to government relate to monitoring zones and biosecurity response zones:

• The extent of costs to government associated with a monitoring zone will vary depending on the size of the area captured, and the monitoring activities that would take place in the zone. That said, given that nature of monitoring activities, it is likely to be small (in particular in comparison to a biosecurity response zone). The declaration of a biosecurity response zone would involve costs for government to put in place the zone and undertake associated activities to address any risks. These measures however are only temporary and would be used on an as need basis, where an Australian Government response is required and is agreed with relevant jurisdictions.

Potential costs and benefits for businesses and society

The key benefit of the proposed changes will be improved management of biosecurity risks in:

- on-going management of risks around key areas where there are high levels of goods and persons entering Australia
- timely and consistent responses to particular incidents where pests or diseases are introduced to Australia.

The potential benefits of this enhanced approach to management of risks will be realised by those industries the measures are put in place to protect (or manage exposure to risks). The extent of these benefits will vary across particular cases that biosecurity zones are used. Better or consistent management of biosecurity incidents are likely to have a benefit in terms of reducing the costs incurred by affected business, governments and other stakeholders (for example by limiting the spread of the pest or diseases).

These costs include:

- loss of revenue from sales of commodities or goods, which cannot go ahead due to the introduction of a pest or disease
- losses associated with damage to industry participants reputation, which can be incurred over a much longer time period than the incident itself
- flow-on costs for associated industries and communities (for example, industry participants providing services to affected industry participants).

The precise costs and benefits of the proposed biosecurity legislation depend on the manner and frequency with which the powers are used, which is uncertain.

Likely frequency of application of powers

The frequency of use of the proposed powers has significant impact on the overall costs and benefits of the proposed changes to powers. It is reasonable to assume that:

- Biosecurity zones will be established around key areas, and are unlikely to be changed significantly over time (ie zones around ports or airports).
- Monitoring zones will be used relatively infrequently, will most often be used in conjunction with biosecurity response zones or around first points of entry.
- Biosecurity response zones will be used infrequently, based on criteria set in regulations (which are still to be developed). The use of these zones will be focused on serious incidents which require post-border management (such as restricting movement of goods and persons).

Summary of impacts

Type of biosecurity zone	Costs to businesses and other stakeholders of declaration of zone	Benefits through improved response to risk	Likely frequency of use of powers
Biosecurity zone (ongoing)	Establishment costs for industry participants within the biosecurity zone (expected to be small)	Benefits in improved efficiency in management of biosecurity risks in areas of high risk	In use continually in key areas (eg ports and airports)
Monitoring zone (ongoing or temporary)	Costs associated with allowing monitoring activities on property	Benefits to regions which may be affected by the spread of an introduced pest or disease (adjoining to biosecurity response zone)	Moderate to low frequency – used in conjunction with biosecurity response zones Also used around first points of entry to monitor potential risks associated with arriving vessels
Biosecurity response zone (temporary)	Costs associated with allowing biosecurity management activities on property, restrictions on movement of persons, livestock and goods	High benefits concentrated within regions or industries directly impacted by the incident (including adjacent areas at risk) Will provide improved ways to manage incidents such as pest and disease outbreaks	Low frequency – used only in the case of the introduction or spread of pests or disease that requires monitoring and control

Public consultation

Environmental organisations suggested the establishment of a biosecurity zone category for high value conservation areas with high biosecurity risks known as 'conservation biosecurity zones', as the basis for implementing biosecurity measures, plans and monitoring. The zones should be declared by the Secretary of the Department of Sustainability, Environment, Water, Population and Communities (SEWPaC) on advice by a scientific committee, and biosecurity arrangements negotiated in bilateral agreements with state and territory governments. While there is scope to apply a zone to address a disease or pest risk the legislation does not allow for a pre-emptive zone for conservation purposes. Whilst the draft legislation clearly covers environmental biosecurity, environmental conservation at the Commonwealth level remains the responsibility of SEWPaC.

Submissions from state governments considered the proposal to increase the Australian government's post border powers in relation to biosecurity zones important. In particular, the provisions that allow the Australian government to monitor for and manage incursions and implement emergency response procedures.

The potential for conflict between the proposed biosecurity legislation and relevant state and territory legislation was also highlighted and clarity regarding roles and responsibilities, and a clear definition of when the Commonwealth may use these powers was deemed critical.

Administrative arrangements on how these powers will be used will be further developed with state and territory governments leading up to the implementation of the new legislation. Information will also be provided to stakeholders in the future as this content is developed.

Other aspects of the legislation

This section briefly considers other less significant aspects of the proposed biosecurity legislation.

Travel movement restrictions

There is a need for government to act to mitigate the risk of spreading communicable diseases to ensure that Australia complies with its international health obligations.

Human Quarantine Officers currently have limited powers to restrict the movement of people out of Australia in instances where there is an increased threat of communicable diseases. Under the proposed biosecurity legislation, the Director of Human Biosecurity would have the ability to restrict a person suspected of having a listed human disease from travelling on an overseas passenger aircraft or vessel.

Biosecurity interventions would be tailored to accommodate an individual's circumstances (eg their health, travel history or future movements), with the ability to escalate to broader responses as information becomes available. For example, an ill passenger could be ordered into isolation, ordered to undergo treatment or vaccination, ordered to stay at home for a period, ordered to report their health status regularly, or simply required to provide accurate contact details. The new legislation also seeks to further implement the International Health Regulations (2005) and provide the Australian Government with powers to prevent, protect against, control and provide a public health response to the national and international spread of disease.

The proposed biosecurity legislation would allow the Director of Human Biosecurity to issue an alert to all border agencies and relevant operators, advising them of the travel restrictions in place. This alert would be used to ensure suspected individuals subject to a traveller movement restriction are not allowed to board an aircraft or vessel.

The cost of travel movement restrictions is expected to be minimal due to the low expected frequency with which the power is expected to be invoked and the associated impact. While it is difficult to estimate the exact number of times this is likely to be used each year, it might be in the range of around 2-3 times per year on average.

Should an individual be identified by Customs at the primary line as being subject to travel movement restrictions and being unable to travel, the impact would be the removal of their baggage from the aircraft or vessel and the voiding of the traveller's boarding pass. Affected individuals would potentially forfeit some or all of any payments made to the airline or vessel and other associated travel costs (eg accommodation at destination).

Management of human remains

Under the *Quarantine Proclamation 1998*, a permit is required for the importation of human remains that are not accompanied by a death certificate stating the cause of death, are not of a high risk nature or where the deaths occurred during transit. The current permit system requires the involvement of staff from Department of Health and Ageing, the Department of Agriculture, Fisheries and Forestry, and the Department of Foreign Affairs and Trade.

Human biosecurity risks associated with imported human remains are negligible due to the:

- low number of imported human remains (approximately 500 human remains are repatriated to Australia each year with less than 250 of these currently requiring an import permit (potentially even less than 100 per year))
- the low likelihood of death from communicable disease of an Australian travelling overseas

- low global incidence or prevalence of the diseases which present a risk to human health in Australia
- high standards of infection control in Australia, particularly for funeral industry participants, which are regulated under occupational, health and safety legislation and practices
- high levels of vaccination, sanitation, hygiene and water safety in most areas of Australia
- high standards of health care available in Australia, and the speed and effectiveness of public health action.

As a result of the negligible level of human biosecurity risk, an ongoing permit system (ie regulation) does not represent an efficient use of Australian Government resources. In the unlikely event that there is a communicable disease outbreak in Australia resulting from imported human remains, public health measures are likely to be successful in managing and preventing the spread of most diseases.

Under the proposed biosecurity legislation, a permit would no longer need to be obtained to transport human remains into Australia, as human remains will generally be permitted to enter Australia without restriction. Requirements will only be applied to specific classes of remains, as specified by the Director of Human Biosecurity. Biosecurity risks associated with individuals who have died in transit will continue to be managed by State Police and the Coroner.

Circumstances which alter the above factors may lead to changes in the human biosecurity risk associated with importing human remains. For example, the import volume and likelihood of death from communicable disease may be increased during wartime; or a large scale outbreak of a communicable disease may occur overseas. In those circumstances, the Australian Government can respond to changes in the human biosecurity risk level by placing import requirements on particular classes of human remains.

From information provided by Department of Health and Ageing, approximately 500 human remains are repatriated to Australia each year with less than 250 of these currently requiring an import permit (potentially less than 100 per year). It is expected that these cases will no longer require an import permit and this would result in two benefits to those needing to repatriate remains into Australia.

Firstly, there is the obvious benefit of avoiding both the associated fees and time cost associated with applying for a permit, estimated as follows:

- lodgement of import permit application fee (permit application fee) \$150
- assessment of import permit application fee (standard good) \$40
- average time to fill out the required documentation online 30 minutes.

Based on the estimate of around 100 permits currently per year, this equates to a NPV over 10 years of around $$158,500.^{22}$

Most importantly for impacted parties however, there would no longer be the emotional cost incurred by those who may have recently suffered the death of a family member and must spend the time and effort navigating government processes when quite often these processes are not related to biosecurity risk and are unnecessary.

Department of Agriculture, Fisheries and Forestry

Based on ABS, Weekly Average Earnings, Australia, May 2012 (fulltime, adult, total earnings) and grossed up to account for on-costs and overheads of 16.5 per cent and 50 per cent respectively. These estimates are based on published guidance that was derived from a number of generic and plausible estimates to be used in the absence of more specific data. (Government of Victoria, 2007, Victorian Guide to Regulation, Department of Treasury and Finance, Melbourne). Please note that this per hour estimate is not a net present value calculation.

Currently, 20 – 40 individuals die in transit to Australia. These would continue to be subject to current arrangements and would continue to fall under police jurisdiction.

Sanctions and offences

The proposed biosecurity legislation has been designed so that the most appropriate sanction for non-compliance can be applied. One major change from the Quarantine Act is the introduction of a civil penalty regime in addition to existing criminal offences, which provides the department with greater opportunity to take action where non-compliance has been identified. Submissions provided as part of the consultation process were generally in support of the civil penalty regime.

The maximum penalties have been developed to respond to acts of serious non-compliance where significant biosecurity harm is caused to animal, plant or human health. The maximum penalty may not be appropriate in all circumstances and it is a decision for the courts to determine the most appropriate penalty during sentencing.

Additionally, the proposed biosecurity legislation maintains the existence of an infringement notice scheme from the Quarantine Act for high volume, low complexity offences for example with airline passengers, and introduces an enforceable undertaking scheme as an alternative to a civil or criminal penalty.

Inspector-General of Biosecurity

As part of its preliminary response to the Beale Review, the Australian Government agreed to establish a statutory office of the Inspector-General of Biosecurity. In advance of the enabling legislation interim arrangements are in place. On 1 July 2009, the government appointed Dr Kevin Dunn as the Interim Inspector-General of Biosecurity to provide independent assurance of the performance and appropriateness of biosecurity systems and risk management measures that are the responsibility of the biosecurity divisions within DAFF. The Interim Inspector-General of Biosecurity is independent of the biosecurity divisions of DAFF and reports to the Australian Government Minister for Agriculture, Fisheries and Forestry. The incremental costs of a permanent Inspector-General of Biosecurity therefore are expected to be minimal. However an Inspector-General of Biosecurity is expected to avoid the need for future Beale and Nairn style reviews.

Regulations

The Governor-General has the power to make regulations if they are required or permitted in the proposed biosecurity legislation or they are necessary or convenient to give effect to it. This type of general regulation power is common across Commonwealth legislation.

The regulations will clarify and provide further detail on what is contained in the legislation and what will be included in policy. It is also anticipated that regulations may be similar to existing regulations. The department will work with the Office of Best Practice Regulation to determine the need for future RIS's.

An example of regulations that are required is in relation to approved arrangements, which requires the relevant Director to be satisfied of the requirements in the regulations before approving an industry arrangement. An example of regulations that may be required to give effect to the proposed biosecurity legislation that are not specifically mentioned in the legislation, are regulations dealing with the response to a biosecurity emergency situation.

Abandoned goods

The proposed biosecurity legislation will also create a trigger for being able to deem potentially hundreds or thousands of goods as abandoned or forfeited each year. The current requirement to hold goods takes considerable time and effort for departmental staff in storing goods for extended periods of time (sometimes up to three months). For each of the goods, it can take staff a total of a few days in sending letters, providing response periods, and following up.

Covering the field for imports

The proposed legislation means that Commonwealth legislation will "cover the field" in respect of the prohibition or restriction of bringing in or importing goods into Australia. This means that the Act will override state or territory laws that relate to bringing in or importing goods to the extent they are inconsistent with Commonwealth laws and that state and territories will not be able to impose measures that are more restrictive than those imposed by the Commonwealth.

The legislation provides considerable flexibility. For example, bringing in certain types of goods could be completely prohibited or could be allowed with conditions. Conditions imposed on the import of goods will be based on the outcomes of a national risk assessment process which takes into account regional differences in pest and disease status.

This clarity in the legislation will increase industry certainty by eliminating any risk of inconsistent requirements imposed by states and territories. States and territories are already restricted, to an extent, from imposing more restrictive conditions as these can place Australia in violation of its international obligations with subsequent risks to trade. However, clarity in the legislation removes any doubt and means any attempts by the states and territories to do so can be readily challenged. Overall, this is expected to provide a benefit to Australia's trade relationships without losing the flexibility to accommodate regional differences.

Overall impact of legislation on biosecurity

The proposed legislation provides a legislative framework for Australia's biosecurity system. It will enshrine Australia's Appropriate Level of Protection (ALOP) in legislation. The World Trade Organization (WTO) 'Agreement on the Application of Sanitary and Phytosanitary Measures' allows WTO members to determine their own level of protection; however, it must be applied in a consistent manner. This is known as the Appropriate Level of Protection. That is, "providing a high level of sanitary and phytosanitary protection, aimed at reducing risk to a very low level, but not to zero." This does not represent any change in Australia's ALOP as it has been agreed administratively with the States and Territories for some time. However, it does provide importers and trading partners with additional certainty that the standard is being applied.

The benefits of the legislation largely relate to its enabling of improved administrative and operational practices that in turn enable more efficient use of available biosecurity resources to target risk to achieve biosecurity outcomes consistent with Australia's ALOP. However, the legislation is not designed to introduce a new or stricter level of protection and, in that sense, it does not change the biosecurity outcomes that are being sought.

Preferred option, implementation and review

Preferred option

This RIS has identified and considered a range of problems with the Quarantine Act. The assessment illustrates the anticipated costs and benefits of the proposed biosecurity legislation compared to the current situation, and demonstrates the potential for improved business processes through approved arrangements, better targeting of resources and greater administrative efficiency.

Moreover there is a broad, unquantified benefit of the proposed biosecurity legislation from improving the overall quality of the legislative framework for biosecurity, including:

- Reducing the costs associated with interpreting complex, prescriptive and outdated legislation (a benefit to both government and business).
- Enabling the benefits of broader reform to be realised (a benefit which is unquantifiable but important to acknowledge in this analysis). Legislative reform will assist the plans for broader reform in biosecurity primarily in the form of more flexible legislative mechanisms that will allow change.

Based on this analysis, proposed biosecurity legislation is assessed as representing an improvement over the base case and is the preferred option for Government consideration.

Implementation and review

The Act will comment one year after Royal Assent. In some instances, transitional arrangements will apply, for example for approved arrangements. Existing QAPs and compliance agreements will remain valid on commencement of the Act. The intent is to transition these existing agreements to approved arrangements within 18 months of commencement and/or as existing QAPs and agreements expire (two and a half years after the legislation receives Royal Assent).

For first points of entry, under the proposed biosecurity legislation there will be a three year transition period once the Act commences which will be one year after Royal Assent, a total period of four years.

The regulations will clarify and provide further detail on what is contained in the legislation and what will be included in policy. It is anticipated that regulations may be similar to existing regulations. The department will work with the Office of Best Practice Regulation to determine the need for future RIS's.

Ongoing monitoring of any reforms will be undertaken by the department to ensure that the objectives are being achieved and whether any further reforms are necessary.

Appendix A International Health Regulation requirements

International Health Regulations core capacity requirements for surveillance and response²³

Community Level

- detect events involving disease or death above expected levels
- report all available information immediately to the appropriate health care team
- implement preliminary control measures immediately

Intermediate Level

- confirm the status of reported events and support or implement control measures
- assess reported events immediately and report essential information to the national level

National Level

- Assessment and notification:
 - o assess reports of urgent events within 48 hours
 - o notify the WHO immediately through the National Focal Point of all potential PHEICs
- Public health response:
 - o determine rapidly the control measures required to prevent furtherspread
 - o provide support hrough specialised staff, laboratory analysis and logistical assistance
 - o provide on-site assistance as required to support local investigations
 - o provide links with senior officials to approve and implement containment/control measures
 - o provide direct liaison with other relevant government ministries
 - o provide links with key operational areas for the dissemination of information
 - o establish, operate and maintain a national public health emergency response plan
 - o provide all of the above on a 24 hour basis

International Health Regulations core capacity requirements for airports, ports and ground crossings²⁴

At all times

• provide access to appropriate medical services and staff, equipment and premises

²³ World Health Organization. 2008. 'The International Health Regulations (2005).' Second edition. World Health Organization, Switzerland, pg 40-41.

²⁴ World Health Organization. 2008. "The International Health Regulations (2005)." Second edition. World Health Organization, Switzerland, pg 41-42.

- provide access to equipment and personnel for transport of ill travellers
- provide trained personnel for the inspection of conveyances
- ensure safe environment for travellers through inspection programs
- provide a program and personnel for the control of vectors and reservoirs in/near points of entry

Responding to events that may constitute a PHEIC

- provide appropriate public health emergency response by establishing and maintaining a public health emergency contingency plan
- provide assessment of and care for affected travellers or animals by establishing arrangements with local medical and veterinary facilities
- provide appropriate space to interview suspect or affected persons
- provide for the assessment and quarantine of suspect travellers
- apply recommended measures to disinsect, derat, disinfect, decontaminate or otherwise treat baggage, cargo, containers, conveyances, goods or postal parcels
- apply entry or exit controls for arriving and departing travellers
- provide access to specially designated equipment and trained personnel for the transfer of travellers who may carry infection or contamination

Appendix B Consultation feedback

In preparing the RIS, the department and the consultant, PricewaterhouseCoopers (PwC), consulted with the Department of Health and Ageing (DoHA).

Industry roundtable

The department and PwC also facilitated an industry roundtable on the RIS on 8th July, 2011. The

outlines the industry associations that participated in the industry roundtable. Each industry stakeholder was given the opportunity to provide additional information via email after the workshop.

Industry roundtable attendees

Shipping and Aviation Group

- Ports Australia
- AQIS Industry Cargo Consultative Committee
- Qantas Airways
- Carnival Australia
- Board of Airline Representatives Australia
- Shipping Australia
- Airports Association
- Conference of Asia Pacific Express Carriers
- Australian Petroleum Production and Exploration Association

Industry Legislation Group

- AQIS Industry Cargo Consultative Committee
- Invasive Species CRC
- Invasive Species Council
- Animal Health Australia
- Plant Health Australia
- Custom Brokers and Forwarders Council
- National Farmers Federation

Distribution and comments on the draft RIS

In May 2012, a draft of the RIS was provided to members of the Industry Legislation Working Group for their consideration and comment. This working group comprises:

- Invasive Animals CRC
- Board of Airline Representatives of Australia
- DHL
- Qantas

- Conference of Asia Pacific Express Carriers
- Carnival Australia
- Plant Health Australia
- AQIS Industry Cargo Consultative Committee
- Animal Health Australia
- Invasive Species Council
- National Farmers Federation
- Shipping Australia
- Australian Petroleum Production and Exploration Association Limited
- Brisbane Airport Corporation
- Customs Brokers and Forwarders Council of Australia Inc
- Ports Australia.

Following the public release of the RIS, PwC participated in 17 consultation meetings organised by the department on the proposed biosecurity legislation. The meetings were with State Government agencies and representatives of industry with some open to the general public (all capital cities and Newcastle). At the meetings, the department presented an outline of the proposed provisions in the draft Biosecurity and Inspector-General of Biosecurity Bills and PwC outlined possible impacts of the provisions in these Bills on stakeholders, based on the analysis included in the draft RIS that was publicly released on 4 July 2012.

The meetings could be characterised as mostly information sessions. Although many stakeholders asked questions and sought clarification of the provisions of the Bills, only a few were in a position to identify specific impacts of the proposed biosecurity legislation on them and/or provide information that would help to improve the analysis in the RIS (eg data or concrete examples that demonstrated a relative change in impact due to the proposed biosecurity legislation compared to the existing legislation). Some stakeholders did identify impacts that were not directly related to the legislation.

This is not surprising as there was a large amount of information for attendees to absorb and in many cases stakeholders did not seem to have extensively reviewed information about the legislation prior to the meetings. Further, much of the proposed biosecurity legislation updates existing legislative provisions and apart from improving clarity, may not result in day to day changes relative to the current situation for many stakeholders. In addition, the Act provides an overarching framework for biosecurity legislation. Much of the detail will be in subordinate legislation. It is expected that it will be easier for stakeholders to understand possible impacts on them when more of the detail in the subordinate legislation and in operational policies is released and/or developed.

Stakeholders were also provided with the opportunity to provide additional information in written submissions.

Approved arrangements

Specific comments/questions:

- Have we considered how the arrangements affect small businesses (RIS presentation emphasises large businesses)?
- The RIS should not imply these arrangements are voluntary eg all quarantine approved premises will need one.

- What are the implications for moving goods under a biosecurity control order between first points of entry/biosecurity zones/a location with an approved arrangement and what are the cost/benefit implications of this?
- How will my existing quarantine approved premises /compliance agreement change will it have to be reworked? Can I keep things the way they are? How can I know the implications for me until I know how audit and compliance arrangements might change? What will be the change in charges?
- The examples of possible savings for business in the RIS do not reflect the proposed changes they could occur under the existing legislation.
- While there are benefits from industry playing an increased role in relation to risk management, approved arrangements could lead to poorer risk management outcomes if not managed properly.
- Universities may have multiple quarantine approved premises each with specific requirements, so any benefits from moving to an approved arrangement will depend on the details and requirements of that approved arrangement.

Issues and proposals for addressing them:

- The presentation and analysis in the RIS emphasised potential benefits for large importers with control of end to end processes of having the option of a single and less prescriptive arrangement. It has been assumed that benefits will mostly accrue to those businesses that do not already have a quarantine approved premises or compliance agreement but would enter into an approved arrangement under the new legislation.
- In most cases, stakeholders were more concerned to understand the transition arrangements for their existing QAPs or compliance agreements. Some of these represented smaller businesses and wanted to understand how the content of their existing arrangements could change and what new costs might be incurred and when they might need to change.
- It is understood that the incremental change for those with existing quarantine approved premises or compliance agreements would be relatively small but with potential to take advantage of additional flexibility that will be available in approved arrangements. The RIS sets out illustrative estimates of transitional costs.
- Some stakeholders commented that most businesses do not have a mix of quarantine approved premises and compliance agreements. This has been clarified in the RIS.
- One stakeholder attended several meetings and several times raised the issue of how the new
 provisions for biosecurity zones and approved arrangements provide for moving goods under
 biosecurity control between these areas. The department held scenario testing sessions with this
 stakeholder to clarify this.

First points of entry

Specific comments/questions:

- How many existing first ports might not apply for 'first point of entry status'? What is likely to be the net change in number as these are transitioned to first points of entry?
- Comment made that about 40 per cent of existing first ports would not meet the new requirements. Does DAFF have a sense of this?
- Could an inland site be considered a first point of entry, eg an intermodal terminal and does this need to be considered in the analysis. If not, what status would it have and what arrangements would cover it?

- Are owners or operators of ports likely to incur the costs one stakeholder's view was that it was the
 operators/stevedores most likely to be impacted but this needed to be clarified, ie who would apply
 for first point of entry status, the owner or operator?
- There may be costs associated with having the ability to accept quarantinable waste for some facilities, but it depends on the specific criteria that are developed.

Issues and proposals for addressing them:

- Although the likely change in number of first ports as they are transitioned to first points of entry cannot be predicted with certainty, it may be possible to provide more information about the number of first ports not actively used as first ports or only used in a very limited way.
- It is difficult to assess in aggregate what proportion of first ports may not meet requirements and may need to invest in additional facilities if first point of entry status is sought. Ultimately, although the regulations may provide some guidance, this will depend on case by case negotiations with DAFF on the nature and requirements of each first point of entry.

Biosecurity zones

Specific comments/questions:

- Stakeholders broadly, and state government representatives particularly, wanted to better understand how the Australian Government would use the proposed powers for declaring biosecurity zones, ie in what circumstances would they use them? How do these powers affect existing state powers and practices? What are specific examples of when they would be used?
- Stakeholders sought clarification about who would be obliged to act (state and territory government or the Australian Government) and how quickly and who would be responsible if there was a failure to act?
- Who would incur the costs of having the zones in place? (Australian or state governments or industry?)
- Some stakeholders sought clarification about whether these zones might be used to manage existing pests rather than new ones.
- Some stakeholders thought that the proposed arrangements could have helped to avoid previous inter-jurisdictional issues (for example in relation to fruit flies).
- Some stakeholders queried who currently pays monitoring costs, eg around airports. Is it industry or Government and who would pay these costs if a monitoring zone was declared? Could this be a cost for Government that isn't recognised in the RIS?
- One stakeholder advised that since most incursions occur in one jurisdiction it is reasonable to assume that the powers would be used infrequently.
- There were different views on whether the powers will lead to a more timely response. Ultimately it depends on how the arrangements will work in practice. Also need to carefully implement the changes to minimise the risk of confusion.
- There will be costs to the Australian Government associated with having and using the new powers.

Issues and proposals for addressing them:

• Explain more clearly in the RIS the interplay between state based and Australian Government powers and how these could be used to implement agreements such as Emergency Animal Disease Response

Agreement, Emergency Plant Pest Response Deed and National Environmental Biosecurity Response Agreement.

• Clarify that the provisions do not compel the Australian Government to act but give it the power to.

Human health provisions

• No substantive comments on the impacts of these provisions outlined in the RIS were recorded.

Other issues raised

Specific comment/questions:

- What is the relationship between the national Appropriate Level of Protection and regional interests given the Australian Government will cover the field? Do they align in, for example, Tasmania (eg in relation to salmon, apples etc?) or will regional interests be negatively affected?
- Inspector-General do aspects of the provisions in this Bill limit scope and impact of role? eg consultation with Director of Biosecurity on work program. What might be the costs associated with the secretariat?
- The provisions for Risk Import Analyses suggest information will be published some stakeholders raised issues related to privacy etc. Is this likely to be any different to current provisions and what would the impacts be?
- New information gathering powers in the proposed biosecurity legislation could increase costs for government and/or industry depending on extent to which used and requirements on business. Can possible costs be acknowledged?
- Members of the National Farmers Federation sought clarification of whether the Australian Government's powers for 'covering the field' in terms of import conditions might apply retrospectively, eg in the case of importing apples to Tasmania.
- One stakeholder asked for the consideration of the impact of transferring some decision making powers from the Minister to the Director of Biosecurity.
- Some stakeholders queried how a situation in which a container or containers could be not be unloaded would affect other cargo/containers if they could not be moved until the other containers were. Would it be managed differently to today and could that result in additional costs for some importers waiting for their goods to be unloaded? What documentation/information gathering is required to facilitate this and what costs would that impose?
- One stakeholder suggested that the RIS should consider an option involving increased harmonisation with food safety importation requirements.
- The RIS should consider the overall impact of the Bill on biosecurity in Australia, and results should acknowledge impacts on the community, government, and industry.

Consultation with States and Territories

Consultation with states and territories has taken place as part of the legislation drafting process and through the consultation period following release of the draft Bills.

Preliminary provisions in the Act include commencement, the objects of the Act, extension of the Act to external territories and concurrent operation with state and territory laws. The Act does not limit concurrent operation of state and territory laws except in relation to the regulation of the importation of goods and ballast water.

The Australian Government will cover the field with respect to importation into Australia and Australian import conditions will be based on the outcomes of a national risk assessment process, taking into account regional differences in pest and disease status. The Australian Government may also choose to prohibit the importation of goods into part of Australia (eg particular states or territories), where scientifically justified.

Additional biosecurity measures can be taken at a state level to respond to regional differences in pest and disease status. States and territories will continue to be consulted through a series of workshops to define this policy and through the Intergovernmental Agreement on Biosecurity.

Submissions on the RIS

A number of written submissions touched on the impact of the proposed legislation and the associated cost benefit analysis. Where relevant, these have been acknowledged and discussed in the body of this RIS. In general, the majority of submissions sought additional detail which the subordinate legislation and supporting administrative guidance material is likely to address. Many stakeholder groups representing diverse perspectives recommended a wide range of proposals they felt would better address the government's aims for biosecurity reforms. The department has considered all submissions and notes that — as can be expected with most regulatory systems—there are some stakeholders calling for more stringent regulation such as in environmental biosecurity and other stakeholders calling for less stringent regulations such as industry groups from the trading sector.

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