

# **Senate Rural and Regional Affairs and Transport Legislation Committee**

**Written Questions on Notice – Wednesday, 11  
February 2015**

**Canberra, ACT**

## **Inquiry into Biosecurity Bill 2014 and related Bills**

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 1 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Inspector-General of Biosecurity

**The Committee asked:**

Some submitters are concerned that the decision to retain the Inspector-General of Biosecurity will reduce operational transparency. Does the bill change the Inspector's current role.

**Answer:**

Yes, the Bill will change the Interim Inspector-General of Biosecurity's (IIGB) role. The current IIGB is a non-statutory position that sits within the Department of Agriculture and is responsible for providing independent reviews of and reports on the performance of biosecurity programs and risk management measures for which the department is responsible.

Currently the IIGB does not have any legislative powers to conduct a review and cannot compel a person to comply with requests to provide information.

The Biosecurity Bill will provide the Agriculture Minister with the power to review the performance of functions, or exercise of powers, by biosecurity officials under one or more provisions of the Bill (clause 567).

These powers will allow the Agriculture Minister to conduct reviews into the biosecurity system to identify opportunities for improvement in the assessment and management of biosecurity risks. As the review powers are provided to the Minister, reviews will be conducted independently from the regulatory function within the department, ensuring independence between the subjects of the review (biosecurity officials) and the powers of the person conducting the review.

It is intended that the Minister delegate the review powers to an appropriately qualified or experienced person such as the Inspector-General of Biosecurity.

Included with the power of review is the power to require a person to answer questions or provide documentation if the Minister believes on reasonable grounds that the person has information or documents relevant to a review (clause 568).

These powers, which are unavailable to the IIGB, will ensure that the reviewer has access to the necessary information to appropriately review processes within the biosecurity system.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 2 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Industry Legislation Working Group

**The Committee asked:**

You noted in your submission that the Industry Legislation Working Group was consulted during the drafting phase of the bill. Will this group be consulted during the drafting of the regulations?

**Answer:**

Members of the former Industry Legislation Working Group will be consulted individually and within specific subject matter groups during the consultation process for implementation of the legislation (including the development of regulations).

The Industry Legislation Working Group was formed to identify, discuss and resolve issues during the development of the high-level and overarching Biosecurity Bill. During 2014 consultation on the Biosecurity Bill also extended to the member corporations of the Industry Legislation Working Group members. For example through the Australian Petroleum Production & Exploration Association, the Department of Agriculture met with BHP, ENi and Caltex to discuss ballast water, installations and first point of entry provisions.

Members of the former Industry Legislation Working Group will now be invited to provide specific expert advice and comments on the regulations that directly relate to their business and industry. For example, the department will work closely with former member organisations such as Shipping Australia, Ports Australia and the Australian Petroleum Production & Exploration Association on ballast water and first point of entry provisions and policies. Former member organisations such as the Invasive Animals CRC, the NFF, Plant Health Australia and Animal Health Australia will be consulted on emergency and onshore provisions and policies.

Members of the Industry Legislation Working Group were informed in October 2014 that while the group as a whole would no longer exist, their expertise and advice as individual organisations would be required in the development of the regulations.

The department will consult more broadly and in more detail on the regulations and administrative policies throughout 2015 and early in 2016.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 3 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Jurisdiction of the Biosecurity Bill

**The Committee asked:**

Why are changes being proposed to Australia's offshore quarantine zone? Would this change compromise Australia's capacity to monitor biosecurity risks?

**Answer:**

The Biosecurity Bill will realign the jurisdiction of the Commonwealth to 12 nautical miles (currently the *Quarantine Act 1908* extends out to 200 nautical miles). The Quarantine Act largely focuses on the regulation of installations themselves and the interactions with international conveyances.

Currently, all international vessels arriving at an installation must meet a number of per-arrival reporting requirements including: Quarantine pre-arrival report, an application for permission to enter an Australian non-proclaimed first port of entry, an application for permission for animals, plants or other goods to be landed at a place that is not a declared port, as well as permissions regarding human health (pratique) and crew transfers.

Installations are remote and are located, in many cases, in deep waters beyond the 12 nautical mile mark. This remoteness means that the installation itself, and any interactions with international conveyances that do not travel on to mainland Australia. As such, the Department of Agriculture has concluded that this is not the primary area of biosecurity risk.

Any installations outside 12 nautical miles will no longer be regulated by the Biosecurity Bill (all installations are currently outside 12 nautical miles).

The Biosecurity Bill will achieve better risk management outcomes by shifting the legislative focus to the conveyances that enter Australian territory. This may include both international and domestic conveyances.

It is movements by conveyances travelling between the installation and mainland Australia that pose the greatest biosecurity risk. This risk comes predominantly from waste and from supplies obtained overseas, which can be transferred to a domestic conveyance and disposed of on the mainland.

It can also be difficult and dangerous for the Commonwealth to undertake monitoring activities far out at sea for international conveyances. There are significant training and

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**Department of Agriculture/Department of Health**

workplace health and safety requirements for the department that are not justified by the level of biosecurity risk posed.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 4 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Jurisdiction of the Biosecurity Bill - Impacts

**The Committee asked:**

What analysis has the government undertaken to determine the proposal's likely impact on affected industries?

**Answer:**

The Biosecurity Bill, on face value, would subject conveyances travelling between Australian territory and an installation outside 12 nautical miles to additional requirements based on the change in jurisdiction. Conveyances may be required to complete pre-arrival reporting or seek permission to land if the conveyance does not travel to a first point of entry. Operators of domestic conveyances that visit installations might incur higher costs, as the conveyance will become subject to biosecurity control each time it enters 12 nautical miles and may have to pre-arrival report and seek permission to land. However, the Biosecurity Bill will allow for pre-arrival reporting exemptions through regulations and applications for a standing permission to enter a non-first point of entry by operators, in order to minimise these costs, as outlined in the Explanatory Memorandum.

As indicated in the response to question 3, regulatory burden has been removed from installation operators as their installations will be beyond the Bill's jurisdiction. As such, all international vessels arriving at the installation will no longer be required to provide pre-arrival reporting to the Department of Agriculture (or the other approvals as per question 3).

The legislation is based upon risk. If the department deems that there are no risks associated with the installation/vessel the level of intervention will be very low (limited to checking that the level of risk remains unchanged). It is not the department's intention to increase regulatory burden and the department wants to work with operators in relation to how the burden can be minimised.

The department has already begun discussions with industry about the development of regulations and policy, including through the peak body (the Australian Petroleum Production & Exploration Association) and industry representatives.

Installation operators will also be able to work with the department to;

- manage any potential biosecurity risks at their installation, which can reduce the costs experienced by the operators of domestic conveyances
- apply for an approved arrangement with the department, potentially with multiple entities or facilities under the one agreement, to manage biosecurity risks.

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**Department of Agriculture/Department of Health**

As individual circumstances need to be taken into account when assessing the installation's level of risk there will be different options available to different industry members to lessen regulatory burden.

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**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question: 5** (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Approved arrangements

**The Committee asked:**

How long will it take the Department of Agriculture to finalise approved agreements and related instruments? Is it possible that the new biosecurity requirements will commence before these arrangements are in place?

**Answer:**

The Biosecurity Bill allows the Commonwealth to partner with industry through a voluntary approved arrangements scheme. Approved arrangements are individual arrangements and are not set as a 'one size fits all' approach. Industry participants may apply for an approved arrangement to manage the biosecurity risks associated with their own operations in the most efficient and effective way.

Approved arrangements replace the quarantine approved premise and compliance agreement schemes in the *Quarantine Act 1908* with a broader and simpler model. Current administrative requirements for facilities and activities undertaken under the quarantine approved premise and compliance agreement schemes of the Quarantine Act are proposed to continue largely unchanged under the approved arrangements scheme. For example, specific requirements for each class of quarantine approved premise will remain unchanged.

The Biosecurity Bill will commence 12 months from receiving Royal Assent. The Department of Agriculture will be developing delegated legislation and administrative guidelines on approved arrangements as part of the implementation program, including engaging stakeholders in policy and drafting where relevant. The delegated legislation will include, for example, the requirements for the approval of an approved arrangement, the circumstances in which an approved arrangement may be transferred and the requirements for the carrying out of audits. It is expected that the delegated legislation will be released for public consultation during 2015.

It is also expected that the department will be in a position to begin negotiations regarding the form and content of approved arrangements in the latter half of 2015, well in advance of the potential commencement of the Biosecurity Bill.

Approved arrangements will provide a wide range of clients with the ability to manage their biosecurity risk in the most effective and efficient manner possible.

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Co-regulatory approvals and compliance agreements under sections 46A and 66B of the Quarantine Act that are in force immediately before the commencement day will automatically become 'transitional' approved arrangements under the Biosecurity Bill. Biosecurity industry participants will also be able to apply to renew their 'transitional' approved arrangements once, for a period of up to three years, effectively having this time to transition to the requirements under the Biosecurity Bill.

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**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 6 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Biosecurity Import Risk Analyses

**The Committee asked:**

Please summarise the difference between the proposed Biosecurity Import Risk Analyses (BIRA), in the bill, and the current Import Risk Analysis prepared under the *Quarantine Act 1908*?

**Answer:**

Under the current legislative framework, the *Quarantine Act 1908* does not reference the import risk analysis (IRA) process. References to IRAs are only contained in the Quarantine Regulations 2000, and the administrative document, the IRA Handbook 2011.

The Biosecurity Bill provides a high level framework for undertaking BIRAs, with details to be contained in the BIRA Regulations once approved by government and tabled in Parliament.

A table has been prepared which compares and contrasts the current arrangements with those proposed under the Biosecurity Bill (Attachment A).

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

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**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 7 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Import Risk Analyses

**The Committee asked:**

When will the department complete its review of the arrangements for Import Risk Analyses?

**Answer:**

The department is preparing an outcomes report which summarises stakeholder issues raised and outcomes of the consultation for the examination of the IRA process and makes recommendations to improve parts of the process.

The outcomes report and associated recommendations will be considered by the government before it is released publicly.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 8 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Biosecurity Import Risk Analyses

**The Committee asked:**

The departments submission emphasises that the Biosecurity Import Risk Analyses will be based on science. Who are the members of the Eminent Scientists Group (ESG)? What is their current and anticipated future role?

**Answer:**

Science underpins the Department of Agriculture's evidence-based policy development, decision-making and service delivery.

The department employs officers with tertiary science qualifications, including in aquatic animal health, botany, ecology, entomology, environmental science, food and nutrition science, geospatial analysis, microbiology, molecular biology, plant pathology, quantitative science, veterinary science and zoology.

IRAs are conducted by technical and scientific officers in the department who have expertise about the goods and biosecurity risks being assessed. An IRA may also include scientific input from external experts, where appropriate.

***Current ESG members***

The current members of the Eminent Scientists Group (ESG) are:

- Dr John Radcliffe AM, Chair
- Dr Mark Lonsdale
- Professor Chad Hewitt
- Professor Tom Kompas

Details of the current membership (name and biographical information) of the ESG and its terms of reference are on the department's website.

[www.agriculture.gov.au/ba/eminent\\_scientists\\_group/esg\\_membership](http://www.agriculture.gov.au/ba/eminent_scientists_group/esg_membership).

***Future role of the ESG***

During the examination of the IRA process the department found that the ESG is highly valued in the IRA process but that improvements could be made to increase its value to the department and to stakeholders. Views from stakeholders supported the continuing use of the

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**Department of Agriculture/Department of Health**

ESG or similar external expert group in the IRA process. However many stakeholders made comments about its structure, role and timing within the process.

The department will provide further opportunity for consultation on the use of external scientific advice when the draft BIRA Regulation under the Biosecurity Bill 2014 and the BIRA Guidelines are released for consultation during 2015.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 9 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Regional differences

**The Committee asked:**

Could you respond to the concern expressed by some submitters that the bill does not formally recognise regional differences in biosecurity risk?

**Answer:**

Provisions written in the Biosecurity Bill 2014 and the Explanatory Memorandum clearly state the consideration and recognition of regional differences as part of the definition of biosecurity risk.

**Chapter 1 Preliminary**

**Part 2 Definitions**

The definition of biosecurity risk within the Biosecurity Bill 2014 states **biosecurity risk** means:

- a. the likelihood of a disease or pest:
  - i. entering Australian territory or **a part** of Australian territory; or
  - ii. establishing itself or spreading in Australian territory or **a part** of Australian territory; and
- b. the potential for any of the following:
  - i. the disease or pest to cause harm to human, animal or plant health;
  - ii. the disease or pest to cause harm to the environment;
  - iii. economic consequences associated with the entry, establishment or spread of the disease or pest.

As a result of stakeholder consultation, a note was added to section 166 of the Biosecurity Bill 2014 noting: 'The level of biosecurity risk associated with the goods may vary according to the place in Australian territory at which the goods are to enter Australian territory or be unloaded, so the conditions may vary accordingly.'(s166)

Australia's import risk analysis process currently provides for the consideration of regional differences so long as it is consistent with our rights and obligations under the World Trade Organization *Agreement on the Application of Sanitary and Phytosanitary Measures* and other relevant international standards.

For an area to be confirmed to have a regionally different pest or disease status, it must be scientifically determined. When determining pest or disease free areas (or low prevalence

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areas) factors such as geography, ecosystems, epidemiological surveillance and the effectiveness of the control measures or eradication programs in place must be considered.

Before an import risk analysis starts the department provides a preliminary pest and disease list to state and territory governments for consideration and confirmation of issues such as whether pests and diseases are under official control (active enforcement of mandatory regulations and procedures with the objective of eradicating or containing a pest or disease of biosecurity concern).

This is consistent with the SPS Agreement and the International Plant Protection Convention and World Organisation for Animal Health (Office International des Epizooties) codes and standards relating to import and pest risk analyses and assessments of regional differences.

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**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 10 (written)

**Division/Agency:** Finance and Business Support, Department of Agriculture

**Topic:** Cost recovery

**The Committee asked:**

Has the cost recovery methodology been developed yet? Please provide the committee with the methodology.

**Answer:**

The Biosecurity Bill allows for the recovery of costs, the Bill does not set or impose any fees.

Yes, the department has a long standing cost recovery methodology. The department operates a policy of full cost recovery for many of its biosecurity and export certification activities in line with Australian Government cost recovery policy. Full cost recovery involves the recovery of the direct and indirect costs of the activities delivered to individual clients and those activities delivered to a client group. Costs are recovered via a fee for service where a service is provided to an individual or via a cost recovery levy (charge) where services and activities are provided to a group of individuals or organisations.

The methodology used in the department ensures that direct and indirect costs of the activity are reflected in the recoverable cost base. Costs are then allocated to a standard framework of outputs. The standard framework informs whether activities are delivered directly to individual clients, or to a client group, and determines whether costs are most appropriately recovered through cost recovery fees or cost recovery levies (charges).

The department allocates indirect costs using a well developed methodology based on appropriate cost drivers. Indirect costs are allocated based on the most appropriate driver, for example staffing levels, headcount, information technology assets, invoices etc. The allocation process is applied to all the department's activities including those funded by appropriation and those that are cost recovered.

The allocation of the cost base to the standard outputs framework is driven by the relative effort departmental resources direct toward the specific activity. This allocation process is informed by an effort survey and is periodically updated during the fee setting process.

The department has an established process for reconciling 'allocations out' with 'allocations in' on a monthly basis. An independent assessment of Agriculture's cost recovery arrangements reported that "a high level review of the allocation system showed it to be driven by sophisticated business rules and subject to regular monitoring, review and

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# Senate Rural Affairs and Regional Affairs and Transport Legislation Committee

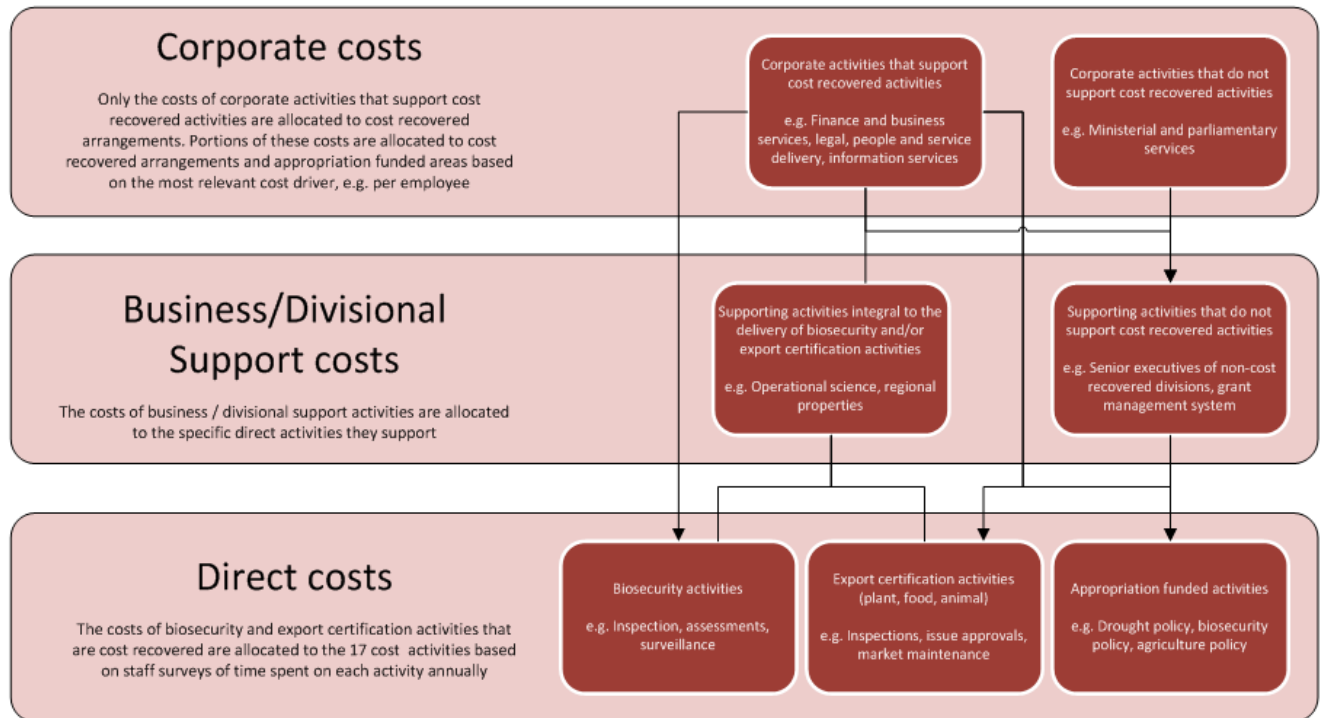
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**Department of Agriculture/Department of Health**

reconciliation. This would indicate that it is robust system and not a 'broad brush' allocation".

### Cost Allocation Flow Chart



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**Department of Agriculture/Department of Health**

**Question:** 11 (written)

**Division/Agency:** Finance and Business Support, Department of Agriculture

**Topic:** Cost recovery

**The Committee asked:**

Will the department's cost recovery framework take into account savings made by the department as a consequence of the key regulatory and operational reforms proposed by the bill?

**Answer:**

The department will revise its costings following implementation of the Biosecurity Bill should it be passed by the Parliament. This would reflect any reduction in the cost base from savings due to regulatory and operational reforms.

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**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 12 (written)

**Division/Agency:** Finance and Business Support, Department of Agriculture

**Topic:** Cost recovery

**The Committee asked:**

Do you agree with the argument made by some submitters that biosecurity risk management has a public good element that should be reflected in the cost recovery framework?

**Answer:**

Consistent with the Australian Government cost recovery policy, the department recovers the costs of biosecurity activities from the recipients of the activity. Those that create the risk or the need for regulation are charged the cost of the activity. Other costs that are not related to the provision of cost recovered activities, and those mandatory functions due to the department being a government entity, are funded by government.

Examples of activities that are not cost recovered include parliamentary liaison services, Commonwealth Budget process, departmental strategic policy development, general legal counsel activities, internal audit, external communications and media.

Government funding also extends to the elements of risk assessment, such as import risk analyses, or assessments of risks under the Northern Australia Quarantine Strategy, where there may not be an identifiable client that can be charged. Those risk assessment elements that can be attributed to activities provided to clients will continue to be cost recovered.

Government funding is also provided for the cost of emergency responses to biosecurity incursions. In the case of responses under the National Environmental Biosecurity Response Agreement, Commonwealth and state governments meet 100% of the costs, although provision is provided for cost sharing with other parties where they can be identified. Responses in relation to production pests under the Emergency Animal Disease Response Agreement and the Emergency Plant Pest Response Deed are cost shared by governments (including the Commonwealth) and industry in agreed cost sharing formulas under the two deeds.

Please provide an estimation of hours spent on QoN response for each officer involved.

<b>Officer</b>	<b>DAFF Level</b>	<b>Hours spent on QoN response</b>
<b>A</b>	Executive Level 1	10
<b>B</b>	Senior Executive Service Band 1	2
<b>C</b>	Senior Executive Service Band 2	1
<b>D</b>		

**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 13 (written)

**Division/Agency:** Service Delivery, Department of Agriculture / Office of Health Protection, Department of Health

**Topic:** Biosecurity, Human Biosecurity Officers and Biosecurity Enforcement Officers

**The Committee asked:**

Are there any minimum qualifications for biosecurity officers? What training procedures and internal guidelines will be developed to ensure that powers are exercised appropriately?

**Answer:**

***Biosecurity Officers***

Powers under the legislation will be exercised by appointed biosecurity officers (see clause 545) who have the appropriate training and knowledge to recognise biosecurity risks and manage them appropriately—supported by extensive technical, policy and scientific expertise.

Biosecurity officers currently undertake general departmental staff training and formalised on the job training which includes competency based assessments, for example:

- Certificate III in Government
- on-the-job assessments
- competency based assessments.

A number of biosecurity officers are scientists who use their expertise to provide high-quality and timely science to support the Department of Agriculture's business.

***Human Biosecurity Officers***

Clause 564 of the Bill provides for the appointment of human biosecurity officers (HBOs) by the Director of Human Biosecurity. The Director may only authorise a person to be appointed as a HBO if the Director is satisfied that the person has appropriate clinical experience and:

- is an employee of the Commonwealth Health Department
- is an officer or employee of a state and territory body responsible for administering health services in that state or territory, or
- is a member of the Australian Defence Force.

These requirements ensure that officials managing human health risks have the appropriate qualifications and experience.

During implementation existing training and internal procedures will be systematically reviewed and updated, and new guidelines will be created for new powers. This work will be completed in sufficient time to allow for the department's staff to be trained on the new

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**Department of Agriculture/Department of Health**

legislation in preparation for commencement. In addition, HBOs will be required to complete a specific human biosecurity operations module.

***Biosecurity Enforcement Officers***

Further to this, biosecurity enforcement officers (see clause 546) are also required to meet the requirements of the Australian Government Investigations Standards (AGIS), consistent with the Commonwealth Fraud Control Guidelines. This includes the requirement that staff involved in investigations meet minimum levels of training or qualifications and that the department meets the minimum standards for effective and efficient management of investigations, including record keeping.

Please provide an estimation of hours spent on QoN response for each officer involved.

<b>Officer</b>	<b>DAFF Level</b>	<b>Hours spent on QoN response</b>
<b>A</b>	Executive Level 1	10
<b>B</b>	Senior Executive Service Band 1	2
<b>C</b>	Senior Executive Service Band 2	1
<b>D</b>		

**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 14 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Guidance material

**The Committee asked:**

What guidance material will be made available to industry to explain the new biosecurity requirements and the proposed offences?

**Answer:**

Through the implementation of the legislation, the department will work with both stakeholders and clients to inform, educate, consult and, where appropriate, co-design the delegated legislation, administrative practises and operational systems that will support the legislation.

Guidance material – including factsheets, frequently asked questions, scenario and procedural documents – will be provided to stakeholders, clients and the community so that they are able to comply with the legislation upon commencement.

Please provide an estimation of hours spent on QoN response for each officer involved.

<b>Officer</b>	<b>DAFF Level</b>	<b>Hours spent on QoN response</b>
<b>A</b>	Executive Level 1	10
<b>B</b>	Senior Executive Service Band 1	2
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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 15 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Offences

**The Committee asked:**

Are the offences targeting the right people, noting concerns Customs Brokers and Forwarders Council of Australia (submission 3) that the civil penalty provisions for providing false and misleading information or documents (clauses 532-533) unfairly target custom brokers who are not in a position to know whether the information is false or misleading but are in fact relying on information received from the cargo owner?

**Answer:**

The Biosecurity Bill contains a modern compliance and enforcement framework with new and improved tools to enable effective and efficient targeting of non-compliant behaviour or activities. This includes a range of penalties, including civil penalties, to ensure that penalties are imposed in proportion to the offence committed, and are balanced and consistent.

Civil penalty orders may be applied for contraventions of civil penalty provisions under the Biosecurity Bill. These orders do not amount to a criminal offence and are largely consistent with the definition and operation of civil penalty provisions under Part 4 of the *Regulatory Powers (Standard Provisions) Act 2014*.

A person providing information to the department should ensure that the information they are providing is true and accurate. Clauses 532-533 provide that a person is liable to a maximum civil penalty of 60 penalty units if a person *knowingly* provides false and misleading information or documents in compliance or purported compliance with the Biosecurity Act.

These clauses are intended to dissuade persons from providing false or misleading information to an official for the purposes of complying with the Biosecurity Act, thereby ensuring that officials have access to information that is relevant, reliable and correct. If an official relies upon false or misleading information it has the potential to reduce the official's ability to assess or manage biosecurity risk

Section 95 of the Regulatory Powers Act provides for a defence of mistake of fact. A person is not liable to have a civil penalty order made against the person for a contravention of a civil penalty provision if: at or before the time of the conduct constituting the contravention, the person: (i) considered whether or not facts existed; and (ii) was under a mistaken but reasonable belief about those facts; and had those facts existed, the conduct would not have constituted a contravention of the civil penalty provision.

Please provide an estimation of hours spent on QoN response for each officer involved.

<b>Officer</b>	<b>DAFF Level</b>	<b>Hours spent on QoN response</b>
<b>A</b>	Executive Level 1	10
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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 16 (written)

**Division/Agency:** Service Delivery, Department of Agriculture / Office of Health Protection, Department of Health

**Topic:** Offences

**The Committee asked:**

Why is the use of strict liability necessary? (E.g. clause 58 creates a strict liability offence of failing to answer a question or provide information).

**Answer:**

When strict liability applies to an offence, the prosecution is only required to prove the physical elements of an offence, they are not required to prove fault elements, in order for the defendant to be found guilty. The defence of honest and reasonable mistake of fact is available to the defendant (see section 9.2 of the *Criminal Code*).

Strict liability is used in circumstances where there is public interest in ensuring that regulatory schemes are observed and it can reasonably be expected that the person was aware of their duties and obligations (for example, through written notices or as indicated on forms).

The Bill contains some strict liability offences. These offences have been used when there is a strong public interest in managing biosecurity risks appropriately and preventing serious damage to human, plant and animal health, local industries, the economy and the environment. The application of strict liability in the Bill and the offences to which it relates have been developed in line with the Senate Standing Committee for the Scrutiny of Bills *Sixth Report of 2002 on Application of Absolute and Strict Liability Offences in Commonwealth Legislation* and the Attorney-General's Department's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*, except for the Chapter 5 offences which impose higher maximum penalties than those recommended in the Guide. Agreement of the Attorney-General was received in relation to these clauses.

Clause 58 provides a strict liability offence where a person fails to comply with a requirement to either answer a question or provide written information under the information gathering powers of Chapter 2 (clause 58). This strict liability offence for failure to provide required information is necessary to address public health risks. The offence is reasonable and proportionate to the legitimate objective as the offence is not punishable by imprisonment and imposes a maximum penalty of 60 penalty units, which is at the lower end of the scale.

Information sought relating to listed human diseases is vital to address public health risk and it is essential that as much information is collected as quickly as possible. This information will be uniquely known to the individual who may be able to provide important details about

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<b>B</b>	Senior Executive Service Band 1	2
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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

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**Department of Agriculture/Department of Health**

the epidemiology of a disease, the source of a disease and the potential exposure of themselves and other individuals to the disease. Ideally this would occur before exposed individuals have the opportunity to depart the point of entry and enter the community and potentially spread the disease to family and friends.

Wherever possible, the Commonwealth will rely on voluntary disclosure. However, in some circumstances, an individual may be unwilling to disclose information about their health status, potential exposure or travel history. In such cases, the need to address public risk justifies the application of the strict liability offence for failure to provide required information.

The monitoring and investigation powers available in Chapter 9 are not appropriate for this purpose as the information being sought must be collected as soon as possible to allow effective management.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 17 (written)

**Division/Agency:** Service Delivery, Department of Agriculture / Office of Health Protection, Department of Health

**Topic:** Exercise of powers

**The Committee asked:**

Would the monitoring and enforcement system proposed by the bill still operate effectively if officers were required to form a reasonable belief or suspicion before exercising certain powers (such as information gathering powers contained in clauses 55 and 56).

**Answer:**

The powers contained in clause 55 are only available in circumstances where a human biosecurity control order (clauses 60 to 67) is in place or an individual is in a human health response zone (clauses 113 to 116). Questions may only be asked in relation to the level of risk to human health.

For a human biosecurity control order to be in place an appropriate officer must first be satisfied that the appropriate circumstances exist. A human biosecurity control order may only be placed on an individual if that individual is showing signs or symptoms of a listed human disease, has been exposed to an individual who has or is suspected of having a listed human disease, or has failed to comply with an entry requirement to provide information about his or her health status.

A human health response zone can only be established if the Director of Human Biosecurity is satisfied that it is necessary to prevent or reduce the risk of a listed human disease emerging, establishing or spreading in Australian territory. The Director of Human Biosecurity must consult with the Chief Health Officer of the state or territory of the response zone, and the Director of Biosecurity.

The powers contained in clause 56 are only available if an officer is satisfied that the individual has one or more symptoms of a listed human disease, has been exposed to an individual who has or is showing symptoms of having a listed human disease, or in relation to human remains, or an individual who has died in transit or on arrival to Australian territory. Similar to clause 55, the requirement to provide information must be for the purposes of preventing the emergence, establishment or spread of a listed human disease in Australian territory, or preventing a listed human disease from spreading internationally.

Being satisfied is a higher order requirement than a reasonable belief or a suspicion. To place such an order on a person on a suspicion is unreasonable. These strict limitations on the power to gather information and require information from individuals ensure that measures

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**Department of Agriculture/Department of Health**

applied relate only to the management of a listed human disease or entry requirements and are proportionate and legitimate.

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**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 18 (written)

**Division/Agency:** Service Delivery, Department of Agriculture / Office of Health Protection, Department of Health

**Topic:** Cooperation with states and territories

**The Committee asked:**

How will the government ensure that where jurisdictional responsibilities overlap, the Commonwealth cooperates with the states and territories? How will states and territories be provided with funding to respond to biosecurity emergencies.

**Answer:**

The Departments of Agriculture and Health will use their existing frameworks with the states and territories to ensure that the Biosecurity Bill works effectively where jurisdictional responsibilities overlap as it does under the Quarantine Act. The Bill also contains a number of opportunities for increased consultation with the states and territories including where consultation is mandated.

Clause 8 of the Biosecurity Bill clarifies that the Act will not operate to exclude or limit the operation of a state or territory law that is capable of operating concurrently with the Biosecurity Bill 2014. There are two exceptions to this where specific parts of the Bill will apply to the exclusion of state and territory laws (commonly known as ‘covering the field’).

*Bringing in or importing goods*

Clause 172 of the Bill clarifies that the Act will apply to the exclusion of any state or territory law that prohibits or restricts the bringing or importation of particular goods into Australia for the purpose of managing biosecurity risks associated with the goods.

This clause is consistent with meeting Australia’s obligations under the World Trade Organization *Agreement on the Application of Sanitary and Phytosanitary Measures*, whereby authority to import goods into Australian territory will also authorise the goods to be imported into a state or territory (unless additional conditions are justified on the basis of confirmed scientific analysis of regional difference).

This clause implements recommendation one of *One Biosecurity: A working partnership* (the Beale Review) and is also consistent with the Intergovernmental Agreement on Biosecurity and the 1995 Memorandum of Understanding on Animal and Plant Quarantine Measures, where all state and territory governments agreed to not apply sanitary and phytosanitary measures which are inconsistent with those set by the Commonwealth.

Please provide an estimation of hours spent on QoN response for each officer involved.

Officer	DAFF Level	Hours spent on QoN response
A	Executive Level 1	10
B	Senior Executive Service Band 1	2
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D		

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**Department of Agriculture/Department of Health**

*Ballast Water*

Clause 265 of the Bill states that the ballast water provisions will apply to the exclusion of any state or territory law that deals with ballast water or sediment. This will enable the creation of a single, Australia-wide ballast water management regime that includes both domestic and international vessel movements.

The ballast water provisions will not exclude or limit the concurrent operation of state or territory laws that relate to the treatment or disposal of ballast water or sediment after it has been removed from a vessel (subclause 265(2)). This recognises that state and territory environment protection laws may impose additional requirements once the ballast water or sediment has been released or remove from the vessel.

*Human biosecurity emergencies*

Chapter 8, Part 2, Division 2 provides the Health Minister with additional powers for the management of human biosecurity risks if the Governor-General declares that a human biosecurity emergency exists. The provisions within this Division are intended to be used for the broad direction of people rather than individuals, who may be managed under state and territory legislation or by human biosecurity control orders under the Bill. These provisions are also designed to give effect to Australia's obligations under the International Health Regulations, for example, to give effect to a recommendation given by the World Health Organization in the event of a public health emergency of international concern.

*General operation with state and territory laws*

There may be state laws that are not able to operate concurrently with the Act in particular cases. For example: a state law which seeks to require animals to be held in one place and a biosecurity measure under Commonwealth law requires particular animals to go to a premises controlled by the Commonwealth or a state law purports to ban the use of a particular vaccine and the Commonwealth law requires its use.

In these instances the state laws may be found inconsistent with the Commonwealth law if challenged in the High Court. If found to be inconsistent, the Commonwealth law would prevail by virtue of section 109 of the Constitution.

There are no proposals to amend the existing funding arrangements with regard to biosecurity emergencies. Where relevant, the Commonwealth will respond to or manage a biosecurity emergency in accordance with the existing management arrangements, including cost-sharing, under the Emergency Animal Disease Response Agreement, Emergency Plant Protection Response Deed and National Environmental Biosecurity Response Agreement.

Please provide an estimation of hours spent on QoN response for each officer involved.

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<b>A</b>	Executive Level 1	10
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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 19 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Biosecurity emergencies

**The Committee asked:**

What would happen if there was a biosecurity emergency and a particular state wanted to handle the situation differently to the Commonwealth?

**Answer:**

The Governor-General may declare a biosecurity emergency if the Agriculture Minister is satisfied that the threat posed by a pest or disease to animal or plant health, the environment or economic activities relating to animals, plants or the environment within Australian territory requires management at a national level and a declaration is necessary to prevent or control the disease or pest.

The declaration of an emergency enlivens the emergency provisions of the Biosecurity Bill and allows for the Commonwealth Agriculture Minister to determine emergency requirements, give directions and take actions to reduce biosecurity risk.

The Director of Biosecurity may make a biosecurity control order or determine a biosecurity response zone during a biosecurity emergency (clause 461 and 465).

During any emergency, the Commonwealth would act in consultation with the state or territory, however, ultimately the Agriculture Minister may determine any requirement that he or she is satisfied is appropriate and adapted to prevent or control the establishment or spread of the disease or pest in Australian territory or a part of Australian territory. As outlined in question 18, where instances of inconsistency are found by the High Court, the Commonwealth law will prevail.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 20 (written)

**Division/Agency:** Service Delivery, Department of Agriculture / Office of Health Protection, Department of Health

**Topic:** Onshore powers

**The Committee asked:**

The Bill greatly expands the powers of the Commonwealth to manage biosecurity in Australia. Do you anticipate that the Commonwealth would choose to use the new powers in relation to onshore risks? How would the role of the states and territories change in relation to post-border activities?

**Answer:**

The Biosecurity Bill legislatively supports the management of biosecurity risk along the biosecurity continuum reflecting the modern operational spread of biosecurity risk management and expanding on the traditional Commonwealth border management and intervention approach.

The Bill is designed to promote effective cooperation between governments in managing on-shore biosecurity risk. The Commonwealth is provided with powers to assess, monitor and manage biosecurity risks associated with a disease or pest incursion within Australian territory and provides a single legislative base to allow for a consistent response where an outbreak may cross state and territory boundaries. For example, by using a biosecurity response zone across the outbreak area, ensuring consistent biosecurity measures are applied across all jurisdictions involved.

The Commonwealth powers practically fall under two main areas: gathering information about the status of a pest or disease and preventing or controlling the spread of a pest or disease within Australian territory. These powers will not replace current state controls or responsibilities; rather they will complement existing arrangements in the management of onshore incursions and existing consultation mechanisms between Commonwealth and state and territory governments, providing additional tools for management of onshore biosecurity risk where appropriate.

Where relevant, the Commonwealth will respond to or manage a biosecurity risk in accordance with the existing management arrangements, including cost-sharing, under the Emergency Animal Disease Response Agreement, Emergency Plant Protection Response Deed and National Environmental Biosecurity Response Agreement.

The Biosecurity Bill also contains the ability to appoint state and territory officers as biosecurity officers (with agreement). Arrangements with state or territory bodies may be

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**Department of Agriculture/Department of Health**

entered into in order to minimise duplication of efforts in the biosecurity sphere. For example, the Commonwealth may enter into an agreement with a state or territory government to have the state or territory's biosecurity officers also become Commonwealth biosecurity officers so they are able to perform both functions. This has multiple benefits, including preventing duplication of services or inspections to meet both Commonwealth and state and territory biosecurity requirements. It also allows biosecurity services to be provided in locations where the Commonwealth does not have facilities.

There are well established links between the governments in relation to managing biosecurity risk including formal consultation mechanisms such as the National Biosecurity Committee (NBC). Members of the NBC were engaged in consultation throughout the development of the Biosecurity Bill and were also updated through the Primary Industries Standing Committee.

There are also a range of existing mechanisms including structures and protocols for the management of human health risks. These mechanisms include the Australian Health Protection Principal Committee and the National Health Emergency Response Arrangements. Such structures and protocols clearly outline consultation and response mechanisms and have been agreed by Commonwealth and state and territory health agencies.

The Commonwealth will continue to encourage the states and territory governments to provide input and feedback in the development of delegated legislation and administrative practices as appropriate.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 21 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Ballast water

**The Committee asked:**

The Committee has heard from some submitters that they were not consulted about the decision to introduce domestic ballast water management in the Bill – could you please respond to this complaint? *See for example* Shipping Australia Limited, Submission 23.

**Answer:**

The Biosecurity Bill 2012 was developed to include an Australian-wide ballast water and sediment management regime, which included the management of both international and domestic ballast water.

Industry was consulted during the development of the Biosecurity Bill 2012, including the introduction of domestic ballast water management through the Industry Legislation Working Group (ILWG). Shipping Australia Limited was consulted directly on the inclusion of this measure as a member of the ILWG.

The Biosecurity Bill 2012 was subject to public consultation, through the release of an exposure draft. The exposure draft phase began on 4 July 2012, closed for formal submissions on 24 October 2012.

There has been no change to the government's ballast water policy position between the two versions of the Bill. However, the requirement for pre-arrival reporting has been extended to all vessels intending to discharge ballast water at clauses 267 and 268

A representative from Shipping Australia Limited was also invited to, and attended a Biosecurity Legislation Update Forum held on 24 October 2014.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

**ANSWERS TO QUESTIONS ON NOTICE**

**Inquiry into the Biosecurity Bill 2014 and related Bills.**

**Department of Agriculture/Department of Health**

**Question:** 22 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Ballast water

**The Committee asked:**

Has the department considered the Australia Shipowners Association request to delay the implementation of the domestic ballast water provisions by 6 years to enable all vessels to be fitted with ballast water treatment systems?

**Answer:**

Following the UN Conference on Environment and Development (UNCED), held in Rio de Janeiro in 1992, the UN International Maritime Organisation (IMO) initiated negotiations to consider the possibilities of developing an internationally binding instrument to address the transfer of harmful aquatic organisms and pathogens in ships' ballast water.

The International Conference on Ballast Water Management for Ships' was held in February 2004 and adopted the International Convention for the Control and Management of Ships' Ballast Water and Sediments (the Ballast Water Management Convention).

Several representatives of maritime industry groups (including the Australian Shipowners Association, the Minerals Council of Australia and Amiad Australia) were present at the 2004 International Conference where the Convention was adopted. These representatives participated in informal drafting groups at this Diplomatic Conference.

Industry were engaged in developing Australia's position for both the 2004 International Conference as well as Australia's position on relevant papers submitted to the Marine Environment Protection Committee in the lead up to the International Conference.

Regular updates on the development of the Convention were provided to the National Introduced Marine Pest Coordination Group – a now former national committee of which industry and state and territories were members. Copies of the draft Convention were provided for members to review and provide comment.

In 2008, *One Biosecurity: A working partnership* (the Beale Review) recommended that the Commonwealth should extend its legislative reach to cover the field with respect to international and domestic ballast water regulation.

The department does not consider that a delayed implementation of the domestic ballast water provisions by 6 years is necessary as the Bill provides vessel owners and operators with a number of options to manage domestic ballast water.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

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These options include:

- discharging at a ballast water reception facility
- undertaking an acceptable ballast water exchange
- using an approved ballast water treatment system
- taking up and discharging of water at the same place, or
- seeking an exemption from the Director of Biosecurity.

The Director of Biosecurity may approve an exemption of one or more discharges of ballast water that are part of the vessel's voyages between specified ports or locations. For example, the Director of Biosecurity may grant an exemption to a vessel which only travels between ports that have a low risk of harmful aquatic organisms and pathogens. The exemption is only for a specified period (up to 5 years) and may be in whole or in part, and may be subject to conditions.

Ballast water exchange and exemptions given by the Director of Biosecurity will limit the regulatory impact of the requirements of the Bill whilst industry prepares for the changes. It is the department's intention to liaise with regulated stakeholders regarding the development of any regulations and administrative policy.

Please provide an estimation of hours spent on QoN response for each officer involved.

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**Senate Rural Affairs and Regional Affairs and Transport Legislation Committee**

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**Department of Agriculture/Department of Health**

**Question:** 23 (written)

**Division/Agency:** Service Delivery, Department of Agriculture

**Topic:** Biosecurity Import Risk Analyses

**The Committee asked:**

Can you describe the clauses in the BIRA process that will improve transparency, accountability and reduce conflicts of interest?

**Answer:**

The Biosecurity Bill improves transparency and accountability of the biosecurity system by amongst others, including provisions for undertaking BIRAs in the legislation. Currently, IRAs are not provided for in the *Quarantine Act 1908*. Additionally, the Biosecurity Bill includes the definition of Australia's ALOP which is not contained in the current legislation.

The department will develop BIRA regulations and guidelines to be made available for public consultation. These documents will include information regarding the processes for consultation and other transparency measures.

Further, the Director of Biosecurity must only take into account the 'objects of the Act' when making decisions under the Act. This provides a legislative mechanism to ensure independence from his role as Secretary of the department. This approach is consistent with other structural arrangements in the Commonwealth related to regulatory risk assessment and decision-making. The objects of the Act are clearly defined at clause 4.

Any decision made by the Director of Biosecurity that is made beyond the legal authority of the legislation, would be ultra vires (beyond power) and potentially invalid. For example, a decision that takes considerations outside of the legislation into account, such as international trade implications.

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**ATTACHMENT A**

	<i>Quarantine Act 1908/Quarantine Regulations 2000</i>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Reference in primary legislation	There is no reference to the IRA process in the Quarantine Act.	<p>The concept of a BIRA is introduced in the Biosecurity Bill.</p> <p>Chapter 3 of the Biosecurity Bill establishes the BIRA process and outlines core requirements, such as the powers of the Director of Biosecurity and the Agriculture Minister, and allows regulations to be made.</p>
Agriculture Minister role	There is no reference to the role of the Agriculture Minister in the Quarantine Act or the Quarantine Regulations.	The Biosecurity Bill outlines that the Agriculture Minister may direct the Director of Biosecurity to commence a BIRA (this direction must be made in writing and tabled in each house of Parliament), but the Director of Biosecurity is not subject to direction by the government in relation to the conduct, findings or outcomes of a BIRA.

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	<i>Quarantine Act 1908/Quarantine Regulations 2000</i>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Guidelines for completing IRAs/BIRAs	<p>There is no reference to guidelines in the Quarantine Act or the Quarantine Regulations.</p> <p>The department provides information on how it conducts IRAs through the publication of the administrative document, the Import Risk Analysis (IRA) Handbook 2011, available on the department's website.</p>	<p>The Biosecurity Bill includes that the Director of Biosecurity may make guidelines setting out matters to be taken into account in conducting a BIRA. These guidelines, if made, are required to be published.</p> <p><b>Note:</b> The department intends to develop BIRA Guidelines which will be released publicly for stakeholder consultation. The BIRA Guidelines will be an administrative document which will include information on how the department conducts BIRAs as well as other details about Australia's biosecurity system.</p>

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	<b><i>Quarantine Act 1908/Quarantine Regulations 2000</i></b>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Regulated steps	<p>There is no reference to the IRA process in the Quarantine Act.</p> <p>Under the Quarantine Regulations the current IRA process has two regulated processes.</p> <p>A standard IRA process includes:</p> <ul style="list-style-type: none"> <li>• announcing the scope and approach of an IRA</li> <li>• publishing a draft IRA report for stakeholder consultation</li> <li>• publishing a provisional final IRA report (providing an opportunity for stakeholders to appeal to the Import Risk Analysis Appeals Panel)</li> <li>• publishing a final IRA report.</li> </ul> <p>An expanded IRA process includes:</p> <ul style="list-style-type: none"> <li>• the processes within the standard IRA above</li> <li>• an option for an issues paper to be released for stakeholder consultation</li> <li>• Eminent Scientists Group review of the revised draft IRAs.</li> </ul>	<p>The Biosecurity Bill includes that the regulations must require the Director of Biosecurity to prepare the following reports as part of the process of conducting a BIRA:</p> <ul style="list-style-type: none"> <li>• A draft BIRA report</li> <li>• A provisional BIRA report</li> <li>• A final report.</li> </ul> <p><b>Note:</b> The department intends to develop draft BIRA regulations which will be released publicly for stakeholder consultation in 2015.</p>

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	<b><i>Quarantine Act 1908/Quarantine Regulations 2000</i></b>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Review	<p>There is no reference to the IRA process in the Quarantine Act.</p> <p>The Quarantine Regulations allow for the Eminent Scientists Group to review revised draft IRA reports in the expanded IRA process only.</p> <p>The department does, administratively, call upon independent experts to review IRA outcomes if required.</p>	<p>Review processes for BIRAs are not provided for in the Biosecurity Bill.</p> <p><b>Note:</b> The department intends to develop draft BIRA regulations which will be released publicly for stakeholder consultation in 2015.</p>

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	<i>Quarantine Act 1908/Quarantine Regulations 2000</i>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Stakeholder consultation	<p>There is no reference to the IRA process in the Quarantine Act.</p> <p>Regulated stakeholder consultation for an IRA is outlined in Quarantine Regulations for when:</p> <ul style="list-style-type: none"> <li>• an issues paper is released (if required)</li> <li>• publishing a draft IRA report</li> <li>• publishing a provisional final IRA report.</li> </ul> <p>Additional stakeholder consultation processes are documented administratively in the IRA Handbook.</p>	<p>Stakeholder consultation during a BIRA is not legislated in the Biosecurity Bill.</p> <p><b>Note:</b> The department intends to develop draft BIRA regulations which will be released publicly for stakeholder consultation in 2015.</p>

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**Department of Agriculture/Department of Health**

	<i>Quarantine Act 1908/Quarantine Regulations 2000</i>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Timeframes for completion	<p>There is no reference to the IRA process in the Quarantine Act.</p> <p>The Quarantine Regulations provide for two regulated timeframes. The timeframe is calculated from the announcement of the IRA to publishing a provisional final IRA report.</p> <p>A standard IRA is required to be completed within 24 months.</p> <p>An expanded IRA is required to be completed within 30 months.</p>	<p>Timeframes for completing BIRAs are not provided for in the Biosecurity Bill.</p> <p><b>Note:</b> The department intends to develop draft BIRA regulations which will be released publicly for stakeholder consultation in 2015.</p>
Australia's appropriate level of protection (ALOP)	Australia's ALOP is not provided for in the Quarantine Act or the Quarantine Regulations.	Australia's ALOP is contained in the Biosecurity Bill.

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	<i>Quarantine Act 1908/Quarantine Regulations 2000</i>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Stop-the-clock provisions	<p>There is no reference to the IRA process in the Quarantine Act.</p> <p>The Quarantine Regulations provide for the counting of time to complete an IRA to be stopped if:</p> <ul style="list-style-type: none"> <li>• the Chief Executive believes that further information is essential to complete an IRA and that a proposer or another person can provide the information; or</li> <li>• the Chief Executive believes that it is essential to undertake research, or to seek substantial expert advice, to complete an IRA; or</li> <li>• a significant national or international quarantine circumstance exists that limits Biosecurity Australia's ability to complete an IRA within the time required.</li> </ul> <p>The Chief Executive must publish a notice stating the reasons for the counting of time to stop.</p>	<p>Stop-the-clock provisions are not provided for in the Biosecurity Bill.</p> <p><b>Note:</b> The department intends to develop draft BIRA regulations which will be released publicly for stakeholder consultation in 2015.</p>

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	<i>Quarantine Act 1908/Quarantine Regulations 2000</i>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Failure to comply with time provisions	<p>There is no reference to the IRA process in the Quarantine Act.</p> <p>The Quarantine Regulations state:</p> <ul style="list-style-type: none"> <li>for an IRA, a failure to comply with the time limits set ... does not affect the validity of a report published by Biosecurity Australia in respect of the IRA.</li> </ul>	<p>Failures to comply with time provisions are not provided for in the Biosecurity Bill.</p> <p><b>Note:</b> The department intends to develop draft BIRA regulations which will be released publicly for stakeholder consultation in 2015.</p>

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	<i>Quarantine Act 1908/Quarantine Regulations 2000</i>	<b>Biosecurity Bill 2014/Draft BIRA Regulations</b>
Additional information	<p>There is no reference to the IRA process in the Quarantine Act.</p> <p>The Quarantine Regulations allow for further information, research and expert advice to be sought in an IRA.</p> <ul style="list-style-type: none"> <li>• If the Chief Executive believes that further information is essential to complete an IRA and that a proposer or another person can provide the information, the Chief Executive may request, in writing, that the proposer, or the other person, provide the information.</li> <li>• If the Chief Executive believes that it is essential to undertake research, or to seek substantial expert advice, to complete an IRA, the Chief Executive may commission the research or advice.</li> </ul> <p>The department does call upon experts throughout the IRA process, when required, to provide expert input and advice, including from independent sources if necessary. This is completed administratively and is not included in the legislation.</p>	<p>Additional information is not provided for in the Biosecurity Bill.</p> <p><b>Note:</b> The department intends to develop draft BIRA regulations which will be released publicly for stakeholder consultation in 2015.</p>

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