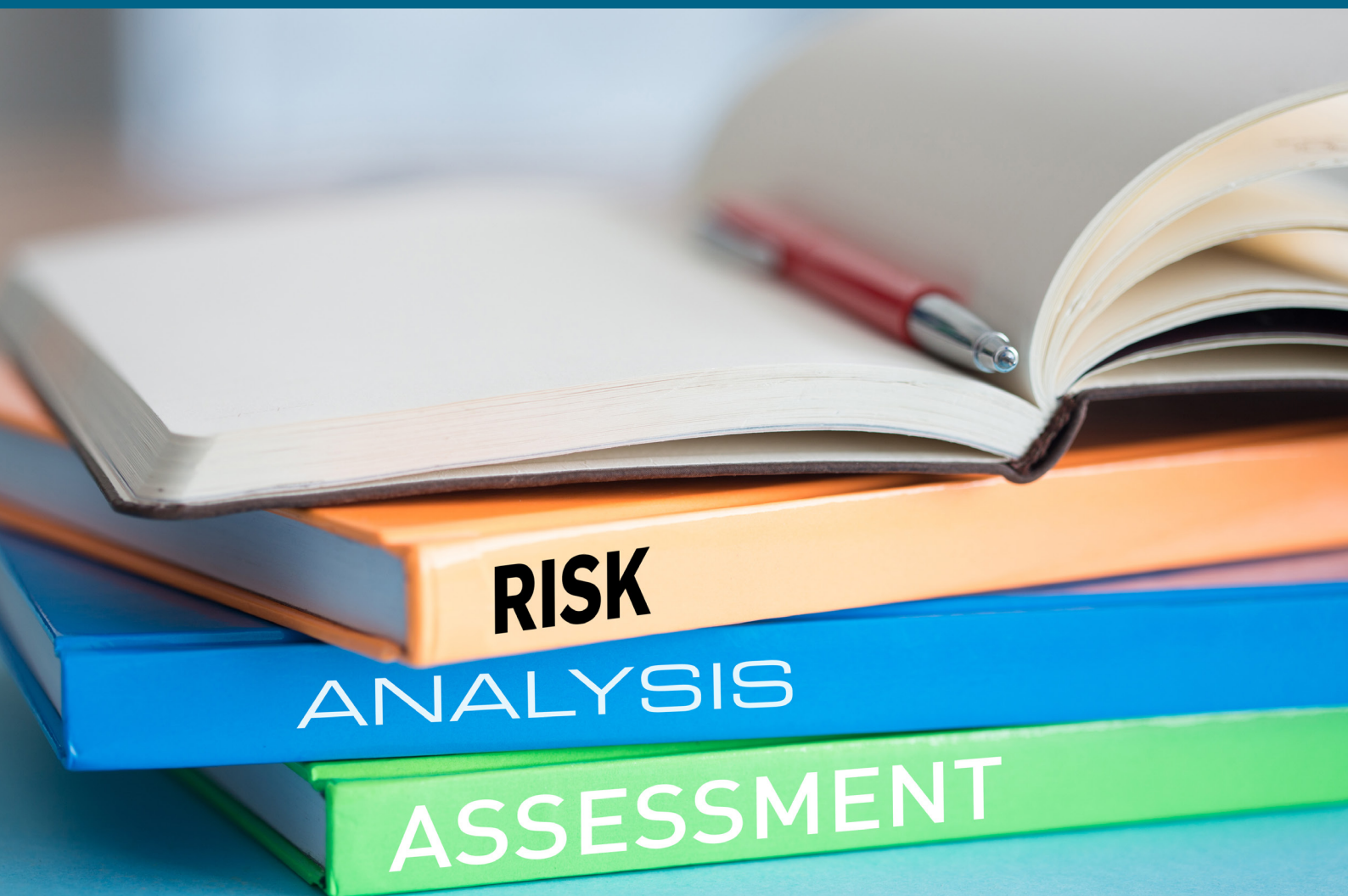




Australian Government
Inspector-General of Biosecurity

Review of the management and application of the import risk analysis process

Review report no. 2024–25/01



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Contents

Executive summary	4
Review recommendations and departmental responses	5
1 The review process	9
1.1 Authority of the Inspector-General of Biosecurity	9
1.2 Objectives and terminology used	9
1.3 Review criteria and sub-criteria	9
1.4 Scope	10
1.5 Observations and assessment	11
1.6 Case studies	11
1.7 Structure of the report	12
2 Background to import risk analysis	13
2.1 Challenges around import risk analysis	13
2.2 Governance and approach to import risk analysis	14
3 The regulation of import risk analysis	15
3.1 The SPS Agreement	15
3.2 International Plant Protection Convention	16
3.3 World Organisation for Animal Health	16
3.4 World Health Organization	16
3.5 Import risk analyses	16
3.6 Market Access and Risk Analysis Board	19
3.7 Findings	20
3.8 Recommendations	20
4 Import risk analysis methodology	22
4.1 International context	22
4.2 Methodologies used in Australia	22
4.3 Group pest risk analyses	22
4.4 Prioritisation of import risk analyses	23
4.5 Findings	23
4.6 Recommendations	23
5 Managing import risk analyses	27
5.1 Observations and assessment	28
5.2 Findings	28
5.3 Recommendations	29
6 Stakeholder communication and engagement	31
6.1 Findings	32
6.2 Recommendations	32
7 Developing import workplans based on import risk analyses	35
7.1 Findings and recommendation	35
8 Looking ahead – future technological developments	37
8.1 Observations and assessment	37
8.2 Findings and recommendations	37
9 Conclusion	39
Acronyms	40
Appendix A Agency response	41
References	46
Table	
Table 1 Criteria and sub-criteria used to guide the review process	10
Figure	
Figure 1 The Biosecurity import risk analysis process	18

Executive summary

Australia's import risk analysis processes are robust and aligned with international standards. The Department of Agriculture, Fisheries and Forestry must consider its stakeholders' diverse expectations while meeting its objectives. The department can better navigate these complexities and achieve optimal outcomes using enhanced methodologies, adhering to international principles and improving transparency. Opportunities exist to further strengthen effectiveness, transparency and importantly, stakeholder trust.

The review's findings indicate that the department is using sound methodologies that are consistent with international obligations. The methodologies align with relevant international standards. Internal administrative processes and procedures are thorough and well-documented. However, several areas for improvement were identified:

- broader use of technical expertise (such as the Chief Veterinary Officer, Chief Plant Protection Officer, Chief Environmental Biosecurity Officer)
- streamlining of plant and animal biosecurity processes where possible
- enhanced oversight through mechanisms like the Scientific Advisory Group (SAG)
- better integration of environmental biosecurity into the risk analysis framework.

These changes would enable a more comprehensive and effective approach to addressing plant and animal import risks.

External stakeholders claim a lack visibility of departmental processes and do not fully appreciate its strengths. Opportunities exist for the department to improve transparency and consistency in its interactions with external stakeholders, especially industry stakeholders. The review highlighted several tensions in these relationships, which varied depending on the risk analysis area(s) and the specific industry stakeholders involved. Failure to address such tensions contributes to process inefficiencies and undermines process outcomes. It is important for the department to improve its communication channels. This would improve the transparency of the process and help build the trust of external stakeholders.

Relationships with state and territory governments have evolved, moving away from siloed approaches to closer collaboration. Significant opportunities exist to create positive working relations with state and territory governments. Platforms like the National Biosecurity Committee (NBC) and its sectoral committees provide mechanisms for fostering cooperation and ensuring consistency across jurisdictions. Achieving consistency of approaches across jurisdictions is critical to streamlining processes and facilitating trade.

Committees involved in import risk analysis would benefit from specialised expertise. Establishing a pool of biosecurity specialists to address knowledge gaps, alongside expanding the role of the SAG to include research institutions, would strengthen the quality of assessments. Formalising systems and processes to regularly update import risk analyses and reduce reliance on corporate knowledge will ensure continuity and consistency as experienced staff retire.

Technology, including artificial intelligence (AI), offers significant potential to enhance the import risk analysis process by automating data collection, improving consistency and increasing efficiency. However, AI systems must be rigorously tested and validated to ensure reliability and address potential biases. A clear strategic plan for integrating AI and other technologies into the risk analysis process is essential, aligning innovation with long-term biosecurity objectives.

While Australia's biosecurity risk analysis framework is robust, addressing the challenges identified in this report will enhance its efficiency, improve stakeholder relationships and create a more resilient and responsive system. By fostering stronger engagement, increasing transparency, addressing skill gaps, leveraging technology and streamlining processes, the department can better manage evolving risks and adapt to the demands of global trade and biosecurity challenges.

Review recommendations and departmental responses

The Inspector-General's 10 recommendations address the issues identified in the management and application of the processes for both 'regulated' (biosecurity import risk analysis; BIRA) and 'non-regulated' (import risk analysis; IRA) – unless they have been identified individually.

The department's full response to the recommendations is also at [Appendix A](#).

Recommendation 1

The department should consider broadening the scope of the role of the Market Access and Risk Analysis (MARA) Board to cover all animal- and plant-related import risk analyses/reviews. In addition, the Board's:

- membership should be extended to include the office of the Australian Chief Environmental Biosecurity Officer in the decision-making processes to ensure environmental biosecurity risks are also addressed satisfactorily
- terms of reference should be reviewed periodically and updated to ensure currency.

Department's response: Agreed. The department will develop a mechanism to achieve improved consistency across animal- and plant- related import risk analyses, with consideration of Australia's obligations in respect of the relevant international standards. In developing this framework, the department will consider existing arrangements such as the MARA board and the established Market Access and Diversification Assistant Secretaries Coordination Group (MADAS), which reports to the Deputy Secretary-led Trade and Market Access Prioritisation (TMAP) Committee. The Chief Environmental Biosecurity Officer is a member of MADAS, so environmental perspectives and concerns will be included in the Group's recommendations.

Recommendation 2

The department should work collaboratively with state and territory agencies, as well as relevant industry bodies and committees such as Animal Health Australia (AHA), Plant Health Australia (PHA) and the Environment and Invasives Committee (EIC) to:

- encourage alignment of domestic non-regulated import risk analyses methodologies with relevant international standards
- formalise engagement points within the import risk analysis process, directly involving the Animal Health Committee (AHC), Plant Health Committee (PHC), EIC and key government agencies.

Department's response: Agreed in principle. The department undertakes risk analyses in accordance with the *Biosecurity Act 2015* (Act) and will continue to work collaboratively with states and territories, Animal Health Australia (AHA), and Plant Health Australia (PHA) on relevant aspects of Biosecurity Import Risk Analyses (BIRAs) and import risk reviews, where appropriate. The department will formalise the engagement points regarding these reviews through the National Biosecurity Committee (NBC) and its sub-committees Animal Health Committee (AHC), Plant Health Committee (PHC), Environment and Invasives Committee (EIC) and the Marine Pest Sectoral Committee, where appropriate. The department also recognises Australia's obligations as a Member of the World Trade Organization (WTO), and notes that the Act ensures that the Director of Biosecurity will align the approach to import risk analysis with both the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the guidelines for import risk analysis published by the international standard setting organisations. The department will continue to encourage alignment of relevant activities of the states and territories, including through NBC, with these international standards.

Recommendation 3

As part of its broader stakeholder communication and engagement strategy, the department should proactively communicate its processes for both regulated and non-regulated import risk analysis by publishing clear guidelines or in a policy document on its website. The guideline or policy document should outline:

- the criteria and rationale used in prioritising import risk analysis for plants/plant products and animals/animal products
- the methodology for assessing cumulative pest risks and the potential consequences within the import risk analysis process
- key stages of the import risk analysis process when the department would communicate with the stakeholders, including face-to-face meetings, when necessary
- establish clear timeframes for reviewing risk analysis applications, completing all import risk analysis and developing associated import requirements and workplans
- notify stakeholders if the development of an operational workplan is not part of the import risk analysis process.

This approach will enhance transparency, provide stakeholders with a clearer understanding of the decision-making process and foster greater trust in the department's import risk analysis processes.

Department's response: Agreed in principle. The department supports the publication of a policy document/guideline that clearly communicates the risk analysis process to the extent that it does not limit the department's ability to achieve the objects of the Act or introduce legal error into the Director of Biosecurity's decision making, including fettering the exercise of powers under the Act, and agrees this policy document/guideline will improve transparency and foster better engagement with domestic and international stakeholders.

Recommendation 4

The department should develop and implement a procedural mechanism to review and assess findings and associated import conditions in previous regulated and non-regulated import risk analyses, ensuring currency of findings and consistency in decision-making across historical analyses.

Department's response: Agreed. The department will continue to review, assess, and update as required the findings of completed risk analyses and associated import conditions through ongoing biosecurity operational activities, including on-arrival inspections, assessment of emerging pest- and disease-specific risks and using advances in technological tools. The department will also develop and implement a system, incorporating current activities, to review and assess existing BIRAs and import risk reviews, recognising this will improve the currency of measures and the consistency of decision-making.

Recommendation 5

The department should review the role of the Scientific Advisory Group (SAG), focusing on:

- the skill set of members, including the adequacy and relevance of their expertise
- the frequency of engagement and the stages of the regulated biosecurity import risk analysis (BIRA) process when the group is consulted
- expanding the group's role to provide technical oversight for non-regulated import risk analyses
- the ability to seek independent expert input when necessary.

Department's response: Agreed. The department values the role of the Scientific Advisory Group to independently verify the department's scientific analysis and agrees to review the role of the Scientific Advisory Group to ensure that it remains fit for purpose.

Recommendation 6

The department should proactively engage with relevant state and territory government agencies to:

- continuously improve mechanisms for sharing risk analysis data and information while leveraging non-regulated import risk analysis work being undertaken by these agencies
- jointly develop a training module for non-regulated IRA, incorporating input from relevant industry groups to enhance their understanding of the process.

Department's response: Agreed in principle. The department will continue to collaborate with state and territory government agencies, including engagement at key points in the BIRA and non-regulated import risk review processes, where appropriate under the Act. The Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer will also continue to facilitate communication of relevant information to state and territory counterparts, industry and internationally through established mechanisms. Through regular review, the department will continue to improve its current work with the states and territories on the delivery of training in biosecurity risk analysis process and methodology.

Recommendation 7

The department should formally include the Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer during internal consultation processes to ensure that international standards are considered appropriately and that recommended treatments and risk management are consistent with domestic animal and plant health and environmental biosecurity policies and practices as relevant.

Department's response: Agreed. The department will continue to include and review internal stakeholder consultation points with the Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer, to the extent this is relevant to decision making under the Act. The department acknowledges the connection of these positions to the Animal Health Committee (AHC), Plant Health Committee (PHC) and the Environment and Invasives Committee (EIC) ensures the department's decision making is informed by relevant domestic animal and plant health and environmental biosecurity policies and practices.

Recommendation 8

The department should proactively gather technical information from stakeholders, carefully assess and offer transparent feedback to stakeholders, clearly explaining the rationale for including or excluding specific information in the decision-making process. This will help foster trust with key industry stakeholders.

Department's response: Agreed in principle. The department will continue to gather and share technical information both nationally and internationally that are relevant to risk analyses. The department will review existing mechanisms for gathering technical and scientific information from stakeholders to ensure stakeholders understand how their input has been considered in the decision-making process, where necessary and permitted under the Act. In accepting this recommendation, the department underscores its commitment to a data-driven culture where decision making is transparent and based on demonstrated evidence.

Recommendation 9


For clarity, the department should regularly review and update the Biosecurity Import Risk Analysis (BIRA) guidelines that were first published immediately after the enactment of the *Biosecurity Act 2015* and have not been updated since.

Department's response: Agreed. The department agrees to regularly review and update its Biosecurity Import Risk Analysis Guidelines – managing biosecurity risks for imports into Australia (2016). The department recognises that regular review of the guidelines will ensure a more flexible and improved risk-based regulatory system to drive more efficient and harmonised processes will be beneficial.

Recommendation 10

The department should formalise the engagement of the Commonwealth Scientific Industrial Research Organisation (CSIRO) and the Centre of Excellence for Biosecurity for Biosecurity Risk Analysis (CEBRA) for joint, issues-based projects on plant, animal and environmental import risk analysis (both regulated and non-regulated) to ensure projects are prioritised and implemented.

Department's response: Agreed. The department currently has MOUs with both CSIRO and CEBRA and is progressing reviews of these formal arrangements. These MOUs form a strategic and collaborative relationship and provide expertise to achieve better public good outcomes for Australia in respect to agriculture, fisheries and forestry. The current reviews of the MOUs will provide an opportunity to embed a more strategic approach to the commissioning of projects to ensure they are better aligned to deliver outcomes for the biosecurity system as a whole and the biosecurity risk analysis processes specifically. This will include ensuring that transition to business is a consideration from project inception.



Dr Lloyd Klumpp

Inspector-General of Biosecurity

28 March 2025

1 The review process

1.1 Authority of the Inspector-General of Biosecurity

Australia's biosecurity system relies on various government programs that ensure the safe international movement of goods and people. These programs, mainly delivered by the Department of Agriculture, Fisheries and Forestry in consultation with other Commonwealth agencies (for example, the Department of Climate Change, Energy, the Environment and Water, the Department of Health and Aged Care and the Department of Defence as required) and industry, minimise the risk of entry, establishment and spread of exotic pests and diseases that could cause significant harm to plants, animals, people and Australia's unique environment.

The Inspector-General of Biosecurity's mission is to enhance the integrity of Australia's biosecurity systems by independently evaluating and verifying the performance of these programs across the biosecurity continuum – pre-border, at the border and post-border. The Inspector-General makes recommendations for system improvements and provides an assurance framework for stakeholders.

The Inspector-General is responsible for reviewing the Director of Biosecurity's performance of functions and exercise of powers. The *Biosecurity Act 2015* and Biosecurity Regulation 2016 legislatively define the Inspector-General's role, authority and independent powers of review.

The Inspector-General is independent of the Minister for Agriculture, Fisheries and Forestry and the Director of Biosecurity (who is also the department's Secretary). The Inspector-General may consider the minister's request for a review and seek immediate action from the Director of Biosecurity (or senior departmental executives) and the minister to protect or enhance the integrity of Australia's biosecurity systems.

1.2 Objectives and terminology used

Two processes of import risk analysis were reviewed. The regulated biosecurity risk analyses and the non-regulated import risk analysis, which includes pest risk analysis. In this document, where the text is referring to the *regulated biosecurity import risk analysis*, the acronym 'BIRA' is used. For the *non-regulated import risk analysis*, the term 'non-regulated IRA' is used. *Import risk analysis* is used to cover the general process.

The objectives of this review were to assess:

1. the processes and procedures for conducting both BIRA and non-regulated IRA – including pest risk analysis (PRA) – in the context of Australia's international obligations to conform to the standards developed by the World Organisation for Animal Health (WOAH) and the International Plant Protection Convention (IPPC).
2. whether the department's import risk analysis processes align with relevant legislation, are shaped by well-designed stakeholder consultation and result in effective biosecurity measures consistent with Australia's appropriate level of protection.

Additionally, the review presents an opportunity to explore contemporary developments in import risk analysis methodologies. It not only outlines current approaches but also offers insights into potential future developments for national biosecurity system.

1.3 Review criteria and sub-criteria

The review is primarily organised around four key criteria and 14 sub-criteria (see Table 1). These are aligned with the components of the import risk analysis process, providing a framework for evaluating the process from start to finish. The criteria also ensured that the broader context of the analysis process in Australia was considered.

Table 1 Criteria and sub-criteria used to guide the review process

No.	Criteria	Sub-criteria
1.	Process conduct Is the conduct of import risk analyses consistent with the intentions of the relevant legislation and legislative instruments?	1) Examination of indicators of consistency 2) Clarification of legislative intentions 3) Assessment of legislative alignment 4) Evaluation of how well the current conduct aligns with the objectives of the legislation and the ability to deliver intended outcomes
2.	Process implementation suitability Is there a fit-for-purpose decision-making framework to plan, prioritise and manage import risk analysis?	5) Review of prioritisation approaches 6) Assessment of challenges in scheduling and managing the process 7) Identification of potential solutions and improvements
3.	Process delivery timeframes Are import risk analyses conducted in a timely manner?	8) Assessment of historical delivery timeframes 9) Identification of factors affecting delivery times 10) Exploration of factors that could improve delivery timeframes 11) Determination of stakeholder expectations regarding delivery times
4.	Stakeholder engagement Are there adequate arrangements to consult and engage relevant stakeholders in the import risk analyses process?	12) Identification of stakeholders 13) Clarification of consultation points 14) Assessment of alignment between consultation points and stakeholder engagement

1.4 Scope

The Inspector-General conducts reviews that focus on elements of Australia’s biosecurity system within the remit of the department. For this review, the Inspector-General’s scope included the following aspects of the biosecurity system managed by the department’s Biosecurity, Operations and Compliance Group:

- The department’s BIRA and non-regulated IRA processes and their alignment with the Biosecurity Act and related legislation.
- The implementation of the legislation through policies and processes for conducting BIRAs.
- Decision-making, planning and prioritisation that result in the conduct of BIRA or non-regulated IRA processes.
- Stakeholder consultation at all stages of the BIRA and non-regulated IRA processes.
- Stakeholder engagement in risk identification and co-designing mitigation measures.
- Project management and timeliness in the BIRA and non-regulated IRA processes.

1.4.1 Out of scope

This review does not assess elements of the biosecurity system managed by state and territory governments, animal and plant industries, or international trade and market access issues. However, aspects of risk analysis outside the department’s remit are included to provide context for the Australian Government’s processes.

1.5 Observations and assessment

In conducting this review, the Inspector-General reviewed extensive documentation from the department's Plant Science and Risk Assessment (PSaRA) Branch and the Animal Biosecurity Branch (ABB). This material covered both the broader policy context and specific BIRA processes, illustrated with case studies from actual plant and animal analyses. Additionally, the documentation received outlined both the general processes for conducting BIRA and non-regulated IRA and the associated administrative requirements, including internal approvals and notifications to both internal and external stakeholders. The Inspector-General reviewed and assessed the information provided to better understand:

- the regulatory framework for BIRA in Australia, including its compliance with national and international standards
- the methodologies employed in conducting BIRA and non-regulated IRA
- the processes and procedures used in conducting BIRA and non-regulated IRA
- how stakeholders are engaged in conducting BIRA and non-regulated IRA
- the ongoing projects involving external organisations, such as CSIRO and CEBRA, assisting in conducting BIRA and non-regulated IRA.

Processes were compared to national and international obligations and relevant published risk analysis standards. Sources were supplemented by interviews (both electronic and in-person) with internal and external stakeholders, including the government bodies at the national, state and territory levels. The interviews allowed for further investigation into the previously reviewed information, as well as direct feedback on stakeholders' experiences in the import risk analysis process. Standard questions were used to gather insights on what worked well, what challenges were faced and suggestions for improving the process.

1.6 Case studies

Case studies were used to review import risk analysis processes and focused on the methodology used. This included processes related to legislation and regulatory alignment, the approvals process, stakeholder engagement (both internal and external) and the delivery of subsequent outcomes.

The case studies were used for this review were:

- plant risk analysis
 - apples from the United States
 - melons from Korea
 - dragon fruit from the Philippines
- animal risk analysis
 - prawns
 - sturgeon fish
 - beef (in the context of lumpy skin disease risk).

1.7 Structure of the report

The import risk process is complex and forms part of a broader trade and environmental system. To evaluate whether the department's methodology is fit-for-purpose, it is crucial to understand the wider context, including the rationale behind the process and its final implications for Australia.

In conducting this review, the Inspector-General carried out a comprehensive assessment of the system, followed by an in-depth examination of its individual components. In the Inspector-General's view, the most effective approach was to investigate the *what, why, how, who* and *when* of the process and its associated activities.

The review is divided into 6 chapters. Chapters 3 to 6 address the 4 key criteria and 14 sub-criteria (Table 1), Chapter 7 addresses the process of developing workplans resulting from completed BIRAs and non-regulated IRAs and Chapter 8 reviews the potential for future technologies to improve the existing import risk analysis process.

The 6 chapters are:

- Chapter 3 – The regulation of import risk analysis
- Chapter 4 – Import risk analysis methodology
- Chapter 5 – Managing import risk analysis
- Chapter 6 – Stakeholder communication and engagement
- Chapter 7 – Developing import workplans from recommendations
- Chapter 8 – Looking ahead – future technological developments.

Although these components are separated for clarity, they are interconnected and form part of a unified system. Each section is approached similarly: beginning with a broad background, primarily based on the Inspector-General's research, supplemented with departmental information and insights from 35 stakeholder interviews conducted during the review process. For each component, the review outlines the findings, followed by recommendations for the minister and the department to consider.

2 Background to import risk analysis

Australia's biosecurity policies are designed to protect the country from the risks posed by exotic pests and diseases, which could enter, establish and spread within Australia – threatening the nation's unique flora and fauna, agricultural and aquaculture industries and human health.

The Australian biosecurity system focuses on three key areas to prevent or respond to the incursion of pests and diseases: overseas, at the border and within the country. The department undertakes a range of biosecurity policy, operational and compliance functions, while also implementing various education, awareness and communication campaigns.

The Biosecurity Act establishes Australia's appropriate level of protection (ALOP). This aims to provide a high level of sanitary and phytosanitary protection by reducing biosecurity risks to a very low level, but not zero. The success of the national biosecurity system in protecting the environment, economy and our way of life depends on the collective efforts of all stakeholders. This is a shared responsibility. The department works across the Commonwealth and in collaboration with state and territory governments, industry, research institutions and community groups to enhance the system and manage biosecurity risks effectively.

Import risk analysis is a key part of managing agriculture and biosecurity both in Australia and internationally. At its core, it involves assessing potential risks and their impacts on things like farming productivity, ecosystem health and economic stability. In the context of this report, the review activities focus primarily on trade-related risks. However, elements of these activities may also relate to environmental biosecurity, which are highlighted where relevant. The environmental aspect – not fully addressed within the scope of this review – has been covered in the Inspector-General's other report (IGB, 2025; forthcoming).

2.1 Challenges around import risk analysis

Any agency responsible for assessing risks faces a variety of challenges. The assessment of biosecurity risks associated with the importation of goods is particularly complex. Key challenges for the department include the following areas.

2.1.1 Expectations

Stakeholders often do not have a common or agreed position about the risk around international imports. Groups such as importers, emerging industries and the public may directly benefit from imports. Other groups may view imports as competition for their own products. Despite these differing views, there is a broad expectation that imports of certain goods should not pose a biosecurity risk.

However, the concept of an ALOP, which accepts very low levels of risk but not zero, makes it impossible to meet some stakeholders' expectation of no risk. This can lead to dissatisfaction with the department's import risk analysis processes. This presents a challenge that is difficult for any agency to address effectively.

2.1.2 Methodology

Risk analysis methods can be highly complex. They generally rely on expert knowledge. While some aspects of the process are quantitative, much of it depends on qualitative analysis. The department uses international standards for import risk analysis processes. These methodologies can be challenging for non-experts to understand or explain, making public communication a significant challenge.

2.1.3 International obligations

Expectations from stakeholders often reflect a limited understanding of Australia's international obligations and how the international trade system operates more broadly. Some stakeholders are either unwilling to accept any level of risk associated with imports or oppose the importation of products that could be produced domestically. This may indicate a failure to recognise the mutual benefits of two-way trade and the role of Australia's risk-based approach in facilitating access to global markets. Addressing this requires education and improved communication about the benefits of international trade to Australia.

2.1.4 Resources and priorities

Import risk analysis processes are resource intensive given the complexity and expertise required. The department, like any organisation, has finite resources. It cannot conduct processes immediately in response to every market access request. Prioritisation of these requests is necessary. Stakeholders may become frustrated if their market access request is not prioritised or expedited, creating additional communication challenges that further strain the department's resources.

2.2 Governance and approach to import risk analysis

The import risk analysis process is a crucial component of Australia's biosecurity system. It allows the Australian Government to assess the biosecurity risks associated with importing certain commodities and provide recommendations on import conditions that achieve Australia's ALOP.

The department conducts import risk analysis with input from technical and scientific experts in relevant fields. The process also includes opportunities for stakeholder consultation at various stages to ensure broad engagement and informed decision-making.

2.2.1 Plant import risk analyses

The Plant Sciences and Risk Assessment (PSaRA) branch within the department's Biosecurity Plant and Science Services Division (BPSSD) is responsible for developing biosecurity import policies and providing scientific advice to ensure the safe importation of plants and plant products. Additionally, the branch:

- conducts weed risk assessments
- offers scientific guidance on the safe importation and release of biological control agents
- works to secure, maintain and enhance trade and market access for Australia's plant-based products
- actively contributes to the development and revision of international phytosanitary standards through its involvement in the IPPC.

2.2.2 Animal import risk analyses

The Animal Biosecurity Branch (ABB) within the department's Biosecurity Animal Division (BAD) is responsible for developing biosecurity import policies and providing scientific risk assessments for the safe importation of animals and animal products, including aquatic species.

The ABB also works to:

- secure, maintain and expand trade and market access for Australian animals and their genetic materials
- provides policy and technical advice on marine pest biosecurity
- plays an active role in the international standard-setting processes for animal, animal product and marine biosecurity.

ABB is structured into three sections based on animal species or commodity type:

- Avian, Biologicals, Companion Animals and Dairy (ABCD)
- Livestock and Zoo Animals (LZA)
- Marine and Aquatic Biosecurity (MAB).

The ABCD and LZA are further organised into units that focus on specific animal species or commodities. Within these sections, import risk analyses are conducted alongside other tasks related to the respective animal groups.

MAB is divided into specialised units: the Aquatic Biosecurity Risk Assessment Unit, which handles all import risk analyses for aquatic animals and their products (both BIRA and non-regulated IRAs) and the Aquatic Biosecurity Policy Unit, which manages policy-related tasks and provides advice on aquatic biosecurity matters. MAB also includes two units dedicated to marine biosecurity, focusing on ballast water and biofouling management.

3 The regulation of import risk analysis

Criterion 1: Is the conduct of import risk analyses consistent with the intentions of relevant legislation and legislative instruments?

Summary:

At a high level, the department's conduct of import risk analyses is consistent with the intentions of the Biosecurity Act and its subordinate legislation, the Biosecurity Regulations 2016. The regulation provides procedural detail. The department's practices align with the regulatory requirements. The regulated BIRA approach aligns with international obligations such as World Trade Organization (WTO) requirements and the SPS Agreement. BIRA has international recognition and is comparable to systems used in New Zealand and Canada. It sets principles that have been adopted domestically (though state and territory methodologies may differ). At a micro level the department's conduct of import risk analysis would benefit internally by being more consistent across animal, plant and environmental biosecurity. It could do this through key process oversight committees such as the Market Access and Resource Analysis (MARA) Board. Expansion of the MARA Board to cover all future import risk analyses would facilitate consistency and could also appropriately address matters such as the environmental and trade risk conflicts. The department should continue to champion consistency of domestic import risk analysis methodology.

It is essential to recognise that the department's import risk analysis work does not occur in isolation. It must be part of a broader international system governed by trade and market access standards and agreements. It is crucial to consider the regulatory and international context in order to understand both the *what and the why of the* import risk analysis system. Much of this context is outlined in the department's Biosecurity Import Risk Analysis (BIRA) guidelines (DAWR, 2016).

Australia has the right to implement measures that maintain ALOP for life and health within its borders as a member of WTO and a signatory to the SPS Agreement. This means Australia can adopt measures to prevent the introduction and spread of pests and diseases, balancing trade facilitation with biosecurity risk management.

However, Australia must also comply with the principles of the SPS Agreement, and the relevant international standards and guidelines set by organisations such as the IPPC and the WOH. These international frameworks guide the development and implementation of Australia's biosecurity policies and practices. This ensures they align with global standards while protecting Australia's environment, industries and public health.

3.1 The SPS Agreement

An SPS (sanitary and phytosanitary) measure is a policy applied to protect human, animal or plant life and health from biosecurity risks arising from pests and diseases. Import requirements or conditions that are set to mitigate such risks can be considered SPS measures. As a signatory to the SPS Agreement, Australia must ensure that these measures are based on sound risk assessments. The risk assessments must:

- align with the standards, guidelines and recommendations developed by the IPPC, WOH the World Health Organization (WHO) and Codex Alimentarius (food code)
- ensure measures are scientifically justified and applied only to the extent necessary to mitigate the identified risk (that is, least trade-restrictive).

Members shall accept the sanitary or phytosanitary measures of other members as equivalent, even if these measures differ from their own or from those used by other members trading in the same product. That is, if the exporting member demonstrates to the importing member that its measures achieve the importing member's appropriate level of sanitary or phytosanitary protection, they should be accepted.

Additional obligations under the SPS Agreement include notifying other WTO members about proposed sanitary or phytosanitary regulations before their implementation, as well as any amendments to such measures that could significantly affect trade (DAFF, 2024a).

3.2 International Plant Protection Convention

The International Plant Protection Convention (IPPC) is an intergovernmental treaty aimed at protecting the world's plants, agricultural products and natural resources from plant pests. The treaty has been ratified by 185 contracting parties including Australia. The IPPC is responsible for the development, adoption and promotion of International Standard for Phytosanitary Measures (ISPMs). These measures are key tools in safeguarding global food security, facilitate safe trade and protect the environment (IPPC, 2024).

In Australia, the plant biosecurity risk analysis methodology is based on:

- ISPM 2: Framework for Pest Risk Analysis (IPPC, 2021)
- ISPM 11: Pest Risk Analysis for Quarantine Pests (IPPC, 2024).

Other parts of the biosecurity process are guided by additional ISPMs and recommendations from the IPPC. Australia has an active role in contributing to and participating in the development of these international standards.

3.3 World Organisation for Animal Health

The World Organisation for Animal Health (WOAH; formerly known as the Office International des Epizooties, OIE), is the global authority on animal health. It is an intergovernmental organisation focused on disseminating information about animal diseases and improving global animal health standards.

WOAH is responsible for setting international standards and certification processes that maintain a standardised global approach to managing animal biosecurity, including risks associated with imports. The methodology used for animal biosecurity risk analysis follows principles like those used in plant biosecurity. It is also based on international guidelines established by WOAH.

3.4 World Health Organization

The World Health Organization (WHO) introduced its International Health Regulations (IHR) in 2005. IHR outlines the rights and obligations of WHO member countries in handling public health events and emergencies, particularly those with potential international or cross-border implications. The IHR framework provides a standardised approach to managing such events, aiming to minimise negative impacts on global trade. While not often directly cited in the import risk analysis process, the IHR indirectly offer guidance on how human biosecurity activities should be conducted (DAFF, 2024a).

3.5 Import risk analyses

The Biosecurity Act and its subordinate legislation, the Biosecurity Regulation 2016, provide the department's legal foundation for identifying and managing biosecurity risks from exotic pests and diseases. The Act establishes Australia's ALOP, which aims to provide a high level of sanitary and phytosanitary protection by reducing biosecurity risks to a very low level, but not zero.

As specified earlier, import risk analyses are classified as either a regulated biosecurity import risk analysis or a non-regulated IRA. A non-regulated IRA may include scientific reviews of existing policies and import conditions or the provision of scientific advice. It also includes pest risk analysis (PRA).

While there are some differences in the technical methodologies used by the BPSSD for plants and BAD for animals – reflecting the different commodities, pathways and respective international standards (such as IPPC for plants and WOAH for animals) – the overarching methodology employed by both divisions aligns with the requirements of the SPS Agreement.

3.5.1 Biosecurity import risk analysis process and steps

A BIRA is a science-based assessment of the biosecurity risks associated with the import of goods regulated under Australian law. Under the Biosecurity Act, a BIRA must be conducted in accordance with the process prescribed in the Biosecurity Regulation 2016 and must consider the factors outlined in the Biosecurity Import Risk Analysis guidelines (DAWR, 2016).

A BIRA is required in the following cases:

- when relevant risk management measures have not yet been established
- when risk management measures exist for a similar good and pest or disease combination, but the likelihood and/or consequences of entry, establishment or spread of pests or diseases differ significantly from those previously assessed.

If these criteria are not met, the department conducts the import risk analysis as a non-regulated IRA.

Under the Biosecurity Regulation 2016, the process for conducting a BIRA follows these key steps (Figure 1):

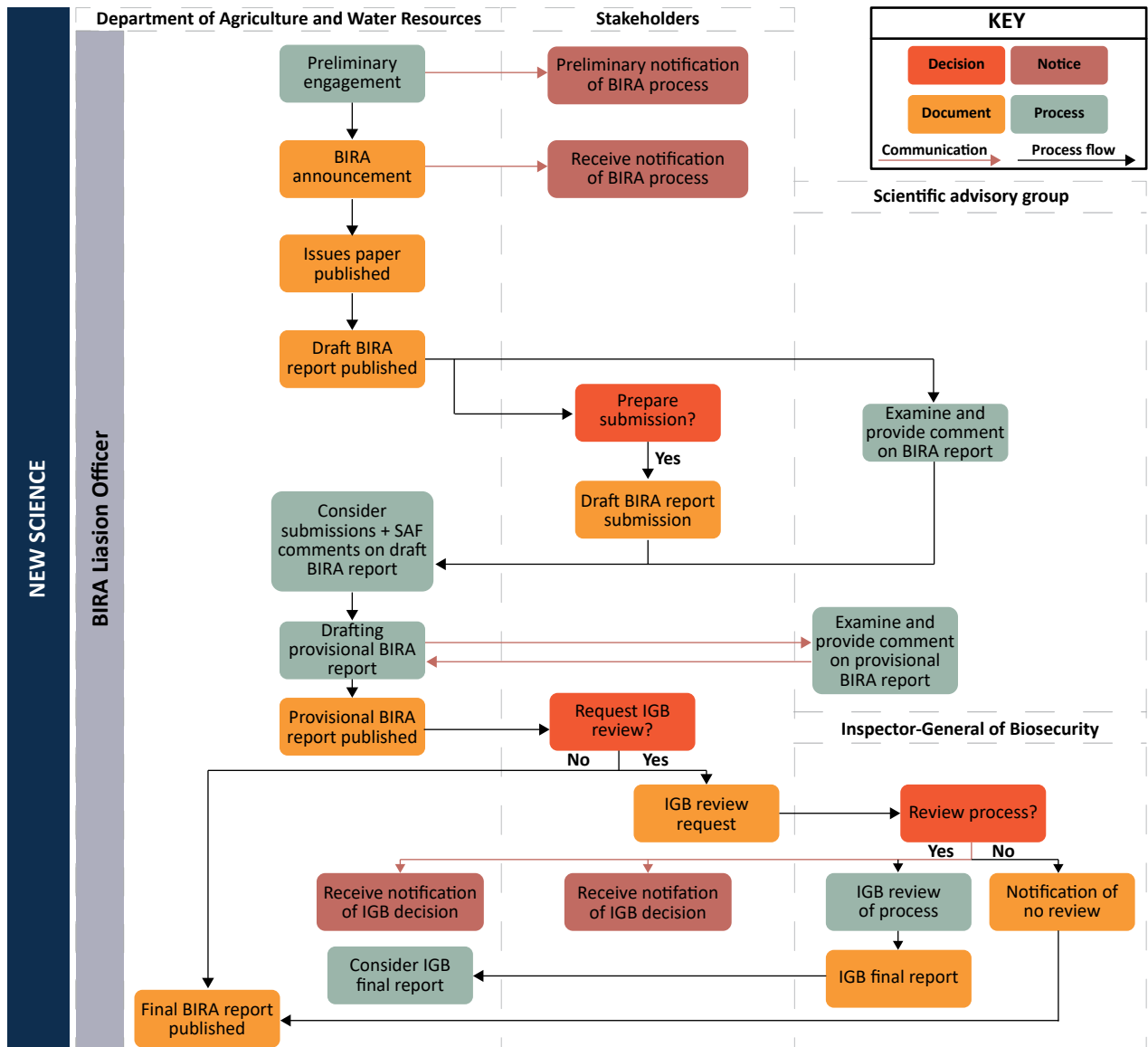
- 1. Appointment of Scientific Advisory Group** – The Director of Biosecurity must appoint a SAG to provide expert guidance throughout the BIRA process.
- 2. Notification of BIRA commencement** – The Director of Biosecurity must publish a notice on the department’s website announcing:
 - a. the commencement of the BIRA process
 - b. the opportunities for public consultation during the BIRA process.
- 3. Preparation and publication of issues paper** – The Director of Biosecurity prepares an issues paper detailing background information on the request, the commodity or goods in question and the key matters to be considered during the analysis. This paper is published on the department’s website.
- 4. Draft BIRA report**
 - a. The Director of Biosecurity must prepare a draft BIRA report.
 - b. This draft must be published on the department’s website, along with an invitation for public submissions regarding the assessment of biosecurity risk associated with the relevant goods, including the proposed biosecurity measures necessary to achieve Australia’s ALOP.
 - c. The public consultation period must be at least 60 calendar days from the publication date.
 - d. If the Director believes the public needs more time, the consultation period may be extended by up to 60 additional calendar days.
- 5. Provisional BIRA report**
 - a. After the consultation period, the Director of Biosecurity prepares a provisional BIRA report and publishes it on the department’s website.
- 6. Request for process review**
 - a. Within 30 calendar days of the provisional BIRA report’s publication, individuals may request the Inspector-General to review the BIRA process.
 - b. If a review is requested and deemed valid, the Inspector-General informs the Director and conducts the review.
- 7. Review outcome**
 - a. If the Inspector-General conducts a review, the Director of Biosecurity must consider any recommendations in the review report and publish a final BIRA review report.
 - b. If no review is requested, the Director of Biosecurity must publish the provisional BIRA report as the final BIRA report as soon as possible.
- 8. Final BIRA report**
 - a. The final BIRA report must be published within 30 months from the day the initial notice was published, unless specific circumstances apply (such as a review or unforeseen delays).
 - b. Any biosecurity measures recommended in the final report will form the basis for the import conditions outlined in import permits issued by the department.

9. Suspension of timeframe

- a. The Director may suspend the 30-month time frame if
 - I. further information, research or expert advice is awaited
 - II. the SAG is reviewing a specific aspect of the BIRA process
 - III. a biosecurity situation of national or international significance arises
- b. The review period by the Inspector-General does not count towards the 30-month timeframe.

10. Completion of the BIRA process – The publication of the final BIRA report marks the end of the process. The recommended biosecurity measures will serve as the foundation for any subsequent import conditions.

Figure 1 The Biosecurity import risk analysis process



Source: DAWR, 2016

Further details about the process and matters considered in conducting a BIRA are available in the Biosecurity Regulation 2016, Biosecurity Import Analysis (BIRA) guidelines (DAWR, 2016) and on the department's [website](#).

3.5.2 Non-regulated import risk analysis process and steps

Non-regulated IRAs involve scientific reviews of existing policies or import conditions and assessments of biosecurity measures in response to new scientific evidence. They are conducted through an administrative process, rather than being mandated by law. However, despite the lack of legal framework, they must still comply with Australia's international obligations.

While a non-regulated IRA broadly follows the technical methodology used in undertaking BIRA, it is not bound by the requirements set out in the Biosecurity Regulation 2016. Specifically, the following steps do not apply when conducting a non-regulated IRA:

- timeframes for completion
- mandatory involvement of the SAG
- formal stakeholder consultation, engagement points and methods
- public release of documents for comment.

Despite these differences, some elements remain consistent across all types of import risk analyses. For instance, a draft report is typically released for stakeholder feedback and the publication of the final report signals the completion of the process. However, the overall process for non-regulated IRAs is tailored to each specific analysis.

3.5.3 Pest risk analysis

In addition to BIRA and non-regulated IRAs – both of which typically address commodity-based risks in response to requests for market access from trading partners – PSaRA also conducts pest risk analysis (PRA). PRA is conducted in response to changes or emerging threats associated with high-impact pests.

For BIRA, all pests and diseases potentially associated with the commodity under consideration are assessed and risk management measures are recommended for any pests and diseases that do not meet Australia's ALOP. In contrast, for a PRA, all risk import pathways (such as, host commodities, hitchhiker pests or intended uses in Australia) are evaluated and risk management measures are proposed for any pathways through which the pest presents a biosecurity risk that does not achieve Australia's ALOP.

Examples of PRAs published by the department include:

- Final pest risk analysis report for *Candidatus Liberibacter* species and their vectors associated with *Rutaceae* (DAFF, 2011)
- Final pest risk analysis report for *Drosophila suzukii* (DAFF, 2013)
- Final pest risk analysis for brown marmorated sting bug (*Halyomorpha halys*) (Department of Agriculture, 2019).

3.6 Market Access and Risk Analysis Board

The Market Access and Risk Analysis (MARA) Board is BPSSD's internal advisory body that:

- makes strategic decisions regarding some plant export and import market access priorities that is, temperate and tropical fruits.
- provides direction and oversees progress of plant market access and risk analysis activities to ensure these activities are consistent with MARA's strategic direction.

The board is composed of senior leaders from key areas across the division. Its role is to make decisions in relation to:

- priorities (including identifying priority markets), based on prioritisation principles and in line with departmental and government objectives
- the strategic value of activities that address priorities
- activity progression, including decisions on scope, prioritisation, resource allocation, suspension, termination and other issues.

3.7 Findings

The department's import risk analysis process is consistent with the intentions of relevant legislation and legislative instruments. However, the Inspector-General notes that there are opportunities for improvement, such as better engagement with environmental biosecurity stakeholders and ensuring consistency across jurisdictions. There are 4 findings:

- 1. Examination of indicators of consistency:** The department's practices adhere to the procedural and regulatory requirements outlined in the Biosecurity Act and associated legislation.
- 2. Clarification of legislative intentions:** The department clearly understands the objectives of the Biosecurity Act. The department recognises the importance of balancing biosecurity protection with trade facilitation under international agreements like the SPS Agreement.
- 3. Assessment of legislative alignment:** The department's import risk analysis processes align with the legislative framework. Methodologies used meet regulatory requirements.
- 4. Evaluation of how well the current conduct aligns with the legislation and the ability to deliver intended outcomes:** While the processes align with the core legislative intentions, further improvements in stakeholder engagement, transparency and consistent application of methodologies are recommended to fully achieve the intended outcomes of legislation.

3.8 Recommendations

3.8.1 Expansion of decision-making and oversight committees

The Inspector-General noted feedback that the MARA Board only deals with part of the plant biosecurity remit – that is, temperate and tropical fruits. The IGB further noted feedback that plant products such as grains, nursery stock, etc. are not considered by the Board. This clearly demonstrates that the Board currently has a very limited application. Therefore, for consistency, the department should consider:

- broadening the Board's scope of its advisory role to cover all animal and plant-related import risk analyses/reviews
- extending the Board's membership to include the office of Australian Chief Environmental Biosecurity Officer in the decision-making processes
- reviewing and updating Board's terms of reference periodically to ensure its currency (Recommendation 1).

Recommendation 1

The department should consider broadening the scope of the role of the Market Access and Risk Analysis (MARA) Board to cover all animal- and plant-related import risk analyses/reviews. In addition, the Board's:

- membership should be extended to include the office of the Australian Chief Environmental Biosecurity Officer in the decision-making processes to ensure environmental biosecurity risks are also addressed satisfactorily
- terms of reference should be reviewed periodically and updated to ensure currency.

Department's response: Agreed. The department will develop a mechanism to achieve improved consistency across animal- and plant- related import risk analyses, with consideration of Australia's obligations in respect of the relevant international standards. In developing this framework, the department will consider existing arrangements such as the MARA board and the established Market Access and Diversification Assistant Secretaries Coordination Group (MADAS), which reports to the Deputy Secretary-led Trade and Market Access Prioritisation (TMAP) Committee. The Chief Environmental Biosecurity Officer is a member of MADAS, so environmental perspectives and concerns will be included in the Group's recommendations.

3.8.2 Alignment of methodologies used domestically with national approaches

A strong suggestion from multiple stakeholders is that the processes employed must be based on international standards. Concerns have been raised about potential differences in standards and approaches between state and territory governments. Significant progress has been made towards consistency, but further work is needed. In cases where alignment is not achieved, it is essential to provide technically sound justifications to trade partners for any divergence. It is understood that DAFF has no authority over domestic risk analysis processes but should, through its involvement in National Biosecurity Committee and its sub-committees, encourage alignment of these processes with international standards. Domestically, the import risk assessment related to plant trade falls under the jurisdiction of the Sub-Committee on Market Access, Risk and Trade. The sub-committee reports to the National Biosecurity Committee (NBC) through the Plant Health Committee (PHC) (Recommendation 2).

Recommendation 2

The department should work collaboratively with state and territory agencies, as well as relevant industry bodies and committees such as Animal Health Australia (AHA), Plant Health Australia (PHA) and the Environment and Invasives Committee (EIC) to:

- encourage alignment of domestic non-regulated import risk analyses methodologies with relevant international standards
- formalise engagement points within the import risk analysis process, directly involving the Animal Health Committee (AHC), Plant Health Committee (PHC), EIC and key government agencies.

Department's response: Agreed in principle. The department undertakes risk analyses in accordance with the Biosecurity Act 2015 (Act) and will continue to work collaboratively with states and territories, Animal Health Australia (AHA), and Plant Health Australia (PHA) on relevant aspects of Biosecurity Import Risk Analyses (BIRAs) and import risk reviews, where appropriate. The department will formalise the engagement points regarding these reviews through the National Biosecurity Committee (NBC) and its sub-committees Animal Health Committee (AHC), Plant Health Committee (PHC), Environment and Invasives Committee (EIC) and the Marine Pest Sectoral Committee, where appropriate. The department also recognises Australia's obligations as a Member of the World Trade Organization (WTO), and notes that the Act ensures that the Director of Biosecurity will align the approach to import risk analysis with both the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the guidelines for import risk analysis published by the international standard setting organisations. The department will continue to encourage alignment of relevant activities of the states and territories, including through NBC, with these international standards.

Case study 1

Apples from the United States

The department initiated this non-regulated IRA based on an application to export apples from the USA's Pacific North-West States to Australia. The department began this analysis in November 2018, releasing a draft report for a 90-day consultation in October 2020. Once stakeholder feedback was considered the final report was issued in October 2022.

Stakeholder feedback

Stakeholder feedback raised concerns about how the arguments were presented, with some feeling that the reasoning was not clear and lacked a consistent standard. While the length of time taken to complete the review was not criticised ('it takes what it takes'), the consultation period was seen as too short, especially for industry groups. Although the Director of Biosecurity extended the comment period, some still felt it was not enough time to fully consider the implications.

Some stakeholders said that the review's level of detail, thoroughness and the final report were not sufficient. The trade requirements and the general approach of the process were acknowledged as acceptable. There were concerns about how the process and methodology were applied. Some stakeholders claimed that scientific literature had been selectively quoted and taken out of context to support predetermined conclusions and desired outcomes.

4 Import risk analysis methodology

The department has continued to develop and update its import risk analysis methodology since 2001. A key part of this process is the risk matrix approach. This approach has been reviewed many times, including in the Peace report from the Senate Rural and Regional Affairs and Transport Committee (Peace, 2013).

Initially, the methodology focused heavily on quantitative risk calculations, but now it includes a mix of semi-quantitative methods and expert opinions. This shift is in line with global best practices for assessing biological risks.

4.1 International context

The main guidelines for WTO member countries on import risk analysis are set out in the IPPC's International Standards for Phytosanitary Measures (ISPMs) for plants and the WOH's Terrestrial Animal Health Code and Aquatic Animal Health Code for animals. While these standards do not go into specific details about the exact methods for import risk analysis, they give enough guidance for countries to develop their own approaches that meet the standards' requirements. Good examples of this are:

- ISPM 2: Framework for Pest Risk Analysis (IPPC, 2021)
- ISPM 11: Pest Risk Analysis for Quarantine Pests (IPPC, 2024).

WTO members are entitled to adopt different approaches, provided these processes meet the requirements of the SPS Agreement and are scientifically justifiable. For example, New Zealand uses well-established and documented procedures like Australia's (New Zealand Ministry of Agriculture and Forestry, 2009). The resulting reports in New Zealand are comprehensive, much like those produced in Australia. A good example is the 2022 review of citrus fruit imports, which resulted in a 552-page report (New Zealand Ministry for Primary Industries, 2022). Similarly, Canada follows a comparable methodology, assessing both the likelihood and consequences of biosecurity risks arising from imported materials (Government of Canada, 2018).

4.2 Methodologies used in Australia

4.2.1 National level

The department provides detailed, publicly accessible information about the import risk analysis process for imported products on its [website](#). This offers a general overview, with links to more detailed components of the process. It explains the context and reasons for these analyses, such as meeting Australia's ALOP, fulfilling international biosecurity obligations and clarifying roles and responsibilities. Current projects are listed, along with both draft and final analysis reports. The website serves as the primary platform for sharing reviews and for legislated consultations.

4.2.2 State and territory level

At the state and territory level, import risk analysis is also used to support local biosecurity laws. While the methods can vary across jurisdictions, the principles remain broadly aligned with the national approach. For example, the Tasmanian Government biosecurity policy and has documented its biosecurity risk analysis framework (DPIPWE, 2010). This framework outlines Tasmania's approach focusing on managing biosecurity risks due to imports as an island state.

Over the past 5 years, state and territory governments have focused on developing rapid risk assessment processes, particularly for plant biosecurity. These processes use the same principles as national import risk analysis but are designed to provide quick risk assessments in time-sensitive situations, such as when biosecurity pests are detected domestically. In such cases, all affected states conduct rapid assessments using a standardised method and the results are then shared to establish a collective view on pathway risks and inform domestic movement restrictions.

4.3 Group pest risk analyses

Pest risk analysis (PRA) involves experts assessing evidence to determine a pest's status, whether it needs regulation and what phytosanitary measures are required to manage the biosecurity risk. Instead of assessing individual pests, the approach evaluates groups of biologically similar organisms, speeding up the assessment process and ensuring greater consistency.

Group PRAs are a new development in risk assessment methodology. They draw on more than 2 decades of individual PRA experience. These analyses are based on robust scientific data, interception records and international pest behaviour observations. As with BIRAs and non-regulated IRAs, public reports are produced and released for stakeholder consultation.

Examples of Group PRAs the department has undertaken to date include thrips, mealybugs, scales and spider mites (DAFF, 2024b).

4.4 Prioritisation of import risk analyses

The biggest challenge identified in this review is the large number of BIRA and non-regulated IRAs that have not commenced. This, combined with limited resources, makes it unlikely that backlogs will be cleared in the near future. The volume of these backlogs – particularly in the plant biosecurity area – necessitates using a prioritisation process. This process functions similarly to a triage system, where analyses with a higher trade value are given priority over those with a lesser economic impact. Prioritisation of pests and diseases of plant biosecurity concern is formally structured, with the MARA Board playing a key role in making these decisions. However, the approach to prioritisation seems more based on an internal understanding rather than a fully documented procedure. The department is aware of the pressure this creates, especially for stakeholders who would benefit from these analyses, but acknowledges the resource constraints.

4.5 Findings

The approach used to plan and manage import risk analysis is generally appropriate. A prioritisation framework is in place, but it lacks necessary detail to comprehensively solve conflicts. The Inspector-General notes that, in some instances, the prioritisation of specific analyses were trade related and influenced by specific market interactions at a particular point in time. While challenges are well-assessed, improvements focus on efficiency rather than addressing systemic resource constraints. There are 3 findings:

- 1. Review of prioritisation approaches:** A prioritisation framework for plants and plant products does exist and is led by the MARA Board. However, it relies on internal understanding rather than a documented and transparent process.
- 2. Assessment of challenges in scheduling and managing the process:** There is a significant backlog of import risk analyses yet to commence, particularly in plant biosecurity. This issue is largely due to resourcing constraints.
- 3. Identification of potential solutions and improvements:** The BPSSD recently initiated Group PRAs to improve efficiency and consistency, providing a mechanism for streamlining the process. However, there is a lack of detailed strategies to fully address the backlog and resolve associated issues.

4.6 Recommendations

4.6.1 Application of standardised import risk analysis processes

The department uses a logical and documented process for import risk assessment. Despite some claims of opacity, the process includes methodologies that conform to international requirements, align with legislative approval points and information and engage stakeholders in a timely manner (Recommendation 3).

4.6.2 Cumulative risk and consequence assessment

Some stakeholders raised concerns about the department's methodology used to assess the cumulative risk of pests across multiple commodities. External stakeholders claimed that the department does not adequately address this thereby creating a potential gap in risk assessment. Similarly, concerns were raised about the lack of transparency in how the department determines the consequences of biosecurity risks (Recommendation 3).

4.6.3 Process of prioritising the order of import risk analyses

The department uses several approaches to prioritise both BIRA and non-regulated IRA for plants and animals with regulatory-based commonalities. An important factor in prioritisation is the trade benefit associated with advancing certain risk analyses over others. While the department appropriately prioritises analyses that provide the greatest benefit to Australia, this approach can disadvantage smaller or emerging industries. Additionally, there seems to be limited external stakeholder awareness regarding how the department considers trade benefits in its prioritisation and timing decisions. This should be made clearer in risk communication. The prioritisation process for plant biosecurity analyses appears well developed, with the MARA Board playing a key role, including an annual meeting to prioritise

import risk analyses for the coming year. However, the criteria and rationale the department uses to prioritise are not readily accessible on its website. The department seems to rely more on shared understanding among those involved than on a formal, documented process (Recommendation 3).

Recommendation 3

As part of its broader stakeholder communication and engagement strategy, the department should proactively communicate its processes for both regulated and non-regulated import risk analysis by publishing clear guidelines or in a policy document on its website. The guideline or policy document should outline:

- the criteria and rationale used in prioritising import risk analysis for plants/plant products and animals/animal products
- the methodology for assessing cumulative pest risks and the potential consequences within the import risk analysis process
- key stages of the import risk analysis process when the department would communicate with the stakeholders, including face-to-face meetings, when necessary
- establish clear timeframes for reviewing risk analysis applications, completing all import risk analysis and developing associated import requirements and workplans
- notify stakeholders if the development of an operational workplan is not part of the import risk analysis process.

This approach will enhance transparency, provide stakeholders with a clearer understanding of the decision-making process and foster greater trust in the department's import risk analysis processes.

Department's response: Agreed in principle. The department supports the publication of a policy document/guideline that clearly communicates the risk analysis process to the extent that it does not limit the department's ability to achieve the objects of the Act or introduce legal error into the Director of Biosecurity's decision making, including fettering the exercise of powers under the Act, and agrees this policy document/guideline will improve transparency and foster better engagement with domestic and international stakeholders.

4.6.4 Currency and consistency

During interviews, several stakeholders highlighted the need to maintain consistency and currency across the technical considerations, findings and subsequent import conditions for similar analyses over time. Currently, the department relies heavily on corporate knowledge to monitor and respond to consistency issues, which poses a vulnerability, particularly as long-term staff leave their positions. Stakeholders suggested developing a standard or tool to ensure checks are made across historical analyses to maintain consistency and prevent contradictions (Recommendation 4).

Recommendation 4

The department should develop and implement a procedural mechanism to review and assess findings and associated import conditions in previous regulated and non-regulated import risk analyses, ensuring currency of findings and consistency in decision-making across historical analyses.

Department's response: Agreed. The department will continue to review, assess, and update as required the findings of completed risk analyses and associated import conditions through ongoing biosecurity operational activities, including on-arrival inspections, assessment of emerging pest- and disease-specific risks and using advances in technological tools. The department will also develop and implement a system, incorporating current activities, to review and assess existing BIRAs and import risk reviews, recognising this will improve the currency of measures and the consistency of decision-making.

Import risk assessments are generally conducted at a specific point in time and there is no formal process to routinely update them. However, the department has mechanisms in place to monitor the changing risk profile of export countries and it can conduct non-regulated IRAs when necessary, depending on resource availability. An advisory process is in place to inform stakeholders of these updates.

- BIRAs are generally undertaken at a specific point in time and there is no formal process to routinely update them. However, the department monitors the changing risk profile of trading partner countries and can conduct non-regulated IRAs as needed, subject to resource availability. For smaller changes in response to evolving risk environments, the department regularly updates its Biosecurity Import Conditions system (BICON) and has an advisory process in place to inform stakeholders of these updates.
- Australia works collaboratively with trading partner countries to address pest risk matters and maintains active connections with them. For example, the department and other countries jointly consider and develop country-specific pest lists. This collaboration helps maintain the currency of analysis findings.
- PSaRA has an officer who oversees risk analyses to ensure consistency across analyses and this appears to be very effective. However, this oversight is not as evident within ABB.
- The plant BIRA process includes on-the-ground verification and in-country visits by technical staff. The department should continue these in-country verification visits, which allow staff to check production approaches and risk management in the exporting country, contributing to the currency and consistency of import conditions.

4.6.5 Role of the Scientific Advisory Group

The Scientific Advisory Group (SAG) is appointed under the Biosecurity Regulation 2016 to provide expert technical support to the department's import risk analysis process. The group is composed of independent experts selected by the Director of Biosecurity under the Biosecurity Regulation 2016. SAG members examine and provide comments on any aspects of the BIRA process and can be called upon to advise on non-regulated IRA matters. The group evaluates both the technical aspects of an analysis and the process itself. The SAG consists of 3 standing members: a chair, an economist and a risk analysis specialist. Additional subject matter experts may be appointed as needed. The SAG has been particularly active in the sturgeon fish BIRA and the prawn non-regulated IRA.

The Inspector-General noted that the role of the SAG in the department's import risk analysis processes is unclear and seems to be ad-hoc. While its functions are clearly defined and published online, the points at which it engages throughout the process need clarification and action. The core membership of the SAG is not necessarily based on technical expertise. Expanding the required skill set of the group and drawing on independent scientific expertise from organisations such as the CEBRA and CSIRO would be beneficial. The SAG could take on a greater role in the non-regulated IRA process, addressing some of the external stakeholder concerns raised in this review and providing high-level technical oversight (Recommendation 5).

Recommendation 5

The department should review the role of the Scientific Advisory Group (SAG), focusing on:

- the skill set of members, including the adequacy and relevance of their expertise
- the frequency of engagement and the stages of the regulated biosecurity import risk analysis (BIRA) process when the group is consulted
- expanding the group's role to provide technical oversight for non-regulated import risk analyses
- the ability to seek independent expert input when necessary.

Department's response: Agreed. The department values the role of the Scientific Advisory Group to independently verify the department's scientific analysis and agrees to review the role of the Scientific Advisory Group to ensure that it remains fit for purpose.

Case study 2

Melons from Korea

This non-regulated IRA was initiated based on an application from Korea to export greenhouse-grown fresh oriental melons and rockmelons to Australia. The department started the process in May 2019, with a draft report released for a 60-day consultation in June 2022. The final report was released in February 2023, after stakeholder feedback was considered.

Stakeholder feedback

Overall, feedback was largely positive about the department's communication and stakeholder engagement once the draft report was completed. The department worked effectively with key stakeholders. However, it was suggested that the department could improve clarity around timeframes, points of engagement and the processes involved. A specific industry meeting was mentioned where a large number of departmental staff were present, but industry attendees felt unclear about the roles of the government officers in attendance. Despite this, the in-person briefing format was considered valuable and seen as an optimal way to engage stakeholders.

It was noted that many industry organisations lack the dedicated resources to fully review the complex and detailed import risk analysis reports. These organisations review the reports as best they can, given their limited capacity. Stakeholders felt that the department may not be fully aware of these resource constraints or take them into account when planning engagement. Additionally, some comments highlighted that the briefing sessions were typically one-way, with industry stakeholders expressing a desire for more interactive input.

While the discussion around the melons/Korea analysis was generally positive, it prompted negative references to the melons/Japan review. Industry stakeholders expressed dissatisfaction with the communication around the melons/Japan review, citing poorly communicated information, outdated content on the website and a general lack of clarity about the status of the review.

5 Managing import risk analyses

Criterion 2: Is there a fit-for-purpose decision-making framework to plan, prioritise and manage import risk analyses?

Summary:

There is no formalised framework that plans and manages import risk analyses in terms of their priority, order and scheduling. Instead, the department considers a range of key factors in prioritising and resourcing specific import risk analyses. Approaches in plant biosecurity are clearly trade related and are influenced by specific market interactions at a particular point in time. Combined with this is a determination of the potential market benefits for Australia's economy. That is, if the undertaking of a particular import risk analysis sooner rather than later could result in the exporting country considering an Australian import application sooner. This market-based approach was considered more definite in plant biosecurity compared to animal biosecurity. A range of other factors were considered in timetabling import risk analysis including resources to undertake the analysis, other competing resources, political considerations and availability of specific expertise.

Criterion 3: Are import risk analyses conducted in a timely manner?

Summary:

How long import risk analyses take was a contentious issue with some external stakeholders. However, views were varied ranging from 'it takes what it takes' to 'it takes far too long in a fast-moving world of trade'. Viewpoints varied, with the beneficiaries of the process generally feeling it took too long, while the potentially impacted industry stakeholders indicated that the longer it took the better, as it delayed any potential trade impacts on them. The only BIRA undertaken under the Biosecurity Act was the importation of sturgeon fish. Though the actual analysis has been conducted within the statutory 30-month period, it was the extended periods and delays leading up to the start of the analysis that caused the proponent stakeholder frustration. This was further aggravated by early indicative advice that the development of import requirements post the analysis 'could take years'. There are no statutory requirements on time outside of a BIRA nor for non-regulated risk analyses. Across the case studies, timeliness concerns were expressed primarily in relation to prawns (non-regulated IRA) and sturgeon (BIRA) with the other case studies presenting as generally acceptable time-periods. Increased transparency is needed with respect to likely time frames – regardless of whether the process is a BIRA or a non-regulated IRA – as part of stakeholder engagement, with consideration to applying administrative time limits on these areas that don't fall under the statutory timeframe of a BIRA.

The application of a sound, fit-for-purpose import risk analysis methodology is crucial to ensure positive outcomes, inform stakeholders (including internal ones) and achieving trade outcomes that align with the Biosecurity Act, thus safeguarding Australia's biosecurity status.

The import risk analysis framework includes the processes and procedures that underpin this methodology and should also include:

- legislative or statutory guidelines, typically outlined in primary legislation ('head-of-power') and supporting regulation
- public-facing explanatory information detailing what happens, when and why. This can be provided through organisational web pages, printed guides and designated opportunities for stakeholder engagement
- administrative instructions and internal guidelines to ensure the risk analysis process is conducted effectively, efficiently and consistently.

Processes and procedures must be independent of the individuals using them. They should remain consistent regardless of staff changes. They must also be regularly updated to stay in line with legislative changes and contemporary risk analysis practices.

5.1 Observations and assessment

The Inspector-General received extensive documentation from the department detailing the general processes involved in conducting both BIRA and non-regulated IRAs, along with the administrative requirements for internal approvals and notifications, both internal and external. This comprehensive and detailed information allowed for an effective assessment of the department's processes and procedures for import risk analysis.

Additionally, the Inspector-General conducted interviews, both electronically and in person, with internal and external stakeholders. These interviews served 2 purposes: to explore further aspects of the information already reviewed and to gather additional insights based on stakeholders' experiences and roles in the process.

For this part of the review, the primary stakeholders were officials from the department's plant and animal biosecurity divisions.

5.2 Findings

As outlined earlier in this review, the framework used to plan, prioritise and manage import risk analysis is mostly effective. While there are established processes in place for these analyses, stakeholders have raised concerns. These regard the transparency and effectiveness of the approaches especially around managing timelines, resources and prioritisation of analyses. Improvements in stakeholder engagement and resource sharing would streamline the process and better manage stakeholder expectations.

- 1. Review of prioritisation approaches:** The prioritisation framework exists but lacks transparency, with concerns over its fairness and documentation.
- 2. Assessment of challenges in scheduling and managing the process:** Significant challenges include resource constraints and inconsistent prioritisation that ultimately hinder the timely and efficient scheduling of import risk analyses.
- 3. Identification of potential solutions and improvements:** Proposed improvements focus on increased stakeholder engagement, the use of group PRAs for efficiency and enhanced transparency in prioritisation and time management to address the identified challenges.

Criterion 3: Are import risk analyses conducted in a timely manner?

Again, the timeliness of import risk analysis was raised as a concern by stakeholders who have expressed frustration over delays. Factors affecting delivery times include resource constraints, process inefficiencies and the need for better collaboration with stakeholders. Suggestions for improvement focus on streamlining processes, sharing technical resources and enhancing early-stage engagement with stakeholders to reduce delays and meet varying expectations.

- 1. Assessment of historical delivery timeframes:** Historical delays in import risk analysis are acknowledged, particularly in plant biosecurity, sturgeon BIRA and prawn non-regulated IRA, but specific quantitative data on timeframes is not provided.
- 2. Identification of factors affecting delivery times:** Key factors include resource limitations, isolated analysis efforts, backlogs and the need for improved information sharing and collaboration with stakeholders.
- 3. Exploration of factors that could improve delivery timeframes:** Proposed improvements include better stakeholder collaboration from the start, enhanced resource sharing and adopting more efficient methods like group PRAs.
- 4. Determination of stakeholder expectations regarding delivery times:** Stakeholders have mixed views; some want quicker analyses, while others understand the need for thoroughness, with calls for better communication of timeframes and justifications.

5.3 Recommendations

5.3.1 Process of initiating and conducting risk analyses

Generally, the approaches for implementing and conducting import risk analysis are more developed and consistent in plant biosecurity compared to animal biosecurity, particularly regarding the initiation of specific analysis activities. In contrast, the processes used in the animal biosecurity sector appear less well-defined, for example, how to determine whether to conduct a BIRA or a non-regulated IRA and how to establish analysis priorities (Recommendation 3).

5.3.2 Consistency in information sharing, training and collaboration

Several stakeholders expressed concerns about import risk analysis being conducted with limited information and resources. This could lead to inconsistencies over time and, more importantly, result in lost efficiency, thereby exacerbating stakeholder concerns regarding analysis timeframes. Some state government stakeholders identified potential efficiencies through better sharing of information, particularly technical data collected during specific import risk analyses. Specifically, enhanced national training opportunities for states and territories were seen as a way to ensure alignment and consistency across processes.

Some stakeholders also raised concerns about perceived departmental arrogance and a lack of accountability, though there was little written evidence to support these claims. Regardless of whether these perceptions reflect the reality, it is important for the department to address them, as they could erode the relationship with key stakeholders, making an already challenging activity even more difficult (Recommendation 6).

Recommendation 6

The department should proactively engage with relevant state and territory government agencies to:

- continuously improve mechanisms for sharing risk analysis data and information while leveraging non-regulated import risk analysis work being undertaken by these agencies
- jointly develop a training module for non-regulated IRA, incorporating input from relevant industry groups to enhance their understanding of the process.

Department's response: Agreed in principle. The department will continue to collaborate with state and territory government agencies, including engagement at key points in the BIRA and non-regulated import risk review processes, where appropriate under the Act. The Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer will also continue to facilitate communication of relevant information to state and territory counterparts, industry and internationally through established mechanisms. Through regular review, the department will continue to improve its current work with the states and territories on the delivery of training in biosecurity risk analysis process and methodology.

5.3.3 Processes of prioritisation and submissions

Prioritisation was flagged by some stakeholders as an unfair process, disadvantaging some proponents while advantaging others. Although this sentiment is understandable, given the significant demand for import risk analysis considerations and existing backlogs, it would be impractical to approach this task without some form of prioritisation (Recommendation 3).

5.3.4 Timeliness

Timeliness emerged as a recurring concern in stakeholder discussions, with comments ranging from the perception that 'all processes take too long' to an understanding that a considerable amount of time is necessary to conduct a thorough analysis. With that said, several stakeholders indicated that efforts are needed to justify the time taken. Suggestions were made for the department to work more closely with stakeholders from an early stage and use existing technical information that stakeholders may already possess, to help shorten the duration of the analysis (Recommendation 3).

5.3.5 Continuous improvement

Despite the mixed feedback regarding the processes used and stakeholder engagement, there was widespread recognition that engagement has significantly improved over the past decade. One suggestion, repeated by various external stakeholders, was to have the reports reviewed externally prior to their finalisation. This would help improve readability, ensure industry accuracy and provide assurance regarding the practicality of the analysis.

Case study 3

Dragon fruit from Philippines

The department initiated this non-regulated IRA based on an application from the Philippines to export dragon fruit to Australia. Work commenced in February 2022, with a draft report released for a 75-day consultation in December 2022. The final report was issued in August 2023, following stakeholder input.

Stakeholder feedback

External stakeholders primarily focused on the disproportionately high and significant consequences of even very low levels of biosecurity risk materialising due to imports, following import risk analysis. Australian dragon fruit growers, for example, have no registered crop protection products to use in the event of an exotic pest incursion, which leaves them more vulnerable in terms of consequences compared to larger, more established industries with greater access to registered crop protection products.

Concerns were also raised about the limited consideration given by the government to the production practices of overseas growers. These growers often have access to a broader range of crop protection products, allowing them to export fruit of lower quality. While this was recognised as a competition and economic issue outside the scope of the risk analysis process, it does affect the engagement strategy. The department needs to better understand the differences across industries in how they engage with stakeholders.

Additionally, industry representatives claimed that engagement during this review process was insufficient, with no acknowledgment of their concerns or the letter submitted with the draft report.

6 Stakeholder communication and engagement

Criterion 4: Are there adequate arrangements to consult and engage relevant stakeholders in the import risk analyses process?

Summary:

The process clearly demonstrates multiple formal stakeholder engagement points throughout the import risk analysis. These consist primarily of information distributed to stakeholders in relation to the process' initiation, report drafting progress, seeking of comments on the draft report and advice on the finalisation of the report. Several stakeholders noted that the department's engagement with them had improved considerably over the last decade. This was due to the introduction of liaison officers, early provision of pest lists and provision of verbal in-person or online briefings. However, comments were also made that at times the nature of the engagement was not necessarily consistent, it was difficult to establish relationships with the department staff due to staff turnover and there were often failures to advise when no progress was being made resulting in communication gaps. Direct engagement with obvious internal stakeholders, such as the chief positions, appeared to be lacking and/or ad-hoc. Some external stakeholder organisations stated they were never recognised as stakeholders. Discussion about stakeholder meetings showed there was a lack of two-way discussions and consisted more of 'being told something', instead of being interactive. In-person briefings were preferred by several stakeholders possibly due to the potential for a more interactive experience compared to on-line briefings. Engagement for seeking stakeholder comments was criticised, with comments that the periods of time allowed for comments involving large complex reports was too short and that it wasn't uncommon for poor timing of comments being sought, such as directly before the Christmas period. In short, there are adequate contact points for stakeholder engagement, such engagement has improved over the last decade, but there is significant room for improvement in how engagement is undertaken with a greater need to truly listen to stakeholders' concerns.

Effective stakeholder engagement in the process is crucial for building trust and confidence among both internal stakeholders (for example, those conducting the risk analysis) and external stakeholders (for example, proponents, affected industries, trade partners). Communication is an integral part of the process.

The biggest challenge in effective stakeholder engagement is ensuring that the most efficient and suitable communication methods are used, while acknowledging that the outcomes of the import risk analysis will not always be fully supported by all stakeholders. Nevertheless, it is essential that the processes, procedures and methods used be clearly explained. Additionally, the rationale behind decisions made during the process should be transparent and be able to be understood by a wide range of stakeholders, both technical and non-technical.

6.1 Findings

Criterion 4: Are arrangements adequate to consult and engage relevant stakeholders in the import risk analysis process?

The department's processes and procedures used in conducting import risk assessment include several formalised touch points with stakeholders. These include information about the initiation, progress and finalisation of reports, as well as opportunities for stakeholders to provide comments. Improvements have been made over the last decade, such as the introduction of liaison officers, early pest list provision and briefings either in-person or online. However, several stakeholders noted challenges, such as inconsistent engagement, difficulties in establishing relationships due to staff turnover and communication gaps resulting from a lack of progress updates. Additionally, some stakeholders felt the engagement lacked two-way communication, with briefings often being one-sided rather than interactive. External stakeholder organisations also pointed out that they were not always recognised as stakeholders.

- 1. Identification of stakeholders:** The process recognises internal and external stakeholders. Engagement has also improved over time, despite some stakeholders feeling overlooked throughout the process.
- 2. Clarification of consultation points:** Consultation points are clearly identified through public advisories and opportunities to comment during various stages of the process. However, there are criticisms regarding the timings of these consultation points and lack of two-way communication.
- 3. Assessment of alignment between consultation points and stakeholder engagement:** Despite stakeholder engagement improving over time, there is also a degree of misalignment regarding inconsistent communication, failure to update on progress and poor timing of opportunities for feedback. Some stakeholders felt that the engagement process did not always align with their needs and the process still lacks the level of engagement needed to foster trust and ensure more meaningful contributions from stakeholders.

6.2 Recommendations

6.2.1 Stakeholder communication and engagement

External stakeholders reported mixed experiences regarding their direct engagement with the department. While some stakeholders noted significant improvements in recent years, others expressed frustration over communication gaps and delays. Concerns were raised about the unrealistic expectations placed on industry peak bodies, particularly about their capacity and available time for review and comment. Timing issues were also mentioned, including the timing of document releases and consultation stages.

A common theme among many stakeholders was the difficulty in comprehending the reports. It may be helpful to consider the readability of external-facing materials, such as using the Flesch-Kincaid readability test, to ensure they are accessible to all stakeholders (Recommendation 3).

Some stakeholders perceived the department to be arrogant in their interactions with industry, which added to their frustration. This perception was exacerbated by a decline in direct engagement, with routine communications often deemed insufficient. Concerns were also raised about the frequent turnover of the departmental staff, which hindered the development of strong working relationships and prevented staff from building specialised knowledge and expertise. One stakeholder noted that their members were often unsure of whom to contact within the department's Plant Biosecurity team, making it nearly impossible to establish constructive working relationships with the departmental officers.

Stakeholder communication has been clearly identified as a key component of the internal processes used by the department in its import risk analysis work, which extends to developing and establishing external engagement processes. The Inspector-General noted that the department has made considerable strides in improving its engagement practices over the past decade. The dedicated team of stakeholder engagement specialists has played a crucial role in these improvements. However, as part of its broader stakeholder communication and engagement plan, the department should ensure that the departmental liaison officer continues to work efficiently and effectively with the stakeholders for the resolution of issues raised.

6.2.2 Timing and length of the consultation period

External stakeholders expressed a need for greater flexibility in how the department engages with them, particularly given the limited resources of industry bodies to assess the complex technical reports produced. This may require extensions to consultation periods and flexibility in scheduling briefing meetings.

Timing was also flagged as a concern. Several industry stakeholders noted that they were often consulted too late in the risk analysis process. Additionally, the timing of report releases and comment periods during the Christmas holidays was criticised by several stakeholders.

While stakeholders generally felt the time taken for the process was acceptable, they indicated that the department should provide more regular updates. A major complaint was the long lead time to initiate analyses, compounded by delays during the analysis phase, which extended the perceived total timeframe to several years (Recommendation 3).

6.2.3 Transparency in the import risk analysis process

Increasing stakeholder understanding of the import risk analysis process would be beneficial. Both interviews and supplied documents highlighted the significant effort involved in the process, including constant checks on the currency of import conditions and monitoring biosecurity changes in other countries that may affect the recommendations.

Consultation with industry stakeholders revealed frustration over perceived differences in risk identification and mitigation approaches across sectors. While there may be valid reasons for these differences, the lack of clarity and explanation has created an information vacuum, leading to assumptions and speculation. Several stakeholders expressed concerns about the lack of transparency in the department's import risk analysis decision-making process (Recommendation 3).

6.2.4 Clarity of roles for Australia's chief biosecurity officers

There seems to be a lack of defined roles for senior technical internal stakeholders, such as Australia's chief biosecurity positions, in the import risk analysis processes. This is despite the relevance of their roles and the highly technical nature of the subject matter. Role definition appears stronger for plant biosecurity than for animal biosecurity. Engagement between those conducting risk analyses and the Chief Veterinary Officer (CVO) is often ad-hoc and when it does occur, the contact is typically limited to 'for information' actions (Recommendation 7).

Recommendation 7

The department should formally include the Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer during internal consultation processes to ensure that international standards are considered appropriately and that recommended treatments and risk management are consistent with domestic animal and plant health and environmental biosecurity policies and practices as relevant.

Department's response: Agreed. The department will continue to include and review internal stakeholder consultation points with the Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer, to the extent this is relevant to decision making under the Act. The department acknowledges the connection of these positions to the Animal Health Committee (AHC), Plant Health Committee (PHC) and the Environment and Invasives Committee (EIC) ensures the department's decision making is informed by relevant domestic animal and plant health and environmental biosecurity policies and practices.

There also appears to be a disconnect with key stakeholder groups, such as PHA, which has expressed a desire for early engagement but feels it lacks recognition by the department. Additionally, PHA conducts its own pest risk analysis for industry plans and may possess valuable information that could assist the departmental processes, optimising resource use (Recommendation 2).

6.2.5 Consideration of stakeholder data and information

Stakeholders broadly acknowledged and praised the technical skills and abilities of the departmental scientists involved in the import risk analysis process. However, frustration arose around engagement and communication interfaces, as well as stakeholders' own limitations in assessing draft reviews and providing constructive comments. While these challenges fall outside the department's control, they should be considered in light of government expectations of the industry and the broader community.

In some cases, stakeholder groups commissioned their own expert studies, only to find that the department appeared to show little interest in incorporating this external work into its analysis, which led to frustration. Additionally, some industry stakeholders offered to share their external expertise at no cost, but the department ultimately overlooked this valuable input (Recommendation 8).

Recommendation 8

The department should proactively gather technical information from stakeholders, carefully assess and offer transparent feedback to stakeholders, clearly explaining the rationale for including or excluding specific information in the decision-making process. This will help foster trust with key industry stakeholders.

Department's response: Agreed in principle. The department will continue to gather and share technical information both nationally and internationally that are relevant to risk analyses. The department will review existing mechanisms for gathering technical and scientific information from stakeholders to ensure stakeholders understand how their input has been considered in the decision-making process, where necessary and permitted under the Act. In accepting this recommendation, the department underscores its commitment to a data-driven culture where decision making is transparent and based on demonstrated evidence.

Case study 4

Prawn importation

An outbreak of white spot disease in southeast Queensland in 2017 triggered this non-regulated IRA of existing prawn import conditions. The department began the analysis in June 2017, releasing a draft report for a 75-day consultation in September 2020. The final report was issued in May 2023, after consideration of stakeholder feedback.

Stakeholder feedback

External stakeholders expressed significant frustration during this review, with many claiming that while the department was available for discussions, it did not effectively listen to industry concerns. Stakeholders further stated that industry experts, engaged by the industry body, presented valuable information that was ignored by the department during the process.

It was noted that true engagement should be two-way, but industry felt that their input was not adequately considered. Stakeholders expressed a desire for a more collaborative approach, including consideration of additional technical advice, but felt their contributions were disregarded. Ad-hoc responses to information provided by industry also contributed to heightened frustration.

When asked how the review process could be improved, common suggestions included fostering collaboration, reviewing industry technical data, increasing transparency and ensuring clear accountability and explanations for the decisions made.

7 Developing import workplans based on import risk analyses

The process of conducting either a regulated BIRA or non-regulated IRA is part of a larger framework. After the import risk analysis is completed, the next step is to develop import requirements based on the analysis findings. These requirements typically form part of a workplan developed between the department and the relevant exporting country. The workplan serves as an operational document that outlines the necessary actions for the exporter/importer.

7.1 Findings and recommendation

7.1.1 Workplan as part of the import risk analysis process

External industry stakeholders did not distinguish between the formal conduct of the import risk analysis (from initiation to report publication) and the subsequent development of the workplan. Although workplans and their development are typically considered outside the scope of the import risks analysis process, stakeholders view them as an essential endpoint of the process. Additionally, the workplan could be considered part of the risk communication stage in the overall process (Recommendation 3).

7.1.2 Timelines for developing workplans post import risk analysis

A source of frustration for stakeholders was the lack of clarity around the timeframes for developing the subsequent import conditions and workplans following completion of import risk analysis. Stakeholders suggested that the department should improve its communication, with clearer guidance on the timelines to enable imports. Several noted that the statutory timeframes associated with the import risk analysis process helped manage expectations and expressed a desire for similar timeframes to be implemented during the lead-up and post-analysis phases to provide more predictability (Recommendation 3).

7.1.3 Collaboration with industry for workplan development

One external industry stakeholder raised concerns about the department's 'secretive' nature of the workplan development process. They stressed the importance of including industry input, citing the practical knowledge and experience that industry stakeholders bring, especially regarding the specific processes and procedures involved. Additionally, concerns were raised that the departmental staff responsible for developing workplans may lack the necessary practical and production knowledge to ensure the plans are feasible and aligned with industry realities (Recommendation 3).

7.1.4 Biosecurity Import Risk Analysis (BIRA) guidelines, 2016

The department first published the Biosecurity Import Risk Analysis (BIRA) guidelines (DAWR, 2016) after the commencement of the Biosecurity Act. The guidelines provide comprehensive information about the department's processes and procedures in conducting BIRAs. The Inspector-General noted that this guideline has not been updated since it was first published in 2016. It is recommended that the department should update the guideline whenever changes are made to the processes or procedures. Preferably the guideline should be reviewed annually to ensure currency of information contained therein (Recommendation 9).

Recommendation 9

For clarity, the department should regularly review and update the Biosecurity Import Risk Analysis (BIRA) guidelines that were first published immediately after the enactment of the *Biosecurity Act 2015* and have not been updated since.

Department's response: Agreed. The department agrees to regularly review and update its Biosecurity Import Risk Analysis Guidelines – managing biosecurity risks for imports into Australia (2016). The department recognises that regular review of the guidelines will ensure a more flexible and improved risk-based regulatory system to drive more efficient and harmonised processes will be beneficial.

Case study 5

Sturgeon fish importation

A BIRA based on an application from a South Australian proponent seeking to import live sturgeon fish to establish a caviar aquaculture industry in Australia was started in June 2022. The draft report was released for a 60-day stakeholder consultation in July 2023. The final report was published in May 2024, after stakeholder feedback is incorporated.

Stakeholder feedback

This review is unique in that it is the first BIRA conducted under the Biosecurity Act. It also differs from previous analyses in that the proponent is an industry-based potential importer, rather than a foreign country wishing to export.

Stakeholders expressed concerns about the department's apparent reluctance to progress the analysis, with resource limitations and other higher-priority tasks initially cited as reasons for delays. Regardless of whether these factors were valid, the result was frustration from the proponent, who experienced extended periods of inactivity. Over time, communication and engagement between the parties diminished, further damaging the possibility of establishing a constructive working relationship.

Compounding the issue, the proponent and other potential beneficiaries viewed the extensive time already invested in addressing changes to the environmental listing of sturgeon fish as part of a lengthy, ongoing government process. The timeline has now stretched to 15 years, with the prospect of enabling imports still seemingly far off.

Procedurally, stakeholders suggested that the department should at least maintain communication with them, even if there is no significant progress to report. Clarifying timelines, especially the steps after the import risk analysis phase concerning the operational aspects of import, is crucial. In this context, providing stakeholders with accurate, ad hoc updates on expected timeframes was identified as the most important form of communication.

Additionally, stakeholders raised concerns by pointing out perceived inconsistencies in how import risk analyses are conducted in the animal and plant sectors. For example, the recent non-regulated IRA regarding the Tomato Brown Rugose Fruit Virus via imported seed was considered adequately mitigated, leading to perceptions that their own proposals, which they believe present lower biosecurity risks, are not being treated with the same level of consideration. These may be perceptions, but the confusion and demand for clarification are very real.

8 Looking ahead – future technological developments

Risk analysis is a dynamic and evolving process, constantly adapting to new methods, techniques and approaches. BIRA and non-regulated IRA are no exception. This review focuses on current practices and evaluates their effectiveness. However, it is also important to anticipate future changes and, where possible, manage them to enhance both the efficiency and accuracy of the import risk analysis process.

In an era of big data, data-driven insights and rapidly emerging technologies (Stone, 2021), those responsible for developing, managing and conducting import risk analyses must stay up to date with advancements and ensure the optimal use of new technologies to improve these activities. The pursuit of continuous improvement does not suggest that the existing system is inadequate; rather, it reflects a commitment to refining processes and procedures to ensure the best possible outcomes over time.

8.1 Observations and assessment

The department provided extensive documentation, which included details on methodology, processes, procedures, stakeholder engagement and ongoing projects with organisations such as CSIRO and CEBRA. The Inspector-General reviewed this information not only for its content and purpose but also for how it was initiated. Additional literature was examined regarding technological developments and their potential application to the import risk analysis process.

The primary source of information for this section came from interviews with relevant scientists at both CSIRO and CEBRA. These organisations were identified as having key expertise in BIRA and a strong understanding of the future of the process and technological applications.

Additionally, questions about technology application were included in interviews with other internal and external stakeholders, although many of these individuals did not possess the relevant technical expertise.

8.2 Findings and recommendations

Discussions with industry stakeholders and a review of the provided documentation suggest that the current process is solid, with one stakeholder describing it as having ‘good bones’. This indicates that the department’s process and methodology used is effective, but there is always room for improvement.

8.2.1 Adoption and use of artificial intelligence

The adoption of findings from forward-looking projects was identified as a key priority. However, discussions highlighted several barriers in adopting this approach such as particularly cultural resistance to change. Practitioners need to feel secure and supported in making changes to their methods. To foster ongoing business improvement, it is crucial to encourage practitioners to adopt new approaches and ensure they feel confident and backed by senior management in doing so.

Stakeholders agreed that technological advancements, particularly in artificial intelligence (AI), could enhance the process both now and in the future. While the idea of using AI to analyse raw data received mixed reactions, with concerns about data reliability and potential bias, there was strong support for developing local AI tools using in-house data. Keeping process and data up to date is key to improving the efficiency of current and future work; however, it should not be at the expense of maintaining the currency of previous import risk analyses. Both CSIRO and CEBRA are working on projects aimed at exploring how these technologies can be used to improve the import risk analysis process.

8.2.2 Engagement with technology specialists

The department has engaged with CSIRO and CEBRA on joint projects to improve processes using emerging technologies. Documentation and interviews reveal that several projects are focused on assessing the current process and identifying ways to improve efficiency and accuracy. However, the drivers behind these initiatives appear to be individual efforts from specific staff rather than part of a larger, strategic plan. While the progress already made in technology and process improvements is encouraging, the lack of a high-level strategic framework for these projects raises concerns. Without senior direction and strategic planning, there is a risk that valuable findings may go unimplemented, opportunities for development may be missed and priorities may not align across projects.

8.2.3 Ongoing collaboration with CSIRO and CEBRA

Both CSIRO and CEBRA are actively developing risk analysis approaches at domestic and national levels, which is a positive development. This collaboration indicates progress towards achieving more consistent and advanced risk analyses both within the country and at the national border.

The Inspector-General noted that the department has engaged with CSIRO and CEBRA for several projects, focused on assessing and improving the current import risk analysis process for better efficiency and accuracy, but there is no clear evidence of strategic implementation of recommended improvements. While the department is effective in collaborating with these organisations on joint, issues-based projects, the drivers behind these initiatives were unclear. They appear to stem more from individual efforts within each organisation rather than from an overarching strategic plan guiding this engagement. Stronger engagement, particularly with CEBRA, around implementation of outcomes would yield a greater return on the significant investment in these projects.

Each project reviewed by the Inspector-General seemed to have originated at the officer level or through requests from staff within the relevant institutions. In the absence of strategic planning or senior-level oversight, there is a risk that the findings from these projects may not be implemented, that opportunities for future development and enhancement could be missed and that project activities may be poorly prioritised (Recommendation 10).

Recommendation 10

The department should formalise the engagement of the Commonwealth Scientific Industrial Research Organisation (CSIRO) and the Centre of Excellence for Biosecurity for Biosecurity Risk Analysis (CEBRA) for joint, issues-based projects on plant, animal and environmental import risk analysis (both regulated and non-regulated) to ensure projects are prioritised and implemented.

Department's response: Agreed. The department currently has MOUs with both CSIRO and CEBRA and is progressing reviews of these formal arrangements. These MOUs form a strategic and collaborative relationship and provide expertise to achieve better public good outcomes for Australia in respect to agriculture, fisheries and forestry. The current reviews of the MOUs will provide an opportunity to embed a more strategic approach to the commissioning of projects to ensure they are better aligned to deliver outcomes for the biosecurity system as a whole and the biosecurity risk analysis processes specifically. This will include ensuring that transition to business is a consideration from project inception.

Case study 6

Beef (in the context of lumpy skin disease risk)

A non-regulated IRA of existing import conditions was triggered by the detection of lumpy skin disease (LSD) in Indonesia in early 2022 and related to the US and Canadian beef access claims. The department commissioned AUSVET Pty Ltd to conduct qualitative (June 2022; Zalcman et al., 2022) and quantitative (November 2022; Hall et al., 2022) risk analyses, with a particular focus on unregulated pathways.

Stakeholder feedback

External stakeholders did not direct any negative comments specifically at this review. They commended the department for the speed and promptness of the review. However, discussions arising from the review revealed concerns about perceived inconsistencies in the approaches to animal and plant biosecurity import risk analysis. For example, stakeholders questioned the 'comparative risk' concept, claiming that cut flower imports pose a greater biosecurity risk than certain types of stockfeed, yet biosecurity restrictions prevent the latter from being imported.

Stakeholders also called for greater transparency in the department's decision-making process, suggesting that the department did not provide clear reasoning behind certain decisions. As noted in other sectors, stakeholders pointed out that limited industry resources prevent them from fully evaluating complex reports.

9 Conclusion

One of the greatest challenges for an organisation like the department is meeting the expectations of all external stakeholders. This is because the stakeholder cohorts have varying interests and have preferred outcomes from import risk analysis process, which may not always align with broader objectives, such as international obligations. However, by clearly documenting methodology, ensuring it aligns with international standards and being transparent about the processes used, the department can optimally fulfill its responsibilities.

The findings of this review indicate that the department is using a solid methodology, consistent with international obligations under the SPS Agreement and aligned with relevant ISPMs. Internal administrative processes are thorough, well-documented and comprehensive, but external stakeholders may not be aware of these strengths. Internal areas identified for improvement include better use of key technical roles (such as, Australian Chief Veterinary Officer, Australian Chief Plant Protection Officer, Australian Chief Environmental Biosecurity Officer), improving consistency across plant and animal biosecurity areas and making better use of existing statutory oversight mechanisms like MARA. Greater integration of environmental biosecurity and risks associated with granting market access for plant and animal imports is also needed.

There are opportunities for the department to improve transparency and consistency in its interactions with external stakeholders, particularly industry groups. The review identified tensions in relationships that varied across import risk analysis areas and with different industry stakeholders. Failure to address these tensions risks threatening process efficiency and undermining outcomes. It is crucial that the department improves communication, engagement and transparency to rebuild confidence and trust with external stakeholders. A positive takeaway was that most external stakeholders, even those dissatisfied with the current system, acknowledged improvements in the department's processes over the last decade. However, they feel more work is needed. Engaging industry stakeholders more effectively, leveraging their technical knowledge and enabling their active participation in the process could address many concerns, build stronger relationships and enhance the overall process.

The department's growing collaboration with state and territory governments was also viewed positively, especially in contrast to previous years when these governments operated in silos. There are still significant opportunities to strengthen and maintain these relationships, ensuring consistency in biosecurity risk mitigation at both the domestic and national levels. The National Biosecurity Committee (NBC) and its sectoral committees (such as PHC, AHC and EIC) provide an important platform for continued cooperation and effective action.

Import risk analyses will remain a central part of Australia's biosecurity system and a critical tool for managing risks associated with imports. The department's ongoing commitment to internationally aligned risk analysis methodologies continue to position Australia as a global leader in BIRA and non-regulated import risk analysis including pest risk analysis. By improving stakeholder engagement and committing to continuous improvement, the department can further strengthen its role in facilitating international trade while effectively managing biosecurity risks.

Acronyms

ABCD	Avian, Biologicals, Companion Animals & Dairy (section)
AHA	Animal Health Australia
AHC	Animal Health Committee
ALOP	Appropriate Level of Protection
BICON	Biosecurity Import Conditions system
BIRA	Biosecurity Import Risk Analysis
BAD	Biosecurity Animal Division
BPSSD	Biosecurity Plant and Science Services Division
CEBRA	Centre of Excellence for Biosecurity Risk Analysis
CSIRO	Commonwealth Scientific Industrial Research Organisation
IGB	Inspector-General Biosecurity
IHR	International Health Regulations
IPPC	International Plant Protection Convention
IRA	Import Risk Analysis
ISPMs	International Standards for Phytosanitary Measures
LZA	Livestock and Zoo Animals (section)
MAB	Marine and Aquatic Biosecurity (section)
MARA	Market Access and Risk Analysis
NBC	National Biosecurity Committee
PHA	Plant Health Australia
PHC	Plant Health Committee
PRA	Pest Risk Analysis
PSaRA	Plant Science and Risk Assessment (branch)
SAG	Scientific Advisory Group
SPS	Sanitary and Phytosanitary (Agreement)
WHO	World Health Organization
WOAH	World Organisation for Animal Health
WTO	World Trade Organization

Appendix A Agency response



Australian Government
Department of Agriculture,
Fisheries and Forestry

ADAM FENNESSY PSM
SECRETARY

20 March 2025

Dr Lloyd Klumpp
Inspector-General of Biosecurity
c/o Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Dear Dr Klumpp

Lloyd,

Thank you for your correspondence of 20 February 2025 providing your report, *Review of the management and application of the import risk analysis process*.

I appreciate the observations and insights provided by this comprehensive review and was pleased to note your positive findings regarding our robust biosecurity risk analysis framework. Your recommendations outlining the benefits from closer consultation and collaboration within and outside the department are both beneficial and actionable. I also recognise the value of enhanced communications and guidance materials and look forward to an improvement in the integration of environmental biosecurity into the risk analysis framework.

The department is committed to the ongoing improvement of the biosecurity system. I acknowledge the recommendations outlined in your report and will seek to ensure that where appropriate, changes are made to ensure that they are implemented effectively in a timely manner.

My formal response to each of the recommendations outlined in your report is at Attachment A.

The department has assessed the report and does not consider the release of any information contained in the report to be prejudicial to the public interest.

Kind regards

Adam Fennessy PSM

Attachment A: Department of Agriculture, Fisheries and Forestry – Agency response to the Inspector-General of Biosecurity report: *Review of the management and application of the import risk analysis process.*

Recommendation 1 – agreed

The department should consider broadening the scope of the role of the Market Access and Risk Analysis (MARA) Board to cover all animal- and plant-related import risk analyses/reviews.

In addition, the Board's:

- membership should be extended to include the office of the Australian Chief Environmental Biosecurity Officer in the decision-making processes to ensure environmental biosecurity risks are also addressed satisfactorily
- terms of reference should be reviewed periodically and updated to ensure currency.

Department response: *The department will develop a mechanism to achieve improved consistency across animal- and plant- related import risk analyses, with consideration of Australia's obligations in respect of the relevant international standards. In developing this framework, the department will consider existing arrangements such as the MARA board and the established Market Access and Diversification Assistant Secretaries Coordination Group (MADAS), which reports to the Deputy Secretary-led Trade and Market Access Prioritisation (TMAP) Committee. The Chief Environmental Biosecurity Officer is a member of MADAS, so environmental perspectives and concerns will be included in the Group's recommendations.*

Recommendation 2 – agreed in principle

The department should work collaboratively with state and territory agencies, as well as relevant industry bodies and committees such as Animal Health Australia (AHA), Plant Health Australia (PHA) and the Environment and Invasives Committee (EIC) to:

- encourage alignment of domestic non-regulated import risk analyses methodologies with relevant international standards
- formalise engagement points within the import risk analysis process, directly involving the Animal Health Committee (AHC), Plant Health Committee (PHC), EIC and key government agencies.

Department response: *The department undertakes risk analyses in accordance with the Biosecurity Act 2015 (Act) and will continue to work collaboratively with states and territories, Animal Health Australia (AHA), and Plant Health Australia (PHA) on relevant aspects of Biosecurity Import Risk Analyses (BIRAs) and import risk reviews, where appropriate. The department will formalise the engagement points regarding these reviews through the National Biosecurity Committee (NBC) and its sub-committees Animal Health Committee (AHC), Plant Health Committee (PHC), Environment and Invasives Committee (EIC) and the Marine Pest Sectoral Committee, where appropriate. The department also recognises Australia's obligations as a Member of the World Trade Organization (WTO), and notes that the Act ensures that the Director of Biosecurity will align the approach to import risk analysis with both the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the guidelines for import risk analysis published by the international standard setting organisations. The department will continue to encourage alignment of relevant activities of the states and territories, including through NBC, with these international standards.*

Recommendation 3 – agreed in principle

As part of its broader stakeholder communication and engagement strategy, the department should proactively communicate its processes for both regulated and non-regulated import risk analysis by publishing clear guidelines or in a policy document on its website. The guideline or policy document should outline:

- the criteria and rationale used in prioritising import risk analysis for plants/plant products and animals/animal products
- the methodology for assessing cumulative pest risks and the potential consequences within the import risk analysis process
- key stages of the import risk analysis process when the department would communicate with the stakeholders, including face-to-face meetings, when necessary
- establish clear timeframes for reviewing risk analysis applications, completing all import risk analysis and developing associated import requirements and workplans
- notify stakeholders if the development of an operational workplan is not part of the import risk analysis process.

This approach will enhance transparency, provide stakeholders with a clearer understanding of the decision-making process and foster greater trust in the department's import risk analysis processes.

Department response: *The department supports the publication of a policy document/guideline that clearly communicates the risk analysis process to the extent that it does not limit the department's ability to achieve the objects of the Act or introduce legal error into the Director of Biosecurity's decision making, including fettering the exercise of powers under the Act, and agrees this policy document/guideline will improve transparency and foster better engagement with domestic and international stakeholders.*

Recommendation 4 – agreed

The department should develop and implement a procedural mechanism to review and assess findings and associated import conditions in previous regulated and non-regulated import risk analyses, ensuring currency of findings and consistency in decision-making across historical analyses.

Department response: *The department will continue to review, assess, and update as required the findings of completed risk analyses and associated import conditions through ongoing biosecurity operational activities, including on-arrival inspections, assessment of emerging pest- and disease-specific risks and using advances in technological tools. The department will also develop and implement a system, incorporating current activities, to review and assess existing BIRAs and import risk reviews, recognising this will improve the currency of measures and the consistency of decision-making.*

Recommendation 5 – agreed

The department should review the role of the Scientific Advisory Group (SAG), focusing on:

- the skill set of members, including the adequacy and relevance of their expertise
- the frequency of engagement and the stages of the regulated biosecurity import risk analysis (BIRA) process when the group is consulted
- expanding the group's role to provide technical oversight for non-regulated import risk analyses
- the ability to seek independent expert input when necessary.

Department response: *The department values the role of the Scientific Advisory Group to independently verify the department's scientific analysis and agrees to review the role of the Scientific Advisory Group to ensure that it remains fit for purpose.*

Recommendation 6 – agreed in principle

The department should proactively engage with relevant state and territory government agencies to:

- continuously improve mechanisms for sharing risk analysis data and information while leveraging non-regulated import risk analysis work being undertaken by these agencies
- jointly develop a training module for non-regulated IRA, incorporating input from relevant industry groups to enhance their understanding of the process.

Departmental response: *The department will continue to collaborate with state and territory government agencies, including engagement at key points in the BIRA and non-regulated import risk review processes, where appropriate under the Act. The Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer will also continue to facilitate communication of relevant information to state and territory counterparts, industry and internationally through established mechanisms. Through regular review, the department will continue to improve its current work with the states and territories on the delivery of training in biosecurity risk analysis process and methodology.*

Recommendation 7 – agreed

The department should formally include the Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer during internal consultation processes to ensure that international standards are considered appropriately and that recommended treatments and risk management are consistent with domestic animal and plant health and environmental biosecurity policies and practices as relevant.

Department response: *The department will continue to include and review internal stakeholder consultation points with the Australian Chief Plant Protection Officer, the Australian Chief Veterinary Officer and the Australian Chief Environmental Biosecurity Officer, to the extent this is relevant to decision making under the Act. The department acknowledges the connection of these positions to the Animal Health Committee (AHC), Plant Health Committee (PHC) and the Environment and Invasives Committee (EIC) ensures the department's decision making is informed by relevant domestic animal and plant health and environmental biosecurity policies and practices.*

Recommendation 8 – agreed in principle

The department should proactively gather technical information from stakeholders, carefully assess and offer transparent feedback to stakeholders, clearly explaining the rationale for including or excluding specific information in the decision-making process. This will help foster trust with key industry stakeholders.

Department response: *The department will continue to gather and share technical information both nationally and internationally that are relevant to risk analyses. The department will review existing mechanisms for gathering technical and scientific information from stakeholders to ensure stakeholders understand how their input has been considered in the decision-making process, where necessary and permitted under the Act. In accepting this recommendation, the department underscores its commitment to a data-driven culture where decision making is transparent and based on demonstrated evidence.*

Recommendation 9 – agreed

For clarity, the department should regularly review and update the Biosecurity Import Risk Analysis (BIRA) guidelines that were first published immediately after the enactment of the Biosecurity Act 2015 and have not been updated since.

Department response: *The department agrees to regularly review and update its Biosecurity Import Risk Analysis Guidelines – managing biosecurity risks for imports into Australia (2016). The department recognises that regular review of the guidelines will ensure a more flexible and improved risk-based regulatory system to drive more efficient and harmonised processes will be beneficial.*

Recommendation 10 – agreed

The department should formalise the engagement of the Commonwealth Scientific Industrial Research Organisation (CSIRO) and the Centre of Excellence for Biosecurity Risk Analysis (CEBRA) for joint, issues-based projects on plant, animal and environmental import risk analysis (both regulated and non-regulated) to ensure projects are prioritised and implemented.

Department response: *The department currently has MOUs with both CSIRO and CEBRA and is progressing reviews of these formal arrangements. These MOUs form a strategic and collaborative relationship and provide expertise to achieve better public good outcomes for Australia in respect to agriculture, fisheries and forestry. The current reviews of the MOUs will provide an opportunity to embed a more strategic approach to the commissioning of projects to ensure they are better aligned to deliver outcomes for the biosecurity system as a whole and the biosecurity risk analysis processes specifically. This will include ensuring that transition to business is a consideration from project inception.*

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