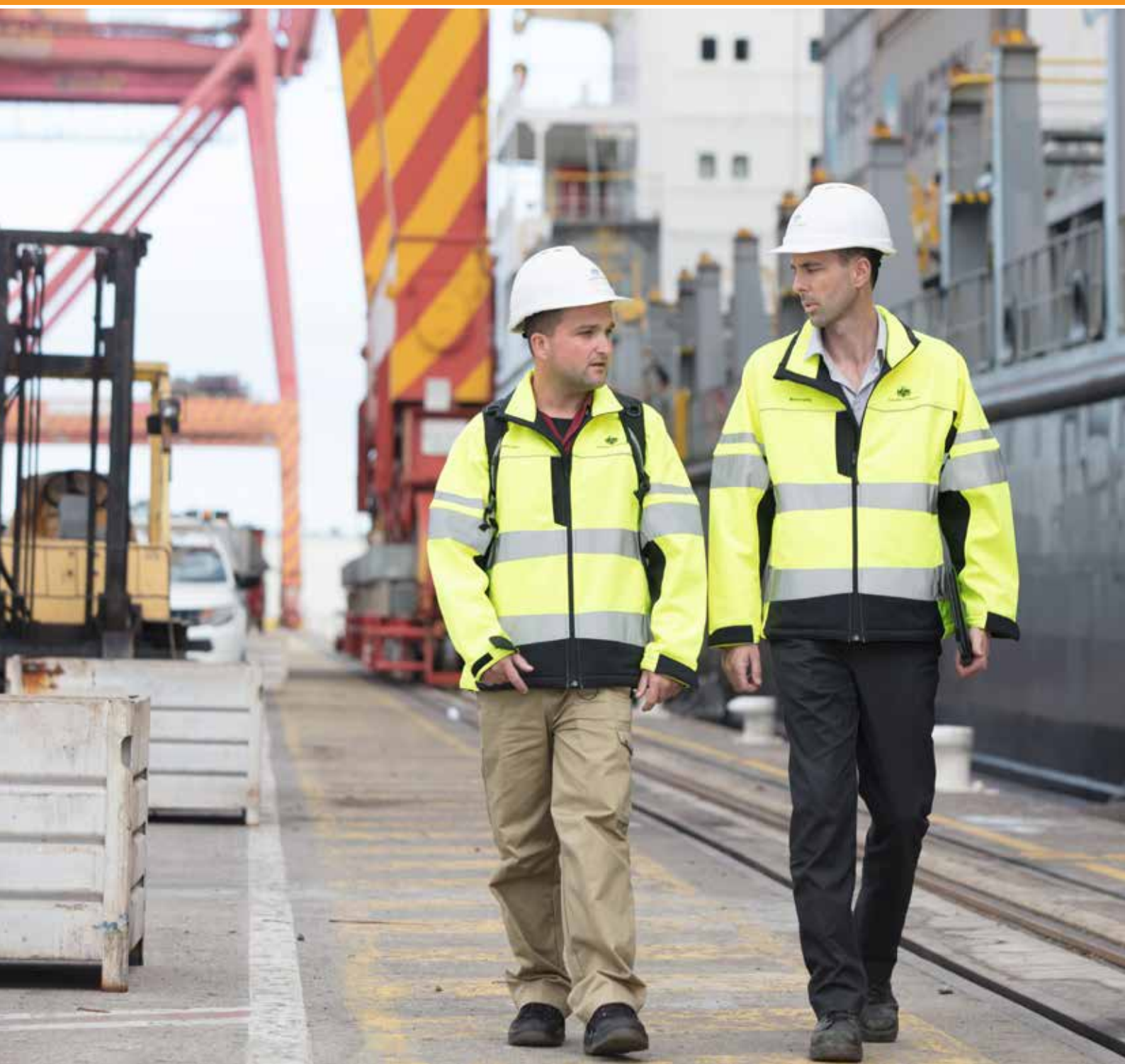




Australian Government
Inspector-General of Biosecurity

Effectiveness of approved arrangements in managing biosecurity risks in Australia

REVIEW REPORT NO. 2019–20/01



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Review process

Purpose

On 15 June 2018 the Minister requested the Inspector-General to consider a review assessing the effectiveness of the Department of Agriculture's (the department) system of approved arrangements under the *Biosecurity Act 2015*, their ability to manage biosecurity risks, and what if any improvements should be made.

The review examined:

- the scope and purposes of approved arrangements (AA) under the *Biosecurity Act 2015*,
- the effectiveness of industry management of biosecurity risks associated with imported goods through different classes of AA,
- processes for departmental management of AA including approval, training, auditing, and sanctioning, and
- what if any improvements should be made to the current arrangements.

Scope

The scope of this review covered operational policy and activities of the department relevant to biosecurity risks associated with the management of approved arrangements. It excluded the responsibilities of state/territory governments and individuals. The review considered:

- governance of the current system of AAs
- effectiveness in classifying and managing different biosecurity functions through AAs
- oversight of the performance of and potential improvements in biosecurity risk management by key classes of AAs
- general improvements to the department's management of the AA system.

Review methodology

During this review, I consulted extensively within and outside the department. In particular, I:

- conducted an entry meeting and subsequent in-person/phone meetings with key stakeholders to:
 - communicate review’s objectives and scope
 - outline responsibilities
 - identify risks related to the review and any appropriate mitigation strategies
 - obtain initial background information regarding management of approved arrangements
 - provide an opportunity for all parties to discuss/brainstorm and seek points of clarification about the proposed review process
- discussed preliminary data/information requirements with relevant departmental officers and requested data/information
- conducted a desk audit of relevant departmental data and documentation (such as, standard operating procedures, policies and communications material), and governance and audit procedures relevant to specific classes of AAs (case studies)
- undertook fieldwork at offices and AAs in Melbourne and Sydney to observe and verify:
 - the department’s procedures and operations in managing AAs
 - risk mitigation processes and mechanisms through specific treatment(s) of imported commodities (case studies)
- considered potential risks, including whether:
 - the department’s risk-based methodologies are inadequate or not applied correctly by staff or industry stakeholders
 - powers under the *Biosecurity Act 2015* are inadequate to manage risks in a timely and efficient manner
 - the department lacks timely internal mechanisms to identify and respond effectively to emerging risks
 - the department does not have sufficient resources or capabilities available to address current and new or emerging biosecurity risks
 - standard operating procedures/instructional material used by the departmental staff are difficult to follow or outdated
 - ICT systems fail to support operational requirements and departmental processes efficiently
 - stakeholders fail to provide the department with appropriate or timely information to allow it to carry out its responsibilities
 - the department fails to provide stakeholders with appropriate or timely information to allow them to carry out their responsibilities.

As required by the *Biosecurity Act 2015* I presented my draft report to the Director of Biosecurity for departmental consideration. The department’s response to my recommendations is included in this report. Further, I provided a copy of my final report to the Director of Biosecurity and the Agriculture Minister.

Summary

1 Background

The *Biosecurity Act 2015* (Cth) enables the Department of Agriculture (the department) to approve public or private industry entities (or biosecurity industry participants) to carry out certain border biosecurity risk management activities, in accordance with specified conditions. Approved arrangement holders enter into a legal obligation with the department agreeing to maintain appropriate biosecurity standards and protocols. Compliance with the conditions of an arrangement is monitored with limited or occasional regulatory oversight.

Biosecurity industry participants may be approved for the receipt, physical containment, storage, inspection and treatment of incoming containers and goods, or be approved to undertake assessment of documentation pertaining to the risk status of imported goods. From June 2016, former Quarantine Approved Premises and Compliance Agreements under the *Quarantine Act 1908* were transitioned to AAs.

2 Classes of approved arrangements

At 1 July 2019 there were 3,474 AAs, divided into 15 classes and 62 subclasses based on their functions and purposes. These classes and subclasses have been developed over many years as different biosecurity challenges arose and are being progressively refined to ensure ongoing fitness for purpose. Adequate timeframes and consultation with the holders of existing AAs are needed to manage transition or variation in conditions while allowing ongoing trade.

To ensure the technical and practical considerations that underpin their differences are not lost by over-simplification during this refinement process, and that the department can effectively oversight their performance, it is important that conditions for each class clearly specify which biosecurity risks the class is managing, and both specific and general measures needed to manage these risks.

3 Governance of approved arrangements

The Compliance Policy branch of the department's Compliance Division oversees the processes for AA conditions development and maintenance, classification, approval, variation, compliance monitoring, suspension and revocation (except where associated with non-compliance response activities). Approval of an AA includes ensuring that the applicant:

- employs at least one 'accredited person' who has passed required training
- is a 'fit and proper person' to hold an AA, and
- has the capability, equipment and facilities needed to carry out the biosecurity activities and manage biosecurity risks authorised under the class for which approval is sought (i.e. can meet class conditions).

Once approved, each non-broker class AA is subject to two probation audits within six months, and if satisfactory moves to an annual audit rate.

The department's Audit and Assurance Group carries out most audits, except for some specialised AA classes where biosecurity risk owners do this, and for broker class AAs where the department's Assessment Client Contact group verify arrangement compliance. Risk owner participation in auditing certain AA classes and instituting prompt action on non-compliance warrants further review.

Non-compliance with AA conditions results in the issuing of Corrective Action Requests (CARs) and may lead to an increased audit rate. Repeated major or critical non-compliance may lead to the AA being asked to show cause why it should not be suspended or revoked. While provision for these consequences exists in the Biosecurity Act, the processes for applying these administrative sanctions appear very time-consuming and weighted to the management of legal rather than biosecurity risks.

4 Broker class arrangements—class 19

Imported goods may have general 'non-commodity' biosecurity risks due to hitchhiker pests and contaminants on or inside containers, or in timber and other packaging. Import conditions for both commodities and non-commodity risks may require goods' import documents to be assessed to determine the level of biosecurity risk associated with each consignment. Class 19 AAs enable accredited brokers or self-reporting importers to assess documents for management of non-commodity concerns of containerised sea freight (NCCC—class 19.1) and also for the automatic entry processing of specified low biosecurity risk commodity groups (AEPCOMM—class 19.2). Holding a class 19.1 AA is a pre-requisite to holding a class 19.2 AA.

Accredited persons operating under class 19 AAs enter information in the Department of Home Affairs' Integrated Cargo System (ICS) to reflect the outcome of their assessment and generate biosecurity directions for the management of imported goods. Ongoing reform of the AEPCOMM system is being undertaken to simplify it, increase its uptake, and expand the commodities and treatments it can handle.

Individual brokers are accredited by passing departmentally approved training for NCCC or for AEPCOMM. Training must be delivered by an approved registered training organisation. Accredited persons must pass approved Continued Biosecurity Competency training annually to maintain accreditation, and participate in training and audit by the Department of Home Affairs Border Force to maintain their brokers' licences.

In June 2019 there were 571 Class 19.1 entities—366 also holding class 19.2 arrangements—with 1,540 accredited persons—970 of whom were also accredited for AEPCOMM.

5 Freight depots and container parks—classes 1, 2.6 and 11

‘Unrestricted’ freight depots at or near ports and airports are approved to manage all types of biosecurity risks while unpacking sea and air containers and cargo referred by the department for biosecurity interventions such as secure storage, inspection and treatment. 41 class 1.1 sea freight depots, and 32 class 1.2 air freight depots, can receive freight that may have non-commodity biosecurity risks; as well as high risk goods such as live animals, human remains or biological material; and other goods with commodity-specific biosecurity risks. Each must contain or be near approved arrangements for cleaning (class 4.3) and for fumigation (class 4.6). Eight class 1.1 depots also hold class 11.2 approval for external container treatment.

Restricted depots (class 1.3—376 approved at June 2019) can store, inspect and treat certain types of sea and air cargo of lower overall biosecurity risk, sometimes after it is referred from an unrestricted depot. Empty shipping container parks (class 2.6—27 approved at June 2019) can only manage container cleanliness.

Each of these AAs must have at least one accredited person who has undergone approved training, and is meant to carry out or directly supervise the biosecurity requirements at all times. They are required to record detections of high and lower risk biosecurity risk material and report high risk detections. Lower risk detection records, and records of inspections which find no risk material, are typically reviewed by the department only at audit, although this information could contribute to better risk profiling/targeting. Easy-to-use digital or app-based reporting systems connected to departmental information systems should be developed for collection of these data.

Departmental biosecurity officers may be stationed at class 1 depots with enough cargo inspection work to justify their presence. However, these inspection staff are not involved in general oversight of how these depots are complying with their AA class conditions. Only the department’s auditors can issue corrective action requests. Greater involvement of Inspection Group officers in ongoing oversight of compliance at depots is desirable.

6 General cargo storage, transport and processing—classes 2 and 3

Class 2 AA sites are used for the unpacking, handling, secure storage, inspection and treatment of containers and cargoes subject to biosecurity control. Various subclasses receive goods presenting very different biosecurity risks that may require different specific risk management measures. For example, class 2.1 AAs manage risks that non-agricultural imports such as car parts, used tyres and agricultural machinery might carry hitchhiker pests and contaminants, while class 2.5.1 AAs manage risks that imported frozen baitfish like sardines might introduce diseases to farmed fish that they are fed to, or to the marine environment.

Class 3 AA sites are used for treatment and processing of certain products which may have passed through class 2 sites before, and where either inadequate processing, cross-contamination of domestic product, or product diversion without processing could allow certain exotic diseases or pests to enter.

For example, uncooked pig meat imports are permitted from countries free of diseases such as foot-and-mouth disease and African swine fever, subject to onshore processing to kill some other pathogens. Processing is carried out in a class 3.2 imported pig meat processing AA, but the product may have passed through a class 2.5.2 AA for temperature controlled storage of imported pig meat, or even earlier through a class 2.8 AA for the temporary storage of refrigerated containers holding imported pig meat. Waste from the processing plant will be disposed of by one or more class 10 AA holders for biosecurity waste transport and disposal, by a class 8 AA treatment method such as incineration or deep burial. Clearly showing the links between these AAs, and the points of verification that risks are being properly managed, could improve current practices, and minimise leakage or diversion of uncooked pig meat.

Imported stockfeed and grain could bring in exotic animal and plant diseases and pests or weeds if not properly managed. Class 3.1 AAs for grain processing must apply required processes rigorously, while classes 2.3 for bulk stockfeed and fertiliser and 2.7 for grain storage must ensure that there is no cross-contamination between shipments or during transport. This is tightly audited by the department.

7 Cargo and biosecurity waste treatment—classes 4, 8 and 10

The department has defined key processes to manage biosecurity risks by approving methods, operators and sites for:

- treatment of goods, containers and packaging in various ways (class 4 AAs)
- disposal of biosecurity waste by different means (class 8 AAs), and
- collection, storage and transport of biosecurity waste (class 10 AAs).

Correct treatment and waste disposal may require tight adherence to technical methods by well-trained operators with correct equipment and facilities. The same processes may be used to manage biosecurity risks associated with exports and domestic trade as well as imports, or need to be internationally standardised.

Fumigation, with methyl bromide and latterly with sulfuryl fluoride, is a key means of dealing with insect pests in many goods, both commodities like cut flowers and fresh produce, and non-agricultural products with hitchhiker pests. The department is trying to improve offshore fumigation by promoting an Australian Fumigation Accreditation Scheme to key suppliers of risk goods, and working with New Zealand to harmonise technical standards. However, tighter management of the AAs offering onshore fumigation of imports is needed. High levels of non-compliance must be addressed in the short term by more effective regulatory action and in the longer term by increasing and verifying requirements for training, and by more efficient processes and equipment such as automated data logging. Harmonisation of requirements for fumigation for import, export and interstate movement is also needed.

8 Biocontainment for research, live plants and live animals—classes 5, 6 and 7

Importing live biological material, plants or animals poses inherently high biosecurity risks that are managed internationally and nationally by a huge range of technical standards.

Class 5 AA biocontainment sites are mainly laboratories used for research, analysis or testing of imported micro-organisms, animal, human and plant products and soil. Subclasses are for biosecurity containment levels (BC) 1 to 4. BC 1 facilities are used for low hazard goods (with subclasses for microbiological, animal and aquatic, plant and plant aquatic facilities). BC 2, 3, and 4 sites handle goods with moderate, significant, or serious and life-threatening risks to animals, plants or humans. AAs in many individual classes may need to comply with appropriate Australian/New Zealand or other standards as well as the AA class conditions.

Class 6 AA sites are used for the post-entry quarantine of nursery stock such as aquatic plants, bulbs, seed lines and cuttings. Subclass 6.1 AA sites are used for medium risk nursery stock that must be confined in plant houses such as glasshouses, and 6.1.1 AAs are for bulbs subject to biosecurity control in open areas. Class 6.7 specifies processes for managing risks associated with medium and high risk nursery stock and seed lines.

Class 7 AA sites are used to hold imported live animals under biosecurity control, with different sub-classes and conditions for different animals, such as aquarium fish, insects, laboratory rodents, Defence and Police dogs, zoo animals and horses.

The vast array of biosecurity risks that must be managed through these AAs, and the ways in which departmental risk owners' work with internal staff and external bodies and technical experts to manage these risks effectively, need examination beyond the scope of this review.

9 Overall improvements needed

AA class and subclass conditions are developed between Compliance Policy Branch and various groups within the department who are the ultimate advisers on managing specific biosecurity risks of different pathways, commodities or processes. Plant and Animal Biosecurity Divisions are considered the 'biosecurity risk owners' for input into AA classes managing plant and animal-related biosecurity risks, but various other departmental groups in Compliance and Biosecurity Operations Divisions may also be involved with other AA classes. The network of 'biosecurity risk owners' is not transparent or comprehensive and needs better definition and expansion to cover all AA classes. Risk owners' roles in overseeing biosecurity risk management for different AA classes also need strengthening.

More effective processes to manage critical non-compliance of an AA by suspending or revoking its approval must be developed. These must focus on timely and effective biosecurity risk management and not merely on legal risk management.

Many entities are approved to handle both imported and exported goods and food, under three different Australian Government acts. While legislative differences may make complete alignment difficult, there are many potential efficiencies in harmonising import and export governance, through a framework which the department is implementing.

Developing an integrated end-to-end information management system for AAs, which replaces outdated software and manual processes for approving AAs and allows online audit recording and online reporting and feedback about their biosecurity risk management outcomes, will be a critical means of ensuring that the AA system remains fit for purpose.

10 Conclusion

Approved arrangements are an indispensable part of Australia's biosecurity system, allowing thousands of specialised businesses to participate in effective management of the biosecurity risks associated with incoming goods. As trade volumes and global biosecurity threats increase, pressures on the approved arrangements system and its management by the department will also grow.

Ongoing streamlining of the systems for classifying and managing AAs will be essential but this must never lose sight of the different biosecurity risks being managed by different classes of AAs. More clarity about specific risks and their management will help industry better understand and fulfil their roles, and will also help the department ensure that these roles are being properly carried out. Greater involvement of technically and practically competent departmental staff in oversighting different AA classes will ensure that key risks are being effectively targeted.

Many AA operators have little incentive apart from business continuity to fully apply required biosecurity risk management measures. Unannounced audits, especially of busy facilities and those handling high-risk goods, must be increased, and a range of prompt and effective sanctions implemented for different levels of non-compliance. A greater role for frontline biosecurity officers in monitoring, reporting and taking action on non-compliance in between audits must be developed.

Better capture and analysis of data verifying the actual performance of biosecurity risk management measures by AAs is needed. This will allow clearer performance reporting both internally across the department and externally to AA operators, their many representative organisations, and other industry and government stakeholders.

The full departmental response to the recommendations is at Appendix A.

Recommendations

Recommendation 1

The department should clearly describe the specific biosecurity risks that need to be addressed by each class of approved arrangements in the *Purpose* section of the class Conditions document, and ensure that the specified conditions clearly manage that risk.

Department's response: Agreed.

The department will review each class of approved arrangements to ensure the biosecurity risks to be addressed by that class are included in the Purpose section of the class requirements document, and that the conditions remain appropriate for the management of those risks.

Recommendation 2

The department should develop a database of accredited persons at approved arrangements, which can be updated by approved arrangement holders and accredited person trainers and accessed by departmental staff.

Department's response: Agreed.

The department currently maintains a register of accredited persons operating under the broker approved arrangements, and the training organisations approved to deliver training that contributes to continued proficiency requirements.

The department is also currently reviewing the policy that underpins administration of the accreditation system for non-broker accredited persons. This review will ensure greater rigour exists in the management of accredited persons including, but not limited to, creation and maintenance of a database of all accredited persons, identification of the AA holder that the accredited person performs biosecurity activities on behalf of, policies for the granting, as well as revocation of accreditation and for re-training.

Recommendation 3

The department should implement a program of unannounced, randomly timed and risk-based audits of approved arrangements, rather than scheduled and announced audits, wherever possible.

Department's response: Agreed.

The department is currently reviewing its risk-based framework for audit scheduling in order to ensure that compliance monitoring is commensurate with risk.

The review will include consideration of additional risk factors for incorporation into compliance monitoring policy as well as review of the types and frequency of compliance monitoring.

The department's current compliance monitoring schedule focusses on AA holders considered to be of highest risk; specifically those newly approved, those for which approval to carry out additional biosecurity activities has recently been given, and those that have had non-compliance detected. The department has recently increased the number of unannounced audits as a proportion of the total number of audits conducted, and will continue to increase randomly timed unannounced audits as part of the audit program of approved arrangements, where possible.

The department is currently reviewing the compliance monitoring policies to ensure they remain fit for purpose and reflect suitable audit frequencies and flexibility.

Recommendation 4

The department should implement a verification program to ensure that departmental policies on the detection and management of non-compliance at approved arrangements are being followed and remain effective and appropriate.

Department's response: Agreed.

The department will review its verification activities to ensure that activities relevant to the detection and management of non-compliance are performed in accordance with relevant and appropriate policies and instructional material.

The department will also commence a review of the existing verification program applied to the compliance monitoring of non-broker approved arrangements to ensure it continues to provide adequate assurance of the effectiveness of compliance monitoring processes.

Recommendation 5

The department should develop guidelines and training for Inspection Group staff to oversight approved arrangements' implementation of class conditions and biosecurity risk management throughout the year to supplement the audit process and improved compliance.

Department's response: Agreed.

The department will seek to enhance Inspection Group staff knowledge of the conditions to which approved arrangements are subject through adoption of a more formal and structured process to that which is currently in place.

Recommendation 6

The department should develop an easy-to-use digital or app-based reporting system connected to departmental information systems for use by approved arrangements staff and departmental inspectors to record and report details of any biosecurity risk material detections or inspections.

Department's response: Agreed.

The department will investigate opportunities to enhance the efficiency of systems for approved arrangement holders and biosecurity officers to record and report details of any biosecurity risk material detections. In particular, the department will look to the current progress and the future opportunities provided through the BIIIS program to provide efficient data capture of biosecurity risk detections.

Recommendation 7

The department should adopt a whole-of-supply-chain approach to some commodity-based import approved arrangement pathways such as those handling imported pig meat, to improve on-shore traceability, and minimise leakage at any stage.

Department's response: Agreed.

The department applies a whole-of-supply-chain approach to suitable commodity-based import approved arrangement pathways to minimise the potential for leakage of biosecurity risk. The department implements various compliance monitoring processes for tracing goods subject to biosecurity control across entity boundaries, ensuring maintenance of biosecurity controls and regulatory compliance.

The department also routinely conducts end-to-end verification and assurance activities to ensure that the regulatory controls are operating effectively.

Recommendation 8

The department, in consultation with state and territory agencies, should consider developing nationally consistent competency based training, assessment and qualification for accreditation and licensing of biosecurity treatment providers.

Department's response: Agreed.

The department, through the National Biosecurity Committee, is currently progressing work to harmonise state, territory and federal approaches to the regulation of biosecurity treatment providers. This includes standardising training requirements, coordinating targeted regulatory operations, enhanced information and intelligence sharing, and coordinated non-compliance response activities. In the work already underway to strengthen the management of accredited persons operating within approved arrangements, the department will also be improving processes governing the issuance of accreditation, integrity assessments and non-compliance responses.

Recommendation 9

The department should develop a comprehensive list of biosecurity risk owners for all classes and sub-classes of approved arrangements and clarify their roles and responsibilities with respect to the different approved arrangement classes.

Department's response: Agreed.

The department will develop a list of internal biosecurity risk owners – areas responsible for identifying risks and risk controls – associated with classes and sub-classes of approved arrangements.

Recommendation 10

The department's approved arrangements' biosecurity risk owners should periodically attend audits to verify that the class conditions are still appropriate and that the approved arrangement is effectively managing the biosecurity risks addressed by the approved arrangement class.

Department's response: Agreed.

Biosecurity risk owners currently attend audits ad hoc or as a matter of standard process, depending on the class of approved arrangement. The department will continue to ensure that biosecurity risk owners attend audits as part of their verification and assurance processes.

Recommendation 11

The department should audit against approved arrangements' standard operating procedures where the biosecurity risk owners determine that there is a high level of technical or specialised class conditions that require standard operating procedures for biosecurity risk management.

Department's response: Agreed.

The department currently audits against standard operating procedures where the biosecurity risk owners have determined these documents are necessary. The department will continue to operate in accordance with this principle and be considered more broadly by biosecurity risk owners.

Recommendation 12

The department should develop more effective policies, processes and instructional material to manage critical non-compliance at an approved arrangement, including clarifying processes for suspension or revocation of its approval, as well as contingency response plans for such eventualities, and timely sanctions for less serious non-compliance.

Department's response: Agreed.

As part of strengthening our regulatory practice the department is currently reviewing our powers and policies to manage the biosecurity risks of critical or major non-compliance by approved arrangements in a timely manner.

Recommendation 13

The department should further develop integrated information technology systems to provide reliable and efficient end-to-end management of approved arrangements, including an online audit recording system, online reporting of approved arrangement biosecurity risk management and robust internal and external reports verifying their performance.

Department's response: Agreed.

As part of the department's integrated information technology systems upgrades, particularly through the BIIS program, we will include functionality to provide reliable and efficient end-to-end management of approved arrangements, including robust reports verifying their performance.



Dr Helen Scott-Orr
Inspector-General of Biosecurity
24 July 2019

Chapter 1

Background

1.1 Industry participation in border biosecurity risk management

Biosecurity is a shared responsibility between Australian and state/territory governments, industry and individuals. The introduction of exotic pests and diseases to Australia could have serious consequences for the Australian community, environment and economy. The 2008 *Review of Australian quarantine and biosecurity* (Beale et al. 2008) concluded that Australia's biosecurity system is often the 'envy of other countries'. Industry participation is an essential component of this system.

Approved arrangements (AAs) form part of the Department of Agriculture (the department) regulatory approach to facilitate trade and manage risks across both import and export pathways. An approved arrangement under the *Biosecurity Act 2015* is an approval given by the Director of Biosecurity that authorises the applicant to carry out specified biosecurity activities; such as assessment, isolation or containment, inspection, sampling and testing, treatment or processing; to manage biosecurity risks associated with imported goods. Approved applicants, known as biosecurity industry participants (BIPs; referred to as approved arrangement holders in this report), must comply with legal obligations or agreed expectations, in order to perform functions on the department's behalf, while the department recognises an established system, procedure or process of the other party, to manage particular risks and so allow for reduced intervention.

The department entrusts AA holders to perform specific biosecurity interventions on imported goods, such as assessment, isolation or containment, inspection, sampling and testing, treatment or processing, through different types of AAs. This places legislative obligations on the AA holders approved to operate an AA according to specific conditions, using their own premises, facilities, equipment and people, without constant supervision by the department but with periodic compliance monitoring or auditing. In turn, the department has an obligation to the Australian public to verify that AA holders are meeting their biosecurity responsibilities.

Approved arrangements may be operated by individuals, companies or other body corporates (such as universities). AA holders may handle goods for themselves or on behalf of others. They may be an importer or receive goods on behalf of importers. AA holders may have single or multiple sites or no specific physical site (such as brokers for document assessment).

Most classes of AAs restrict specific tasks to accredited persons, who are required to successfully complete approved training—provided on-line by a third-party provider or in house—relevant to the AA they work under. Different classes such as brokers and fumigators have their own specific and very different training requirements.

Approved arrangements can be varied, partly or wholly suspended, or revoked, after either application by the AA holder or action by the department.

1.2 Arrangements under *Quarantine Act 1908*

A system of legislated arrangements evolved under the *Quarantine Act 1908*, until this Act was superseded in June 2016. It provided for two types of legislated arrangements:

Quarantine approved premises (QAPs) were physical sites used to perform specified quarantine activities, with specific facilities and procedures required to be in place to manage the biosecurity risk. Each physical site required its own arrangement, with an annual departmental registration fee.

Compliance agreements (CAs) were nearly all non-site specific agreements, mainly with import brokers, to undertake particular procedures on behalf of the department, so that upon assurance being given, the department could release those goods. From a quarantine risk perspective, it did not matter where brokers conducted their business.

1.3 Arrangements under the *Biosecurity Act 2015 (Cth)*

Under chapter 7 of the *Biosecurity Act 2015* (the Act), the department established approved arrangements with industry to handle and process imported goods subject to biosecurity control. These AAs replaced both QAP and CA arrangements. Implementation of the Act did not significantly change either the number of AAs or the nature of biosecurity activities performed. While the new Act provides increased flexibility in structuring of AAs, industry have tended to structure their arrangements as they did previously. At July 2019 the department was managing around 3,500 AAs that are not legislatively tied to a physical location and can cover any biosecurity activity.

Between June 2016 and December 2017, CA and QAP agreement holders were put on a *transitional approved arrangement* and given 18 months to comply with requirements of the *Biosecurity Act 2015*. The department implemented only changes necessary to transition to the new legislation to minimise disruption to industry and service delivery functions and facilitate successful transition within the required timeframe.

Chapter 2

Classes of Approved arrangements

2.1 Classification system

Section 46A of the *Quarantine Act 1908* provided for a Director of Quarantine to approve a place where goods of a specified class that were subject to quarantine may be treated or otherwise dealt with. The department developed a structure of classes within which commodities that presented similar risks or required similar intervention could be handled at places approved under a consistent set of conditions.

Following introduction of the *Biosecurity Act 2015*, the AA structure continues to consist of classes (high level groupings based on commodity, type, risk, activity, goods status) and sub-classes (finer separation by similarity). For example, class 7 is for animal containment or isolation, with sub-classes for specific species such as class 7.1–Ornamental fin fish.

Each class and sub-class of AAs is defined by an AA conditions document available on the department's website. Each class is described on the department's website with conditions that are essential to maintain approval and ensure compliance with departmental requirements. To better align legislative and regulatory intent, the former terms 'requirements' and 'criteria' used to describe regulatory controls have been changed to 'conditions'. The concept of requirements still exists, but this now refers to things that are pre-requisite to approval (for example, the applicant must be a fit and proper person).

In July 2019, 3,474 AAs were operating under 15 classes (Table 1). Of these, 577 were broker AAs (class 19) who employed 2,510 broker accredited persons. Most of these AAs are class 2, a mix of agriculture and non-agriculture products, temperature-controlled storage, fresh fruit, cut flowers and empty shipping container parks (27.3 per cent), class 5 biosecurity containment (21.6 per cent), class 19 brokers (21.5 per cent) and class 1 depots (11.9 per cent). More AAs are in metropolitan areas (86.2 per cent) with the majority registered in Victoria (29.4 per cent) and New South Wales (28.9 per cent).

TABLE 1 Approved arrangement classes, by state and territory, 8 July 2019

Class Type	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
1 Depots	135	160	103	35	58	17	11	3	522
2 Cargo and containers	382	368	176	108	141	13	3	6	1,197
3 Produce, grain processing	22	31	11	3	4	1	0	0	72
4 Treatment or cleaning	117	155	117	51	33	19	7	3	502
5 Containment	245	270	178	96	99	38	8	16	950
6 Plants	16	54	14	21	16	10	0	14	145
7 Animals	50	35	40	11	14	8	0	8	166
8 Disposal of waste	12	8	13	7	7	1	2	1	51
10 Biosecurity waste management	40	59	82	15	66	6	12	7	287
11 Container management	2	3	2	1	0	0	0	0	8
12 Fumigation	9	14	17	5	12	1	1	0	59
13 Second conveyances	0	0	0	0	3	0	0	0	3
14 Nuts, inspection of air cargo	3	1	0	0	0	0	0	0	4
19 Brokers	222	178	95	20	52	4	1	5	577
95 Insectaries	0	2	0	1	0	0	0	0	3

Source: Quarantine Premises Register, Department of Agriculture

2.2 Proposed changes to approved arrangement classifications

The extensive list of AA classes developed over many years as different biosecurity challenges arose.

The conditions for a class or sub-class of AAs are grouped under:

1. purpose: describes the activity of the AA
2. location: specific site conditions such as close proximity to a first point of entry
3. prerequisites: an AA holder may need to hold approval for other AAs
4. isolation: a biosecurity area that goods can be moved to and stored in
5. security: security measures that prevent removal of goods under biosecurity control
6. biosecurity area: specifications and use of the biosecurity area required under 'isolation'
7. hygiene: a clean biosecurity area free of pests, weeds and other contaminants
8. inspection: a suitable area where biosecurity inspections can be conducted
9. waste: disposal of dunnage and biosecurity waste
10. records: appropriate record keeping
11. administration: any changes to the AA site that need reporting, and
12. general: any general requirements that may apply to the AA site.

Condition groups 1 to 11 in general prescribe high level biosecurity principles and conditions applicable to all classes of AA. The conditions of approval for each class, while containing these conditions, are broader in scope.

Confusingly, group 12 'general: any general requirements that may apply to the site' may contain a mixture of general and specific conditions, which makes these documents difficult to read and audit against. The general section of conditions often includes many elements that belong in previous sections. For example, the class 1.1–sea and air freight depots' general section has 28 conditions, including three isolation, one hygiene, four security, three records, and three administration conditions that should be included in previous sections. Many of these conditions are listed as critical non-compliance. Better clarity could improve AA holders' ability to comply with conditions and better manage risks.

Current AA class conditions are often infrastructure- and procedure-based, focussing on the overarching intent of border biosecurity control and safety but in a very prescriptive way.

In attempts to standardise management of AAs, the purpose of creating individual classes has sometimes become obscure. This at times makes it difficult for people wishing to apply for an AA to understand and determine which class is applicable to them.

The purpose briefly describes the specific activity that AAs of that class are permitted to undertake, sometimes which commodities it handles, and sometimes specifically what is not allowed. The purpose does not currently explain what is the biosecurity risk that needs management by each class—this could be the same or similar for several classes.

In some AA class condition documents, it is necessary to read nearly to the end of the document to find the specific measures required to manage particular biosecurity risks, which is presumably why the class was created. For example, in the Conditions document for class 2.5.1–Temperature controlled storage of specified baitfish—there is no definition of baitfish in the Definitions section, and no inkling of any reason why this is a separate subclass from other class 2 AAs. The main clue to the specific purpose of the class comes in Table 10A—Office and record keeping, as follows:

10.2 The following additional records must be retained for specified baitfish requiring:

- thawing—for each thaw (*Sardinops* spp. and *Scomber* spp.) to include:
 - date of thaw
 - start and finish times of thaw
 - quantity thawed
- release (*sardinops*, *scomber*, *clupea* and *sprattus*) or sale to end users—required for each release or sale:
 - end user details (name, address, licence or registration number)
 - date of release
 - quantity released.
- Non-compliance—Major.

Reform of the AA classification system is undertaken periodically to streamline the underlying processes. Greater clarity in specifying the overall purpose of each class and sub-class, and ensuring that the Conditions documents are written to clearly manage these risks, could help improve this situation, as could a decision-tree to guide people wishing to apply for an AA to select the correct class. Streamlining of classifications can be undertaken if classes are initially grouped under similar biosecurity risks.

However, overgeneralisation may obscure specific risks associated with particular commodities or pathways.

The biosecurity risk management target should be stated in the Purpose section of each AA class Conditions document. The Conditions document should clearly set out the outcomes desired from conditions required to manage both specific and general biosecurity risks, in a manner that can be clearly understood by end-users and audited against.

Recommendation 1

The department should clearly describe the specific biosecurity risks that need to be addressed by each class of approved arrangements in the *Purpose* section of the class Conditions document, and ensure that the specified conditions clearly manage that risk.

To ensure that the AA class conditions remain contemporary, fit-for-purpose and relevant, the department's AA section continually reviews and updates AA classes:

- enhancing scope of classes to better reflect the activities permitted (or not permitted) to be undertaken,
- grouping of conditions by key arrangement outcomes, and
- simplifying and reducing duplication of conditions.

This may lead to incorporation of several classes (or sub-classes) into a single class (Table 2).

TABLE 2 Reclassification of approved arrangements, June 2019

Class code	Name	Type of change	Reason for change
5.2	Biosecurity containment level 2	Under review	Broken down into commodity/activity type as per BC1
6.2	Aquatic plants	Removed	No longer active
6.4	Open quarantine areas approved for bulbs	Subsumed into class 5.14: BC1 Plant Facilities	Merger with AA class 5.14 BC1 Plant
6.5	Laboratories for tissue culturing imported nursery stock	Subsumed into class 5.14: BC1 Plant Facilities	Merger with AA class 5.14 BC1 Plant
6.6	Open quarantine areas for cereal seed lines imported from New Zealand	Subsumed into class 5.14: BC1 Plant Facilities	Merger with AA class 5.14 BC1 Plant
7.2	Biosecurity insectary containment level 2	Will be subsumed into AA class 5.2 through containment facility requirements' review process	To be subsumed into AA class 5.2
8.4	Other treatment of biosecurity waste	AA holders who undertake cleaning of international aircraft rotational equipment to class 4.2	Simplification
10.1	Autoclave treatments	Merged into class 8.3 – Autoclave	Duplication
10.3	Deep burial treatment	Merged into class 8.2 – Deep burial	Duplication
10.4	Incineration treatment	Merged into 8.1 – Incineration	Duplication
11.1	Empty container scheme	No longer active	Linked to class 2.6 Empty shipping container parks
12.1	Onshore fumigation	Changed name to methyl bromide fumigation	Added class 12.2 Sulphuryl fluoride fumigation
14.3	Air container inspections	Introduced new AA	For CAPEC members

BC1 biosecurity containment level 1, **CAPEC** Conference of Asia Pacific Express Carriers

A new activity can instigate a new class and set of conditions being developed. For example, a new class 14.3 was established in 2018 for the inspection of air cargo for members of the Conference of Asia Pacific Express Carriers (CAPEC)—companies that focus on the growth area of express delivery of international parcels. This AA class provides conditions for activities involving inspection of specific goods reported as a Self-Assessed Clearance (SAC) declaration, and management of contamination on the goods by the biosecurity industry participant. SACs are imported goods valued at less than \$1,000. The value of imported goods is not related to biosecurity risk. The department facilitates a quarterly meeting with CAPEC members to discuss topics relevant to them, including approved arrangements. However, the requirements for class 14.3 AAs are not on the department's website so it is difficult to ascertain how any specific risks are being managed by this class.

Class conditions are generally updated annually. Any proposed changes to classes must undergo two stages of administrative process of communicating changes and providing 'right of reply' to industry members of the class, namely:

- notice of intention to vary the arrangement, outlining the changes and offering the opportunity for the AA holders to show cause as to why their AA should not be varied, and notice of decision to vary the arrangement, confirming implementation and date of effect of the changes.

Therefore changes to class conditions (urgent, inconsistent, omissions) are difficult to implement quickly. Conditions known to be insufficient or incorrect may not be addressed in a timely manner that may also impact on legal and biosecurity risk.

Chapter 3

Governance of approved arrangements

Approved arrangements are a complex system and several departmental groups have a role in operation of the system. These groups are spread both geographically and structurally, reflecting the wide dispersal of arrangements across Australia, and the complexity and variety of tasks required to administer them.

3.1 Overall coordination

The governance and oversight of the performance of AAs is jointly managed nationally by four biosecurity divisions in the department:

- **Compliance Division**
 - Compliance Policy branch oversees the processes for classification, approvals, debt collection, training and reform, including managing the AA information technology systems, as well as coordinating and providing technical input on fumigations and some other treatments.
 - Compliance Control branch provides technical input into certain import conditions and some treatments (such as disinsection) and is the risk owner of non-commodity pathway concerns such as rural destinations and container cleanliness.
 - Enforcement and Sanctions branch undertakes fitness and propriety assessments for persons and entities applying to hold AAs, as well as enforcement activities, investigations and initiation of punitive sanctions.
 - Compliance Testing and Intervention branch oversees suspensions and revocations resulting from non-compliance.

Overall, there are about 35 Compliance Division staff involved in AA governance of AAs.

- **Biosecurity Operations Division**
 - Audit and Assurance Group (AAG) oversees auditing of AAs, as well as undertaking auditor training, and assurance and verification functions.
 - Assessment and Client Contact Group assesses documentation to monitor broker AA compliance activities, assesses treatment records, and processes requests for movement of imported pig meat.
 - Inspections Group staff inspect imported goods and conveyances, mainly at AAs.
 - Science and Surveillance Group provides identification for pests and diseases intercepted at the border and carries out border surveillance including at AAs.

Biosecurity Plant and Animal Divisions

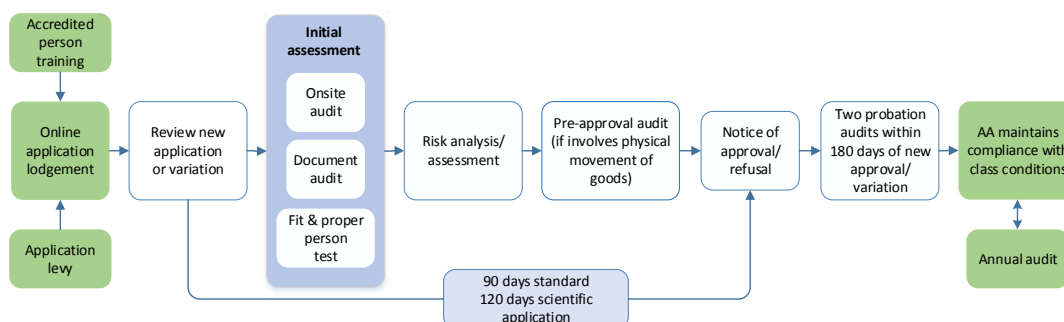
- Scientific staff in these divisions assess import permit applications, issue permits, and provide technical support on AA class conditions to manage plant and animal biosecurity risk. They are considered the ‘biosecurity risk owners’ for specific risks associated with different plant- and animal-related biosecurity imports.

3.2 Approval of arrangements

The AA section records the application, checks it for completeness and prerequisite information prescribed in applicable class conditions such as site maps, and charges the AA application levy.

The department reviews the applicant’s proposed arrangement against specific class conditions. The preliminary audit considers the capability of the applicant to carry out the arrangement, including having necessary equipment, facilities and trained personnel, to ensure biosecurity risks can be effectively managed. The application is forwarded to the Fit and Proper Persons section for assessment and to Audit and Assurance Group for documentary or site auditing as required (Figure 1).

FIGURE 1 Department of Agriculture—process for assessing new and varying approved arrangement applications



The **fit and proper person (FPP)** test under section 530 of the Biosecurity Act provides the department with powers to address risks posed by entities that breach the Act. It provides a level of assurance that applicants are suitable to manage the associated biosecurity risks and will operate within the scope of their approval.

The FPP test is conducted on persons connected with the legal entity and only some associates are considered at the time of application. If an AA closes down and reopens under a new legal entity name with new contacts it is difficult to establish whether new contacts have any link or association with the previous contacts. The FPP check assesses the persons listed on the application as well as persons not listed such as directors, shareholders and holders of import permits. The application places the onus on the applicant to provide information on their own staff’s history.

The FPP test must be applied within legislated timeframes when deciding to approve or vary an application for a proposed or approved arrangement. The department’s delegate must have regard to a range of matters under the Act, such as the applicant’s criminal history, Commonwealth debts and previous sanctions on importation or approved arrangement when determining whether a person is fit and proper.

The FPP function is a critical component of the system of AAs. Without the timely provision of FPP assessment reports, the department is unable to satisfy legislated processing timeframes for considering applications for new AAs. From 1 July 2016 to 30 June 2018, 1,105 FPP assessments were completed by the Enforcement and Sanctions branch of the department's Compliance Division, with the majority (1,037) for non-broker arrangements. For this period, 52 (4.7 per cent of total assessments) were found to have FPP concerns. FPP concerns can result in a number of different outcomes including refusals, revocations, suspensions, variations or non-standard conditions being imposed. FPP concerns may also lead to the implementation of informal mitigation strategies such as increased audit schedules or further investigation and monitoring.

Between 1 January and 30 June 2019, there were seven assessments relating to AAs with FPP concerns. Of these one resulted in the potential revocation of the AA (ongoing matter), one in the refusal of an application and five in non-standard conditions being imposed.

Approval of the AA, based on the outcomes of the preliminary audit, and information supporting the fit and proper person test, is given by a delegate of the Director of Biosecurity, provided they determine that the residual biosecurity risk associated with the arrangement is acceptable. On AA approval, the holder becomes a 'biosecurity industry participant' under the Biosecurity Act.

AA holders must report certain changes in circumstances such as a proposed change in departmental approved process or changes to certain management roles. Some of these changes may require a variation to the approved arrangement. The department reviews compliance with class conditions via an audit program. The audit program involves a higher rate of auditing for new approved arrangement holders and those that have previously failed audits. Broker approved arrangements are also subject to random assessment of documentation.

3.3 Accredited persons and training requirements

Accredited persons are people who have successfully completed required training relevant to the AA class they work under. Many of the AA conditions list accredited persons to be present or supervising the management of biosecurity risks. Failure to do so results in major or minor non-compliance.

For non-broker AA accreditation (broker training requirements are discussed in Chapter 4), the accredited person training provided through the department covers:

- general awareness of the importance of biosecurity
- role and responsibilities of accredited persons
- containment of biosecurity risks
- treatments
- processing
- security
- isolation
- hygiene
- inspections
- dunnage and waste disposal, and
- record keeping.

For most AA classes, training to accredited persons may be delivered in two ways:

- online training—the department provides generic biosecurity training content, with no details of specific AA site requirements, to a third-party service provider, who adds graphics, animation or other tools for interactive learning, or
- in-house training—developed and delivered by the AA. AAs must keep records showing the currency of training delivered to, and competence of, all accredited persons, and must present records of attendance for accreditation training when requested by the department. The department does not approve the content of training but does assess the competence of individuals in the performance of biosecurity activities through approval assessment, and probationary and annual audits.

The list of accredited persons who have passed on-line training is kept on a third party online training database and is accessible by departmental staff. However, there is no record on this database which links an accredited person to a particular AA. Also, the list does not include those accredited persons that only receive in-house training. Accredited persons at AA sites like freight depots can vary significantly over a year due to the large casual transient workforce associated with the industry. The department is made aware of any new accredited persons only at the time of audit. An audit is most likely to be re-scheduled if an accredited person is not available at the time of an audit, due to only partial scope of the audit being covered.

Recommendation 2

The department should develop a database of accredited persons at approved arrangements, which can be updated by approved arrangement holders and accredited person trainers and accessed by departmental staff.

The department measures whether the training is sufficient through the audit process. This verifies accredited persons understanding of the conditions to which the arrangement is subject and their ability to perform their functions as an accredited person in a compliant fashion. Testing of theory and observation of the performance of activities and review of records indicates training effectiveness and suitability.

In-house training may address only general conditions for all AAs and be insufficient to ensure that accredited persons can manage the biosecurity risks associated with certain AA classes, and extra training may be required.

For example, there is no single fumigation training standard across the different states and territories. However, the department has a fumigation standard and training that is nationally consistent. Fumigators must successfully complete training with a department-approved trainer to be accredited to conduct fumigations.

Bulb grow-out sites (class 6.11) are exempt from accredited person training requirements, due to the very low biosecurity risk of the bulbs they handle.

Federal police and defence dog AAs (class 7.8) are also exempt from accredited person training requirements, as the department cannot regulate another Australian government department. It is questionable why this class should exist if they are not regulated by the department. The department could simply provide these entities with relevant training material to conduct their own in-house training.

3.4 Auditing approved arrangements

Audit and Assurance Group (AGG) of the department's Biosecurity Operations Division conducts most audits across both import (biosecurity) and export arrangements apart from broker class approved arrangements which are discussed in chapter 4.

There are three main types of biosecurity AA audits:

- **Pre-approval audits**—conducted prior to new proposed arrangements, addition of a new AA class, varying an existing AA, or revoking a suspension of approval to ascertain whether suspension can be lifted.
- **Probation audits**—conducted after the approval of a new arrangement, as well as some variations, suspension or revocation of an existing arrangement, a failed audit or detection of critical non-compliance. Upon approval of a new arrangement, or varied arrangement, AA sites are subject to two 'probation' audits within 180 days. This ensures early detection of non-compliance or inability to comply with the department's conditions. When the AA passes two consecutive probation audits, the audit rate reduces to one audit per year. If an audit is failed, the audit rate is re-set to the probation rate.
- **Scheduled audits**—are conducted within 12 months of the previous audit, depending on the level of regulatory intervention required (due to level of biosecurity risk associated with the arrangement).

The above audit types may be conducted with or without prior notification to the AA management, as either announced or unannounced audits. Some years ago, the department tried to ensure that at least every second audit was unannounced. However, unannounced audits of some AAs can be difficult to implement as depots may be unmanned except when receiving or dispatching goods, requiring further follow-up visits. Conducting unannounced audits on certain entities, such as mobile treatment providers and authorised officers, has been hampered by the department not knowing the location or activity of the entity until the activity has occurred.

As a response to resource constraints, from January 2010 onwards the department implemented a program of largely announced, scheduled audits of all non-broker AAs at least annually.

Nevertheless, unannounced audits of busy AAs should be possible and are likely to present a truer picture of how the AA carries out its biosecurity functions. In particular, they are more likely to show whether or not accredited persons are carrying out or directly supervising the biosecurity functions, as required in most class conditions.

The department is now adjusting its risk-based audit work program to include more unannounced audits, especially where greater levels of non-compliance are found. An unannounced audit program puts industry on notice that they can be audited at any time. Unannounced audits are most effective when the AA is conducting operations. The frequency should be based on the biosecurity risks managed by the AA, compliance history, or specific reasons to suspect a non-compliance.

Recommendation 3

The department should implement a program of unannounced, randomly timed and risk-based audits of approved arrangements, rather than scheduled and announced audits, wherever possible.

3.5 Non-compliance management of approved arrangements

AA holders are required to comply with the Biosecurity Act 2015, which allows the department to prescribe conditions relevant to activities to be undertaken and give them directions to manage biosecurity risks.

Section 429(1) of the *Biosecurity Act 2015* states:

If a biosecurity officer is satisfied that it is necessary to do so to manage biosecurity risks associated with the operation of an approved arrangement, a biosecurity officer may give the biosecurity industry participant covered by the arrangement a direction in relation to the operation of the arrangement.

Failure by an AA holder to comply with the conditions of their arrangement (including import permit conditions and biosecurity directions), can result in the department ordering corrective action, or suspension or outright revocation of the arrangement, depending on the type and severity of non-compliance (Table 3).

TABLE 3 Types of non-compliance criteria for approved arrangements

Type	Criteria
Critical	- Action, inaction or contravention of departmental conditions that result in the release or the imminent removal of goods subject to biosecurity control without prior written direction or approval from the department. - Deliberate failure to comply with a departmental direction.
Major	- Action, inaction or contravention of departmental conditions to remove goods subject to biosecurity control without prior written direction or approval from the department. Example: An AA holder fails to secure goods that are subject to biosecurity control secure to prevent access and removal by unauthorised persons. - Action, inaction or contravention of departmental conditions that impedes the ability of departmental officers to effectively monitor and manage compliance with departmental conditions. Example: An AA holder fails to provide a safe working environment for biosecurity officers inspecting goods. - Action, inaction or contravention of departmental conditions that results in cross-contamination between goods subject to biosecurity control and other goods, or the environment.
Minor	Action, inaction or contravention of departmental conditions that compromise the integrity of systems, processes or premises. Example: An AA holder fails to maintain records of accredited persons handling goods subject to biosecurity control.

Detection and reporting of non-compliance under an AA may occur while the AA is being audited, or at any time by departmental staff, by third parties or by AA holders who report themselves. Once non-compliance has been detected it is reported through the appropriate channel as noted in Table 4.

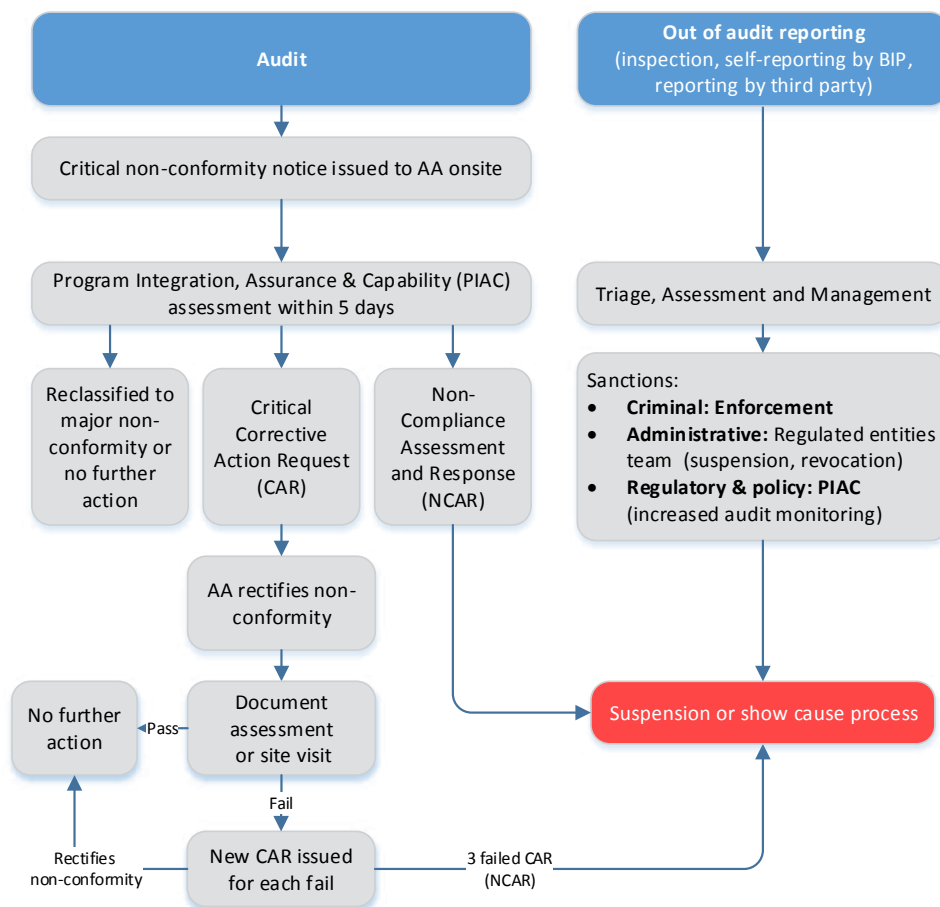
TABLE 4 Primary channels for reporting non-compliance at an approved arrangement site

Mode of detection of a non-compliance	Details
During audit	Usually detected by auditors and are recorded in the audit report and on the Corrective Action Request (CAR) form that are provided to the AA holder. Audit reports and CARs are prepared by AAG and are recorded in the department's Quarantine Premises Register (QPR) system.
Outside audit	Detected by any departmental officer including inspectors, surveillance, targeting, compliance and enforcement officers. These are reported using the non-compliance report (NCR).
Third parties and public	The department's Redline (1800 803 006) is a free call 'hotline' for people to confidentially report information about suspected breaches of Australian biosecurity, meat or food inspection laws. Occasionally, these Redline reports relate to non-compliance at an approved arrangement. These are also reported using the non-compliance report (NCR).
Self-reporting by approved arrangement holders	AA holders may also detect and self-report non-compliances to the department. Self-referrals are reported directly to Audit staff for assessment, response and recording. Self-reported critical non-compliance is managed by the department on a case-by-case basis.

Recording, assessment and response or referral of non-compliance found at audit

On completion of each audit, the auditor provides the AA holder with a written audit report, containing the audit result (pass or fail), details of evidence and findings of compliance and/or non-compliance, and records audit findings in QPR. The audit result is determined by the number and classification of non-compliances found during the audit. One or more critical non-compliance, three or more major non-compliances, or seven or more minor non-compliances, will result in a failed audit, and moving the AA back to the probation audit rate.

Auditors are responsible for assessing and dealing with minor and major non-compliances and may issue directions for the AA holder to rectify these in a specific timeframe, through corrective action requests (CARs). Failing rectification, a new CAR is issued. The department may issue three such requests for the same non-compliance. Auditors must notify any critical non-compliance found to the Audit and Assessment Group's Program Integration, Assurance and Capability (PIAC) section, which must assess each one and notify the AA holder in writing within five days by a critical non-compliance notice. This may result in a critical corrective action request (CAR), movement to the probation audit rate and/or a show cause process. Continuing failed audits result in escalation to the department's Non-Compliance Assessment and Response (NCAR) section and initiation of a notice to show cause why the AA should not be suspended or revoked (Figure 2).

FIGURE 2 Overview process for handling critical non-compliance

Non-compliance detected outside of audit and Redline reports are assessed and referred by NCAR's Triage, Assessment and Management (TAM) team. Once assessed, the four primary recipients of non-compliance reports are:

- Enforcement team—to initiate criminal sanctions, if required
- NCAR's Regulated Entities Team—to apply administrative sanctions
- PIAC and the Compliance and Response Team—regulatory and policy sanctions
- Other program areas.

At any point in this process, the department may reclassify the status from a critical to a major or minor non-compliance. This could be for a variety of reasons such as that the AA has provided evidence they are rectifying the critical non-compliance, but require more time to implement. The department then reports the audit as a pass with non-compliance.

Verification is needed that departmental policies on dealing with non-compliance are being followed. The severity of a non-compliance is determined by the severity at the time it was identified. While the deadline for rectification may be increased, retrospectively downgrading the severity of the non-compliance will give a false picture of the level of compliance.

Recommendation 4

The department should implement a verification program to ensure that departmental policies on the detection and management of non-compliance at approved arrangements are being followed and remain effective and appropriate.

Between October 2017 and March 2019 the quarterly rate of auditing AAs remained fairly constant at around 23 per cent, while the total non-compliance showed a steady increase in critical and major non-compliance (Table 5). Critical non-compliance detections more than doubled for the October–December 2018 quarter, a period which included more targeted unannounced audits of certain AA classes, with subject matter expert involvement.

Critical non-compliance detections more than doubled for the October–December 2018 quarter, a period which included more targeted unannounced audits of certain AA classes.

TABLE 5 Non-compliance audit outcomes, October 2017 to March 2019

Quarter	AA's audited	Non-compliance				
		Audits	Critical	Major	Minor	Total
December 2017	3,445	893	0	209	92	301
March 2018	3,454	790	23	239	125	387
June 2018	3,447	756	17	249	104	370
September 2018	3,434	813	25	330	104	459
December 2018	3,447	681	55	347	115	517
March 2019	3,475	755	28	341	116	485

The audit results for different classes of AAs between 1 January 2019 and 31 March 2019 are shown in Table 6. These need further consideration by many different departmental sections to interpret the implications for biosecurity risk management by those AA classes. There may also be significant workload implications for auditors and other groups involved in follow-up and management of non-compliance.

TABLE 6 Performance of approved arrangement sites, 1 January to 31 March 2019

Class	Class name	AAs Audits		Passed		Passed with NC		Failed		Pending	
		No.	No.	No.	%	No.	%	No.	%	No.	%
1	Biosecurity depots	524	334	183	54.8	111	33.2	36	10.8	4	1.2
2	General cargo	1,205	699	422	60.3	223	31.9	48	6.9	6	0.9
3	Processing	73	46	26	56.5	14	30.4	6	13.0	0	0.0
4	Treatments	476	503	257	51.1	170	33.8	69	13.7	7	1.4
5	Facilities	948	743	561	75.5	156	21.0	18	2.4	8	1.1
6	Post-entry plants	144	121	79	65.3	35	28.9	4	3.3	3	2.5
7	Animals	166	66	43	65.1	18	27.3	5	7.6	0	0.0
8	Destruction (sites)	51	65	37	56.9	25	38.5	3	4.6	0	0.0
10	Destruction (process)	280	188	97	51.6	70	37.2	18	9.6	3	1.6
11	Container inspection	8	9	4	44.4	5	55.6	0	0.0	0	0.0
12	On-shore fumigation etc.	55	68	12	17.6	22	32.3	32	47.1	2	2.9
13	Second conveyance	3	2	2	100.0	0	0.0	0	0.0	0	0.0
14	Air container inspection	4	5	5	100.0	0	0.0	0	0.0	0	0.0
Total –		3,474	1,530	1,009	65.9	423	27.6	84	5.5	14	0.9

AA approved arrangement. NC non-compliance.

Show cause process

The show cause process begins when non-compliance is serious enough to warrant the revocation, suspension or variation of an approved arrangement. The department requests the AA holder to provide a written response as to why their AA should not be suspended or revoked. They need to provide evidence to support their case, including any measures implemented to prevent a recurrence of the non-compliance. This forms part of the regulatory response, as it provides procedural fairness for the AA holder and enables the relevant departmental area to make an informed decision.

The outcome of the show cause process may result in:

- suspension of an arrangement, in part or in whole, for a specified period
- revocation of the arrangement
- variation to an approved arrangement, or
- allow the arrangement to continue.

Regulatory response actions to revoke, suspend or vary an AA is primarily dependent on what proof the department has, as well as the entity's attitude and capability to cease or rectify the non-compliance. Any actions or regulatory intervention should only be enough to manage the risk. Figure 3 shows the regulatory actions applied to AA holders depending on their attitude or capability.

FIGURE 3 Regulatory action matrix

Attitude/capability	Action		
	Inadvertent non-compliance	Opportunistic non-compliance	Deliberate non-compliance
No improvement during suspension	Extend suspension (90 days)	Revoke	Revoke
Previous suspension	Suspend (90 days)	Suspend (180 days)	Revoke
Seeking to exploit	Suspend (90 days)	Suspend (180 days)	Revoke
Able but not willing	Referral to relevant area	Suspend (90 days)	Revoke
Willing but not able	Suspend/vary	Suspend/vary	Revoke

Chapter 4

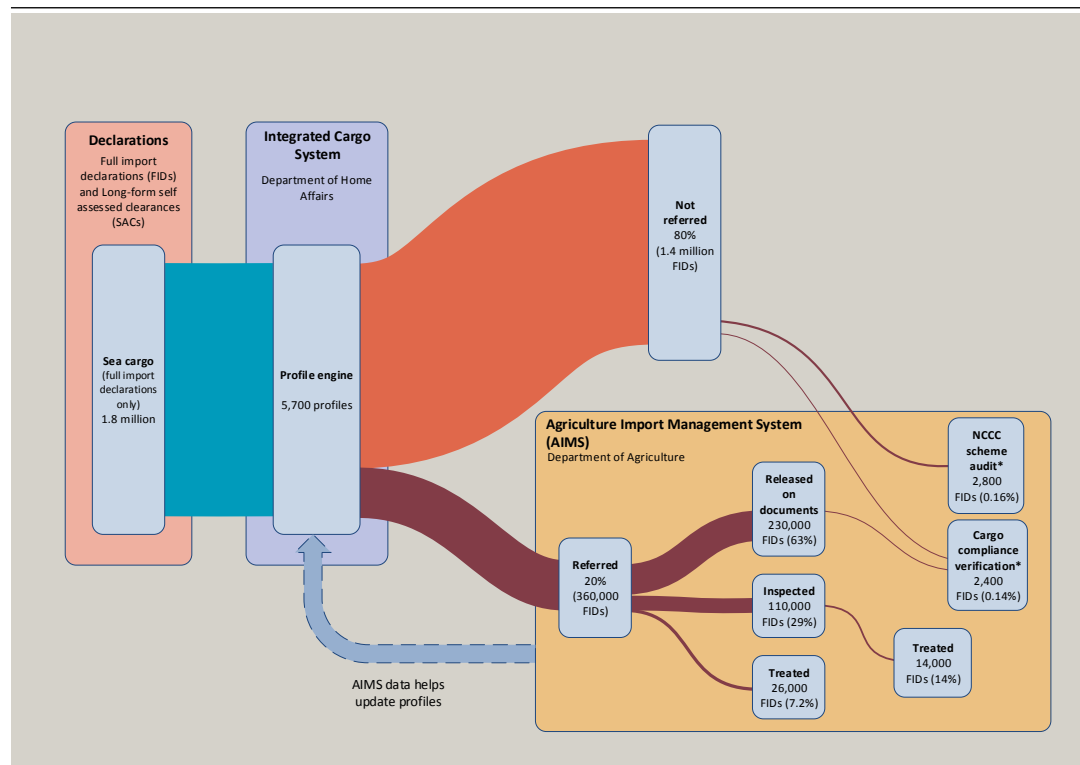
Broker class arrangements— class 19

4.1 Biosecurity risks managed by broker classes

Biosecurity risks posed by imported goods are broadly classified by the department as non-commodity and commodity risks. Non-commodity risks are the risks of those goods introducing exotic pests and diseases entry directly or in biosecurity risk material on transportation pathways and packaging (also known as hitchhiker pest and contaminant risks), while commodity risks are the risks of particular commodities introducing exotic pests or diseases to Australia. Import conditions for both commodity and non-commodity risks may require documentation relating to the goods to be assessed to determine the level of biosecurity risk associated with the goods.

Brokers and self-reporting importers must complete customs declarations for all imported goods. Broker class 19 AAs enable accredited persons (customs brokers and self-reporting importers) to perform document assessment and input information into the Integrated Cargo System (ICS) in order to generate an automated biosecurity direction for containerised sea freight consignments that have non-commodity concerns (class 19.1) and/or commodity concerns for selected commodities (class 19.2).

The Department of Agriculture provides and updates risk profiles within Home Affairs' ICS, so that the ICS risk engine can identify those declarations which may indicate known or potential biosecurity risk. The department employs a rigorous profile effectiveness and review program to ensure the ongoing accuracy of ICS profiles. The ICS risk engine refers consignments with commodity or non-commodity concerns—where information in the declarations lodged by accredited and non-accredited brokers matches a risk profile—to the department's Agriculture Import Management System (AIMS) for further assessment. In 2017–18, around 80 per cent of incoming containerised sea cargo consignments were not referred to the department for further biosecurity risk assessment (Figure 4). Consequently the accuracy of these broker declarations and assessments is a critical first step in Australia's biosecurity.

FIGURE 4 Processing of commercial containerised sea cargo imports, 2017–18

*Non-commodity for containerised cargo clearance (NCCC) scheme audit is conducted on full container load (FCL) and less than container load (LCL) cargo. The NCCC scheme audit figures are for consignments that have no other profile matches. Cargo compliance verification is only conducted on FCL sea cargo.

4.2 Broker class types, numbers and distribution

Class 19.1: Non-commodity for containerised cargo clearance

Class 19.1 AAs are for the assessment of non-commodity documentation and management of non-commodity biosecurity concerns associated with goods imported as containerised sea freight. They must employ or contract at least one accredited person. They must also notify the department of accredited persons who will perform the approved activities and their customs broker licence number, and obtain a Branch ID from the Department of Home Affairs, enabling them to lodge import declarations in the ICS.

Activities covered under this arrangement include:

- assessing documentation for full container load (FCL), full container multiple house bills (FCX) and less than a container load (LCL) sea freight
- assessing destination postcodes for FCL and FCX sea freight to identify those that will be unpacked in rural areas
- applying a code in the ICS to generate a biosecurity direction in AIMS that is used for the assessment and management of non-commodity biosecurity risk associated with the imported goods
- receiving and ensuring compliance with biosecurity directions generated by AIMS.

Class 19.2: Automatic entry processing for commodities

Class 19.2 AAs enable accredited persons (customs brokers and self-reporting importers) to perform document assessment and generate biosecurity directions for imported goods that have commodity biosecurity concerns by applying a code in ICS or via third party software. They must also hold a current class 19.1 approved arrangement with at least one employed or contracted person who is accredited for class 19.1, to manage non-commodity risks.

The specific imported types of cargo (Table 7), which are further divided into Customs tariff classifications, are subject to biosecurity control and managed in accordance with the department's Biosecurity Import Conditions System (BICON).

TABLE 7 Types of cargo in-scope for automatic entry processing for commodities in 2018–19

Type of cargo	Country	Mode of transport
Seafood for human consumption	All countries	Airfreight, FCL/X, LCL
Dairy products for human consumption from New Zealand	New Zealand	Airfreight, FCL/X
New tyres	All countries	Airfreight, FCL/X
New and used vehicles, aircraft and parts, machinery and parts and equipment	All countries	Airfreight, Break Bulk, FCL/X, LCL
Highly processed wooden and manufactured wooden articles	All countries	Airfreight, FCL/X, LCL
Cane, rattan articles and bamboo products	All countries	Airfreight, FCL/X, LCL
Timber and timber products	All countries	Airfreight, FCL/X, LCL
Milled rice for human consumption	All countries	FCL/X
Fresh garlic and garlic shoots for human consumption	All countries	Airfreight, FCL
Fresh onions and shallots for human consumption	Netherlands, New Zealand, United States	FCL
Semi-processed onions and shallots	China	FCL
Milling products for human consumption	All countries	FCL
Highly refined organic chemicals and substances	All countries	FCL
Brown marmorated stink bug target high-risk goods	France, Georgia, Germany, Greece, Hungary, Italy, Romania, Russia, United States*	Break bulk, FCL/X, LCL

FCL Full container load single supplier-single importer. **FCL/X** Full container load multiple suppliers. **LCL** Less than container load. *More countries are in scope for 2019–20 season.

Activities covered under this arrangement, include:

- assessing documentation for commodities in scope of the arrangement
- applying an automatic entry processing for commodities (AEPCOMM) code to generate a biosecurity direction in AIMS which will be used for the assessment and management of commodity biosecurity risk associated with the goods
- receiving and ensuring compliance with biosecurity directions generated by AIMS.

Automatic entry processing (AEP) forms part of the non-commodity for containerised clearance (NCCC) and AEP for commodities (AEPCOMM) approved arrangements.

Broker accreditation and training

The department records details of accredited and trained persons registered with the department and working for entities holding a class 19.1, or 19.1 and 19.2, AA in the Quarantine Premises Register (QPR) database. These records are cross-referenced by departmental systems AIMS and BICON to ensure that only accredited persons can use these systems when lodging import declarations. For this administrative purpose only, class 38 is used in QPR.

- Class 38.1 is for accredited persons accredited and operating under class 19.1 NCCC.
- Class 38.2 is for accredited persons accredited and operating under class 19.2 AEPCOMM.
- Class 38.3 records details of Registered Training Organisations (RTO) who deliver a unit of competency 'Comply with biosecurity border clearance' for accredited persons. The class was developed for RTO's to obtain access to a BICON AEPCOMM user account for training purposes. There are currently three RTO's registered as a class 38.3 to deliver this unit.

The department has established relationships with industry bodies, including the Customs Brokers and Forwarders Council of Australia (CBFCA) and Freight Trade Alliance (FTA), to provide consistent training to accredited persons and to facilitate communications with industry. The department engages with the class 19.1 and 19.2 approved arrangement holders via CBFCA and FTA conferences, the DCCC and the AEP Reform Working Group. Additional engagement happens via email notification, webinars and Industry Advice Notices on an 'as needed' basis.

Continued Biosecurity Competency (CBC) sessions are held at minimum annually and more frequently as required to enable accredited persons operating under class 19.1 and 19.2 AAs to maintain their accreditation. Lists of industry members who have attended training sessions are provided to the department in order to maintain their accreditation by CBC provider. Class 19 accredited persons must hold a custom broker's licence. As a condition of use of this licence, brokers must complete annual continuing professional development (CPD) obligations as required by Australian Border Force. System checks authenticate users when lodging declarations in the ICS.

At June 2019, AA class 19.1 (broker arrangements) had the largest number of AA holders. These AAs are concentrated in Victoria and New South Wales (Table 8). Each class 19.1 approved arrangement has a branch identification associated with it, however entities are allowed to work nationally with no specific physical location.

TABLE 8 Distribution of broker class approved arrangement sites, July 2019

Class code	Name	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
19.1	NCCC	222	178	95	20	51	4	1	0	571
	Accredited persons (NCCC)	664	509	213	41	103	6	4	1	1,541
19.2	AEPCOMM	132	118	68	13	31	4	1	0	367
	Accredited persons (AEPCOMM)	416	334	140	20	52	6	2	1	971

NCCC non-commodity for containerised clearance. **AEPCOMM** Automatic Entry Processing for Commodities.

Note: Entities that hold a class 19.2 AA also hold class 19.1. 204 entities hold only class 19.1. Accredited persons for class 19.2 are also accredited for 19.1 570 individuals are accredited for class 19.1 only.

Automatic entry processing for commodities reform

Between November 2015 and June 2018 the department undertook an Automatic Entry Processing for Commodities (AEPCOMM) reform project, aiming to increase uptake of AEPCOMM by expanding the range of commodities and simplifying the system, and thereby :

- reduce workload and time pressure on the department's Assessment group
- increase departmental resources available to target goods with a higher biosecurity risk, by in-depth documentation assessment, inspection and verification
- develop stronger partnerships with industry to manage and promote biosecurity, and
- allow quicker issuing of biosecurity directions and release of containers for brokers and importers.

Only commodities assessed by departmental biosecurity risk owners as being of low biosecurity risk are included in AEPCOMM. In May 2017 additional commodities, including unfinished timber, milling products and frozen molluscs, were added to the arrangement, and more will be added throughout 2019.

In June 2018 system enhancements improved capability for the department to add commodities to AEPCOMM and simplify lodgement processes under the NCCC arrangement for non-commodity risk, and added a refined compliance model with a revised audit and sanction regime.

This new AEP functionality was validated with the inclusion of goods subject to brown marmorated stink bug (BMSB) measures onto AEPCOMM in September 2018 (Box 1). However, in the 2018–19 BMSB season industry uptake of AEPCOMM was only 27 per cent of potential entries.

Box 1 Variation to Automatic Entry Processing for Commodities for brown marmorated stink bug season

From the 26 September 2018, the Automatic Entry Processing for Commodities (AEPCOMM) arrangement was varied to include goods subject to brown marmorated stink bug (BMSB) measures. AEPCOMM accredited brokers could use the arrangement to clear FCL/FCX cargo. The use of AEPCOMM for BMSB-risk cargo primarily facilitated onshore methyl bromide fumigation of target high-risk BMSB goods by an approved onshore treatment provider.

During the 2018–19 BMSB season there were 357 AEPCOMM approved arrangements and 944 AEPCOMM accredited persons registered with the department. Over 41,000 Full Import Declarations were in-scope for AEPCOMM, however only 27 per cent were processed through AEPCOMM, possibly due to extra charges introduced at the time. A total of 7,250 entries subject to high risk BMSB consideration were cleared without document assessment intervention by the department. Broker compliance with verification activities during this period was 99.3 per cent.

An AQIS Entity Identifier (AEI) number allowed removal of entries treated offshore from the system, but many brokers failed to use this facility, resulting in a high volume of unnecessary referrals to the department for assessment.

Uptake of AEPCOMM has been identified by the department as an area where greater industry participation will help reduce the work load on biosecurity operations assessors and improving efficiencies for industry. The department is looking to increase the volume of entries processed on AEPCOMM through a program of continuous improvement in functionality, commodity expansion and increased industry engagement.

Post reform some areas that have been identified for improvement include:

- better systems integration with other departmental schemes such as the compliance based inspection scheme
- better document accessibility for AEP lodgements by third party software, and
- identifying offshore biosecurity treatments on import declarations lodged via AEP.

4.3 Types and volumes of lodgements handled

About 25 per cent of all import declarations referred to the department through AIMS are lodged using NCCC (19.1) or AEPCOMM (19.2) approved arrangements to manage the clearance of the goods (Table 9).

TABLE 9 Import declarations lodged by class 19 brokers, July 2016 to December 2018

Year	Import declarations (no.)	Declarations lodged with NCCC concern (no.)	Total lodgements using NCC (%)	Declarations lodged using AEPCOMM (no.)	Total lodgements using AEPCOMM (%)
2016–17 to 2017–18	899,000	78,000	8.7	152,000	16.9
July 2018 to December 2018	279,000	21,040	7.5	50,400	18

From 1 September 2018 to 30 April 2019 there were 51,037 Full Import Declarations were subject to high risk BMSB onshore measures, of which 34,145 (67 per cent) were in scope for AEPCOMM usage, with 9,286 entries (27 per cent) processed via AEPCOMM. However, a portion of these entries were still referred to the department primarily for verification purposes or due to processing errors.

4.4 Verification of broker approved arrangement compliance

The department undertakes ongoing compliance monitoring for broker class AAs mainly by document assessment verification at the brokerage AA branch level, and may also undertake other business assurance activities such as targeted assessment and audits.

There are two categories for verifying broker assessment of import declarations lodged under class 19.1:

- Category 1—where the accredited person declares no non-commodity concerns.
- Category 2—where the accredited person declares non-commodity concerns, or lodges an import declaration for goods under class 19.2 AEPCOMM arrangement.

Items for verifications are selected based on system rules in the ICS and AIMS. Where an import declaration is selected for document assessment verification, the department will direct the broker to provide documentation used to support the assessment. The documentation is used by officers in the Assessment Client Contact branch to review the broker's assessment and lodgement in ICS and determine compliance with AA conditions.

The department assesses broker class AA at different rates based on findings of previous audits. Newly approved broker class 19.1 AA commence at the standard review level of 0.2 per cent of all their category 1 cargo lodgements in ICS (Figure 5). Newly approved class 19.2 AA and category 2 class 19.1 lodgements start on the probation level of 100 per cent for ten consecutive documents assessment verifications per commodity group. As compliance is demonstrated, the rate of verification decreases (Figure 6).

FIGURE 5 Verification rates for category 1 non-commodity for containerised cargo clearance lodgements

Review level	Verification rate	Compliant	Consequence of non-compliance by category		
			Minor	Major	Critical
Census	100% lodgements until corrective action addressed		Remain on census	Remain on census	Remain on census
Probation	100% for 20 consecutive lodgements		Restart count		
Heightened	100% for 10 consecutive lodgements		Restart count	Restart count	
Increased	100% for 5 consecutive lodgements		Restart count		
Standard	0.2%				

FIGURE 6 Verification rates for category 2 AEPCOMM and NCCC with non-commodity concerns lodgements

Review level	Verification rate	Compliant	Consequence of non-compliance by category		
			Minor	Major	Critical
Census	100%	All compliant verifications until corrective action addressed	Remain on census	Remain on census	Remain on census
Probation	100%	10 consecutive compliant verifications	Restart count		
Heightened	25%	15 consecutive compliant verifications	Restart count		
Standard	5%	5 consecutive compliant verifications	Restart count		
Standard	1%	Ongoing			

Overall compliance with NCCC and AEPCOMM approved arrangements is very good, staying above 98 per cent since 2017.

Between July 2016 and June 2018 financial years, there were 5,095 AEPCOMM and 6,703 NCCC entries electronically referred to the department for assessment for broker approved arrangements. There was one onsite audit conducted during this period.

The audit and sanctions policy governing broker approved arrangements compliance was significantly updated as part of the June 2018 AEP reform. Random verification rates are now placed against individual AEPCOMM commodity groups as opposed to the previous flat 3 per cent verification rate across the class.

From July to December 2018, there were 3,440 AEPCOMM and 2,523 NCCC entries electronically referred to the department for assessment for broker approved arrangements, with a consistent compliance rate of 99 per cent across NCCC and AEPCOMM approved arrangements. There were no onsite audits conducted during this period.

A Cargo Compliance Verification (CCV) program can provide extra assurance of correct broker declarations about sea container biosecurity, although the physical inspections performed through CCV are aimed at verifying the accuracy of declarations made by the exporters/suppliers/packers of sea cargo, not the broker's assessment of the declarations.

Current CCV data collection systems do not identify the party or parties responsible for non-compliance. Therefore, analysing trends in non-compliance by different groups, such as brokers, is not easy. From August 2018 to June 2019, 134 entries were recorded in CCV that had potential broker involvement as a reason for non-compliance. From these entries, 10 (7.5 per cent) non-compliances were attributed to broker errors (Table 10). Eight brokers were involved out of the 10 non-compliances. Seven of those brokers hold a 19.1 AA. There were 37 other bypass inspections or 'seals intact' issues where broker error could have contributed.

TABLE 10 Broker non-compliance recorded through cargo compliance verification, August 2018 to June 2019

Non-compliance	Broker responsible	Possible broker contribution
Fumigation certificate did not meet requirements (AEP verification)	1	1
Bypass inspection	4	12
Packing declaration did not meet Minimum standards (AEP verification)	1	1
Packing declaration not presented	1	0
AEI not declared in ICS by broker	1	0
Undeclared timber—commodity	0	2
Undeclared timber packing	0	1
Unpacked prior to officer in attendance	0	5
Goods released prior to imported food inspection	1	0

Chapter 5

Freight depots and container parks—classes 1, 2.6 and 11

5.1 Purpose and functions of sub-classes

Approved arrangement sites used for the deconsolidation of sea and air cargo, inspection and treatment of goods, containers and Universal Loading Devices (ULDs). There are three sub-classes:

Class 1.1: Sea and air freight depots (unrestricted) are AA sites approved for the management of all biosecurity risks associated with freight consignments. This may include initial non-containerised machinery inspections, rural container inspections, external container inspections and the storage, inspection or treatment of incorrectly certified agricultural products from khapra beetle countries. These depots must be located within the metropolitan area near a first point of entry for goods (from vessels) where a permanently based biosecurity officer is stationed. The AA holder must hold approval for AA classes 4.3—cleaning, and 4.6—fumigation, in order to hold approval for this class.

Class 1.2: Air cargo terminal are AA sites used for the unpacking, inspection, fumigation and cleaning of airfreight (air cargo terminal and airfreight depot operations, for example, bond type depots). They can accept delivery of all air freight commodities but may require separate approval for inspection functions. AAs must be in the airport precinct and have access to washing facilities with the fumigation areas either onsite or at another AA site. These sites are approved for:

- storage, inspection and/or treatment of air cargo from all countries with correct or incorrect certification holding or with unknown import conditions
- receipt, inspection and holding of live animals prior to trans-shipment or pick-up and delivery to a quarantine station
- receipt and holding of human remains
- receipt and holding of biological material
- holding and/or treatment of dunnage and non-ISPM 15 compliant packing, and
- inspection and/or treatment of personal effects.

Class 1.3: Sea and air freight depot (restricted) are AA sites used for the deconsolidation of sea and air cargo. These sites are approved for:

- storage, inspection and/or treatment of cargo from countries with correct certification and correct or incorrect packing documentation
- inspection and/or treatment of personal and household effects
- inspection and/or treatment of military cargo and vehicles
- commodity verification tailgates
- cleaning and re-inspection of break bulk machinery (after initial inspection at an approved arrangement class 1.1 site or wharf) when appropriate and approved sites are available
- containerised machinery inspections and the fumigation and cleaning of these goods when appropriate and approved sites are available
- holding and/or treatment of dunnage and non-ISPM 15 compliant packing.

Class 1.3 AA sites are not approved for non-containerised machinery inspections, fresh fruit and vegetable inspections, cut flower inspections, external container inspections, the receipt, holding, inspection of live animals, or the storage, inspection or treatment of incorrectly certified agricultural products from khapra beetle countries. However, they may be approved to conduct external container inspections if they meet other departmental conditions.

Class 2.6: Empty shipping container parks are AA sites used for the handling, storage, internal examination and treatment of empty shipping containers that are subject to biosecurity control. These sites are not approved to carry out any other biosecurity operations.

Class 11.2: External Container Scheme are AA sites within class 1.1 unrestricted depot AAs, that are used for the removal of external contamination from imported shipping containers leaving the port, including the domestic conveyance used to move the container. Containers and conveyances that fall under the scope of this class of AA do not require re-inspection by a biosecurity officer following cleaning treatment. The AA holder is responsible for assessing the cleanliness of cleaned containers and related transport and complying with any other direction required to be undertaken at the depot, after which the container and conveyance can leave without re-inspection or further direction from the department.

5.2 Numbers and distribution, department's engagement mechanisms

Approved arrangement class 1.3 has the largest number of AA holders. These AAs are concentrated in Victoria and NSW (Table 11).

TABLE 11 Distribution of approved arrangement sites, classes 1, 2.6 and 11, July 2019

Class	Name	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
1.1	Sea and air freight depot (unrestricted)	9	2	15	7	4	3	1	0	41
1.2	Air cargo terminal	5	8	11	6	5	1	2	2	32
1.3	Sea and air freight depot (restricted)	122	149	78	21	48	13	8	3	442
2.6	Empty Shipping Container Parks	3	12	4	7	3	0	0	0	29
11.2	External container scheme	2	3	2	1	0	0	0	0	8

Classes 1.2 air cargo and 1.3 sea and air cargo depots must have access to washing facilities and fumigation on-site or at another department-approved AA site. There is inconsistency and some confusion in these conditions. For example, class 1.2 has no specific pre-requisite to have class 4.3 cleaning and 4.6 fumigation, even though this class is approved for holding and/or treatment of cargo with unknown import conditions. This section needs to be revised for clarity and simplicity.

There is some inconsistency between First Point of Entry (FPOE) requirements and class 1 AA requirements. An FPOE port is required to provide particular facilities to gain recognition as a FPOE port but extra AA facilities may be mandated that do not match the FPOE requirements. For example, class 1.2 air cargo terminals have specific conditions for holding transhipped dogs and cats en route to quarantine that are not specified in the FPOE requirements.

The conditions for all accredited persons under these classes are similar. However the management of sudden unavailability of an accredited person, as part of a contingency plan, is a minor non-compliance for classes 1.1, 1.2 and 2.6, but a major non-compliance for class 1.3.

A class 1 AA site can request to have departmental staff stationed at their site if they are able to demonstrate they have more than 5.5 hours of inspection work. The number of staff stationed is dependent on the amount of work required at the AA. There are 10 manned class 1.1, two manned class 1.2 and four manned class 1.3 depots. Manned depots allow inspectors to be available at the site or can be quickly sent to nearby AA sites. In Sydney, the deployment efficiency of inspectors is increased as class 1.1 depots need to be within 2 km of the Port Botany precinct and airport.

Manned depots can change the relationship between the inspectors and the AA site. The department's culture at these sites may tend towards over-servicing which is underpinned by the department's 2016 Client Service Charter. The department needs to provide staff with appropriate regulation training to ensure they can fully perform their regulatory duties.

Recommendation 5

The department should develop guidelines and training for Inspection Group staff to oversight approved arrangements' implementation of class conditions and biosecurity risk management throughout the year to supplement the audit process and improved compliance.

5.3 Compliance auditing

In 2017–18 there were a total of 1,277 audits for freight depots and container parks (Table 12). Up to 10 per cent of these arrangements failed an audit.

TABLE 12 Audit and non-compliance status of approved arrangement sites, classes 1, 2.6 and 11, 2017–18

State/Territory	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
Arrangements	134	171	106	37	58	17	11	3	537
Total audits	324	383	273	88	133	40	28	8	1,277
Failed audits	11	22	9	3	8	0	0	0	53
Critical non-compliance	0	0	2	0	0	0	0	0	2
Major non-compliance	128	270	196	46	87	13	1	2	743
Minor non-compliance	29	92	88	37	48	5	2	1	302

5.4 Biosecurity risk material detection and recording

Biosecurity risk material (BRM) is an overview term referring largely to hitchhiker pests or contaminants (also known as non-commodity concerns) that may be detected on imported containers, goods, non-commodity items and packaging, particularly at freight depots and container parks. Examination of these items at an AA may reveal high risk, lower risk or no BRM, classed respectively as biosecurity risk levels 3, 2, or 1. The department prescribes actions that must be taken by accredited persons for each risk level (Table 13).

This classification is appended to the AA Requirements document for class 2.6–Empty container parks, with an instruction that the AA should complete and maintain a record for each imported container. It is a very useful classification that clearly sets out non-commodity risks and actions to be taken.

Separately, the department publishes instructions for staff at class 1.1–Unrestricted freight depots and class 1.3–Restricted freight depots for completing a BRM record via a downloadable template on its website. This form also requires accredited persons to record whether or not wooden packaging material and dunnage are marked are with an ISPM 15 compliant stamp, but does not record negative findings of notifiable contaminants (BL1) (Box 2).

TABLE 13 Management of biosecurity risk material at approved arrangement sites

Biosecurity risk level	Category of biosecurity risk material	Action required
Biosecurity level 3 (BL3)—requires departmental intervention	Animals (including hitchhiker pests): - live or dead animals or parts of animals, snails, skeletons - live or dead insects - evidence of insects (egg castings) and insect damage	Following detection: - immediately close container doors - move container to biosecurity area - contact the department - record as BL3 - after departmental treatment, check for BL2 - if in doubt about the biosecurity risk of any material, contact the department
Biosecurity Level 2 (BL2)—biosecurity risk material permitted to be removed from site	Animal material: - animal droppings - animal blood and/or other body fluids - skinned hide, loose bones, skin and hair not attached to a carcass - feathers - brushes, bedding Plants and plant material: - bark - cane baskets, hats - dunnage and/or wooden packing - fruits and vegetables - seeds - straw, wreaths, sawdust - plant leaves, stems, flowers, pine cones, bamboo, rattan, sphagnum, husks, rice hulls Soil or earth: - minerals and ores - soil, stones, pebbles All food and/or food items Miscellaneous: - fruit cartons - water or containers with liquid	For any materials in this category: - move container to biosecurity area for cleaning - remove biosecurity materials - for liquids and wet materials, wash or steam clean - for dry materials, sweep or vacuum - for animal products, final wash using disinfectant or water (more than 90°C) approved by the department - dispose of waste using biosecurity waste bin - dispose of dunnage/wooden packing - for autoclave or incineration, place in biosecurity waste bin, or store in the biosecurity dunnage area - check that no biosecurity materials remain - record as BL2
Biosecurity Level 1 (BL1)—no biosecurity risk material detected	No biosecurity risk material present	Record as BL1

Box 2 Example of biosecurity risk material record

AA site name: ABC Depot Pty Ltd				State: NSW						AA site number: 00000					
				Container type		Container contaminants				Timber packaging/dunnage			Notifiable contaminants (notify the department immediately)		
Date	Accredited Person	Entry number	Container number	FCL	LCL	Straw	Seed/ grain	Animal faeces	Soil	Bark	If bark is present, is timber marked with ISPM 15 stamp? (Please circle)		Live insects or frass	Live animals	Dead anima
11/07/2019	Tom	AAAA 11	ABC123	X			X			X	Yes	No			
11/07/2019	Dick	BBBB 22	DEF456	X							Yes	No			X
11/07/2019	Harry	CCCC 33	GHI789		X					X	Yes	No			
											Yes	No			

Example 1 (row 1): An FCL consignment of goods was found to contain grain on the container floor and bark was present on the timber packaging. The timber packaging was marked with an ISPM 15 compliant stamp.

Example 2 (rows 2 and 3): A container was opened and a dead animal was found inside the container. The doors were closed immediately and the department was notified. After a departmental officer had removed the dead animal from the container the goods were unpacked. Bark was found on the timber packaging on one of three LCL consignments within the container. The timber packaging was not marked with an ISPM 15 compliant stamp.

Class 1.1 and 1.3 AAs must record these as part of their conditions. They must also retain records for six months on site and 18 months before disposal. However, the department never requests these records, although they may be viewed at audit.

When an AA holder detects BRM at the premises they are supposed to record and contact the department (depending on the biosecurity level). This information is valuable for reporting, profiling and planning. The current method of recording is through the BRM report, which is paper based after being downloaded from the department's website. A more effective method would be the use of a smartphone application that can be used to record all information about BRM detection, including photographs.

The BRM record is an important assurance method to determine the cleanliness of the sea container import pathway and could also be used by AAs dealing with break bulk cargo. The data could be used for assurance analysis but appears to be a low priority. It is unclear what the department is doing with this data, or where it is being recorded. The department should develop an easy-to-use digital or app-based reporting system connected to departmental information systems to make the recording and reporting of BRM easier for AAs. A facility should be included for feedback to the AA and other industry players involved in the supply chain as well as to relevant sections of the department, to improve biosecurity risk management at all levels. The same system could be used by frontline biosecurity officers to record BRM detections, and feed data into AIMS for better hitchhiker pest and contaminant risk management over time.

Recommendation 6

The department should develop an easy-to-use digital or app-based reporting system connected to departmental information systems for use by approved arrangements staff and departmental inspectors to record and report details of any biosecurity risk material detections or inspections.

5.5 Surveillance around approved arrangement sites

Compliance with AA conditions is monitored in accordance with the AA general policies. These policies prescribe audit as the primary tool for this. While AA surveillance is not precluded under the general policies, there has been a long-standing preference for audit resources to be committed to performing full scope audit, and achieving policy targets to that end. However, the lack of resourcing has prohibited the department from undertaking planned surveillance activities.

Surveillance of AA sites and surrounding areas is undertaken by the Operational Science and Surveillance Group. The National Border Surveillance (NBS) team conducts surveillance at first points of entry and biosecurity AAs with a focus on early detection of exotic pests, collection of intelligence on the susceptibility and vulnerability of sites, to pest invasion and provision of feedback on the effectiveness of border-related biosecurity policies.

Between 1 October 2017 and 31 March 2018, NBS team conducted 588 site visits and surveys at capital cities and remote first points of entry, approved arrangements and associated or adjoining premises. During the surveys, 5,845 plants, 5,505 invertebrates and 123 samples with symptoms of plant diseases were collected and identified. Among the identified organisms were detections of five different exotic snails that had established in three different locations in Victoria, two detections of red imported fire ants from two locations within the eradication zone in Queensland, one detection of browsing ant in a location in Western Australia and one of a *Monomorium* ant in Queensland. The results of targeted surveillance for the presence of *Xylella fastidiosa*—carried out between December 2017 and March 2018 at selected cruise ship terminals, airport sites and class 2.4 AAs—were negative.

Potential non-compliances identified through surveillance, failure to follow direction or notification from other department operational and policy groups may lead to an unannounced audit being conducted by departmental auditors.

Chapter 6

General cargo storage, transport and processing—classes 2 and 3

6.1 Purpose and functions of sub-classes

Class 2 AA sites are used for deconsolidation, handling, storage, inspection and treatment of cargo and containers that are subject to biosecurity control and are generally located within the metropolitan area of a declared port that has a permanent biosecurity officer. This class has 11 sub-classes handling goods with very different biosecurity risks (Table 14).

TABLE 14 Class 2 approved arrangement sub-classes

Class code	Name	Permitted activity
2.1	Non-agricultural products	Deconsolidation, handling, storage, inspection and treatment of certain goods and equipment that are subject to biosecurity control (for example, car parts, used tyres and containerised agricultural machinery)
2.2	Agricultural products	Deconsolidation, storage and inspection of goods that are subject to biosecurity control, but are processed or packaged in such a way as to preclude the possibility of external contamination (for example, cocoa, rice, nuts and straw articles)
2.3	Bulk stockfeed and fertiliser	Receival, storage, inspection and treatment of bulk commodities that are subject to biosecurity control (for example, fertiliser and stockfeed)
2.4	Fresh produce, nursery stock and cut flowers	Deconsolidation, handling, storage, inspection and treatment of fresh fruit and vegetables, cut flowers (including foliage which forms part of the consignment) and nursery stock (excluding tissue cultures) that are subject to biosecurity control. Other biosecurity areas may be located onsite including fumigation and devitalisation.
2.41	Airfreight perishables	Verification of consignment packaging for airfreight perishables and securing of airfreight perishable consignments for transport
2.5	Temperature controlled storage	Receival, storage, and inspection of commodities requiring temperature controlled storage conditions (for example, imported cheese, seafood and nuts for cold disinsection treatment)

continued ...

TABLE 14 Class 2 approved arrangement sub-classes *continued*

Class code	Name	Permitted activity
2.5.1	Temperature controlled storage of specified baitfish	Receival, storage, inspection and thawing of specified baitfish that are subject to biosecurity control
2.5.2	Temperature controlled storage of imported pig meat	Storage and handling of imported pig meat that is subject to biosecurity control
2.7	Grain storage	Storage and handling of bulk imported grain commodities such as corn, wheat, barley and sorghum
2.8	Temporary storage of containerised refrigerated pig meat	Temporary storage of refrigerated containers holding imported pig meat that is subject to biosecurity control, prior to movement to a class 2.5.2 or 3.2 AA site

Class 3 AA sites are used for the processing and treatment of different goods subject to biosecurity control, generally located within the metropolitan area of a declared port that has a permanent biosecurity officer. There are four sub-classes (Table 15) for the processing of different commodities. They are essentially class 2 AAs with an added processing step where the parameters specified in the relevant import permit for the commodity in question are duplicated in the class conditions. Goods may pass between class 2 and 3 AA sites and require to be maintained under biosecurity control until they are processed satisfactorily.

TABLE 15 Class 3 approved arrangement sub-classes

Class code	Name	Permitted activity
3.0	Produce processing	Unpacking FCL containers and the storage, inspection and processing of goods subject to biosecurity control (for example, hides for tanning, hunting trophies for taxidermy (tanneries), sesame seed for manufacture into tahini, feather processing and nut processing)
3.1	Grain processing	Processing of bulk imported grain commodities such as corn, wheat, barley and sorghum
3.2	Imported pig meat processing	Handling, storage, transport and processing of imported uncooked pig meat solely for human consumption and the disposal of associated waste products
3.3	Imported uncooked prawn product processing	Processing of imported uncooked prawn product for human consumption

6.2 Case study: imported pig meat—sub-classes 2.52, 2.8 and 3.2

Australia only imports uncooked pig meat from countries free of serious diseases, such as foot-and-mouth disease and African swine fever, but allows imports from countries that are not free of other diseases such as porcine epidemic diarrhoea and porcine respiratory and reproductive disease, on the basis that the meat must be cooked on arrival to destroy target pathogens.

During 2017–18 over 160,000 tonnes of raw pork were imported into Australia (APL 2018). This product can only be used for processing into pre-cooked product like ham or bacon or for smallgoods like salami and sausages. There could be risks of illegal diversion of imported raw pork to the domestic market, with consequent livestock disease risks, if strict biosecurity control is not maintained on product until it is properly processed.

More than half of all class 3.2 AA imported pig meat processing sites are located in Victoria (Table 16).

TABLE 16 Distribution of AA sites that may handle imported pig meat, July 2019

Class code	Name	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
2.52	Temperature controlled storage of imported pig meat	17	9	9	3	3	0	0	0	41
2.8	Temporary storage of containerised refrigerated pig meat	4	2	4	0	1	0	0	0	11
3.2	Imported pig meat processing facility	7	11	4	3	2	0	0	0	27

From 2017–19, 8.9 per cent of AA sites that may handle imported pig meat failed an audit. There were 17 critical and 158 major non-compliances (Table 17).

TABLE 17 Audit and non-compliance status of approved arrangement sites, sub-classes 2.52, 2.8 and 3.2, 2017–19

Audit and compliance details	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
Arrangements	25	20	16	6	6	0	0	0	73
Total audits	84	76	65	24	20	0	0	0	269
Failed audits	7	7	6	3	1	0	0	0	24
Critical non-compliances	3	3	11	0	0	0	0	0	17
Major non-compliances	44	39	49	17	9	0	0	0	158
Minor non-compliances	7	7	12	1	3	0	0	0	30

There is no clear traceability of uncooked product through the whole of the onshore supply chain (from AAs managing frozen storage, to the processing facility through to the waste disposal site). Clearer specification of this in the conditions for each AA class in the supply chain could make operating requirements clearer for both the AA holder and the auditors. Assurance of the waste pathway is performed through the audit of individual arrangements under applicable classes responsible for different steps of the pathway. For example, waste disposal from imported pig meat class 3.2 sites is not traced from the facility through to the disposal site. A processor will receive receipts demonstrating their waste has been collected by an approved transporter as biosecurity waste but this transporter is not necessarily associated with the waste treatment facility. The end treatment facility may be independent of both the transporter and the waste generating facility and responsibility is handed over at each stage of the pathway. Assurance is gained for the individual management of the biosecurity waste but imported pig meat waste is not specifically audited along the entirety of the pathway.

Recommendation 7

The department should adopt a whole-of-supply-chain approach to some commodity-based import approved arrangement pathways such as those handling imported pig meat, to improve on-shore traceability, and minimise leakage at any stage.

6.3 Case study: imported bulk stockfeed and grain—sub-classes 2.3, 2.7, 3.0 and 3.1

Imported grain and plant-based stockfeed pose a high biosecurity risk because they provide a direct pathway for the introduction and spread of exotic pests and diseases that can harm humans, animals, crops and the environment. For example, foot-and-mouth disease, Newcastle disease, infectious bursal disease, Karnal bunt and khapra beetle can spread through these products and could greatly impact our grain and livestock industries. For plant based stockfeed the biosecurity risk is primarily managed offshore through processing with onshore verification inspections conducted at a class 2.3. For imported bulk grain the biosecurity risk is managed offshore through sourcing from a country with low plant and animal health risk combined with onshore controls including storage and processing at class 2.7 and 3.1 AAs.

The major types of stockfeed are hay, processed plant-based stockfeed and bulk grain. Hay has never been imported into Australia for stockfeed as it poses too high a biosecurity risk. Some imports are regular, providing ingredients such as soybeans for further formulation into processed feed for different livestock or aquaculture species. Others, like bulk grain such as wheat, are rare and mainly occur at times of drought, as Australia normally produces sufficient wheat for all domestic needs (Box 3).

A permit is required for any plant based stockfeed and grain imports. Every permit application is considered on a case-by-case basis and is subject to a risk assessment to allow specific consideration of the biosecurity risks posed by the proposed import pathway.

For bulk grain, the assessment of the AA site and the transport route considers a range of factors relevant to the management of biosecurity risk including proximity to agricultural production, potential hosts (animal and plant) and transport routes (especially passage through agricultural areas).

Box 3 Bulk import of wheat

In 2018 severe drought conditions across eastern Australia saw a 20 per cent fall in Australia's winter crop production. The ABC reported in May 2019 that the department issued a permit to import bulk wheat from Canada. Australian-owned Manildra Group needed the high protein wheat for processing at its Shoalhaven Starches plant at Nowra, NSW. This was the first import permit issued for imported grain since 2007. The wheat shipment arrived in Port Kembla, NSW in June 2019.

A further two import permits were issued with another eight import applications for bulk wheat, canola, corn and sorghum from Canada and the United States under various stages of assessment.

Grain grower groups expressed concern that grain imports could jeopardise Australia's biosecurity. However, very tight conditions apply. Inspections to verify biosecurity risk management are undertaken by a biosecurity officer during and on completion of unloading at each port; during receipt and out-loading from each AA site, and following decontamination at each AA site.

A department-approved and audited Process Management System must be put in place outlining the processes for sourcing, movement and loading offshore and movement, storage and processing within Australia. A department-approved Site Operations Manual must be in place for the AA site outlining the processes for managing the grain within the AA site. Approval of the site is only given if department conditions are met at desk and site audit. During 2018–19, the department's Plant Import Operations (PIO) branch spent approximately 20 to 60 hours for desk audit of AA classes 2.3, 2.7 and 3.1. They also spent approximately 14 to 20 hours for auditing each of these AA sites.

Table 18 shows the distribution of AA sites in the various classes which may handle imported bulk stockfeed or grain.

TABLE 18 Distribution of approved arrangements handling imported stockfeed and grain, July 2019

Class code	Name	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
2.3	Bulk stockfeed/ fertiliser	15	26	17	18	28	10	0	0	114
2.7	Grain storage	1	0	0	0	0	0	0	0	1
3.1	Grain processing	1	0	1	0	0	0	0	0	2

Non-compliance performance rates

The total amount of failed audits for imported stockfeed and grain was 1.1 per cent, with no critical non-compliances recorded (Table 19).

TABLE 19 Audit and compliance status of approved arrangement sub-classes 2.3 and 3.1, 2017–18

Audit and compliance details	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
Arrangements	18	27	18	20	28	10	0	0	121
Total audits	35	60	47	50	59	21	0	0	272
Failed audits	0	1	2	0	0	0	0	0	3
Critical non-compliances	0	0	0	0	0	0	0	0	0
Major non-compliances	5	23	25	11	10	3	0	0	77
Minor non-compliances	2	10	8	5	8	0	0	0	33

Chapter 7

Cargo and biosecurity waste treatment—classes 4, 8 and 10

7.1 Purpose and functions of sub-classes

Class 4 AA sites are sites used for the treatment and/or cleaning of goods, containers and packaging material that are subject to biosecurity control. There are six sub-classes (Table 20).

TABLE 20 Class 4 approved arrangement sub-classes

Class code	Permitted treatment
4.1	Heat treatment
4.2	Gamma irradiation
4.3	Cleaning
4.4	Seed cleaning
4.5	Ore treatment
4.6	Fumigation

7.2 Case study: fumigation—sub-classes 4.6, 12.1 and 12.2

Fumigation with methyl bromide, and latterly with sulfuryl fluoride, is a key means of dealing with insect pests in many goods, both commodities like cut flowers and fresh produce, and non-agricultural products with hitchhiker pests.

Class 4.6—Fumigation sites are AA sites used for the fumigation of goods subject to biosecurity control and are not approved for any other biosecurity operations, except where the site has separate approval under another class. The majority of AAs in this class are located in Victoria (36 per cent) and Queensland (23.5 per cent) (Table 21).

The number of entities holding a class 4.6 approval increased rapidly from 14 in December 2017, to 58 in June 2018, up to 300 in December 2018, and remained at 299 in June 2019 (Appendix B). This was presumably due to extra need for more onshore fumigation of more types and consignments of cargo due to BMSB measures, as well as other departmental requirements.

TABLE 21 Distribution of approved arrangements for fumigation, July 2019

Class code	Name	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
4.6	Fumigation	57	109	74	28	16	9	3	3	299
12.1	Methyl bromide fumigation	9	9	14	4	6	1	1	0	44
12.2	Sulphuryl fluoride fumigation	1	3	2	1	3	0	0	0	10

On 30 July 2018 the department updated conditions to replace fumigation area specific conditions with the requirements of the Australian Fumigation Accreditation Scheme (AFAS) methyl bromide fumigation standard, to ensure consistency in conditions across affected classes.

Class 12.1 and 12.2 Fumigators—Fumigation of goods subject to biosecurity control must only be performed by accredited fumigators operating under AA class 12.1 or 12.2. Class 12.1 was previously called ‘Fumigation’ and referred only to methyl bromide fumigation.

On 5 September 2018 the department announced the new class 12.2–Sulphuryl fluoride fumigation. On 10 September 2018 the department changed the class 12.1 name from onshore fumigation to methyl bromide fumigation.

Fumigator training, accreditation and licensing

Fumigator AA holders must be accredited by the department to conduct fumigation treatments. The accreditation training is delivered by either an approved third-party provider or by departmental staff.

The department’s Audit and Assurance Group conducts audits to verify that the staff conducting fumigations:

- are accredited by the department
- hold a fumigator’s licence issued by the state/territory they are in, and
- are complying with the conditions of the AA, including complying with the correct fumigation methodology.

Competency of the company personnel acting under the AA is not actively managed other than through audit, and is determined through interviewing accredited personnel, observing fumigations and examining fumigation records.

There is no national standard for a fumigation licence as all states and territories have separate requirements. For example, in NSW fumigators must hold a licence issued by the Environmental Protection Agency, while other states have different requirements.

There is a clear need to strengthen the regulation of onshore treatment providers and have consistent treatment methodologies across AAs. Moving towards the departmental methyl bromide fumigation methodology nationally is a good start. However it will also require a nationally consistent competency based training, assessment and qualification for the national accreditation and licensing of biosecurity treatment providers.

Recommendation 8

The department, in consultation with state and territory agencies, should consider developing nationally consistent competency based training, assessment and qualification for accreditation and licensing of biosecurity treatment providers.

Non-compliance performance rates, instances and consequences

There are 42 class 12.1 AAs operating across Australia. Between February 2016 and February 2019, 36 per cent of audited class 12.1 AAs recorded critical non-compliances. Of these, almost half have had repeated non-compliances resulting into suspensions of two sites.

From October 2018 the department undertook unannounced audits on eight class 12.1 AAs due to alleged circumvention of fumigation conditions. The audits included both on-site observation of activities and a desktop review of treatment records with significant non-compliances identified. The majority of incidents related to failure to comply the correct fumigation procedure. Since AAG began unannounced audits, all sites recorded critical non-compliances.

Non-compliance by offshore fumigators was highlighted during the 2018–19 brown marmorated stink bug (BMSB) season. The IGB's review of the *Management of the biosecurity risks of BMSB entering Australia* noted non-compliance from offshore and onshore operators, as well as methodology inconsistencies between domestic operators. The department has tried to improve offshore fumigation by promoting an Australian Fumigation Accreditation Scheme to key suppliers of risk goods, and working with New Zealand to harmonise technical standards.

However, tighter management of the AAs offering onshore fumigation of imports is needed. High levels of non-compliance must be addressed both by more effective regulatory action and by increasing and verifying requirements for training and more efficient processes and equipment such as automated data logging. Harmonisation of requirements for fumigation for import, export and interstate movement is also needed.

Chapter 8

Biocontainment for research, live plants, and live animals—classes 5, 6 and 7

8.1 Purpose and functions of sub-classes

The department approves commercial, private and government sites for the purposes of holding certain types of material subject to biosecurity control. To gain this approval there are both containment and procedural conditions that must be met.

Class 5 AA sites are used for research, analysis and/or testing of imported biological material including micro-organisms, animal and human products and soil. This class has four sub-classes (Table 22), and includes microbiological facilities, animal facilities and plant laboratories, whether integral or separate to the site. The department requires that all class 5 AAs sites conducting biosecurity containment activities must comply with:

- the design and construction aspects of the Australian/New Zealand Standards AS/NZS 2982.1:1997 (Laboratory Design and Construction), and
- AS/NZS 2243.3:2002 (Safety in Laboratories).

To determine if sites have met these Standards, a department-approved third-party assessor assesses the sites against the relevant standards. At June 2019, there were nine approved assessors.

There may be merit in simplifying the issuing, and subsequent administration and auditing, of different arrangement approvals at the same institution. For example, NSW Department of Primary Industries' Elizabeth Macarthur Agricultural Institute holds ten separate class 5.2 AAs for containing low to moderate risk goods, all different rooms within the one laboratory block for microbiological diagnosis and research; and two class 5.3 AAs for containing goods with significant biosecurity risk in the east and west sections of the higher security virology block.

Class 6 AAs are sites used for the post-entry quarantine of live plants—nursery stock such as aquatic plants, bulbs, seed lines, and cuttings and for process management at these sites. Class 6 has three sub-classes (Table 22).

Class 7 AAs are used for holding imported animals, with seven sub-classes for different types of animals (Table 22). Some of these subclasses may be subsumed into class 5.

TABLE 22 Distribution of approved arrangements sites, classes 5, 6 and 7, July 2019

Class code	Name	NSW	Vic.	Qld	SA	WA	Tas.	NT	ACT	Total
5.1	BC1 Containment of low hazard goods	1	0	4	1	0	0	0	0	6
5.11	BC1 microbiological	150	112	35	45	67	19	2	7	437
5.12	BC1 animal and aquatic	25	7	5	6	4	1	0	0	48
5.14	BC1 Plant facility	6	10	4	1	5	1	0	0	27
5.141	BC1 Plant aquatic facility	0	0	0	0	1	0	0	0	1
5.142	BC1 Plant rose scion wood	0	2	0	0	0	0	0	0	2
5.2	BC2 Containment of low to moderate risk goods	55	128	111	37	19	17	5	4	376
5.3	BC3 Containment of goods with significant risk	2	8	17	0	2	0	1	1	31
5.4	BC4 Containment of goods with life-threatening risks	1	2	0	0	0	0	0	0	3
6.1	Medium risk nursery stock in plant house, glasshouse, poly house/tunnels	4	4	5	8	7	3	0	11	42
6.11	Bulbs in open fields	5	43	10	7	6	6	0	0	77
6.7	Plant process management system	4	2	2	2	3	1	0	2	16
7.10	Fertile poultry hatching egg facility—holding of fertile eggs and stock	0	0	0	0	0	0	0	0	0
7.1	Ornamental fin fish – holding of live freshwater and marine fin fish	14	9	7	1	4	0	0	0	35
7.12	Horses-isolation, examination and testing of imported horses	1	3	0	0	0	0	0	0	4
7.2	Biosecurity insectary containment level 2	3	7	7	0	1	0	0	1	19
7.3	Biosecurity insectary containment level 3	1	2	5	0	0	0	0	1	9
7.5	Laboratory rodents	10	8	11	6	6	0	0	2	43
7.6	Laboratory xenopus	3	1	1	1	0	0	0	1	7
7.7	Laboratory fish	1	2	1	0	1	6	0	0	11
7.8	Defence & police dogs returning from overseas	1	0	1	0	1	0	0	1	4
7.9	Zoo animals—Isolation, examination and treatment of imported zoo animals	11	2	5	3	1	2	0	3	27
Total		298	352	231	118	128	56	8	34	1,225

8.2 Complex technical and governance issues

Classes 5, 6 and 7 AAs may be highly technical and specialised as they are designed to receive and handle often hazardous and high-risk importations (such as pathogens, diseases and viruses for scientific study and research purposes). They are often subject to extra complex safeguards and standards, including regulation by other government agencies, such as the Office of the Gene Technology Regulator, or the Therapeutic Goods Administration, as well as biosecurity controls. A range of international, national and state-based rules may apply.

Due to the different animals, plants, pests and pathogens which they may handle, different sections of the department with specialised scientific knowledge may need to oversight different facilities, as discussed in Chapter 9.1 of this report. A fuller review of the department's management of these AA classes is needed but is beyond the scope of this current review.

Chapter 9

Overall improvements needed

9.1 Biosecurity risk owners

The department considers certain areas of its divisions, branches or sections to be 'biosecurity risk owners' for certain imported goods. These risk owners are responsible for determining the biosecurity risk and the controls that must be applied to goods to effectively manage these biosecurity risks, including import permit and AA conditions.

There are clear risk owners for plant-, animal- or microbial-related imports in Biosecurity Plant or Animal Divisions, with further delegations to various branches or sections for development of import conditions, and for onshore management of specific risks through different AA classes.

For example, Plant Import Operations (PIO) branch is the risk owner for class 6 AAs handling live plant imports, while Animal and Biological Imports (ABI) branch is the risk owner for most class 7 AAs which handle live animal imports. An exception is for insectaries, where PIO may be involved with AAs handling insects of potential plant biosecurity risk, while ABI is involved with AAs handling bees, and insects of potential animal or human biosecurity risk. These branches are also the risk owners for subclasses or facilities in classes 2–General cargo, 3–Processing and 5–Biocontainment, that solely handle commodities posing specific plant or animal biosecurity risks. Risk owners in Plant Division also develop and own BICON cases for timber packaging and unacceptable packaging.

Biosecurity Plant and Animal Divisions may be joint risk owners of imports that could imperil plant or animal biosecurity, such as stock feeds, in terms of setting import conditions and overall pathway oversight. However, Plant Import Operations branch is the risk owner for the onshore management of imported stockfeed through AA classes 2.3–Bulk stockfeed, 2.7–Grain storage, 3.0–Produce processing and 3.1–Grain processing. Plant Import Operations also intends to review and update existing conditions for 27 of the 39 facilities in class 3–Produce processing.

The roles and responsibilities of Plant and Animal Division biosecurity risk owners in regard to these different AA classes may include:

- contributing to the development of AA class conditions
- assessing and approving AA locations and operation manuals and process management system documents for some commodities
- granting import permits with specific conditions to individual AA holders
- providing technical expertise to AA section and/or AA holders, and
- jointly undertaking occasional audits of AAs alongside Audit Group staff or providing technical advice to Audit Group staff.

Identifying a biosecurity risk owner for a class of AAs is an important step toward ensuring that the performance of a class of AAs in managing specific biosecurity risks can be assessed over time, by appropriate verification measures, and that appropriate responses to non-compliance can be developed and implemented in a timely manner.

The drive to standardise AA class conditions where possible, for administrative simplicity, must be balanced against the necessity of imposing specific conditions for AAs managing certain specific risks. In some cases, risk management measures are incorporated in import permits rather than class conditions, but this may lead to the specific biosecurity risk not being addressed in the future when the import permit expires. Conversely, there may be significant impracticalities associated with an approach of including import conditions in the AA for every commodity that may be imported and dealt with under the AA.

However, there are no defined biosecurity risk owners for classes of AAs dealing with some broader non-commodity risks or for the oversight of providers of treatments, such as fumigation, which may be technically complex. The roles of sections of Compliance or Biosecurity Operations divisions (for overseeing treatment providers or general onshore risk management sites and processes) are less well defined. The department already uses technically or practically competent staff in these Divisions to provide input to AA class condition development, periodic risk-based auditing and oversight of performance of these AAs in managing the identified biosecurity risks. Arguably, the department should identify responsible sections in these divisions as the biosecurity risk owners for each AA class and sub-class which do not already have a designated risk owner.

For example, a Broker group within Compliance Division's Legislative Reform and Assessment Policy (LRAP) section manages the class 19 and class 38 broker arrangements, and also provides regular Continued Biosecurity Competence training for brokers to maintain their accreditation. This group of staff oversees the compliance of brokers with documentary requirements through the broker accreditation scheme, but does not get regular reports about practical verification or non-compliance detected through the Cargo Compliance Verification scheme.

Another group within the LRAP section oversees both offshore and onshore standards, schemes and providers for fumigation and other treatments, and effectively operates as the owner of the biosecurity risks related to fumigation and other treatments. Departmental onshore and offshore risk owners need to be the same for this specialised function. Review is also needed by biosecurity risk owners of current AA requirements for treatment providers to reference treatment methodologies and standards across all classes where treatments occur to ensure consistent and auditable application, and to promote technical innovation.

Biosecurity Operations Division (BOD), particularly the Inspection Group, has the greatest regular oversight of the performance of many more general AA classes that deal with multiple cargoes, such as class 1 and 2 depots, and generic onshore processes such as cleaning and biosecurity waste management. Their greater experience in dealing with practical issues associated with these sites and classes warrants them being given greater responsibility in customising the class condition documents to be easily understood and workable by the different AA holders, and better able to be audited against. This may warrant certain sections or groups in BOD being designated as the biosecurity risk owners for certain AA classes.

The network of biosecurity risk owners is not transparent and needs better definition.

Recommendation 9

The department should develop a comprehensive list of biosecurity risk owners for all classes and sub-classes of approved arrangements and clarify their roles and responsibilities with respect to the different approved arrangement classes.

The role of biosecurity risk owners in auditing certain AA classes, and providing prompt advice when required on actions needed to manage critical non-compliance, also warrants better definition.

Some audits are conducted by the biosecurity risk owners. For example, audits of class 7.12–Horse importation AAs are conducted by departmental veterinarians in Animal and Biological Imports branch due to the complexity of technical aspects of the biosecurity risk management.

In other cases, biosecurity risk owners may initially or periodically attend audits in collaboration with the departmental auditors. Class 6.7 is for the approval of sets of operating procedures, known as Process Management Systems, for post-entry quarantine sites used for the growth and release of high- and medium-risk live plants, including seeds and some nursery stock. Class 6.7 is linked to physical AA sites (generally classes 5.1, 5.2 and 6.1) in which the activities outlined within the class 6.7 operating procedures may be performed. Plant Import Operations branch develop these often complex systems and attend audits of some AAs using them. However, they may never be involved with audits of other AAs in classes 5.14–Biocontainment level 1 plant facilities, 6.1–Medium risk nursery stock, or 6.11–Bulb grow-out facilities, for which they are the risk owner, even though, if there is a serious problem at such an AA, it may come back to them to resolve or recommend on.

When possible, the risk owners of different AA classes should periodically conduct or attend audits alongside Audit Group staff to verify that the class conditions are still appropriate and that the AA is effectively managing the biosecurity risks addressed by the AA class.

Recommendation 10

The department's approved arrangements' biosecurity risk owners should periodically attend audits to verify that the class conditions are still appropriate and that the approved arrangement is effectively managing the biosecurity risks addressed by the approved arrangement class.

The department's auditors use the department's Biosecurity Import Conditions (BICON) database to determine which directions and biosecurity activities are to be applied to the specific commodity. The exports model is very similar in that there are multiple activities conducted however rather than have classes manage each activity, registered operations are applied based on what the operator has scoped into their operation or AA manual based on a set of controls appropriate to operations.

The current AA regulatory framework does not compel the entity to have an active approach to managing biosecurity risk themselves, as this is only done through audit. This contrasts to the requirements for export AAs that require the entity to have clear management control over their system. Manuals and standard operating procedures (SOPs) are not required or audited against for biosecurity AAs unless the risk owner has identified this as a requirement such as for live horses, birds and imported grain. This approach should be considered more broadly by biosecurity risk owners once defined.

Recommendation 11

The department should audit against approved arrangements' standard operating procedures where the biosecurity risk owners determine that there is a high level of technical or specialised class conditions that require standard operating procedures for biosecurity risk management.

9.2 Better management of non-compliance

Timely management of biosecurity risk

Departmental officers sometimes need the ability to suspend operations of an AA immediately when a critical non-compliance has been identified.

Section 429 of the Act provides wide-ranging power to biosecurity officers to manage non-compliant situations, including the power to direct an AA holder to not carry out an activity in accordance with their approved arrangement. However, while the Biosecurity Act allows arrangements to be immediately suspended or revoked if the Director of Biosecurity is satisfied that the grounds for revocation or suspension are serious or urgent, prescriptive legislative process requirements in the Act in relation to suspension and revocation of arrangements make it very difficult to take immediate action on critical non-compliance.

Currently, various departmental groups may make decisions and take actions on identified non-compliance by individual AAs in isolation from one another. This lack of co-ordination can result in confusion and incompatible legal decisions being made in the absence of all relevant information, sometimes compromising the department's ability to take decisive action when necessary. The department should clarify the roles and responsibilities of each group such that there is no overlap, duplication, or inconsistency, and review the policy and instructional material that supports each departmental group in delivering work outputs.

There is an urgent need to develop better policies, processes and training, to enable biosecurity officers to manage and respond to critical AA non-compliance promptly but fairly and consistently. It is equally important that officers are trained in correct evidence gathering to ensure immediate suspensions can be justified.

The department should consider policy to apply direct penalties for serious non-compliance and impose administrative sanctions or on-the-spot fines for less serious non-compliance.

Recommendation 12

The department should develop more effective policies, processes and instructional material to manage critical non-compliance at an approved arrangement, including clarifying processes for suspension or revocation of its approval, as well as contingency response plans for such eventualities, and timely sanctions for less serious non-compliance.

9.3 Import and export governance framework

The department administers and regulates many activities and entities under the *Biosecurity Act 2015*, the *Export Control Act 1982*, and the *Imported Food Control Act 1992*. Some entities are approved arrangements for both imported and exported goods. The department is aligning and harmonising its responsibilities across these three separate acts. The scope of this work is wide-ranging and includes alignment of various internal and external policies, processes, conditions, systems and documents.

On 31 October 2018, the department finalised the Import and Export Arrangements Framework. This framework is the department's formal policy position for consistency in the development, implementation and governance of approved arrangements. The framework provides transparent processes to ensure all import and export arrangements meet appropriate standards of governance, risk management and assurance. It is used when the department considers establishing any new arrangements. Current arrangements are assessed against the framework over time.

Export registered establishments (EREs) are audited against *Export Control Act 1982*, policies and Approved Arrangement Manuals (standard operating procedures). Biosecurity AAs are audited against policies and conditions. One set of audit criteria outlining key elements or outcomes to be met should be applicable to all audits.

For example, all Food Import Compliance Agreements (FICA) are audited against a list of outcomes regardless of size or nature of the business.

The department's import and export audit policies regarding audit rates or frequency do not align, which delays the scheduling process and can result in the same client/premise being audited multiple times during the year. Similarly, the audit terminology and audit sanctions rates differ across imports and exports, as do the prescribed consideration period timeframes for new applications.

In addition, current IT systems need to facilitate information sharing across import and export functions to facilitate compliance and identify issues across both pathways.

In the longer term, it will be important to ensure that alignment of some aspects of the department's work do not yield more complex coordination and governance overheads, or introduce expedient compromises that could undermine the effectiveness of the department's regulatory performance across its portfolio responsibilities.

9.4 Integrating information management systems

Due to the complexity of the system of approved arrangements and the many touchpoints approved arrangements have with the department, the department relies on many in-house and external information technology (IT) platforms, systems and information management tools to support different aspects of management of approved arrangements. Key areas and platforms include:

- AA Application processing and administration, changes and variations—AA Online Application, Quarantine Premises Register (QPR)
- Training and accreditation—Guardian
- Audits—AAG Scheduler spreadsheet, Audit NSD monthly spreadsheet
- Compliance, sanctions management and enforcement—iCAR, JADE/Investigator
- Performance reporting—Hyperion, App Tracker and Excel spreadsheets such as Monthly snapshot spreadsheet, Result Pending Report spreadsheet, Daily Report and Weekly Report
- Cargo and importation of goods—Integrated Cargo System (ICS), Biosecurity Import Conditions database (BICON), Permits system, Agriculture Imports Management System (AIMS), Mail and Passenger System (MAPS).

Many of these systems have outlived their usefulness and need renovation or linkage.

Improved AA Online Application system

The primary information system used by the department's AA section for the registration, maintenance and management of approved arrangements is the Quarantine Premises Register (QPR) database—a legacy system developed years ago to administer arrangements under the Quarantine Act.

Despite numerous changes and the introduction of supporting applications and IT workarounds, QPR became less fit for purpose in managing intricacies of the new provisions of the Biosecurity Act after 2016. Importantly, QPR did not manage workflows nor provide 'point-in-time' historical information.

Many former problems around complexity, duplication and administrative burden still remained under the Biosecurity Act. For example, an AA holder with 44 AAs would be contacted 44 times regarding a change to class conditions made by the department. Similarly, a AA holder who would like to apply to vary their arrangements would be required to apply to vary them all individually, even if they would like to do the same thing at all AAs.

Prescriptive and restrictive class conditions led to a high number of variation applications being received from AA holders when their equipment, processes or procedures did not adhere specifically to these conditions. This also applied to new applications; any proposed arrangement not adhering specifically to the class conditions, had to apply for 'non-standard' conditions, involving further admin by both the applicant and the department. Conversely, less prescriptive conditions risk ambiguity and a loss of auditability and enforceability.

Other problems with the old systems included:

- limited linkages between import and export systems to inform audits of importer/exporter businesses
- difficulties interrogating systems to obtain information needed to prepare for an audit
- no support for automated alerts to prompt reviews after an AA failed an audit, and
- no end-to-end approved arrangement management.

Departmental auditors noted that reporting audit findings using automated online systems would reduce the amount of time they spent on administration, enabling them to spend more time at AA sites observing processes.

To address these and other issues, in July 2018 the department's Biosecurity Integrated Information System (BIIS) Program launched a new Approved Arrangements pilot—to develop a suite of systems to replace QPR and provide additional processing capabilities. The AA pilot impacted five users directly and delivered foundational capabilities that could be extended, for example, to include AA broker assessment.

BIIS's AA project assumes a very broad definition of approved arrangements, including arrangements undertaken by third parties in relation to agreed activities usually conducted under biosecurity, imported food or export legislation; and agreements with overseas governments and entities to perform biosecurity risk mitigation activities.

The project aims to improve business processes and better support a risk-based approach to biosecurity management, by ensuring data from border operations, audit results and other intelligence sources are integrated and analysed to inform evidence-based decision making.

It is achieving these aims by delivering workflow support for assessments and audits of AAs, to eliminate over 100 manual process steps and remove the need for multiple databases and manual workarounds. This should lead to improved timing of AA application processing, allowing for resource redistribution and automation of risk controls.

A fully integrated IT system should include an online audit system to allow departmental auditors to focus on high value audit activities rather than manual administrative tasks, and an online reporting system to capture information and evidence from departmental inspectors and approved arrangements.

Integration of the complete end-to-end AA workflow, due for completion by October 2019, will provide opportunities to show when different departmental groups are in the process of making both legislative and administrative decisions regarding individual AAs, or taking action in regard to identified non-compliance, and hopefully assist in improving communication and responding in a co-ordinated manner across the department. Appropriate departmental implementation of this improved workflow, and further development of the workflow tool, should be expedited.

Better information systems can support better internal and external communication, but must be designed with the aim of providing clear, relevant and timely information back to those who are trying to manage risks on the ground, as well as those framing policy or managing compliance. Frontline user needs should be identified and prioritised in system design. It will be important to provide robust internal and external reporting tools, which allow biosecurity risk owners and frontline staff, as well as AA operators, timely access to relevant information which they need to verify that AAs are managing biosecurity risks effectively.

Recommendation 13

The department should further develop integrated information technology systems to provide reliable and efficient end-to-end management of approved arrangements, including an online audit recording system, online reporting of approved arrangement biosecurity risk management and robust internal and external reports verifying their performance.

9.5 Clearer communication about approved arrangements

The content and recommendations in this review are intended to support better understanding of the approved arrangements system by the departmental staff who administer it, the many private and public entities who hold AAs and thus become 'biosecurity industry participants', and the wider industries and public whom they serve.

Due to the complexity of the system, many departmental groups have roles to play in operating it. Progressive clarification of these roles and responsibilities must be undertaken collaboratively, while identifying gaps and duplications in work processes and streamlining them to improve efficiency and co-ordination.

A culture of better dialogue and mutual respect between the different biosecurity risk owners, the frontline staff actually interfacing with AA holders and their staff, and the various sections of Compliance Division must be fostered—not easy when all groups are under tremendous resourcing and time pressures, which can lead to frustration and disempowerment. Better communication can help overcome this.

The department's progressive revision of AA class conditions, to make them clearer and prioritise biosecurity risk management, should improve communication with AA holders and applicants. This should supplement and strengthen existing departmental communication via industry notices and emails targeting specific AA class groups, activities and industries, and broader consultation with a wide range of stakeholders.

Chapter 10

Conclusion

Approved arrangements are an indispensable part of Australia's biosecurity system, allowing thousands of specialised businesses employing tens of thousands of people to participate in effective management of the biosecurity risks associated with incoming goods. As trade volumes and global biosecurity threats increase, pressures on the approved arrangements system and its management by the department will also grow.

The AA system is vast in geographic distribution and technical complexity, and difficult to maintain. No one in the department has full oversight of all aspects of the system.

Ongoing streamlining of the systems for classifying and managing AAs is necessary, but central administrators must never lose sight of the different biosecurity risks being managed by different classes of AAs. More clarity about specific risks and their management by AA classes will help both private and public AA holders better understand and fulfil their roles. Greater involvement of technically and practically competent staff in overseeing different AA classes will be needed to ensure that key risks continue to be effectively targeted. Further in-depth reviews of certain classes of AAs are warranted.

Many AA operators have little incentive apart from business continuity to fully apply required biosecurity risk management measures. Unannounced audits, especially of busy facilities and those handling high-risk goods, must be increased, and a range of prompt and effective sanctions implemented for different levels of non-compliance. A greater role for frontline biosecurity officers and biosecurity risk owners in monitoring, reporting and taking action on non-compliance in between audits must be developed. Targeted verification programs for different aspects of border biosecurity risk management must be strengthened.

Better capture and analysis of data verifying the actual performance of biosecurity risk management measures by AAs is needed. This will allow clearer performance reporting and both internally across the department and externally to AA operators, their many representative organisations, and other industry and government stakeholders.

Ongoing emphasis on clearly seeing how different parts of the system function, and encouraging continuous improvement in processes to make them less bureaucratic and more effective, will be challenging but essential.

Appendix A

Agency response



Australian Government
Department of Agriculture

SECRETARY

Dr Helen Scott-Orr
Inspector-General of Biosecurity
PO Box 657
MASCOT NSW 1460

Dear Dr ^{Helen}Scott-Orr

Thank you for providing me with your review report, *Effectiveness of Approved Arrangements in Managing Biosecurity Risks in Australia*.

The department agrees with the recommendations of the report and I am pleased to advise that work has already commenced to implement responses to the recommendations.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Daryl Quinlivan'.

Daryl Quinlivan

24 July 2019

Department of Agriculture and Water Resources responses to recommendations

Recommendation 1

The department should clearly describe the specific biosecurity risks that need to be addressed by each class of approved arrangements in the *Purpose* section of the class Conditions document, and ensure that the specified conditions clearly manage that risk.

Response:

Agreed.

The department will review each class of approved arrangements to ensure the biosecurity risks to be addressed by that class are included in the Purpose section of the class requirements document, and that the conditions remain appropriate for the management of those risks.

Recommendation 2

The department should develop a database of accredited persons at approved arrangements, which can be updated by approved arrangement holders and accredited person trainers and accessed by departmental staff.

Response:

Agreed.

The department currently maintains a register of accredited persons operating under the broker approved arrangements, and the training organisations approved to deliver training that contributes to continued proficiency requirements.

The department is also currently reviewing the policy that underpins administration of the accreditation system for non-broker accredited persons. This review will ensure greater rigour exists in the management of accredited persons including, but not limited to, creation and maintenance of a database of all accredited persons, identification of the AA holder that the accredited person performs biosecurity activities on behalf of, policies for the granting, as well as revocation of accreditation and for re-training.

Recommendation 3

The department should implement a program of unannounced, randomly timed and risk-based audits of approved arrangements, rather than scheduled and announced audits, wherever possible.

Response:

Agreed.

The department is currently reviewing its risk-based framework for audit scheduling in order to ensure that compliance monitoring is commensurate with risk. The review will include consideration of additional risk factors for incorporation into compliance monitoring policy as well as review of the types and frequency of compliance monitoring.

The department's current compliance monitoring schedule focusses on AA holders considered to be of highest risk; specifically those newly approved, those for which approval to carry out additional biosecurity activities has recently been given, and those that have had non-compliance detected. The department has recently increased the number of unannounced audits as a proportion of the total number of audits conducted, and will continue to increase randomly timed unannounced audits as part of the audit program of approved arrangements, where possible.

The department is currently reviewing the compliance monitoring policies to ensure they remain fit for purpose and reflect suitable audit frequencies and flexibility.

Recommendation 4

The department should implement a verification program to ensure that departmental policies on the detection and management of non-compliance at approved arrangements are being followed and remain effective and appropriate.

Response:

Agreed.

The department will review its verification activities to ensure that activities relevant to the detection and management of non-compliance are performed in accordance with relevant and appropriate policies and instructional material.

The department will also commence a review of the existing verification program applied to the compliance monitoring of non-broker approved arrangements to ensure it continues to provide adequate assurance of the effectiveness of compliance monitoring processes.

Recommendation 5

The department should develop guidelines and training for Inspection Group staff to oversight approved arrangements' implementation of class conditions and biosecurity risk management throughout the year to supplement the audit process and improved compliance.

Response:

Agreed.

The department will seek to enhance Inspection Group staff knowledge of the conditions to which approved arrangements are subject through adoption of a more formal and structured process to that which is currently in place.

Recommendation 6

The department should develop an easy-to-use digital or app-based reporting system connected to departmental information systems for use by approved arrangements staff and departmental inspectors to record and report details of any biosecurity risk material detections or inspections.

Response:

Agreed.

The department will investigate opportunities to enhance the efficiency of systems for approved arrangement holders and biosecurity officers to record and report details of any biosecurity risk material detections. In particular, the department will look to the current progress and the future opportunities provided through the BIIS program to provide efficient data capture of biosecurity risk detections.

Recommendation 7

The department should adopt a whole-of-supply-chain approach to some commodity-based import approved arrangement pathways such as those handling imported pig meat, to improve on-shore traceability, and minimise leakage at any stage.

Response:

Agreed.

The department applies a whole-of-supply-chain approach to suitable commodity-based import approved arrangement pathways to minimise the potential for leakage of biosecurity risk. The department implements various compliance monitoring processes for tracing goods subject to biosecurity control across entity boundaries, ensuring maintenance of biosecurity controls and regulatory compliance.

The department also routinely conducts end-to-end verification and assurance activities to ensure that the regulatory controls are operating effectively.

Recommendation 8

The department, in consultation with state and territory agencies, should consider developing nationally consistent competency based training, assessment and qualification for accreditation and licensing of biosecurity treatment providers.

Response:

Agreed.

The department, through the National Biosecurity Committee, is currently progressing work to harmonise state, territory and federal approaches to the regulation of biosecurity treatment providers. This includes standardising training requirements, coordinating targeted regulatory operations, enhanced information and intelligence sharing, and coordinated non-compliance response activities. In the work already underway to strengthen the management of accredited persons operating within approved arrangements, the department will also be improving processes governing the issuance of accreditation, integrity assessments and non-compliance responses.

Recommendation 9

The department should develop a comprehensive list of biosecurity risk owners for all classes and sub-classes of approved arrangements and clarify their roles and responsibilities with respect to the different approved arrangement classes.

Response:

Agreed.

The department will develop a list of internal biosecurity risk owners – areas responsible for identifying risks and risk controls – associated with classes and sub-classes of approved arrangements.

Recommendation 10

The department's approved arrangements' biosecurity risk owners should periodically attend audits to verify that the class conditions are still appropriate and that the approved arrangement is effectively managing the biosecurity risks addressed by the approved arrangement class.

Response:

Agreed.

Biosecurity risk owners currently attend audits ad hoc or as a matter of standard process, depending on the class of approved arrangement. The department will continue to ensure that biosecurity risk owners attend audits as part of their verification and assurance processes.

Recommendation 11

The department should audit against approved arrangements' standard operating procedures where the biosecurity risk owners determine that there is a high level of technical or specialised class conditions that require standard operating procedures for biosecurity risk management.

Response:

Agreed.

The department currently audits against standard operating procedures where the biosecurity risk owners have determined these documents are necessary. The department will continue to operate in accordance with this principle and be considered more broadly by biosecurity risk owners.

Recommendation 12

The department should develop more effective policies, processes and instructional material to manage critical non-compliance at an approved arrangement, including clarifying processes for suspension or revocation of its approval, as well as contingency response plans for such eventualities, and timely sanctions for less serious non-compliance.

Response:

Agreed.

As part of strengthening our regulatory practice the department is currently reviewing our powers and policies to manage the biosecurity risks of critical or major non-compliance by approved arrangements in a timely manner.

Recommendation 13

The department should further develop integrated information technology systems to provide reliable and efficient end-to-end management of approved arrangements, including an online audit recording system, online reporting of approved arrangement biosecurity risk management and robust internal and external reports verifying their performance.

Response:

Agreed.

As part of the department's integrated information technology systems upgrades, particularly through the BIIIS program, we will include functionality to provide reliable and efficient end-to-end management of approved arrangements, including robust reports verifying their performance.

Appendix B

Approved arrangement classes

A list of approved arrangement classes, by states and territories

Class code	Name	Jul 2017	Dec 2017	Jun 2018	Dec 2018	Jun 2019
1.1	Sea and air freight depot (unrestricted)	45	45	44	41	41
1.2	Air cargo terminal	35	35	36	38	40
1.3	Sea and air freight depot (restricted)	435	429	428	436	442
2.1	Non-agricultural products	72	64	66	63	61
2.2	Agricultural products	597	603	611	607	606
2.3	Bulk stockfeed/fertiliser	116	119	120	117	114
2.4	Fresh fruit, vegetables & cut flowers	43	44	43	44	48
2.41	Verification of packaging for airfreight perishables	0	15	19	21	25
2.5	Temperature controlled storage	220	226	224	228	228
2.51	Temperature controlled storage of specified baitfish	26	28	28	24	24
2.52	Temperature controlled storage of imported pig meat	39	41	40	41	41
2.6	Empty shipping container parks	30	30	30	30	29
2.7	Grain storage	6	6	5	5	6
2.8	Temporary storage of containerised refrigerated pig meat	11	11	11	11	11
3.0	Produce processing	35	37	38	38	39
3.1	Grain processing	6	6	5	5	5
3.2	Imported pig meat processing facility	27	27	27	27	27
3.3	Imported uncooked prawn product processing	0	2	2	2	1

Class code	Name	Jul 2017	Dec 2017	Jun 2018	Dec 2018	Jun 2019
4.1	Heat treatment	19	19	19	18	19
4.2	Gamma irradiation	5	5	5	5	5
4.3	Cleaning	24	46	87	191	140
4.4	Seed Cleaning	12	12	12	12	12
4.6	Fumigation	14	14	58	300	299
5.1	Biosecurity containment level 1 (BC1)	481	468	9	10	6
5.11	(BC1) Microbiological facilities	0	24	444	443	437
5.12	(BC1) Animal & aquatic facilities	0	6	39	43	48
5.14	(BC1) Plant facilities	0	0	39	37	27
5.2	Biosecurity containment level 2	384	377	376	375	376
5.3	Biosecurity containment level 3	33	32	32	31	31
5.4	Biosecurity containment level 4	4	4	3	3	3
6.1	Medium risk nursery stock	81	72	45	44	42
6.11	Bulbs	83	80	82	80	77
6.2	Aquatic plants	1	1	0	0	0
6.3	Rose scion wood for budding	4	3	2	2	2
6.7	Plant process management	0	16	16	16	16
7.1	Ornamental fin fish	43	42	43	39	35
7.1	Fertile poultry hatching eggs	1	1	1	1	1
7.12	Horses	3	4	4	4	4
7.2	Biosecurity insectary containment level 2	22	19	19	20	19
7.3	Biosecurity insectary containment level 3	9	9	9	9	9
7.5	Laboratory rodents	42	42	43	43	43
7.6	Laboratory xenopus	9	9	9	8	7
7.7	Laboratory fish	11	11	11	12	11
7.8	Defence & police dogs	3	3	3	3	4
7.9	Zoo animals	26	27	28	28	27
8.1	Incineration	5	6	7	7	7
8.2	Deep burial	15	19	18	20	20
8.3	Autoclave	16	18	18	18	17
8.4	Other treatments for biosecurity waste	26	29	8	8	7
10.1	Autoclave treatments	16	1	0	0	0
10.2	Biosecurity waste collection	108	108	111	115	114
10.3	Deep burial treatment	16	1	0	0	0
10.4	Incineration treatments	5	0	0	0	0

Class code	Name	Jul 2017	Dec 2017	Jun 2018	Dec 2018	Jun 2019
10.5	Biosecurity waste storage	71	43	46	47	46
10.6	Biosecurity waste transport	126	124	124	124	118
11.1	Empty container scheme (MT)	2	2	0	0	0
11.2	External container scheme (ECS)	8	9	9	9	8
12.1	Methyl bromide fumigation	43	43	44	47	44
12.2	Sulphuryl fluoride fumigation	0	0	0	0	10
13.1	Second conveyance	0	4	5	3	3
14.1	Nuts and nut products	0	1	1	1	1
14.3	Inspection of air cargo	0	0	0	0	3
19.1	Non-commodity for containerised cargo clearance	0	560	559	571	576
19.2	Automatic entry processing for commodities	0	344	337	356	372

Glossary

Term	Definition
Accredited person	A person who has successfully completed specified training approved by the Department of Agriculture.
Agriculture Imports Management System (AIMS)	Departmental system to control and record importations of goods and commodities of biosecurity concern and store and track associated directions that apply to importations, their movements and treatments.
Approved Arrangement (AA)	A voluntary legislative agreement between the department and another party to carry out specified activities to manage biosecurity risks associated with imported goods.
Biosecurity Import Conditions database (BICON)	The department's repository of conditions that apply to imported goods to mitigate and manage biosecurity risks.
Biosecurity Industry Participant (BIP)	Section 14 <i>Biosecurity Act 2015</i> (approved arrangement holder)
Biosecurity risk owner	Positions or groups within the department who are the ultimate advisers on managing specific biosecurity risks of different commodities, processes or pathways.
Break bulk	Break bulk is cargo that is transported by sea but not in a shipping container or bulk in ship holds. Examples include machinery, vehicles and timber.
FCL	Full Container Load (single supplier – single importer)
FCX	Full Container Load (multiple suppliers – single importer)
Hyperion	An Oracle database query platform used to interrogate QPR information.
Integrated Cargo System (ICS)	Department of Home Affairs system to monitor and track international movement of goods into and out of Australia. The department uses the ICS to refer imported goods into AIMS and highlight selected commodities for intervention.
JADE/Investigator	Departmental restricted access case management system to store and record all information and intelligence relating to criminal allegations and investigations.

Term	Definition
LCL	Less than a container load (multiple suppliers – multiple importers)
Mail and Passenger System (MAPS)	Departmental system to record non-compliance information of international travellers/passengers, and international mail and parcel items, including seizures of non-compliant goods at international first ports of entry or at international ('gateway') mail centres.
Non-commodity	Any article transported to Australia in conjunction with a commodity being imported, such as wooden packing.
Permits system	Departmental database used to store, manage and administer import permits. Many import permits are issued to approved arrangements and biosecurity industry participants.
Quarantine Premises Register (QPR)	Departmental database used to record approved arrangement types, biosecurity industry participant's details, audit results and what biosecurity directions have been activated for a site.
Training	Departmental accredited training required by a person associated with the management of biosecurity risk of an approved arrangement.

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