On 16 June 2016 the Biosecurity Act 2015 (Cth) came into force. This legislation replaced the Quarantine Act 1908 (Cth) which had regulated biosecurity in Australia for over a century. Impetus for the change arose from a number of reviews (the Nairn Report and later Beale Review) into Australia's biosecurity system. These identified systemic flaws that were causing the country to be vulnerable to incursions of foreign pests and diseases through the administration of an archaic regulatory regime. The Biosecurity Act 2015 (Cth) includes new terminology, increased powers for the regulator and additional requirements for industry. The responsible agency, the Department of Agriculture and Water Resources, has stated that the new biosecurity laws are designed to be user-friendly, to be flexible and responsive to changes in technology and future challenges, to remove cluttered and confusing sections of the Quarantine Act 1908 (Cth) and to achieve the difficult balance of making biosecurity regulation risk-based and equipping the regulator with strong enforcement powers while also being economically prudent and supportive of increasing Australian trade and market access. This column analyses such claims, including the short, and long-term implications of providing biosecurity officers with two sets of authorising legislative powers and sharing the responsibility of biosecurity emergencies with the Department of Health.

Keywords: biosecurity; quarantine; Public Health Law; risk-based assessment

INTRODUCTION

The Constitution of Australia provides the Commonwealth legislative power to create quarantine laws through the nationhood power of s 51(ix).1 On 30 March 1908 the Quarantine Act 1908 (Cth) (Quarantine Act) received Royal Assent by the former Governor-General, Lord Henry Northcote. The broad scope of the legislation enabled the Commonwealth to take protection and prevention measures to ensure diseases and pests did not enter and proliferate in Australia.2 Section 2A of the Act established the Australian Quarantine and Inspection Service (AQIS) and initiated the federal takeover of all quarantine stations in Australia from State and Territory hands.3 The Quarantine Act was a milestone for Australia in that it marked the beginning of a national approach to regulate the incursion of biological threats to the country’s people, fauna and flora. However, the legislation was drafted at the beginning of the 20th century when travellers and goods arrived by ship. As such, the focus of the government during this period was to protect Australia from outbreaks of “quarantinable diseases” the likes of bubonic plague, small pox, yellow fever and cholera. In the decades following the early 1900s global trade has gradually increased as economies have grown and along with it, a legacy of biological invasions.4

1 Commonwealth Constitution of Australian Act s 51(xi).
2 Quarantine Act 1908 (Cth) Pt 1 s 4.
3 Quarantine Act 1908 (Cth).

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Being a geographically isolated country, Australia had the opportunity to learn from afar by observing disease invasions placing other nations under significant economic and political strain. Where Great Britain viewed quarantine law as being “anti-commercial, anti-social and anti-Christian”, Australia invested in regulating this area and developed one of the most strictly enforced systems in the world. As Australia grew as a nation and increased its international trade through the 20th century and early 21st century, a number of reviews were conducted to evaluate the efficiency and effectiveness of the quarantine system. The most significant review that led to legislative change and which will be examined in this column, is One Biosecurity (the Beale Review). The Biosecurity Act 2015 (Cth) brought much needed changes to an out of date regulatory system. The new streamlined structure of the legislation is said to provide the regulator with more compliance and enforcement powers while making it easier for people and goods to navigate biosecurity requirements.

This new age risk-based regulatory system needs to achieve a difficult balance. On the one hand there must be adequate restrictions in place to protect Australia from pests and diseases, but on the other hand compliance requirements should not impede the ability and capability to trade with other nations. This column analyses what lead to the largest transformation in the history of Australian biosecurity regulation and the major changes brought in by the new legislation.

**REVIIEWS THAT DROVE CHANGE: AUSTRALIA OUTGROWS THE QUARANTINE ACT**

For those who originally drafted the Quarantine Act, the scale of globalisation of modern trade just was not predictable. In the 108 years following the passage of that Act, however, it was amended almost 60 times by the federal government. This was in response to increasing trade and travel, technological advancements, agricultural expansion and emerging biosecurity threats. Australia’s quarantine regulatory system has been reviewed numerous times and the resulting recommendations generally placed strong focus on streamlining administrative and operational procedure. One of the most important reviews that paved the way for One Biosecurity was the 1996 report titled Australian Quarantine a shared responsibility (The Nairn Report). The establishment of this review committee was in response to mounting public concerns regarding the adequacy of quarantine policy and programs administered by AQIS. This followed a number of highly politicised incursions of exotic pests and diseases in the early 1990s.

The Nairn Report examined the governments quarantine functions as a whole and provided 164 recommendations of which the then Labor government accepted 149. Of those recommendations refused included the establishment of an independent statutory body to oversee the activities of what was then known as the Department of Primary Industries and Energy (now DAWR). Perhaps this was an attempt of industry to reduce red tape through internal oversight. Nevertheless, despite the Nairn Report not being so ambitious as to try and reinvent the legislative wheel, it did lay important groundwork for a major overhaul of Australia’s quarantine regulation. The committee recommended a fresh approach

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6 Maglen, n 5, 197.
8 Quarantine Act 1908 (Cth) Endnote 4 Amendment History.
13 Department of Agriculture and Water Resources, n 12.
14 Department of Agriculture and Water Resources, n 12.
to quarantine that encompassed a range of improvements including staggering regulatory checkpoints at pre-border, border and post-border compliance monitoring stations. Increased consultations with industry and trading countries was encouraged to enable AQIS to address issues offshore during pre-border assessments reducing the likelihood of problematic unchecked people and goods arriving to Australia, being refused entry and then having to be deported.

The Nairn Report also recommended the continuous use and improvement of scientifically based risk analysis to drive a targeted, transparent and cost-effective compliance monitoring programs. It highlighted the need for using databases and information technology to detect import threats, target staff resources to high risk border activities and establish quality assurance arrangements with low risk importers. The improved risk analysis method promoted in the report ultimately comprised of risk assessment, risk management and risk communication. There were also a number of recommendations that bolstered Australia’s international position on quarantine. Although the nation’s quarantine system was already well recognised, the vigilance of Australia’s biosecurity was under fire.

The uptake of the Nairn Report’s recommendations by the Australian Government transformed quarantine regulation for Australia. A decade later an independent review of Australia’s quarantine and biosecurity arrangements was conducted by an eminent four person panel led by former senior public servant Roger Beale. The Beale Review found that Australia’s biosecurity system operated well and is the envy of many countries due to its comprehensiveness, transparency and scientific rigour. However, it was detailed that the system has been criticised at home and abroad sparking the need for far-reaching changes to be implemented. Primary criticisms included carelessness, excessive time delays, political interference and poor communication with stakeholders. The Beale Review put forward 80 recommendations to the government which revolved around three principles; an integrated biosecurity continuum involving risk assessment and monitoring, surveillance and response pre-border, at the border and post-border; risk assessment reflecting scientific evidence and rigorous analysis; and shared responsibility between the Commonwealth, State and Territory governments and between businesses and the general community. It also responded appropriately to calls from the community for a zero risk quarantine policy by labelling it unattainable and undesirable. To operate this type of system would mean that every passenger, every bag and suitcase, and every container of cargo would need to be searched and even sampled and analysed. The Beale Review acknowledged that this would not only be counterproductive, but also be impossible to resource.

The review recommended that it was time for the Australian Government to rid itself of the term “quarantine” in favour of “biosecurity”. The panel stated that “quarantine” carried a negative and defensive connotation as opposed to “biosecurity” being proactive and functional. The most influential recommendation to come out of the Beale Review was the endorsement of new legislation to replace

15 Department of Agriculture and Water Resources, n 10, 7.
16 Department of Agriculture and Water Resources, n 10, 8, 9.
17 Department of Agriculture and Water Resources, n 10, 13–17.
18 Department of Agriculture and Water Resources, n 10, 10.
19 Department of Agriculture and Water Resources, n 10, 5, 23, 26, 31.
21 Beale, n 7, XI.
22 Beale, n 7, XV.
23 Beale, n 7, XV.
24 Beale, n 7, XV.
25 Beale, n 7, XVI.
26 Beale, n 7, XVI.
27 Beale, n 7, XVII.
the Quarantine Act. Among the supporting recommendations the panel insisted that the new Act draws on a much broader set of constitutional powers to extend the reach of biosecurity law which included:

- provisions to deal with national biosecurity emergencies;
- additional powers and resources to regulate post-border biosecurity;
- legislative power to deal with international and domestic water ballast regulation; and
- powers to override State and Territory law (subject to the National Biosecurity Agreement (NBA)).

The new biosecurity legislation would also be underpinned by a NBA in order to improve communication and collaboration with all States and Territories. However, despite the intent of this recommendation to include the local jurisdictions in biosecurity decision-making, the power ultimately still resided with the Commonwealth.

Arguably, to bring biosecurity regulation into the 21st century with new legislation would not be complete without having some guiding principles and setting realistic goals. The administrative complexities and exorbitant compliance costs arising from the outdated Quarantine Act needed to be systematically addressed. To drive home the legislative change argument the Beale Review suggested that the new biosecurity system be firmly placed upon five pillars. They are, in no particular order:

1. implementing a risk-based approach to biosecurity regulation;
2. managing biosecurity across a continuum; offshore, at the border and onshore;
3. building stronger partnerships with stakeholders;
4. using an intelligence-led and evidence-based decision-making to inform regulation; and
5. modernising legislation, technology, funding and business systems.

The review also proposed complex changes to the organisational structure of Australian biosecurity regulation.

First, the panel recommended the establishment of a National Biosecurity Commission (NBC) including a Director of Biosecurity. This office would be responsible for biosecurity policy determination, import risk analyses and state biosecurity controls. Second, the panel proposed to combine AQIS, Biosecurity Australia and the Product Integrity, Animal and Plant Health Division to form a National Biosecurity Authority. The Authority would be responsible for administering the new Biosecurity Act 2015 (Cth). Third, the panel recommended an independent office of the Inspector General of Biosecurity (IGB) be established to conduct internal audits of the National Biosecurity Authority. Finally, the remaining (what was then known as) Department of Agriculture, Fisheries and Forestry (DAFF) would undertake trade and market access duties as well as provide administrative support for the IGB.

Of course, the recommendations laid out by the One Biosecurity panel were not to be achieved with the current level of funding. In order to achieve the model proposed by the Beale Review, an annual funding increase of $260 million was recommended. In addition, the panel indicated that an investment of $225 million into upgrading biosecurity information technology and business systems was also needed. The source of the funding was suggested to come out of tax payer pockets and the cost recovery efforts of the Commonwealth.

The Beale Review was able to build on the foundations of the Nairn Report and provide a solid biosecurity model that would enable the government to bring biosecurity regulation into the 21st century.

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28 Beale, n 7, XXIX.
29 Beale, n 7, XXXII.
30 Beale, n 7, XXXI–XLVI.
31 Beale, n 7, XXI.
32 Beale, n 7, XXI.
33 Beale, n 7, XXI.
34 Beale, n 7, XXI.
35 Beale, n 7, XXVIII.
On 30 September 2008 the *One Biosecurity* review was signed and submitted to the then Labor Minister for agriculture, fisheries and forestry, Tony Burke. At the time the Rudd government had been in office less than a year, had recently delivered their first budget and was busy preparing an economic stimulus package in response to the global financial crisis. It was safe to presume that biosecurity reform was not a high priority on the parliamentary agenda.

**MODERNISING AUSTRALIA’S BIOSECURITY: BETTER LATE THAN NEVER**

Despite the financial crisis preoccupation of the Rudd government, the Commonwealth got its act together quickly and provided a formal preliminary response to the Beale Review before the end of 2008. The government heeded the advice of the panel by agreeing in principle to adopt all 84 recommendations. The Commonwealth’s response acknowledged that factors including Australia’s ever-growing reliance on trade, increases in passenger numbers and cargo, and outbreaks of disease have exposed significant weaknesses in the current system. Furthermore, the threats of agri-terrorism and climate change are areas of growing concern. The government recognised that a robust biosecurity system could not only prevent the incursion of pests and disease, but also provide Australia with a unique trade advantage of being a reputable producer of safe food, plants and livestock. Despite the positive response from the Commonwealth, over the next few years the plan to reform Australia’s biosecurity received little media coverage, if any at all. Attention was squarely focused on the publicised leadership stoush between former Prime Minister Kevin Rudd and former Prime Minister Julia Gillard, and the impending implosion of the Australian Labor Party.

Despite the roller-coaster ride of the Labor government during this period, the DAFF had started laying the groundwork for implementing the recommendations of the Beale Review. In March 2012 the Department published a report that provided a snapshot update of its progress towards reform. The report stated that new legislation was under development with a Biosecurity Bill to be introduced to Parliament in late 2012. Unsurprisingly, the establishment of the NBA and NBC was rejected by the government in the report echoing the 2011 announcement to retain all biosecurity services within DAFF. However, the government upheld its initial commitment to create a statutory office of the Inspector-General of Biosecurity to provide independent oversight of departmental biosecurity functions.

The report outlined significant funding measures to be implemented by the Commonwealth. An investment of $481 million into the biosecurity reforms was planned over the next four years. This included an additional $205 million for border operations undertaken by Australian Customs and Border Protection Service. The report also confirmed that an Intergovernmental Agreement on Biosecurity was signed by the Prime Minister and all States and Territories except Tasmania in January 2012. The agreement was designed to strengthen partnerships between the Commonwealth, State and Territory governments as proposed in the Beale Review.

In late November 2012 the Senate jointly referred the first *Biosecurity Bill 2012* (Cth) and the *Inspector-General of Biosecurity Bill 2012* (Cth) for inquiry and report. An extension was granted until November 2013 but the Bill lapsed as a result of the 2013 Federal Election. A year later the current

36 Beale, n 7, IX.
39 Australian Government, n 38.
41 Department of Agriculture and Water Resources, n 20, 22, 25.
42 Department of Agriculture and Water Resources, n 20, 24, 43.
government got the wheels moving again and introduced the *Biosecurity Bill 2014* (Cth) to the House of Representatives. The Bill was part of a package including four other supporting Bills:

- *Biosecurity (Consequential Amendments and Transitional Provisions) Bill 2014* (Cth);
- *Quarantine Charges (Imposition-General) Amendment Bill 2014* (Cth);
- *Quarantine Charges (Imposition-Customs) Amendment Bill 2014* (Cth); and
- *Quarantine Charges (Imposition-Excise) Amendment Bill 2014* (Cth).

The *Biosecurity Bill 2014* (Cth) finally passed both houses of Parliament on 14 May 2015 and received Royal Assent on 16 June 2015. The *Biosecurity Act 2015* (Cth) is co-administered by the Ministers responsible for agriculture and water resources, and health. Following Royal Assent the *Biosecurity Act 2015* (Cth) had a latency period of one year before it came into force on 16 June 2016. Between this period the DAWR undertook extensive consultation with governments, industry groups, trading partners, health professionals and the general public to ensure a smooth transition. Throughout the consultation the department received over 100 submissions providing comments and recommendations regarding the new law and the Biosecurity Legislation Implementation Program. This was important for a number of reasons. Despite the Act not radically changing the existing operating functions of the DAWR, there was a need to dismantle some of the prehistoric policy structures established by the *Quarantine Act* as well as reform a number of ongoing regulatory programs to line-up with the incoming legislation.

To assist industry with understanding and adapting to the *Biosecurity Act 2015* (Cth), the DAWR also developed an online Introduction to the Biosecurity Act Interactive Learning tool which can be accessed via the departmental website.

**STREAMLINED BIOSECURITY**

The Department understood that 108 years of quarantine regulation could not be changed overnight let alone within a single year. To ensure a smooth transition, the DAWR adopted a three-stage approach over five years with phase one underway as soon as the Act came into force on 16 June 2016. To assist all parties with the staggered transition, the Parliament enacted the *Biosecurity Consequential Amendments and Transitional Provisions Act 2015* (Cth). This legislation enables the DAWR to carry out its pre-border, border and post-border compliance functions concurrently under the *Quarantine Act* and the *Biosecurity Act 2015* (Cth). For example, if a notice had been issued under the *Quarantine Act* in relation to goods, the person must still comply even if the Act has been repealed since the notice was served.

The *Biosecurity Act 2015* (Cth) was designed to provide a solid platform for the DAWR to make biosecurity modern and flexible, as was the panel’s objective in the Beale Review. The Act itself is not significantly different from the *Quarantine Act*, although clever drafting has produced a piece of legislation that is not just more organised but also more functional. New terminology is one of the noticeable differences in the *Biosecurity Act 2015* (Cth). Quarantine officers are now referred to as Biosecurity Officers and Biosecurity Enforcement Officers in order to fall in line with overarching changes. Items and vehicles have been grouped together to avoid confusion and streamline inspection procedure. Imported cargo,
plant and material have been categorised as “goods”, and aircraft, vessels and ships are now termed “conveyances”.52 These small terminology changes arise from layout and structure improvements in the new Act.

The Biosecurity Act 2015 (Cth) is a 723-page document, more than two and half times the length of the Quarantine Act. The length, however, does not render the new Act more complex or more laborious to read and apply. The structure and layout of the Biosecurity Act 2015 (Cth) is considerably more succinct and has been carefully crafted for increased useability. Biosecurity risks have been separated into individual parts rather than bundled together. For example, the Quarantine Act grouped together vessels, persons and goods which made the requirements for individual biosecurity risks difficult to isolate and interpret.53 The Biosecurity Act 2015 (Cth) has resolved this issue by dividing individual biosecurity risks and their requirements into four chapters comprising of:

- human health;
- goods;
- conveyances; and
- ballast water and sediment.54

The biosecurity risk chapters are followed by supporting chapters outlining administrative tools including monitoring, control and response, and compliance and enforcement.55 Powers to manage biosecurity outbreaks and emergencies have also been properly defined in the new legislation. Where the Quarantine Act has these powers littered throughout various parts of the Act, the Biosecurity Act 2015 (Cth) has collated them together by allocating an entire chapter to dealing with emergencies.56 The layout improvements to the Biosecurity Act 2015 (Cth) certainly warrant recognition. The self-contained chapters for operational regulation and biosecurity management have been structured well and can be located easily. An important operational change within Ch 9, Compliance and Enforcement, is the adoption of the Regulatory Powers (Standard Provisions) Act 2014 (Cth) (RP Act).57 Being one of the first pieces of legislation to adopt the RP Act, the Biosecurity Act 2015 (Cth) has structured a number of provisions to align or be defined by the RP Act. Similarly, monitoring, investigation and warrant powers of biosecurity officers within the Biosecurity Act 2015 (Cth) must be carried out in accordance with the RP Act.58 The Parliaments aim for this initiative was an attempt to provide a standardised framework for federal compliance and enforcement powers that relate to regulatory schemes conducted under Commonwealth statutes. Although it is clear in the Biosecurity Act 2015 (Cth) when the RP Act is triggered, the ability of authorised officers at the coal face to exercise their powers in accordance with two pieces of legislation may cause operational issues.

A significant component of streamlining Australian biosecurity regulation was shifting to a model of risk-based regulation. This type of regulatory approach involves allocating resources in proportion to the risks to society, considering both the impacts themselves and the likelihood that they will occur.59 The Nairn Report was the first review to flag the necessity for the DAWR to adopt a scientific risk-based approach to its regulatory activities.60 This was again echoed heavily by the Beale Review in 2008. Thankfully, this instigated a broader commitment from the Commonwealth to risk regulate

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52 Biosecurity Act 2015 (Cth) Ch 1 Pt 2(9) ss 16, 19.
53 Quarantine Act 1908 (Cth) Pt IV.
56 Biosecurity Act 2015 (Cth) Ch 8.
58 Biosecurity Act 2015 (Cth) Ch 9 Pts 1–3.
60 Department of Agriculture and Water Resources, n 10, 10–12.
Australian biosecurity. Aside from a raft of internal policy changes at the DAWR, the new biosecurity legislation contains provisions that align with risk-based regulatory principles. For example, goods that are imported into Australia are now required to be evaluated against Biosecurity Import Risk Analysis (BIRA). This system is designed to identify conditions that need to be met by the importer in order to manage the level of risk associated with the goods. The *Biosecurity Act 2015* (Cth) has also boldly taken risk characterisation one step further with a definition. Ch 1 of the Act defines the appropriate level of protection for Australia against biosecurity risks as a “high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not to zero”. Such provisions explore the interface of trade and biosecurity laws where some nations have alleged that phytosanitary protections, for example, are sometimes used as covert mechanisms that protect local industries from economic competition rather than hazardous pests. A related testing area will involve the threshold under this legislation for application of the precautionary principle and whether it excludes from liability good faith determinations of regulators made on that basis.

**CONCLUSION**

The *Biosecurity Act 2015* (Cth) is the starting point of a long overdue overhaul of Australia’s biosecurity system. The Nairn report, despite its less than subtle push for the privatisation of quarantine regulation, arguably should have instigated a much more significant biosecurity reform by the government in 1996. A decade later those ideas were effectively re-enforced through the Beale Review and supported by one important recommendation, a new piece of legislation. Government commitment was delivered in full with increased funding, a reform of DAWR policy and programs, and the passing of the *Biosecurity Act 2015* (Cth). The reform was well balanced with a focus on protecting Australia from incursions of foreign pests and diseases through risk-based regulation without unnecessarily impeding travellers and trade. The layout and structure of the *Biosecurity Act 2015* (Cth) provides importers, exporters, travellers and Australia’s trading partners with clear and concise information of their biosecurity obligations when they enter this country. The DAWR and its officers are equipped with a strong set of compliance and enforcement tools to monitor, control and reduce biosecurity threats to Australia. Of course, the Act is still in its infancy and the DAWR may encounter operational challenges as a result of the Commonwealth exploring new ways to regulate. However, with good governance and independent oversight from the new Inspector-General of Biosecurity these issues can be identified and resolved quickly.

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61 Australian Government, n 38.
63 *Biosecurity Act 2015* (Cth) Ch 3 Pt 2(165).