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Cc: Williamson, David; Coordination; JANIEC, Stefanie
Subject: APVMA Draft Senate Submission [DLM=For-Official-Use-Only]
Attachments: Senate Inquiry submission - Final Draft - 10 Mar 17.docx

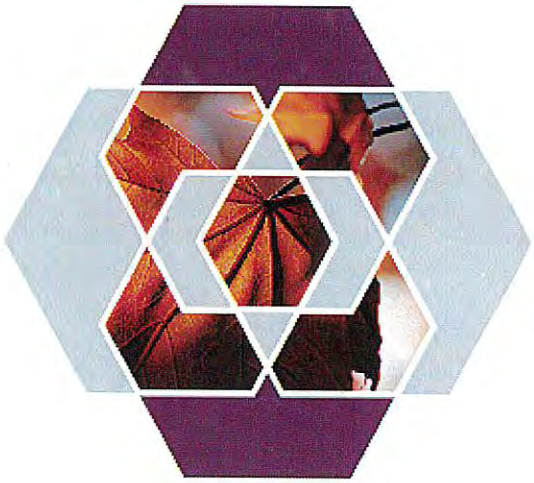
For-Official-Use-Only

Hi there – attached is our draft submission for the senate inquiry. We are on track to submit this afternoon – we are just doing final number and formatting checks. Any comments would be welcome by lunch time. Cheers Kareena

For-Official-Use-Only

Australian Government

Australian Pesticides and
Veterinary Medicines Authority



MARCH 2017

Submission to the Finance and Public Administration References Committee Inquiry:

The operation, effectiveness and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) welcomes the opportunity to provide a submission to the Finance and Public Administration References Committee Inquiry: The operation, effectiveness and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016.*

The APVMA is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemical products proposed for supply and use in Australia. The APVMA evaluates the safety and performance of chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected.

On 24 November 2016, Senator the Hon Mathias Cormann, Deputy Leader of the Government in the Senate and Minister for Finance, issued a Government Policy Order which specifies that corporate Commonwealth entities with agricultural policy or regulatory responsibilities are to be located in a regional community that is near a main campus of a regional university recognised for research and teaching in the field of agricultural science. The Government Policy Order applies to the APVMA.

On 25 November 2016, the Deputy Prime Minister and Minister for Agriculture and Water Resources, the Hon Barnaby Joyce MP, announced that the government had approved $25.6 million to fund relocation of the APVMA to Armidale in regional NSW.

The APVMA is undertaking extensive planning to relocate the organisation to Armidale while ensuring it is able to operate out of Canberra throughout the transition period and continue to provide high quality services for the agvet industry, focused on ensuring agvet chemical products are safe, effective and do not impact on trade.

This submission provides a high level overview of the roles and responsibilities of the APVMA and outlines the approach to planning for the relocation, how the agency proposes to perform its functions from Armidale and manage risks relating to the move. An overview of key reform activities being concurrently progressed by the APVMA to streamline the registration process and better align regulatory effort with regulatory risk, including initiatives under the *Agricultural Competitiveness White Paper* is also provided.

1 ROLES AND RESPONSIBILITIES OF THE APVMA

The APVMA has been the statutory authority responsible for the regulation of agvet chemicals since 1993.

Before agvet chemical products can be legally sold, supplied or used in Australia, they must be evaluated and registered by the APVMA through the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). The states and territories are responsible for regulating and managing the use of agricultural and veterinary chemical products once they are sold.

More than 11 000 pesticide and veterinary medicine products are currently registered in Australia, including products for treating crop and garden diseases and pests, and medicines for treating agricultural and companion animals. Over time, the scope of products regulated by the APVMA has grown due to advances in technology, increased numbers of generic products, changes to farming practices and a shift to products for the increasingly large companion animal sector.

The APVMA works primarily with companies manufacturing and marketing agricultural chemical products and veterinary medicines, and their representatives, in performing these functions.

The APVMA handles over 5 000 applications each year and takes a systematic, scientific, evidence-based approach to making decisions about whether a chemical or proposed use for the chemical meets statutory criteria. The APVMA evaluates the safety and performance of chemicals intended for sale in Australia, to ensure that the health and safety of people, animals, crops and the environment are protected. Registered products must also not unduly jeopardise Australia's trade with other countries.

The APVMA does not undertake independent research into agvet chemicals. We rely on analysis of data and information submitted by applicants, the majority of which is generated and assessed according to established guidelines.

Our work supports primary industries—agriculture, forestry, horticulture and aquaculture—by allowing the supply of safe, effective animal health and crop protection products. Our work also supports consumers, by ensuring that household and garden pesticides, pool chemicals and pet products are safe to use.

Our role extends beyond registration of pesticides and veterinary medicines to encompass a range of activities aimed at protecting Australians and ensuring that products are safe. We license and audit veterinary manufacturers to ensure adherence to APVMA-prescribed manufacturing standards. We also monitor the market for compliance, and review and take regulatory action on registered pesticides and veterinary medicines when concerns are identified.

The APVMA is a portfolio agency of the Minister for Agriculture and Water Resources.

1.1 Legislative framework

The APVMA is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act). The Administration Act sets out the role of the APVMA to undertake the responsibilities conferred on it by the states and territories under the NRS.

Functions and powers are conferred on the APVMA by the Administration Act, the *Agricultural and Veterinary Chemicals Code Act 1994* and the *Agricultural and Veterinary Chemicals Code* (Agvet Code). The Agvet Code provides for the evaluation, registration and control of agricultural and veterinary chemical products and related matters.

The APVMA is a corporate Commonwealth entity under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and is nearly fully cost recovered with approximately 40 per cent from application fees and 60 per cent from industry sales levies. The APVMA collects the levies.

1.2 Functions and Powers

The APVMA is responsible for assessing and registering agricultural and veterinary chemical products proposed for supply and use in Australia, and for controlling them up to the point of retail sale.

The key functions of the APVMA, which are set out in section 7 of the Administration Act, are to:

- assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products
- ensure that approvals and registrations for active constituents for chemical products, chemical products and labels for containers for chemical products comply with the Agvet Code, and the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Code Regulations)
- provide information to the Australian Government and its agencies, and the states and territories, about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for such products, and cooperate with the Australian Government and its agencies on matters relating to the management and control of chemical products
- collect and publish relevant information and statistics on approvals and registrations granted and permits and licences issued under the Agvet Code
- with the Australian Government and its agencies, and the states and participating territories, facilitate a consistent approach to the assessment and control of agvet chemicals
- exchange information relating to chemical products and their use with overseas and international bodies that have similar functions to those of the APVMA, and
- report to or advise the Minister on matters relating to the performance of the APVMA's functions.

The APVMA fulfils these functions by:

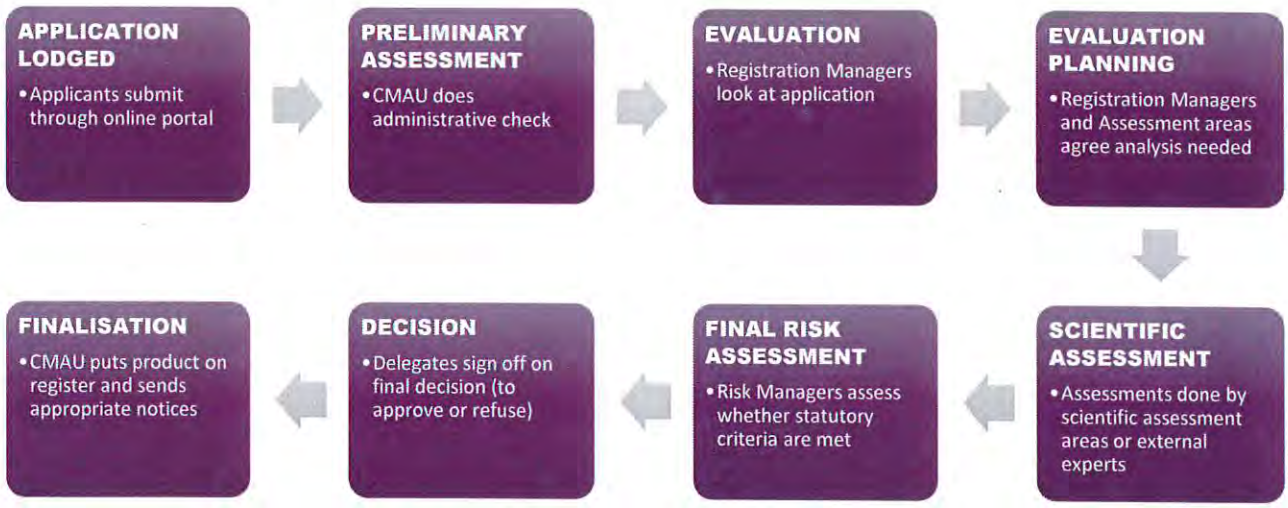
- assessing and registering new chemicals, approving new uses for existing registered products and approving changes to existing registered products
- approving labels for registered products
- assessing and approving active constituents for proposed or existing registered products
- issuing permits for minor use, research, emergency use, import and export of agvet chemicals
- reviewing existing chemicals to ensure they are safe to use
- undertaking compliance and engagement activities to ensure products and active constituents available for use comply with the Agvet Code
- managing a licensing scheme for veterinary manufacturers.

1.3 The work of the APVMA

Assessing applications for registration of agvet chemicals comprises the majority of the work of the APVMA. In doing so, a common process is used across the broad range of applications submitted to the APVMA. In summary (and shown in Figure 1):

- Applicants submit applications online
- Case Management and Administration Unit (CMAU) officers undertake preliminary assessment and the application passes through to regulatory scientists – noting that everything is electronic (not paper based)
- regulatory scientists determine what scientific assessments are needed to make a decision and necessary assessments are commissioned (either internally or through external service providers)
- Once assessments are complete, a decision is made about whether a product can be registered.
- CMAU does the administrative tasks to finalise the registration and ensure entered it is on the register.

FIGURE 1: REGISTRATION PROCESS



The APVMA also runs a licensing scheme for veterinary manufacturers. Third party auditors submit reports to the APVMA for consideration and action. Staff within this team have experience in the manufacturing sector and work is underway to move the systems underpinning the licensing scheme to being fully online.

The compliance and enforcement team operates a risk-based process to assess and respond to reports of non-compliance against agvet legislation. Record keeping systems are in place to ensure any investigations are clearly documented. Compliance staff have been trained in agvet legislation and also hold compliance specific qualifications.

There is a small in-house legal team that provides advice essential to ensuring that APVMA's operations conform to the complex legislative framework under which the APVMA operates.

1.4 APVMA operating model

The APVMA operates from premises in Canberra with one staff member from the compliance team based in Western Australia. APVMA staff are employed under the *Australian Public Service Act 1999*.

The APVMA is structured around four programs:

1. Registration Management and Evaluation – management and decision making on registration of agvet chemical products; primary point of engagement with the chemical industry; and ancillary functions under the Agvet Code and associated legislative framework.

2. Scientific Assessment and Chemical Review – technical assessment and advice for registration of agvet chemical products; assessment of active constituents; and chemical review (reconsiderations).

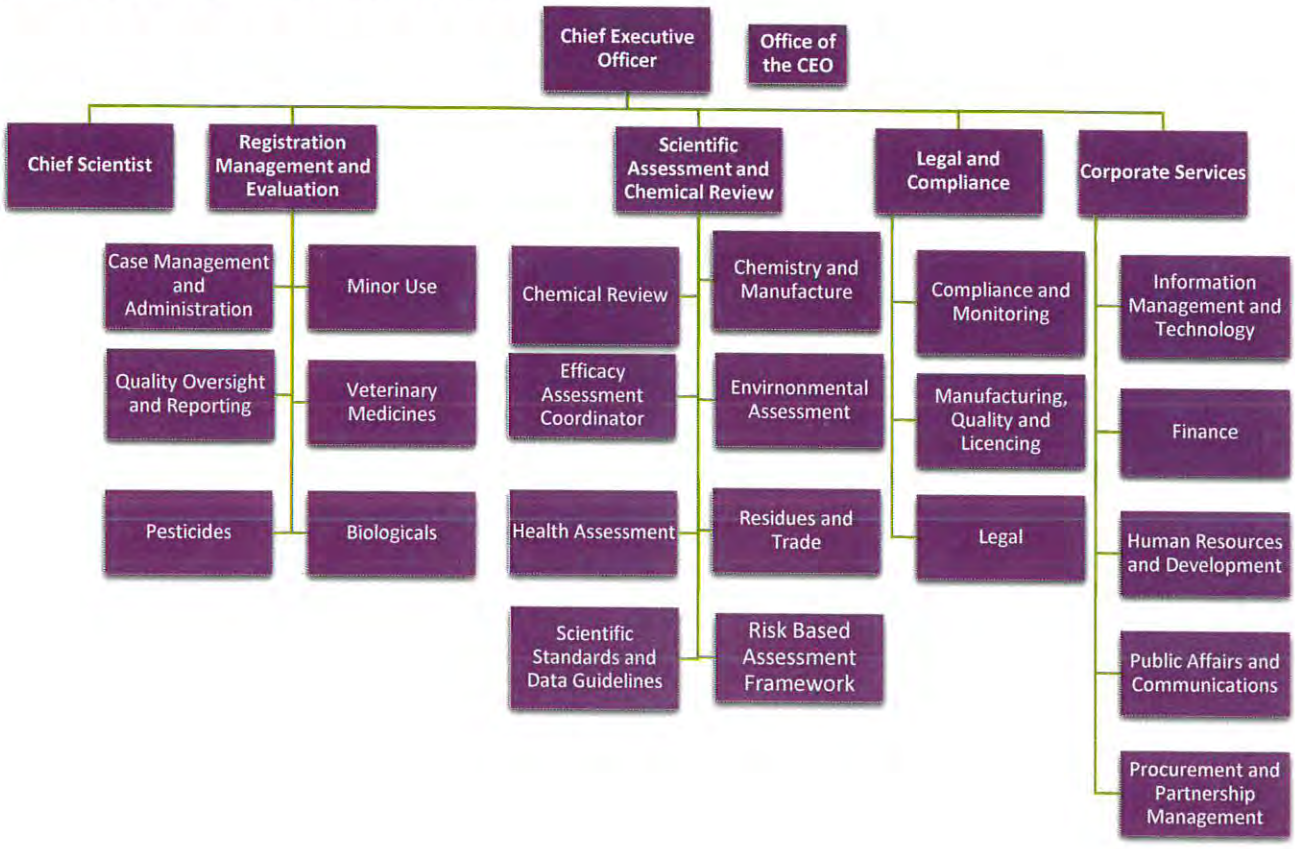
3. Legal and Compliance – legal services; compliance and monitoring of obligations under the Agvet Code and associated legislative framework; and licensing of veterinary chemical product manufacturers.

4. Corporate Services – IT, finance, human resources, communications and contracts and procurement.

These programs are supported by an Office of the Chief Scientist to ensure scientific frameworks and practices meet appropriate standards and take account of emerging technologies, as well as the executive team and coordination support.

The organisation structure is in Figure 2.

FIGURE 2 – APVMA ORGANISATION STRUCTURE



Staff profile

As at 15 February 2017, the APVMA employed 197 FTE – 161 FTE were employed on an ongoing basis and 36 FTE on a non-ongoing basis. The staffing profile is outlined in Table 1.

TABLE 1: APVMA STAFFING PROFILE – AS AT 15 FEBRUARY 2017

	Casual/Non-ongoing	Ongoing	Total
Regulatory scientists	8.8	74.5	83.3
Case management & administration	4.6	28.5	33.1
Legal and compliance	5	20	25
Corporate – IT	7.6	14.8	22.4
Corporate - Other	7	12.7	19.7
Agriculture White Paper funded positions	2	3.8	5.8
Executive and coordination	1	7.8	8.8
TOTAL	**36**	**162.1**	**197.3**

What is a regulatory scientist?

The work of the APVMA is focused on regulatory science.

Regulatory science involves a pragmatic application of the scientific method for the purpose of making a decision about whether to allow something (eg chemicals) to be used within the defined legislative framework and timeframes.

Conventional science involves the application of the scientific method for understanding some physical, chemical or biological phenomena. It tends to be curiosity driven, forward looking and speculative.

What differentiates regulatory science from conventional science is that decisions are based on analysis and interpretation of existing scientific knowledge and, where necessary, assumptions to address data gaps or uncertainty. Regulatory scientists do not generate new lines of enquiry to answer questions, instead relying on available information to make a decision.

While regulatory science incorporates a variety of scientific disciplines, it is in itself a specialised field of science. As well as holding conventional scientific qualifications (for example in toxicology, veterinary medicine and chemistry), regulatory scientists are trained in risk analysis, public administration and regulatory decision making.

Regulatory scientists are highly trained specialist positions. Most regulatory science training is done on-the-job as there are currently no formal courses in regulatory science and it tends to be specific to legislative frameworks. It takes many years to train a regulatory scientist to be able to evaluate complex applications.

Staff movements

From 1 July 2016 to 15 February 2017, 48 staff left the APVMA (this includes four staff who notified their resignation at this date). Of the 48 staff who have left, 20 were regulatory scientists and 35 were experienced permanent staff members (Table 2).

TABLE 2: SEPARATIONS BY PROGRAM AND YEARS OF SERVICE

	Casual/ Non-ongoing	Ongoing	Total	Total years of service
Regulatory scientists*	2	18	20	91
Case management and administration	4	2	6	1*
Legal and compliance	4	5	9	28
Corporate – IT	1	4	5	17
Corporate - Other	2	4	6	29
Executive and coordination	0	2	2	38
TOTAL	**13**	**35**	**48**	203

* Staff had less than one year service

Over the same period, 57 staff commenced with the APVMA, the majority being non-ongoing staff, particularly in IT and case management and administration. The figures relating to regulatory scientist commencements are skewed by the recruitment associated with the APVMA taking over the health assessment function from the Department of Health from 1 July 2016.

TABLE 3: STAFF COMMENCEMENTS – 1 JULY 2016 TO 15 FEBRUARY 2017

	Casual/Non-ongoing	Ongoing	Total
Regulatory scientists*	8	9	17
Case management and administration	11	2	13
Legal and compliance	6	1	7
Corporate – IT	10	0	10
Corporate - Other	8	1	9
Executive and coordination	1	0	1
TOTAL	**44**	**13**	**57**

* Four ongoing and one non-ongoing regulatory scientists were recruited to perform health assessment functions following APVMA taking responsibility for from the Department of Health on 1 July 2016.

1.5 Current performance against legislative timeframes

The APVMA releases detailed performance statistics each quarter. The December quarter 2016 statistics were released on 8 February 2017 and are provided at **Attachment A**.

The December quarter 2016 statistics showed that performance against timeframes was steady or improved across all applications (products, permits and actives), except for pesticide product applications. This result was not unexpected due to the loss of key staff from that area and a number of key staff taking leave.

Table 4 provides a summary of the December quarter 2016 key statistics.

TABLE 4: APPLICATIONS PROCESSED – DECEMBER QUARTER 2016

	Commenced	Finalised	Within Timeframe	2015/16 in timeframe	In Progress	In progress still within timeframe
Pesticides	180	156	50%	57%	524	69%
Veterinary medicines	176	164	87%	80%	326	72%
Total Products	356	320	69%	66%	850	70%
Permits	132	110	83%	70%	171	67%
Actives	187	199	88%	70%	300	91%
TOTAL	**675**	**629**	**78%**	**68%**	**1321**	**74%**

There are forward indicators that suggest there will be downward pressure on the timeframe performance statistics in coming quarters:

- The work in progress has increased to over 1300 applications at the end of December 2016 – 150 more applications than at the end of 2015
- Of those applications still being assessed, one in four are overdue, down from one in five applications overdue at the end of the September quarter.

The APVMA is actively managing the backlog to ensure as many applications are finalised as possible within the resources available to the agency and that the time taken to finalise applications after the due date is minimised.

The APVMA is also implementing a range of measures to improve the efficiency of the agency and reduce the regulatory burden on applicants in order to streamline the processing of applications and support performance during the transition. These measures are discussed in Section 5.

2 THE GOVERNMENT POLICY ORDER

On 24 November 2016, Senator the Hon Mathias Cormann, Deputy Leader of the Government in the Senate and Minister for Finance, issued a Government Policy Order (GPO) which specifies that corporate Commonwealth entities with agricultural policy or regulatory responsibilities are to be located in a regional community that is near a main campus of a regional university recognised for research and teaching in the field of agricultural science. A regional community is defined as being a community that is not within 150 kilometres by road of Canberra or the capital city of a State. The GPO applies to the APVMA.

On 25 November 2016, the Deputy Prime Minister and Minister for Agriculture and Water Resources, the Hon Barnaby Joyce MP, announced that the government had approved $25.6 million to fund relocation of the APVMA to Armidale in regional NSW.

The GPO does not explicitly state the APVMA is to move to Armidale. Other locations, like Wagga Wagga, meet the criteria contained in the GPO. However, funding for the relocation provided by Government is tied to the APVMA moving to Armidale. Therefore, the APVMA CEO, as the statutory officer responsible for the APVMA, made the decision that the APVMA will relocate to Armidale in order to meet the requirements of the GPO.

All decisions about the implementation of the GPO is the responsibility of the APVMA under the provisions contained in the Administration Act.

Background

On 12 May 2015 the Hon Barnaby Joyce MP, Minister for Agriculture, wrote to the APVMA CEO about possible relocation of the APVMA to Armidale or Toowoomba and sought advice about whether the APVMA would be willing to relocate and, if so, which location would best suit the needs of the agency.

The APVMA CEO wrote to the Minister on 31 July 2015 advising that she was unable to support the current proposal to relocate the APVMA to either Toowoomba or Armidale at that time due to the magnitude of expected losses of expertise and experience. The APVMA CEO indicated that, therefore, she would have concerns about her ability to perform her legislative obligations under the Administration Act should the APVMA relocate. However, the APVMA CEO also noted that the *Public Governance, Performance and Accountability Act 2013* may provide an option to make a GPO to effect the relocation and stated she would work with the Minister to enact the government's policies and transition strategies.

The APVMA undertook an extensive program of staff consultation, information sessions, site visits and surveys and sought views from key agricultural and chemical industry groups that engage with the APVMA and the APVMA Advisory Board in preparation of their response on the possible relocation of the APVMA.

As part of the Cabinet process in the lead up to the issuing of the GPO, the Hon Barnaby Joyce MP, Deputy Prime Minister and Minister for Agriculture and Water Resources, wrote to the APVMA CEO on 10 November 2016 seeking advice on the application of the draft GPO to the APVMA, how it will be implemented and how risks will be mitigated. The APVMA CEO responded on 18 November 2016, providing a copy of the Relocation Strategy, which was subsequently made public (at **Attachment B**).

3 THE PLAN FOR RELOCATION

3.1 Context and assumptions

Previous staff surveys (conducted in 2015 and 2016) indicated a limited number of existing staff were willing to relocate to Armidale, with less than 10 regulatory scientists indicating a willingness to move. While the exact numbers of existing staff intending to move to Armidale is unknown at this time, even if there is a significant increase in numbers from these surveys, there will be capability gaps across the organisation, particularly in regard to regulatory scientists. Therefore, it is not feasible to recreate what exists in Canberra in Armidale – new approaches to the APVMA's business must be found.

The Department for Agriculture and Water Resources (DAWR) engaged consultants Ernst & Young (EY) to assess the economic costs and benefits of relocating the APVMA from Canberra to Armidale, to examine the risks of relocation and effective strategies or plans that could address the identified risks and to analyse the economic impacts on Canberra and Armidale. EY identified the following risks:

- the APVMA may be unable to relocate, or recruit and replace, key APVMA executive, management and technical assessment staff
- during the transition and in the short-term, the APVMA may not be able to sustain its rate of effort for registration of new agricultural and veterinary chemical products
- the APVMA may be unable to maintain and grow its capability in the medium-term
- the APVMA may have reduced access to agvet chemical stakeholders.

EY suggested a number of mitigation strategies, including short and medium term phased transition to Armidale, development of a new business model, regulatory scientist training program, relocation/incentive packages, outsourcing technical assessment work and technological solutions to assist collaboration and engagement.

The APVMA considered phasing the transition by moving teams prior to the full relocation. On balance, this approach was not pursued as the current IT system would not support a split operation and the time and resources it would take to set up a secure and fully functional interim office in Armidale would detract from the effort needed to develop the permanent accommodation solution. The logistics and support needed to run the Canberra office and an Armidale office while building a new facility was assessed as being too much of a burden on a small agency and detrimental in the longer run to a smooth transition to Armidale.

The other strategies suggested by EY have been picked up in the planning for the relocation to Armidale.

In terms of long term accommodation in Armidale, an exercise by DAWR in 2016 found that there were no suitable pre-existing buildings in Armidale and that a new facility would need to be built.

The APVMA holds a large amount of confidential commercial and other highly sensitive information. The security and protection of this information is of paramount importance to the companies who register products and to all staff in the agency. Throughout the process of relocation, a major focus will be on ensuring electronic and physical security of information on agvet chemicals.

3.2 Overview of approach to relocation

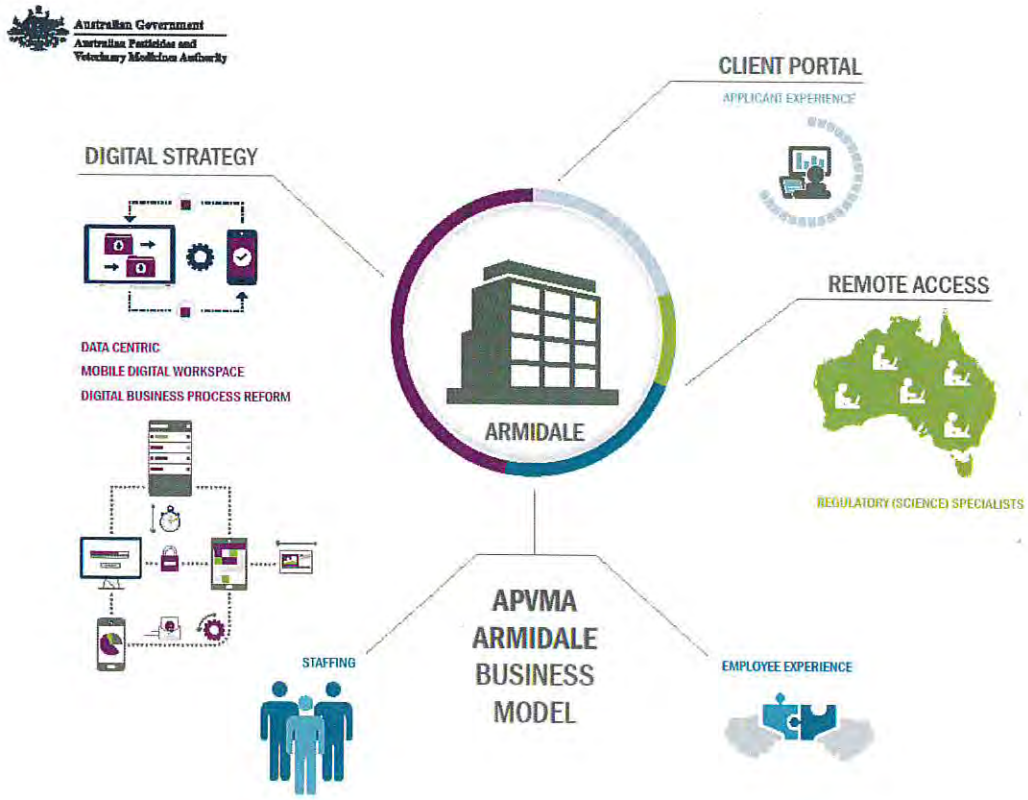
The APVMA released a relocation strategy in November 2016 (at **Attachment B**) which outlines the broad activities needed to efficiently transfer APVMA functions from Canberra to Armidale. The relocation strategy is focussed on what needs to happen to move the APVMA, while minimising potential issues during the transition, and to maximise capacity when it operates from Armidale.

The key components to the proposed approach to relocate the agency to Armidale, as represented in Figure 3 are:

- establish a network of regulatory scientists working both remotely and in Armidale
- develop a modern and collaborative workspace in Armidale that can showcase the next generation of public sector operations from regional Australia
- take the client experience to the next level by embracing a full online experience for applicants
- implement a new digital strategy to enable the APVMA to work effectively in this new business model.

The strategy is necessarily high-level as the detailed transition planning is currently underway.

FIGURE 3 – KEY COMPONENTS TO ARMIDALE OPERATING MODEL



This model is currently undergoing careful thought and planning, particularly in terms of making remote working effective on the scale envisaged, and whether feasible alternate approaches exist. However, at this stage, other options to retain access to a critical mass of regulatory expertise have not been identified.

3.3 Relocation activities

There are nine broad categories of work underpinning the relocation of the APVMA to Armidale:

1. Developing the **business model** for how the APVMA will operate in Armidale.
2. Designing and implementing a **digital strategy** to underpin the new business model, including developing a remote working framework and capability.
3. Establishing appropriate arrangements for **property** in Armidale and managing the Canberra facility.
4. Developing **people strategies** for current business needs, the future Armidale workforce, the transition team, retention and relocation, and the health and wellbeing of staff and their families.
5. Developing a **knowledge management** framework to ensure the knowledge and experience of staff leaving the agency can be captured, new starters can be trained more quickly and appropriate information systems designed to underpin the future operation of the APVMA.
6. **Communication and engagement** to ensure APVMA staff are fully informed of progress and available options and for stakeholders to be aware and involved in key elements of the relocation.
7. **Governance and risk management** to ensure the overall projects are managed appropriately and potential risks are identified early and appropriate mitigation strategies put in place.
8. Detailed **planning and logistics** for an efficient relocation.
9. **Finance and reporting** to underpin accountability for the expenditure and effort assigned to the relocation.

All of these activities are linked by a proactive approach to change management.

The progress made in the three months since the GPO was issued is covered in the next section.

3.4 Indicative timeframes

There are five phases planned for the relocation:

- **Phase 1: Planning** (until end June 2017) – focusing on developing the Armidale business model, the digital strategy and the approach for long term accommodation in Armidale. A transition office will be opened in Armidale.
- **Phase 2: Preparation for relocation** (July 2017 to March 2019) – involving the construction of the Armidale facility, digital build and testing, scheduling for the physical removal and finalisation of staff intentions and Armidale workforce strategy.
- **Phase 3: Final systems testing and site preparation** (April 2019 to June 2019) – with final testing of IT systems for use on site and remote set up of Armidale office.
- **Phase 4: Relocation** (from July 2019) – transfer of staff to Armidale and remote working arrangements or assist staff with redeployment or redundancy.
- **Phase 5: Windup of Canberra Office** (from July 2019) – implementation of strategy for accommodation until end of lease period and make good of Canberra building.

These timings are indicative only and will change once more detail is available about the construction of new office accommodation in Armidale.

4 PROGRESS ON RELOCATION ACTIVITIES

The information presented in this section is current as of 10 March 2017.

4.1 Armidale business model

Pegasus Economics has been engaged to assist in developing detail on how the APVMA will operate in Armidale, including a draft organisational structure and governance arrangements. Once finalised the business model will identify key business processes and how they will be performed by the APVMA. The organisational and management structure will allow staff to identify how they fit within the business structure, including detailing those positions which will need to be located in Armidale and those which may be eligible to operate remotely.

The project is exploring:

- Identification of functions and roles that need to be physically provided from the Armidale office
- Other roles and functions that do not need to be provided from Armidale and the potential for these functions to be delivered in other ways
- The capacity of external service providers to fulfil APVMA operational requirements once in Armidale
- The extent that teleworking can support APVMA's functions and roles
- Risks and mitigation strategies attached to new business models
- Governance arrangements, particularly if there is a distributed workforce
- Implications for operational management of the agency
- Changes required, if any, to structures, systems and processes.

Work associated with broader policy and legislative settings are out of scope of this project – ongoing legislative reform and options to reduce regulatory burden is part of the work being led by the Department of Agriculture and Water Resources. Matters relating to the transition period from now to when the APVMA is in Armidale is also out of scope – it is covered under a separate project relating to transition planning.

Consultation has begun with APVMA staff and stakeholders with the final report due end April 2017. This report will then form the basis of the detailed planning and logistics required to move the agency to Armidale.

4.2 Digital strategy

To successfully operate from Armidale, the APVMA will need secure systems that connect staff members with each other and with clients. We will design and build them to be flexible and able to quickly adapt to our changing needs. We will automate processes where possible to increase the efficiency of our business.

The digital strategy focuses on three key elements:

- Becoming a data centric organisation – so information can be managed through a controlled, verified and managed 'single source of truth' with full data integration between systems, processes and applications.
- Enabling a mobile digital workplace – with corporate systems and information able to be securely accessed anywhere and anytime with fully online and intuitive collaborate tools.

- Developing an 'end to end' and interconnected business process operating from one platform, with interconnected business portals and automated touch points and minimal data entry.

The concept provides opportunities to improve efficiency for industry and the APVMA and will reduce the administrative burden on clients and staff in the long run. It will be a significant IT build and, as such, the APVMA is working to ensure that the design of the integrated system and the underlying business processes is well planned.

The APVMA is in the process of engaging a digital partner to prepare a detailed proposal with costings to build and implement a new system for consideration by government this financial year.

The other component of the digital strategy is the design of the remote working framework. Remote working is more than technology – it needs to ensure people working remotely are connected with the workplace and each other, they have appropriate support, training and development, and appropriate mechanisms are in place to manage and monitor workload and performance. There is also a range of work health and safety and security matters that must be worked through.

Preliminary work is underway as part of the business model consultancy in terms of looking at how other agencies manage remote working arrangements. The draft remote working framework is currently scheduled for completion at the end of June 2017.

4.3 Property

There are three components to property relating to the relocation: the permanent building in Armidale, a small transition office in Armidale and the Canberra office.

Armidale – permanent building

The APVMA will require accommodation to be built in Armidale to house the agency. The overall timing of the relocation will be dependent upon the schedule for completing the building.

The intention is to enter a lease arrangement with a private developer. The APVMA received a briefing on 21 December 2016 from the property consultants involved with the expression of interest run by the DAWR to test the Armidale market. A specialist senior executive commenced with the APVMA on 6 March 2017 to manage the procurement process relating to the permanent building.

Armidale – transition office

The APVMA is currently assessing office space in Armidale to open a small transition office to house the CEO, chief operating officer, chief scientist and other members of the executive when they are in Armidale, members of the transition team, community liaison and a small locally recruited administration team to undertake APVMA functions that do not require full security access to online systems or access to physical files. The aim is to have this office operational in March 2017.

Canberra – current office

The lease on the Canberra office ends in October 2020. Management of ongoing maintenance of the building is required and planning for the exit of the premises will be undertaken over the next 12 months.

4.4 People strategies

There are a number of strategies in place and being developed which are critical to support both the continued operation in Canberra during the transition and the relocation of the agency.

Workforce planning - Armidale

A specialist HR company, Bull & Bear, has been engaged to assist the APVMA with workforce issues throughout the transition and to lead the workforce planning for the future business model. The workforce planning component will commence once the business model is finalised, including the design of a graduate program to support the future scientific capacity of the agency. The APVMA has joined the DAWR 2018 graduate program to begin the process of bringing in new graduates from next year. A workforce plan, coupled with a recruitment strategy, will be developed to deliver on the agreed business model for Armidale.

Key assumptions that underpin the anticipated workforce profile for operating from Armidale include:

- **Staff willing to relocate to Armidale** – Previous staff surveys suggest only 10-15 per cent of current staff may consider relocating to Armidale. Nevertheless, every effort will be made to encourage staff to move with the agency to ensure there is a critical mass of experienced people in Armidale.
- **Digital solution** – The APVMA can establish a digital solution that will support a large proportion of regulatory scientists working remotely from anywhere in Australia, working collaboratively and seamlessly connected to the Armidale office.
- **Remote working arrangements** – The APVMA is able to manage the human resource implications including work health and safety, performance management, IT security and physical security of the remote working arrangements.
- **Local recruitment** – The APVMA is able to source suitably skilled people (particularly in the case management, administration and corporate areas) from the Armidale region or attract new staff to Armidale.
- **Use of contractors and outsourced arrangements** – the APVMA is able to secure services from appropriate sources to fill capability gaps.

Workforce strategies - Canberra

The APVMA is experiencing higher than expected staff departures. While the preference is for current staff to remain with the APVMA and transition to Armidale, the APVMA acknowledges that a number of staff will choose to leave prior to the relocation. The APVMA also acknowledges that potential employees may be willing to work for the APVMA while in Canberra, but will not want to move to Armidale. Similarly, there are a number of new recruits who have signalled their willingness to move to Armidale. Therefore, the APVMA has taken a multi-layered approach to attracting potential staff through offering ongoing positions and a range of non-ongoing positions of various terms to suit the needs of the individual.

The APVMA conducted a general recruitment round in late 2016 which attracted over 200 applications. The APVMA is using this pool to select people to fill the multiple vacancies across the agency. Further general recruitment rounds and targeted regulatory science processes are planned and are expected to be a regular occurrence over the next few years.

The APVMA is also exploring options to use specialist employment agencies, different scientific networks and links to other regulators, both in Australia and internationally, to attract staff and fill vacancies. Contractors and consultants are also being used where possible and appropriate.

Health and wellbeing

It is a challenging time for staff and their families as they make decisions about their future. The pressures on staff resulting from staff departures is also significant. The APVMA places a high importance on looking after the health and wellbeing of staff. Change management consultants, Bull & Bear, are regularly on site and monitoring the situation. Twenty-four hour employee assistance arrangements are in place. The APVMA leadership team also proactively addresses issues that may impact on the health and wellbeing of staff and promotes a range of social and health-related activities to support staff.

Retention policy

Given that a relatively small proportion of current staff is expected to move to Armidale, an attractive retention package will be provided to retain as many staff as possible until the Canberra office closes to ensure business continuity, contribution to the design and implementation of the revised business model and digital strategy, training of new recruits and ensuring appropriate knowledge transfer is undertaken. The draft retention policy provided to staff in December 2016 included a retention bonus, professional development, career management assistance and a range of other workplace support. This policy closed for staff consultation at the end of February 2017. Comments are being worked through and finalised with staff.

Relocation policy

The draft relocation policy for people permanently transferring to Armidale has been provided to staff for consultation. Key components of the draft policy include relocation assistance, salary bonuses and return flights to Canberra for one year. This policy closed for staff consultation at the end of February 2017. Comments are being worked through and finalised with staff.

Transition team

The relocation will be led by the Chief Operating Officer (COO), who is overseeing all corporate and relocation related services to ensure the relocation happens with as minimal disruption as possible to services to support business as usual. Following approval by the Public Service Commissioner in December 2016, two new senior positions have been recruited to support the COO:

- **Relocation Operations Manager** – responsible for the overall planning, scheduling and delivery of the logistics of the relocation (including property related matters), as well as ensuring appropriate risk management, procurement, governance, record keeping and staff liaison arrangements are in place.
- **Digital Strategy Executive Director** – responsible for ensuring the digital strategy is designed and delivered to underpin the Armidale business model, including overseeing linkages to 'business as usual' systems and the new digital strategy as well as the transition from the existing system to the new system.

The Relocation Operations Manager commenced on 6 March 2017 and the Digital Strategy Executive Director commenced on 23 February 2017. These leaders are in the process of forming their teams. A range of contractors and consultants will be engaged for specialist tasks.

4.5 Knowledge management

Knowledge management is a high priority, given the numbers of people leaving the agency and the need to bring on new (inexperienced) staff quickly. Bull & Bear has begun work on capturing the key elements of information and knowledge needed for the various job families within the APVMA and is in the process of designing a framework to ensure knowledge is captured and conveyed during the transition and appropriate strategies are in place to manage information under the new Armidale business model.

4.6 Communication and engagement

A communication strategy is being implemented to support staff and stakeholders during the transition as well as manage associated media and issues. Seftons Communications has been engaged to manage the communications surrounding the relocation.

The focus to date has been on providing information to staff and handling media following the November 2016 announcement. A program for communicating to stakeholders began in January 2017, as well as a program to provide information about the Armidale region to staff. Senior APVMA staff members visited Armidale on 14 December 2016 to meet with a range of local stakeholders, including the Armidale Regional Council and the University of New England. Regular visits to Armidale are planned to ensure the integration of the APVMA into the local community is a positive experience for all parties.

APVMA staff are actively involved in the design of the Armidale business model and in other elements of the relocation. Stakeholders will be engaged in various activities relating to the relocation, primarily through the APVMA Relocation Advisory Committee (ARAC).

The APVMA Relocation Advisory Committee

ARAC was established by the APVMA CEO to provide strategic advice on major aspects of the relocation and the transition of the APVMA from Canberra to Armidale. ARAC is made up of representatives from the APVMA, peak industry bodies as well as Armidale Regional Council, University of New England and the Department of Agriculture and Water Resources.

ARAC is not a decision making body and does not have any direct say on the day-to-day management of the relocation project or the allocation of resources. The purpose of ARAC is to:

- assist with the design of the business model for the APVMA operating out of Armidale
- provide input to the design and delivery of the digital strategy to underpin the Armidale business model
- identify strategic risks and advice on mitigation strategies related to the relocation of the APVMA
- identify relocation related stakeholder issues and advice on engagement and communication activities and issues management (as appropriate)
- provide high level oversight of the progress against key milestones
- consider other relevant issues referred to ARAC by the APVMA CEO.

The ARAC Terms of Reference are at **Attachment C**.

4.7 Governance and risk management

The development and transition to a new business model for the APVMA operating out of Armidale is a complex task. Identifying risks and mitigation strategies is a critical part of the planning phase. The APVMA Executive and ARAC will be the primary forums for continual analysis and updating of the risk framework, with a specialist risk management position to be established as part of the transition team. The APVMA Audit and Risk Committee will also play a critical function in ensuring appropriate frameworks are in place to identify and manage risk.

The key strategic risks impacting on the APVMA that relate to current operations from Canberra and the transition to Armidale have been identified as risks to:

- delivery of legislative obligations and completion of the relocation in a timely manner
- potential for making inappropriate decisions that result in significant harm, loss or liability
- maintenance of organisational capability and staff wellbeing
- relationships with stakeholders
- digital and systems capability
- financial sustainability.

There is a high risk of impacts on business continuity throughout the transition period from anticipated staff departures (particularly the possibility of losing highly skilled and experienced staff), the lengthy time it takes to train new starters, and the re-tasking of existing staff to support critical work underpinning the transition. The impact on the quality and timeliness of decision making will be carefully monitored and managed. The APVMA has also begun work on a fast track basic training program for regulatory scientists commencing with the agency.

The ability of the APVMA to meet legislated timeframes will be affected during the transition to Armidale. The APVMA continues to look at ways to improve the efficiency of business systems and other measures to reduce the burden on staff in performing their duties. The APVMA also recognises the potential uncertainty for applicants in knowing when their applications will be finalised. Work is underway on mechanisms to more easily provide applicants with expected completion dates, including ways to communicate any uncertainty around timeframes.

4.8 Planning and logistics

Detailed planning for the logistics of the move will commence shortly, given the recent engagement of a Relocation Operations Manager. The overall timeframes will be driven by timeframes associated with the building of office accommodation in Armidale.

4.9 Finance and reporting

A budget of $25.6 million has been provided by government to support the relocation. Additional funding for the digital strategy will be determined by government in coming months. The detailed budget is currently being developed now that the Relocation Operations Manager and the Digital Strategy Executive Director has commenced.

5 APVMA REFORM INITIATIVES

As well as managing the relocation of the APVMA to Armidale and the processing of applications, the APVMA is continuing its long term change agenda for efficiency improvements, implementing lower regulatory pathways to registration and improving customer service.

5.1 Business continuity and improvements

Business continuity continues to be a focus with people leaving and new recruits starting. In addition to the recruitment underway, the APVMA is adopting a range of measures to ensure legislative obligations can be met with a less experienced workforce, focussing on improving efficiency and reducing regulatory burden and assessment effort.

Industry have requested that the APVMA continues to prioritise applications according to existing methods. The priority at present is on how more accurate estimates of application due dates can be provided to applicants and mechanisms by which applicants can shift priorities for assessments within their own portfolio of applications.

The APVMA continues to look at its processes to identify efficiencies, with a significant process improvement recently implemented which will significantly reduce the time and effort in assessing environmental impacts of veterinary medicines. Work is also underway with streamlining the issuing of notices for refusal or approval of generic products, which will significantly reduce the effort required in finalising these applications.

The APVMA is undertaking a project focusing on end to end registration to improve internal efficiency and transparency in dealing with registration processes. The objective of the project is to design and implement a systematic way to use workflow for handling applications from beginning to end, supported by effective systems and processes. Current state processes have been developed for several application types and work is underway to identify systems and process improvements. While the main focus of this work is to inform the development of the new digital strategy, the outcomes will also benefit current operations.

The APVMA is also focusing on ways to make it easier for applicants to make an application, while at the same time ensuring new starters are able to more quickly understand the legislative requirements for assessment of the variety of applications dealt with by the APVMA. To that end, the APVMA has developed the concept of the 'Top 20', which is a profile of the most common applications submitted to the APVMA. For each item in the Top 20, there will be targeted guidance material for applicants (as opposed to them having to gather information from a variety of sources) and assessment guidelines for staff, which will cut down the initial phases of evaluation and avoid delays through asking for unnecessary information. The APVMA is discussing this concept with industry in March 2017 to finalise the 'Top 20' and map out a process for its implementation.

5.2 Taking a lower regulatory approach to registration

The 2016-17 budget included $7.3 million over four years to implement the APVMA's components of the Agricultural Competitiveness White Paper reforms. The scope of this work will primarily focus on investigating and implementing lower regulatory approaches for all applications that the APVMA receives for active constituent approvals, product registrations and variations.

The APVMA has developed a plan for gradually introducing these alternate and more efficient pathways over the next two years, supported by funding allocated through the White Paper. The activities outlined below fall within the scope of this program.

International assessments

The APVMA has developed guidance for industry on accepted international data, standards and assessments including OECD guidelines, assessments and standards by OECD members and agencies. A technical policy framework will be published in March 2017 following extensive consultation with industry.

The key features of this framework are:

- Definitions of acceptable international assessments, including their potential scope and a list of organisations whose assessment reports the APVMA will accept,
- A clear statement that the active constituent or product which is the subject of the international assessment must be identical to the active constituent or product intended for approval or registration, respectively, in Australia,
- Listed criteria that the international assessment must fulfil to be acceptable to APVMA,
- Requirements covering the submission of multiple assessments and underlying data or studies
- Confirmation of how the APVMA will use the data provided, including a clear statement that the APVMA does not simply adopt the conclusions of an international assessment—each international assessment must be fit-for-purpose and supported by studies that fulfil our regulatory (data) requirements, and
- Guidelines for the submission of an international assessment.

The APVMA has provided guidance to staff on how to handle international assessments and it is now up to industry to submit international assessments in support of registration applications. Industry are being encouraged to discuss any international assessments with the APVMA prior to submission to ensure the best use can be made of this data and information.

Technical guidance

The APVMA has published adopted relevant international technical guidance material, including from the OECD. Re-working of applicable APVMA data guidelines to better align with international technical guidance material (including the incorporation of OECD Data Point Numbering into the pesticide data guidelines) and providing greater clarity to applicants on the Australian-only information contained in APVMA data guidance material is required.

Contestable assessment services

The APVMA is conducting a pilot for efficacy assessments to be obtained by applicants prior to submitting an application. The pilot commenced on 1 July 2016 utilising approved external scientific reviewers already engaged by the APVMA and will conclude in June 2017. Companies can nominate to participate in the pilot. To date, two applications have been received by the APVMA through this pilot.

Crop groupings

The APVMA is working with Department of Agriculture and Water Resources on a project to improve access to chemical products for use on minor crops by streamlining registration requirements.

An official Australian crop groups list, and the individual crops which form these groups, has been finalised and published. The next phase to be progressed is to review and update data guidelines to identify representative crops from each group which can be used to generate acceptable data for safety, efficacy and trade criteria.

The APVMA is also about to commence a project to determine which permits are suitable for conversion to full registration.

Enhancing user experiences

The objectives of the enhanced applicant experience suite of projects are to obtain a clear understanding of what applicants want from the APVMA, to explain more clearly how to make a registration application and navigate the application system, and improve technical guidance material.

A Usability Review of our online services/channels is complete. Opportunities for short/medium and long term have been identified and work is underway to implement these.

Fully modular assessment system

The APVMA is defining the conceptual framework, business requirements and legislative changes required to support a fully modular assessment system for applications. This will enable tailoring of assessments and regulatory treatment to individual applications. The modular system will be flexible and better able to make use of international or third party assessments and crop groupings. A proposal is being agreed with the Department of Agriculture and Water Resources for inclusion in broader reform to agvet chemical regulation. Consideration of the design requirements will be included in the digital strategy for operation of the APVMA from Armidale.

Fast-track registration

Since 29 July 2016, the APVMA has piloted a fast-track registration pathway for companies wanting to repack their own products. As at 21 February 2017, we have received 17 applications: four are being processed; eight did not meet the fast-track criteria and have been processed via the normal Item 8 pathway; and five eligible applications had their products registered in an average of 10 days. This compares to the legislative timeframe for these types of applications of three months and is also less than the 21-day timeframe we set ourselves for the pilot.

The pilot used IT enhancements and internal process revisions to reduce the time taken to process these applications. This initiative was directly responsible for identifying the business change to allow upfront payment of the full application fee, implemented on 24 November 2016.

The APVMA is continuing the fast-track registration pathway for applications that meet the same criteria set for the pilot. Before we widen the scope for the types of applications that can use the fast-track pathway, we need to make further enhancements that will make processing these applications less onerous. We are reviewing the lessons learnt from the pilot to identify business processes and legislative changes that could improve the current process.

Standards for low risk products

Registration standards will define the conditions under which the APVMA is satisfied in relation to a particular group of products. Products that meet the requirements of the standard could achieve registration through the fast-track registration system. The APVMA will need to develop guidance material for industry in developing such standards. Monographs for low risk ingredients or classes of ingredients would again define the conditions under which such an ingredient would be considered 'low risk'. Consultation with dairy sanitiser and anti-fouling paint industry members is ongoing to determine how this approach may be useful for those products. The APVMA will then explore this option with other industry sectors where appropriate.

Notifiable variations

In September 2016, the APVMA expanded the list of notifiable variations – minor changes that are accepted by notification, rather than an application – as an outcome of the lower regulatory approaches to registration project. Five new items were added to the list of notifiable variations which allow companies to make minor changes to active constituents, products and labels through a simpler and faster process of notification. The APVMA will continue to look for other application types that may be suitable to be a notifiable variation.

GLOSSARY

Administration Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
Agvet chemical products	Agricultural and veterinary chemical products
Agvet Code	*Agricultural and Veterinary Chemicals Code*
Agvet Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
Agvet Code Regulations	*Agricultural and Veterinary Chemicals Code Regulations 1995*
ARAC	APVMA Relocation Advisory Committee
APVMA	Australian Pesticides and Veterinary Medicines Authority's
CEO	Chief Executive Officer
COO	Chief Operating Officer
DAWR	Department for Agriculture and Water Resources
EY	Ernst & Young
GPO	Government Policy Order
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
OECD	Organisation for Economic Co-operation and Development
PGPA Act	*Public Governance, Performance and Accountability Act 2013*

ATTACHMENTS

Attachment A	APVMA Performance Statistics - December Quarter 2016
Attachment B	APVMA in Armidale: Relocation Strategy
Attachment C	The ARAC Terms of Reference