





**Chapter 3**  
Annual  
performance

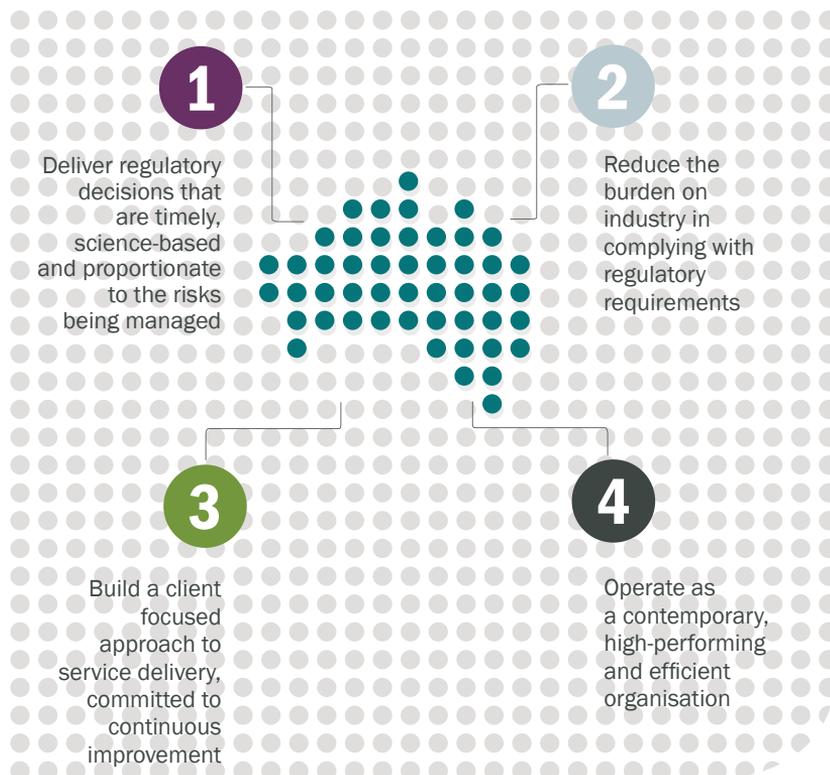
## Strategic framework and reporting

Four strategies outlined in the APVMA *Corporate plan 2015-20* and *Operational plan 2016-17* have helped the agency to achieve its purpose and objectives (Figure 2):

- **Strategy 1—Decision making:** Deliver regulatory decisions that are timely, science-based and proportionate to the risks being managed
- **Strategy 2—Regulatory burden:** Reduce the burden on industry in complying with regulatory requirements
- **Strategy 3—Client focus:** Build a client-focused approach to service delivery, committed to continuous improvement
- **Strategy 4—High performance and efficiency:** Operate as a contemporary, high-performing and efficient organisation.

### OUR STRATEGIES

*Our purpose is underpinned by four strategies*



**Figure 2:** APVMA strategies

## Statement of preparation by the Chief Executive Officer

I, as the accountable authority of the APVMA, present the 2016–17 annual performance statement of the APVMA, as required under paragraph s39(1)(a) of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). In my opinion, these annual performance statements are based on properly maintained records, accurately reflect the performance of the entity and comply with subsection 39(2) of the PGPA Act.

### **Dr Chris Parker**

Chief Executive Officer  
29 September 2017

## Results against performance criteria

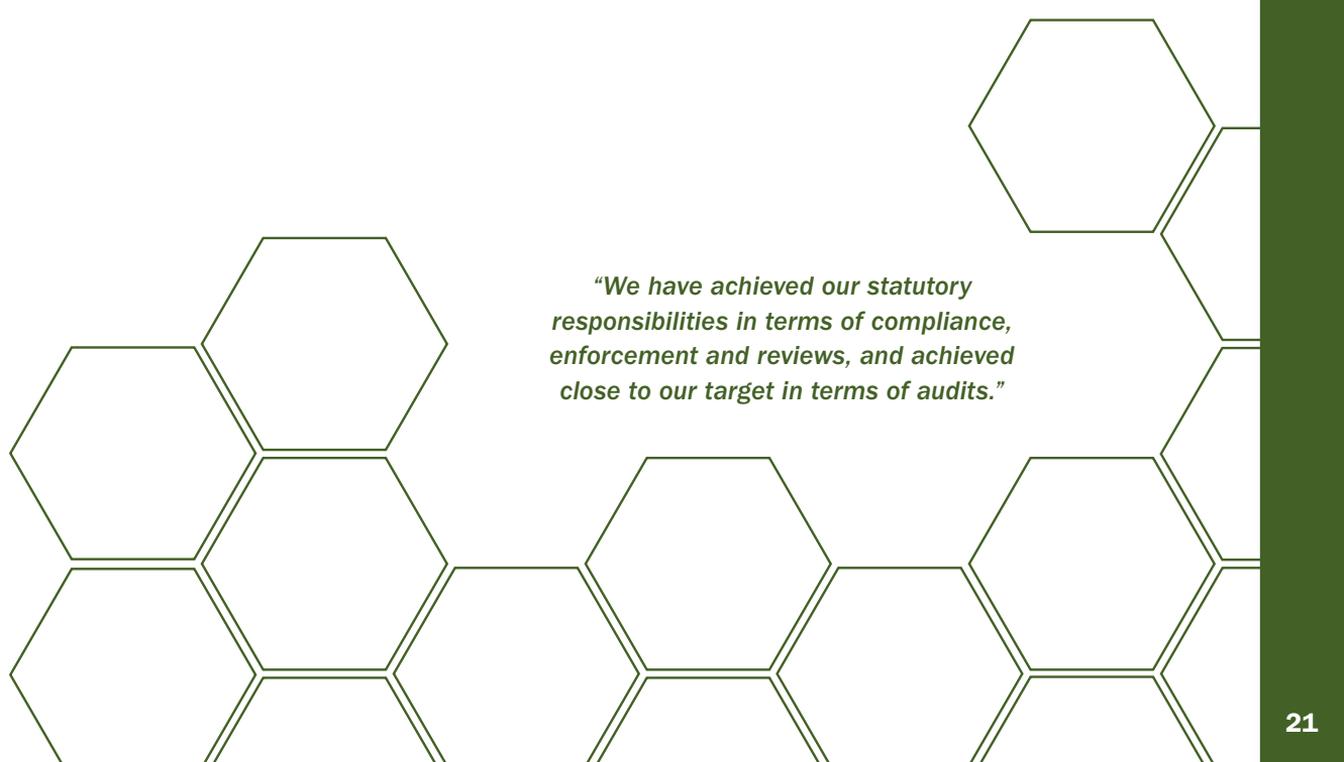
This chapter provides the results of our performance against:

- three performance criteria listed in the *APVMA Portfolio Budget Statement* (PBS)
- 22 performance criteria listed in the *APVMA Corporate plan 2015–20* (including the three PBS criteria).

Each performance criterion has one or more metrics, as outlined in the *APVMA Operational plan 2016–17*. Results at the metric level are presented in tables, with one table for each performance strategy. A summary and explanation of the performance against the strategy is provided at the beginning of each strategy section.

### *Variation from the APVMA Portfolio Budget Statement*

There have been no variations from the PBS in 2016–17.



***“We have achieved our statutory responsibilities in terms of compliance, enforcement and reviews, and achieved close to our target in terms of audits.”***

## Strategy 1—Decision making

Deliver regulatory decisions that are timely, science-based and proportionate to the risks being managed

### *Summary of performance*

APVMA regulatory decisions are based on robust, risk-based scientific evaluations. To achieve this, we aim to:

- complete regulatory decisions within specified timeframes
- undertake, in a timely manner, regulatory responsibilities to register products, approve activities, license veterinary manufacturers, review chemicals and ensure compliance in the marketplace
- undertake actions proportionate to the regulated risk being managed
- improve the quality and consistency of our regulatory decision making through the use of committees (registration quality, science quality and enforcement)
- use regulatory science to underpin quality regulatory decision making
- deliver and implement regulatory science projects.

Table 2 provides a summary of activities related to regulatory decisions this year. We have achieved our statutory responsibilities in terms of compliance, enforcement and reviews and achieved close to our target in terms of audits; but achieved below our target in terms of timeframes for completion of applications.

**Table 2:** Activities related to APVMA regulatory decisions, 2016–17

Types of regulatory decisions	Commenced	Finalised/ issued	In progress
Pre-application assistance	139	139	34
Product registration—pesticides	1 013	750	673
Product registration— veterinary medicines	654	596	389
Actives	738	648	370
Permits	505	459	226
Items 8L, 8M, 8P	267	282	17
Item 25	15	16	14
Notifiable variations	995	967	53
Import consents	803	788	6
Certificates of export	343	335	19

### Explanation of performance

The APVMA is a mature organisation with sound processes that have been developed and tested over many years, including compliance and enforcement approaches and risk management strategies. These processes support our core business of delivering timely science-based regulatory decisions.

Although there were some delays in audits because of logistical issues, 84 per cent of audits were completed as per the schedule and auditing quality was not affected. There was a reduction in the timeframe and completion performance for product applications in the second half of the year. These results were influenced by a high turnover of staff in Registration Management and Evaluation and initial delays in recruiting and training suitable skilled staff.

Table 3 provides a summary of our progress of regulatory decisions within timeframes under Strategy 1.

**Table 3:** Strategy 1—Decision-making results

Percentage of applications completed within timeframes	<i>Corporate plan 2015–20</i>	<p>This year, the APVMA:</p> <ul style="list-style-type: none"> <li>• commenced assessment of 2910 applications for products, actives and permits, and finalised 2453 applications (Table 4)</li> <li>• achieved overall performance rates of 69% within timeframe, including               <ul style="list-style-type: none"> <li>– 59% for product registration (pesticides 45%, veterinary medicines 77%)</li> <li>– 88% for active approvals</li> <li>– 71% for permits.</li> </ul> </li> </ul> <p>Timeframe performance reports are published each quarter, and are available on our website under '<b>Performance statistics</b>'.</p>

**Table 4:** Applications processed by the APVMA, 2016-17

Application type		Started	Finalised	Finalised within timeframe	
					In progress
<b>Products</b>	Pesticides	1 013	750	45%	673
	Veterinary medicines	654	596	77%	389
	<b>Subtotal</b>	<b>1 667</b>	<b>1 346</b>	<b>59%</b>	<b>1 062</b>
<b>Actives</b>		738	648	88%	370
<b>Permits</b>		505	459	71%	226
<b>Total</b>		<b>2 910</b>	<b>2 453</b>	<b>69%</b>	<b>1 658</b>

Percentage of compliance and enforcement activities completed within timeframes

*Corporate plan 2015-20*

The agvet legislative framework has no timeframes for compliance and monitoring actions; we aim to complete cases in the shortest time possible. This year, the Compliance and Monitoring section:

- closed 199 formal matters
- worked on more than 200 enquiries regarding agvet law or processes.

**Key activity:** Undertake, in a timely manner, regulatory responsibilities to register products, approve activities, license veterinary manufacturers, review chemicals and ensure compliance in the marketplace

Performance measure	Source	Result against performance measure
100% of statutory notices issued by Compliance are gazetted in accordance with legislative requirements	<i>Operational plan 2016-17</i>	Under the Agvet Code, if the APVMA issues a statutory recall notice we must publish a notice in the APVMA Gazette within 14 days. This year: <ul style="list-style-type: none"> <li>• one statutory recall notice (a Stop Supply) was gazetted within 14 days</li> <li>• three other compliance statutory notices (Notice to produce and Notice to attend), were issued; however, they were not required to be gazetted.</li> </ul>

Performance measure	Source	Result against performance measure																																				
Good manufacturing practice (GMP) audit program implemented as per APVMA schedule	<i>Operational plan 2016-17</i>	<p>The APVMA conducts GMP audits of Australian and overseas manufacturing facilities to confirm that manufacturing facilities of veterinary chemical products comply with the APVMA's Manufacturing Principles and the Australian Code of GMP for Veterinary Chemical Products.</p> <p>This year, 86% of audits were carried out on schedule (Table 5). Delays were attributed to timing and availability of auditors (eg the due date falling on a public holiday or auditor unavailability), 93% of audits were completed within one week of the due date.</p> <p><b>Table 5: APVMA GMP audits, 2016-17</b></p> <table border="1"> <thead> <tr> <th>Quarter</th> <th>Audit location</th> <th>Number completed</th> <th>Within timeframe</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Australia</td> <td>19</td> <td>94.7%</td> </tr> <tr> <td>Overseas</td> <td>8</td> <td>87.5%</td> </tr> <tr> <td rowspan="2">2</td> <td>Australia</td> <td>16</td> <td>87.5%</td> </tr> <tr> <td>Overseas</td> <td>5</td> <td>80%</td> </tr> <tr> <td rowspan="2">3</td> <td>Australia</td> <td>17</td> <td>71%</td> </tr> <tr> <td>Overseas</td> <td>4</td> <td>100%</td> </tr> <tr> <td rowspan="2">4</td> <td>Australia</td> <td>17</td> <td>94%</td> </tr> <tr> <td>Overseas</td> <td>4</td> <td>50%</td> </tr> <tr> <td><b>Total</b></td> <td></td> <td><b>90</b></td> <td><b>86%</b></td> </tr> </tbody> </table>	Quarter	Audit location	Number completed	Within timeframe	1	Australia	19	94.7%	Overseas	8	87.5%	2	Australia	16	87.5%	Overseas	5	80%	3	Australia	17	71%	Overseas	4	100%	4	Australia	17	94%	Overseas	4	50%	<b>Total</b>		<b>90</b>	<b>86%</b>
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No applications to be overdue by more than three months from 1 January 2017	<i>Operational plan 2016-17</i>	There were 193 applications overdue by more than three months on 1 January 2017.																																				
Reduce the duration of applications and average decision time by item	<i>Operational plan 2016-17</i>	<p>The APVMA assesses applications against 26 item numbers across several categories. The average decision time for applications (Table 6) is:</p> <ul style="list-style-type: none"> <li>• products: 6.7 months</li> <li>• actives: 5.2 months</li> <li>• permits: 3.8 months.</li> </ul>																																				

**Table 6:** Applications and time to finalisation, 2016-17

Type of application	Item	Standard applications (months)			Extended applications (months)		
		Number finalised	Actual average duration	Legislated assessment period	Number finalised	Actual average duration	Legislated assessment period
New product (new active)	1	7	35.4	18.0	N/A	N/A	25.0
	2	17	29.6	Variable (14.4*)	23	23.1	Variable (19.2*)
New product (existing active)	3	0	0.0	18.0	1	27.1	25.0
	4	N/A	N/A	18.0	N/A	N/A	25.0
	5	13	11.5	8.0	10	13.7	12.0
	6	10	20.1	8.0	17	16.6	12.0
	7	125	4.5	3.0	36	8.0	5.0
	8	118	3.3	3.0	29	5.2	5.0
	9	1	1.7	2.0	1	4.0	4.0
	10	97	11.1	Variable (7.6*)	103	14.4	Variable (12.8*)
	10A	32	2.0	Variable (2.0*)	1	6.4	Variable (3.9*)
	Product variations	11	N/A	N/A	10.0	N/A	N/A
12		198	3.6	3.0	14	6.3	5.0
13		10	2.2	3.0	N/A	N/A	5.0
13A		220	0.7	1.0	N/A	N/A	N/A
14		141	8.2	Variable (6.7*)	111	9.5	Variable (10.1*)
Actives	15	3	33.9	14.0	1	21.7	20.0
	16	2	16.2	9.0	N/A	N/A	13.0
	17	488	3.8	7.0	57	7.6	11.0
	18	86	5.5	7.0	9	9.6	11.0
Permits	19	10	2.0	3.0	1	3.4	5.0
	20	173	2.3	3.0	10	5.9	5.0
	21	103	6.9	Variable (4.9*)	17	9.7	Variable (10.5*)
	22	57	1.0	Variable (4.0*)	5	4.7	Variable (10.2*)
	23	70	3.4	3.8	13	8.6	9.4
	112a	5	0.6	Variable (0*)	N/A	N/A	N/A

N/A = no applications were finalised for that item in the reporting period

\* Some items have variable legislated assessment periods because they are modular. Each application will have a different expected duration. The figure in brackets after 'Variable' shows the average expected timeframe for these items. The average expected timeframe may change each reporting period, depending on the nature of applications.

<b>Key activity:</b> Undertake actions proportionate to the regulated risk being managed		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Risk management frameworks and policies are in place and regularly assessed	<i>Corporate plan 2015–20</i>	<p>Policies are in place and regularly assessed.</p> <p>The APVMA developed new guidance for industry on the use of international data, standards and assessments.</p> <p><b>See also</b> <i>Key activity: Align technical guidelines and guidance material with international requirements, unless there is a justifiable reason not to and Key activity: Develop an online ‘fast-tracked’ registration system for applications requiring lower levels of regulatory intervention.</i></p>
Lower regulatory effort is applied to activities of lower regulatory risk	<i>Corporate plan 2015–20</i>	<p>In September 2016, the APVMA expanded the list of notifiable variations—minor changes to active constituents, products and labels that are accepted by a simpler and faster process of notification, rather than an application—as an outcome of the lower regulatory approaches to registration project. Five new items were added to the list. The APVMA will continue to look for other application types that may be suitable to be a notifiable variation.</p> <p><b>See also</b> <i>Key activity: Develop an online ‘fast-tracked’ registration system for applications requiring lower levels of regulatory intervention and Key activity: Develop at least four standards for lower regulatory risk product types.</i></p>

Performance measure	Source	Result against performance measure
Compliance and enforcement strategies are consistent with agreed risk management	<i>Corporate plan 2015-20</i>	<p>The APVMA has a publicly available <i>Compliance and enforcement strategy 2015-17</i> that has three central compliance and enforcement approaches: education, engagement and enforcement.</p> <p>Supporting this strategy is a compliance plan for 2016-17, which includes a risk-assessment approach that is embedded in our case management workflows. Risk assessment includes consideration of the seriousness of the noncompliance and the degree to which safety of human health, animals or the environment may be compromised. The actions undertaken by the Compliance and Monitoring section aim to ensure that any enforcement action is proportionate and efficient.</p> <p>The APVMA's Enforcement Committee oversaw critical decisions on compliance and enforcement matters, such as the use of investigative warrants and statutory enforcement notices.</p>
<b>Key activity:</b> Improve the quality and consistency of our regulatory decision making through the use of committees (registration quality, science quality and enforcement)		
Performance measure	Source	Result against performance measure
Number of internal reviews and Administrative Appeals Tribunal (AAT) applications that result in reversal of decision	<i>Operational plan 2016-17</i>	This year, five internal reviews reversed an earlier decision. Four of the matters were instances where applications had been lodged with the AAT but by consent were remitted to the APVMA for reconsideration following a Federal Court decision.
<b>Key activity:</b> Use regulatory science to underpin quality regulatory decision making		
Performance measure	Source	Result against performance measure
Improvements in regulatory science capability are consistent with agreed priorities and strategies	<i>Corporate plan 2015-20</i>	We liaised with industry experts specialising in nanotechnology and biotechnology, and will continue to do so to anticipate future regulatory challenges and required management approaches.

Key activity: Deliver and implement regulatory science projects		
Performance measure	Source	Result against performance measure
Project milestones are met	<i>Operational plan 2016-17</i>	<p>This year, we:</p> <ul style="list-style-type: none"> <li>developed a cross-agency (APVMA, Department of Agriculture and Water Resources) decision tree for risk profiling of live imported microorganisms intended for use in veterinary vaccines. The Animal Division of Department of Agriculture and Water Resources has assumed responsibility for assessment of risk for genetic recombination/reassortment</li> <li>finalised consultation and drafted a report on antimicrobial resistance. Release of the report is scheduled for the first half of 2017-18</li> <li>developed and documented an approach to the regulation of new agvet chemical products based on emerging technologies. 'Ecological risk assessment of nano-enabled pesticides: A perspective on problem formulation' has been submitted to the <i>Journal of Agricultural and Food Chemistry</i></li> <li>finalised consultation and published a report on Regulatory Scientist Training and Skills Requirements Survey Results, completed in November 2016, which has informed the development of the Accelerated Regulatory Science Training Program, an initiative that will be deployed in 2017-18</li> <li>delivered presentations to staff on gene-drive technology, briefed inductees on the role of the Office of the Chief Scientist, and prepared staff presentations on veterinary drug residues (to be delivered in 2017-18).</li> </ul> <p>On 8 November 2016 the APVMA held a science feature day in Canberra as part of a two-day industry information and education session. The theme of the day was 'Regulatory science and innovation in the global context'. Several expert speakers shared their ideas about what the future of regulation and science in the global context might be, and how that may impact industry and regulators such as the APVMA. The event was attended by more than 180 people.</p>

Performance measure	Source	Result against performance measure
Timeframes for chemical reviews are met and work plans published	<i>Operational plan 2016-17</i>	<p>This year, we:</p> <ul style="list-style-type: none"> <li>● completed the reviews of omethate (December 2016) and dimethoate (March 2017) within the expected completion dates</li> <li>● progressed the remaining 15 reviews and published reports into               <ul style="list-style-type: none"> <li>– paraquat toxicology (October 2016)</li> <li>– neomycin target animal safety (January 2017)</li> <li>– chlorpyrifos toxicology (May 2017)</li> <li>– methiocarb occupational health and safety (May 2017)</li> </ul> </li> <li>● completed a detailed assessment of glyphosate.</li> </ul>

## Strategy 2—Regulatory burden

Reduce the burden on industry in complying with regulatory requirements

### *Summary of performance*

It is important that our regulatory processes support industry operations. To that end, they need to be easy to navigate and use, and should enable the APVMA to work as efficiently and quickly as possible. To achieve this, we aim to:

- remove unnecessary impediments to the efficient operation of regulated entities
- develop an online ‘fast-tracked’ registration system for applications requiring lower levels of regulatory intervention
- develop at least four standards for lower regulatory risk product types
- increase the use of assessments from comparable regulators in decision making
- align technical guidelines and guidance material with international requirements, unless there is a justifiable reason not to
- seek efficiencies in conducting assessments through more contestability
- streamline and coordinate compliance and monitoring approaches
- ensure compliance and licensing activities are consistent with regulatory risk
- define crop groups and provide associated guidance material to streamline the registration process.

The 2016–17 federal budget included \$7.3 million over four years to implement the APVMA's components of the Agricultural Competitiveness White Paper reforms. This work focuses on investigating and implementing lower regulatory approaches for all applications for active constituent approvals, product registrations and variations. Supported by the white paper funding, the APVMA has developed a plan to introduce more efficient pathways for registration during the next two years. The activities outlined under this strategy fall within the scope of this plan.

This year, we developed a number of new approaches that aim to reduce the burden on industry in meeting regulatory requirements when an application is submitted and assessed.

We have developed guidance for industry about the use of international data and standards in applications, and are reworking our data guidelines to better align with the international material. We are also starting to define the supports required for a fully modular assessment system for applications. In coming years, further use of this system will enable us to use international or third-party assessments and to tailor assessments and regulatory treatment to individual applications.

We launched a pilot project enabling applicants to obtain efficacy assessments before submitting an application, and are working on projects to improve access to chemical products for use on minor crops by streamlining registration requirements and to determine which permits are suitable for conversion to full registration.

We have put into place a fast-track system for low-risk applications that will help streamline regulatory assessment and product registration. This system has been well received and is already reducing administrative burdens and accelerating registration for eligible products. In addition, we are consulting with industry about the use of listed standards to define the conditions under which a group of products can be fast-tracked.

In relation to enforcement and monitoring, the APVMA assesses 100 per cent of noncompliance allegations on time. Most allegations (83 per cent) were assessed as low risk and were resolved through education and negotiated compliance. We continued proactive monitoring and engagement with external law enforcement and regulatory bodies.

### *Explanation of performance*

The APVMA is learning from international best practice in developing a fast-track system to better meet industry and stakeholder needs. This has made good progress this year.

**Table 7:**

Strategy 2—Regulatory burden results

<b>Key activity:</b> Remove unnecessary impediments to the efficient operation of regulated entities		
Performance measure	Source	Result against performance measure
Demonstrated understanding of the operating environment for the regulated entities	<i>Corporate plan 2015–20</i>	This year, we: <ul style="list-style-type: none"> <li>• used stakeholder feedback to improve guidance material and the user experience of online information registration systems</li> <li>• mapped end-to-end business processes to streamline assessment processes, and identified and implemented lower regulatory approaches</li> <li>• continued to engage clients and stakeholders to better understand their needs and our operating environment</li> <li>• extended our environmental scan as part of agency planning</li> <li>• invited registrants to present to APVMA staff on the process of product discovery, research and development, and post market activities to support a broader understanding of the operating environment for regulated entities.</li> </ul>
International data guidelines, standards and assessments adopted to reduce effort to register agvet chemicals	<i>Corporate plan 2015–20</i>	The APVMA has developed guidance for industry on international data, standards and assessments, including Organisation for Economic Co-operation and Development guidelines, standards and assessments. In March 2017, we published the <i>Guidance for applicants – submission of international data, standards and assessment</i> .  <b>See also</b> <i>Key activity: Align technical guidelines and guidance material with international requirements, unless there is a justifiable reason not to.</i>
Efficient and effective APVMA business processes	<i>Corporate plan 2015–20</i>	This year, we finalised the semiautomated decision document template (November 2016) and used the template for all new applications.

**Key activity:** Develop an online 'fast-tracked' registration system for applications requiring lower levels of regulatory intervention

Performance measure	Source	Result against performance measure
Achieve key project milestones	<i>Operational plan 2016-17</i>	<p>From July to December 2016, the APVMA piloted a fast-track registration pathway for companies wanting to repack their own products; this is still available to applicants. The pilot:</p> <ul style="list-style-type: none"> <li>• used IT improvements and internal process reform to reduce the time taken to process lower-risk applications</li> <li>• allowed up-front fee payment, saving time for applicants and the APVMA.</li> </ul> <p>As at 30 June 2017:</p> <ul style="list-style-type: none"> <li>• we had received 36 applications: seven met the fast-track criteria, 27 did not meet the fast-track criteria and have been processed via the normal item 8 pathway; and two were withdrawn</li> <li>• the seven eligible applications had their products registered in an average of 26 days; slightly more than the 21-day timeframe set for the pilot and slightly less than the three-month legislative timeframe for these applications</li> <li>• we are continuing the fast-track registration pathway for applications that meet the criteria set for the pilot</li> <li>• we are reviewing the pilot to identify business processes and legislative changes that could improve the process before we increase the types of applications that can use the pathway.</li> </ul>

**Key activity:** Develop at least four standards for lower regulatory risk product types

Performance measure	Source	Result against performance measure
Complete standards for dairy sanitisers, swimming pool products, antifouling paints and household insecticides	<i>Operational plan 2016-17</i>	<p>Listed standards define the conditions under which the APVMA is satisfied about a particular group of products. Products that meet the standard could achieve fast-track registration. This year:</p> <ul style="list-style-type: none"> <li>we continued consultation with members of the dairy sanitiser and antifouling paint industries to determine how this approach may be useful for those products. In 2017-18 we plan to explore this approach with other industry sectors where appropriate</li> <li>we are developing guidance material for industry wanting to develop standards.</li> </ul>

**Key activity:** Increase the use of assessments from comparable regulators in decision making

Performance measure	Source	Result against performance measure
Number of applications using data assessments, standards and decisions from comparable regulators	<i>Operational plan 2016-17</i>	<p>Data submitted for major applications that have been considered by comparable regulators are commonly submitted and used by the APVMA in assessments. The APVMA continues to reference international standards, including pharmacopoeial standards from the Food and Agriculture Organization of the United Nations (FAO), Europe, Britain and the United States of America.</p> <p>This year:</p> <ul style="list-style-type: none"> <li>15 assessments by comparable international regulators contributed to component assessments across human health, residues and environment</li> <li>publicly available international assessments were used to establish environmental endpoints for an additional 30 assessments</li> <li>international assessments (Joint FAO/World Health Organization Meetings on Pesticide Residues) supported the residues component assessments for 24 minor use permits.</li> </ul>

**Key activity:** Align technical guidelines and guidance material with international requirements, unless there is a justifiable reason not to

Performance measure	Source	Result against performance measure
<p>International data guidelines, standards and assessments adopted to reduce effort to register agvet chemicals</p>	<p><i>Operational plan 2016–17</i> Regulator Performance Framework</p>	<p>The APVMA has adopted international technical guidance material and advanced the rework of data guidelines to better align with the international material. This work involved:</p> <ul style="list-style-type: none"> <li>• defining acceptable international assessments, including their potential scope and a list of organisations whose assessment reports we will accept</li> <li>• developing guidelines for the submission of an international assessment, including criteria that the assessment must fulfil to be acceptable to the APVMA (eg the active constituent or product in the international assessment must be identical to the active constituent or product intended for approval or registration in Australia)</li> <li>• developing requirements covering the submission of multiple assessments and underlying data or studies</li> <li>• confirming how we will use the data provided, including a clear statement that the APVMA does not simply adopt the conclusions of an international assessment—each assessment must be fit for purpose and supported by studies that fulfil regulatory requirements</li> <li>• providing clarity to applicants on the Australian-only information contained in APVMA guidance material.</li> </ul> <p>We provided guidance to our staff on how to handle international assessments and industry can now submit international assessments in support of registration applications.</p>

<b>Key activity:</b> Seek efficiencies in conducting assessments through more contestability		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Efficacy contestability pilot milestones are met	<i>Operational plan 2016-17</i>	<p>This year:</p> <ul style="list-style-type: none"> <li>the APVMA launched a pilot project to enable applicants to obtain efficacy assessments before submitting an application</li> <li>the pilot opened to submissions on 1 July 2016 as scheduled</li> <li>10 applications were received through the pilot.</li> </ul> <p>The pilot has been extended by 12 months to allow more applications to be considered.</p>
Proportion of assessments done by external scientific reviewers	<i>Operational plan 2016-17</i>	<p>This year, the majority of efficacy assessments, 57% of environment and 30% of human health, were undertaken by private sector reviewers. The Australian Government Department of the Environment and Energy undertook 12% of environment assessments completed this year.</p>

<b>Key activity:</b> Streamline and coordinate compliance and monitoring approaches		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Monitoring and enforcement strategies allow for a range of regulatory responses	<i>Corporate plan 2015-20</i>	<p>The <i>Compliance and enforcement strategy 2015-17</i> sets out a risk-based approach to dealing with matters of noncompliance in a proportionate and efficient manner. The Compliance and Monitoring section assesses and prioritises allegations of noncompliance within five working days. This year:</p> <ul style="list-style-type: none"> <li>199 compliance cases were resolved; 100% of allegations were assessed on time</li> <li>83% of all allegations were assessed as low risk and were resolved through education and negotiated compliance</li> <li>for matters assessed as medium or high risk, engagement and various enforcement strategies were used, including             <ul style="list-style-type: none"> <li>four statutory notices</li> <li>seven formal warnings</li> <li>five infringement notices (totalling \$31 500)</li> <li>two investigation warrants</li> <li>two monitoring warrants</li> <li>one compulsory stop supply.</li> </ul> </li> </ul>

Performance measure	Source	Result against performance measure
<p>Compliance activities are responsive to business needs of regulated entities, where relevant</p>	<p><i>Corporate plan 2015-20</i></p>	<p>This year, the Compliance and Monitoring section:</p> <ul style="list-style-type: none"> <li>● conducted proactive monitoring activities in response to concerns from industry and other regulators about certain product types in the marketplace, including <ul style="list-style-type: none"> <li>– sampling and testing approved trifluralin active and formulated products containing trifluralin and fipronil; the active and products analysed were found to be within specification and legislative requirements</li> </ul> </li> <li>● continued engagement with external law enforcement and regulatory bodies to limit the supply of unregistered products in the Australian marketplace, including <ul style="list-style-type: none"> <li>– 27 engagements with the Australian Border Force in response to alert activations of suspected unregistered chemical products being imported into Australia; some of the unlawful products were re-exported and 16 letters were issued to the Customs Comptroller General to request the disposal of imported unregistered chemical products</li> </ul> </li> <li>● met with horse and greyhound racing regulators Australia-wide as part of a joint effort to disrupt the flow of unregistered veterinary chemical products in the racing industry</li> <li>● issued three evidentiary certificates to assist racing integrity units in their investigations.</li> </ul>

Performance measure	Source	Result against performance measure
<p>Information requested from regulated entities is necessary and acted upon</p>	<p><i>Corporate plan 2015-20</i></p>	<p>For each matter of noncompliance, the Compliance and Monitoring section sent an average of three information requests. The information requested helps us to assess the validity and scale of the noncompliance and, in most cases, is provided voluntarily by the organisation concerned. In most cases, information exchanges result in a negotiated compliant outcome. This year, we:</p> <ul style="list-style-type: none"> <li>● issued two notices to produce and one notice to attend to compel regulated entities to provide information relevant to investigations; the use of these coercive powers was endorsed by the APVMA's Enforcement Committee</li> <li>● conducted label audits of 182 registered products (products containing clethodim or fenamiphos; and sheep ectoparasiticide and household insecticide products)</li> <li>● contacted 59 companies with requests for label information and sent advisory letters outlining issues requiring rectification.</li> </ul>

<b>Key activity:</b> Ensure compliance and licensing activities are consistent with regulatory risk		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Risk management frameworks and policies are in place and regularly reassessed	<i>Operational plan 2016–17</i>  Regulator Performance Framework	<p>The Manufacturing Quality and Licensing section conducts audits and licenses manufacturers using a risk-based model. In these:</p> <ul style="list-style-type: none"> <li>• manufacturers are divided into categories based on the types of products they produce and are audited in accordance with the manufacturing risk associated with that product; for example, sterile product manufacturers (classed as category 1) are audited more frequently than manufacturers of premix-type products (category 4), because the good manufacturing practice (GMP) requirements for sterile products are much more involved</li> <li>• the number and severity of non-conformances is assessed to help determine the interval between audits; for example, a manufacturer with a low number of minor non-conformances will have a longer audit interval, whereas a manufacturer with a high number of major non-conformances will have a shorter interval.</li> </ul> <p>This year, we commenced a review of our new audit scheduling model to ensure that the agency manages licensing risks effectively. Data to inform a review of the strategy were collated and will be analysed in 2017–18.</p> <p>The <i>Compliance and enforcement strategy 2015–17</i> is reviewed every three years and will be reviewed in 2017–18.</p>

Performance measure	Source	Result against performance measure
<p>Lower regulatory effort is applied to activities of lower regulatory risk</p>	<p><i>Operational plan 2016-17</i></p> <p>Regulator Performance Framework</p>	<p>Low-risk cases are those that have a small number of products involved and that demonstrate a limited risk to human health, animals, the environment and trade. For such cases, education is our main compliance response. Education informs the noncompliant organisations of their regulatory responsibilities and helps to establish a pathway to future compliance. This year, 83% of the APVMA's 199 compliance cases were rated as low risk.</p> <p><b>See also</b> <i>Key activity: Undertake actions proportionate to the regulated risk being managed, Key activity: Develop an online 'fast-tracked' registration system for applications requiring lower levels of regulatory intervention and Key activity: Develop at least four standards for lower regulatory risk product types.</i></p>
<p>Monitoring and enforcement strategies allow for a range of regulatory responses</p>	<p><i>Corporate plan 2015-20</i></p> <p>Regulator Performance Framework</p>	<p>This year:</p> <ul style="list-style-type: none"> <li>● 207 new compliance cases were progressed, applying proportionate responses to bring contravening parties back into compliance and provide future deterrence</li> <li>● two investigative warrants to gather evidence were issued</li> <li>● a compulsory recall notice was issued to stop the supply of an unregistered chemical product</li> <li>● 27 importations were checked in three maritime ports. Most of these were compliant and not held at the border; two imports of around 40 tonnes of unregistered agricultural chemical products were returned to their source countries, 200 litres of unregistered termiticide were referred to the Australian Border Force for disposal, and around two litres of unregistered veterinary performance chemical products were detained and either re-exported or referred to the Australian Border Force for disposal.</li> </ul>

Performance measure	Source	Result against performance measure
Compliance activities are responsive to business needs of regulated entities, where relevant	<i>Corporate plan 2015–20</i> Regulator Performance Framework	<b>See actions in</b> <i>Key activity: Streamline and coordinate compliance and monitoring approaches.</i>
Information requested from regulated entities is necessary and acted upon	<i>Corporate plan 2015–20</i> Regulator Performance Framework	<p>The APVMA may request information related to an application for a licence or a variation to a licence. Information is:</p> <ul style="list-style-type: none"> <li>• requested only if it is necessary to advance the application, particularly if it is critical to the audit</li> <li>• promptly reviewed to enable the application to progress and to facilitate the audit of the facility.</li> </ul> <p>The APVMA may also request information to ensure that overseas sites of manufacture comply with GMP criteria; to register or vary details of veterinary chemical products, the product must be manufactured in either an APVMA-licensed facility, or a facility that is recognised to be compliant with the GMP code. Information provided is reviewed within one week to allow the application to progress.</p> <p><b>See also</b> <i>Key activity: Streamline and coordinate compliance and monitoring approaches.</i></p>
<b>Key activity:</b> Define crop groups and provide associated guidance material to streamline the registration process		
Performance measure	Source	Result against performance measure
Achieve key milestones	<i>Corporate plan 2015–20</i>	<p>The APVMA is working on a project to improve access to chemical products for use on minor crops by streamlining registration requirements (in collaboration with the Department of Agriculture and Water Resources). This year:</p> <ul style="list-style-type: none"> <li>• Phase 1 was completed with an official Australian crop groups list published that includes the individual crops in these groups</li> <li>• work commenced on Phase 2 to identify representative crops from each group that can be used to generate acceptable data for safety, efficacy and trade criteria; a final listing of crop groups, representative crops and guidance material will be published in 2017–18.</li> </ul>

## Strategy 3—Client focus

Build a client-focused approach to service delivery, committed to continuous improvement

### *Summary of performance*

The APVMA works with a range of stakeholders and it is important that our information and communication facilitates stakeholder actions and interactions. To achieve this, we aim to:

- ensure communication with regulated entities is clear, targeted and effective
- develop a clear understanding of applicant needs and wants about the registration process
- review communication with applicants about how to make a registration application and navigate the registration system and maintain tracking of progress
- improve the quality and quantity of guidance information for applicants
- ensure active contribution to the continuous improvement of regulatory frameworks
- monitor and act on trends in client feedback
- ensure openness and transparency in dealings with regulated entities
- provide clear information about agency performance.

This year, we worked on a range of projects 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 to improve our communication and technical guidance material.

We completed a review of our online channels and information, and of outgoing letters, notices and emails. Opportunities for short-, medium- and long-term improvements have been identified and work is underway to implement these. We have made initial changes to the website, and a subsequent review found that user searches and discoverability of guidance material has improved. We implemented newsletter, notice and email templates; initial data on the rate and nature of client responses indicate user comprehension has improved.

We published the *Guide to completing an online application* and *Guidance for submission of international data standards and assessments*, and a project to improve other guidance material for most product applications has commenced including conducting industry workshops. We continue to collect voluntary feedback about the pre-application assistance (PAA) process, and this year 100 per cent of applicants agreed that the information and guidance material for this process was clear.

We consulted publicly on 45 regulatory decisions and proposed changes to operational policy and development of guidelines. We received at least 7100 calls and 8800 emails about applications, and have implemented a case manager model for enquiries which has improved the continuity of handling. Subscriptions to the *APVMA Gazette* continue to increase.

### Explanation of performance

The review of our information and communication showed that improvement can be made in many areas. We are therefore working to systematically improve our online offerings and our interactions with stakeholders. Feedback to date on these improvements is encouraging.

We received increased media enquiries and interest in the management and performance of our business following the relocation announcement.

**Table 8:**

Strategy 3—Client focus results

<b>Key activity:</b> Ensure communication with regulated entities is clear, targeted and effective		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Level of satisfaction with information and guidance materials	<i>Corporate plan 2015–20</i>	<p>Feedback from stakeholders confirms that APVMA information and guidance material can be improved and we are working on a range of projects to bridge the gap between client expectations and experiences.</p> <p>This year:</p> <ul style="list-style-type: none"> <li>• the usability of the APVMA website was reviewed (October 2016) to gain a clearer understanding of what applicants and other users need from the website and online services portal; recommendations were prioritised for implementation in early 2017</li> <li>• Google search was implemented on the website in February 2017 and analytics have demonstrated improvements to our user searches and discoverability of guidance material</li> <li>• we published the <i>Guide to completing an online application</i> and <i>Guidance for submission of international data standards and assessments</i></li> <li>• we developed project plans for a series of Agricultural Competitiveness White Paper and business improvement activities to be implemented between 2017 and 2019 to improve satisfaction with regulatory guidance materials</li> <li>• satisfaction with online information and guidance material was monitored and feedback actioned by relevant business areas</li> <li>• we have redesigned the Our Science web pages and content will be implemented in 2017–18</li> <li>• we received and addressed where required to               <ul style="list-style-type: none"> <li>– 40% positive, 30% negative, 30% neutral ratings provided through a feedback mechanism at the bottom of each web page containing guidance material</li> <li>– 6% positive, 43% negative, 51% neutral feedback reports through a form on the online services portal.</li> </ul> </li> </ul>

Performance measure	Source	Result against performance measure
<p>Level of satisfaction with the quality and timeliness of advice on decisions</p>	<p><i>Corporate plan 2015-20</i></p>	<p>This year:</p> <ul style="list-style-type: none"> <li>• subscriptions to the <i>APVMA Gazette</i> grew to 2354, an increase of 6.4%, indicating continued satisfaction with information about APVMA decisions communicated through this publicly available channel</li> <li>• we implemented a case manager model for enquiries which has improved the continuity of handling</li> <li>• at least 7100 calls and 8800 emails were received by the APVMA Case Management and Administration Unit, representing a decrease of approximately 25% on the previous year. The decrease in general enquiries has been influenced by the successful implementation of an account management system, with many applicants able to contact their dedicated case manager directly. A restructured phone system has diverted calls to the correct APVMA area without the need for triaging through the Case Management and Administration Unit.</li> </ul>

Performance measure	Source	Result against performance measure
Extent and satisfaction with APVMA consultative processes	<i>Corporate plan 2015–20</i>	<p>The APVMA consults on all major changes to operational policy and guidelines before finalisation. This year:</p> <ul style="list-style-type: none"> <li>• there were around 3200 unique visits to the public consultation pages of the APVMA website, indicating strong visibility and accessibility of APVMA consultations</li> <li>• we consulted publicly on 45 regulatory decisions and proposed changes to operational policy and development of guidelines, including <ul style="list-style-type: none"> <li>– finalising APVMA policies and guidance material for the use of international standards, assessments and data</li> <li>– review of the good manufacturing practice audit framework</li> <li>– consideration of a revised policy for prioritisation of APVMA workload and application assessments</li> <li>– continuation of pilot programs for applicants to source efficacy assessments before application and for fast-track registration systems for applications of low regulatory concern</li> <li>– a proposal to leverage assessments and decisions in New Zealand for non–food producing animals</li> <li>– proposed changes to safety and use instructions through the chemical reconsideration of dimethoate</li> </ul> </li> <li>• we held a workshop (February 2017) to establish client expectations for improved regulatory guidance material.</li> </ul>

<b>Key activity:</b> Develop a clear understanding of applicant needs and wants about the registration process		
Performance measure	Source	Result against performance measure
Achieve key project milestones	<i>Operational plan 2016-17</i>	<p>The website usability review informed activities that have progressed in 2016-17 and are expected to be completed by June 2018, including:</p> <ul style="list-style-type: none"> <li>• addressing core usability issues</li> <li>• undertaking a content audit</li> <li>• undertaking a terminology review</li> <li>• reviewing information architecture and testing any new architecture with users</li> <li>• reviewing the user interface design of the homepage to provide users with direct paths to key site features and content.</li> </ul> <p><b>See also</b> <i>Key activity: Ensure communication with regulated entities is clear, targeted and effective.</i></p>
Demonstrated understanding of the operating environment of the regulated entities	<i>Operational plan 2016-17</i> Regulator Performance Framework	<p>A two-day industry information and engagement event was held in Canberra during November 2016. Of the attendees, including 180 stakeholders, 95.95% either strongly agreed or agreed that the session was a useful and worthwhile forum for consultation.</p> <p>The event allowed stakeholders to engage in two-way feedback, and provided a forum for the APVMA to listen to challenges and opportunities impacting the regulated industry.</p> <p>Industry sessions complemented APVMA's traditional consultation channels in 2016-17.</p> <p><b>See</b> <i>Key activity: Remove unnecessary impediments to the efficient operation of regulated entities.</i></p>
Extent and satisfaction with APVMA consultative processes	<i>Operational plan 2016-17</i> Regulator Performance Framework	<p><b>See</b> <i>Key activity: Ensure communication with regulated entities is clear, targeted and effective.</i></p>

Performance measure	Source	Result against performance measure
Level of stakeholder engagement in implementing regulatory frameworks	<i>Operational plan 2016–17</i> Regulator Performance Framework	<p>We continue to engage stakeholders in the planning of APVMA business improvement projects.</p> <p>In February 2017, we held workshops to establish client expectations for improved regulatory guidance and delivery of fast-tracked registration.</p> <p>From 2017–18, stakeholders will be engaged in a series of Agricultural Competitiveness White Paper and business improvement activities that are designed to increase user satisfaction with regulatory guidance materials.</p>
Satisfaction with APVMA online systems for submitting and managing applications	<i>Operational plan 2016–17</i> Regulator Performance Framework	<p>Several features aimed at streamlining applications have been added to APVMA online systems this year.</p> <p><b>See</b> <i>Key activity: Develop an online ‘fast-tracked’ registration system for applications requiring lower levels of regulatory intervention, and Key activity: Ensure communication with regulated entities is clear, targeted and effective.</i></p>
Customer services standards met	<i>Operational plan 2016–17</i> Regulator Performance Framework	<p>This year:</p> <ul style="list-style-type: none"> <li>• phone messages and emails were checked daily by the enquiries team and replies made within the one-day standard for phone calls and five-day standard for written enquiries</li> <li>• we responded to 35 media inquiries; 70% of responses were within agreed deadlines</li> <li>• website content review systems were appropriately maintained and feedback from the website was monitored and acted on daily to improve online information</li> <li>• content published to the APVMA website was continuously quality checked to ensure compliance with Australian Government online and accessibility standards.</li> </ul> <p><b>See also</b> <i>Key activity: Ensure communication with regulated entities is clear, targeted and effective.</i></p>

**Key activity:** Review communication with applicants about how to make a registration application and navigate the registration system and maintain tracking of progress

Performance measure	Source	Result against performance measure
Level of satisfaction with information and guidance materials	<i>Operational plan 2016-17</i> Regulator Performance Framework	This project is expected to be completed by June 2018. In 2016-17, project plans were developed and endorsed that will improve guidance material for the majority of product applications.
Feedback about the quality of pre-application assistance (PAA)	<i>Operational plan 2016-17</i> Regulator Performance Framework	We continue to collect voluntary feedback about different aspects of the PAA process. This year we received 12 submissions, and: <ul style="list-style-type: none"> <li>• 100% of applicants agreed that the information and guidance material for making a PAA request was clear</li> <li>• 100% of applicants advised that the advice received would assist them in preparing an application to the APVMA</li> <li>• 92% agreed that the online system for submitting a PAA application was easy to use</li> <li>• 83% of applicants were satisfied with the clarity of the advice</li> <li>• 83% agreed that the format, fees and timeframes were appropriate.</li> </ul>

**Key activity:** Improve the quality and quantity of guidance information for applicants

Performance measure	Source	Result against performance measure
100% of correspondence provided to applicants/registrants assessed as comprehensive and easily understood	<i>Operational plan 2016-17</i> Regulator Performance Framework	A correspondence improvement project began in 2015-16 with a full audit of all outgoing letters, notices and emails. Feedback has identified priority products for action and we commenced work in 2016-17 to improve correspondence products.  This year, we implemented newsletter, notice and email templates; initial data on the rate and nature of client responses indicate improvements in user comprehension.

<b>Key activity:</b> Ensure active contribution to the continuous improvement of regulatory frameworks		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Level of stakeholder engagement in implementing regulatory frameworks	<i>Corporate plan 2015–20</i>	<b>See</b> Key activity: Develop a clear understanding of applicant needs and wants about the registration process.
Feedback is provided to inform the development or amendment of regulatory frameworks	<i>Corporate plan 2015–20</i>	<b>See</b> Key activity: Ensure communication with regulated entities is clear, targeted and effective.
<b>Key activity:</b> Monitor and act on trends in client feedback		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Feedback mechanisms are in place and used to improve services to regulated entities	<i>Operational plan 2016–17</i> Regulator Performance Framework	<b>See</b> Key activity: Ensure communication with regulated entities is clear, targeted and effective and Key activity: Develop a clear understanding of applicant needs and wants about the registration process.
Documented procedures in place to facilitate engagement with the Department of Agriculture and Water Resources and relevant state and territory agencies	<i>Operational plan 2016–17</i> Regulator Performance Framework	This was completed in 2017 and engagement is being undertaken in line with these procedures.
<b>Key activity:</b> Ensure openness and transparency in dealings with regulated entities		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Performance information is published	<i>Corporate plan 2015–20</i>	APVMA Operational Performance reports are produced quarterly and are published on the website within six weeks of the end of the quarter. The APVMA annual report is produced according to government guidelines and the 2015–16 report was delivered on time.

Performance measure	Source	Result against performance measure
Feedback mechanisms are in place and used to improve service delivery to regulated entities	Corporate plan 2015-20	<b>See</b> Key activity: Ensure communication with regulated entities is clear, targeted and effective and Key activity: Develop a clear understanding of applicant needs and wants about the registration process.
<b>Key activity:</b> Provide clear information about agency performance		
Performance measure	Source	Result against performance measure
Performance information is published	Operational plan 2016-17  Regulator Performance Framework	<b>See</b> Key activity: Ensure openness and transparency in dealings with regulated entities.

## Strategy 4—High performance and efficiency

Operate as a contemporary, high-performing and efficient organisation

### Summary of performance

Developing and maintaining efficient and effective business systems and resources are essential to our organisation. To achieve this, we aim to:

- ensure a high level of organisational health and financial viability
- provide clear work instructions and management controls
- ensure business systems support the efficient operation of the agency
- streamline the end-to-end registration process in line with the project plan deliverables
- complete the review of the good manufacturing practice (GMP) assessment programs
- implement the IT Strategic Plan to support information management, staff capability and service delivery
- develop our digital strategy and capability
- implement recommendations from the Protective Security Policy Framework (PSPF) review
- ensure organisational sustainability
- implement the APVMA people strategy
- closely manage the APVMA budget
- implement the learning and development strategy.

This year, we have focused on two key areas: staffing and IT.

We have recruited and inducted a high number of staff, and focused training on technical and scientific processes. We are focused on programs and initiatives to support our staff.

We have continued to develop and improve our IT systems to support efficient submission and processing of agvet applications, including an upgrade of the EDRMS; implementation of an internal instructional material library for the proactive management of APVMA policies, processes and procedures; and the migration and decommissioning of legacy business systems. We developed the *ICT strategic plan 2016–19*, and started to develop an APVMA Digital strategy to enable the operation of the APVMA from Armidale.

### *Explanation of performance*

This year we have experienced a higher-than-anticipated staff separation rate. We continue to review our human resource capabilities to make sure staff have the right skills to deal with challenges that face the APVMA. We are continuing to focus on reviewing and redesigning our strategies around recruitment, retention, knowledge management and building our scientific capability.

**Table 9:** Strategy 4—High performance and efficiency results

<b>Key activity:</b> Ensure a high level of organisational health and financial viability		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
APVMA workforce is motivated and skilled	<i>Corporate plan 2015–20</i>	<p>This year:</p> <ul style="list-style-type: none"> <li>we engaged 85 people through 39 individual recruitment actions and five bulk processes; induction and onboarding have been given a high priority</li> <li>100% of those new employees have completed online and face-to-face induction training</li> <li>an audit of the APVMA's knowledge and knowledge management practices was conducted and led to the development of a knowledge management strategy</li> <li>we organised career management sessions for eligible staff; these have been well attended and positively received</li> <li>21 employees have completed a Diploma of Leadership and Management</li> <li>we designed and offered a range of activities including Health Week to support our staff</li> <li>the APVMA Social Club continues to conduct events.</li> </ul> <p><b>See also</b> <i>Work health and safety.</i></p>

Performance measure	Source	Result against performance measure
<p>Efficient and effective business processes and financial management systems in place</p>	<p><i>Corporate plan 2015-20</i></p>	<p>This year, we:</p> <ul style="list-style-type: none"> <li>● mapped the registration process for key application types</li> <li>● conducted a detailed review of the existing registration process</li> <li>● identified process improvements that support efficiency gains during the relocation period</li> <li>● identified business requirements for a new application registration system.</li> </ul> <p>These activities have been undertaken to inform the digital strategy that will help the APVMA to build a streamlined system to support its future operations in Armidale. These activities have also enabled the streamlining of registration processes to remove inefficient or unnecessary steps, and better align effort with risk.</p>

Performance measure	Source	Result against performance measure
Information technology supports information management, staff capability and service delivery	<i>Corporate plan 2015–20</i>	<p>The APVMA has online systems to support information management, staff capability and service delivery, including:</p> <ul style="list-style-type: none"> <li>● online services to support the electronic submission of agvet applications by registered users</li> <li>● an internal portal for managing the end-to-end registration process for agvet applications</li> <li>● an EDRMS to support organisational information management</li> <li>● an online learning management system</li> <li>● an internal instructional material library (IML) for the proactive management of APVMA policies and processes.</li> </ul> <p>This year, several initiatives were completed to improve service delivery in these areas, including:</p> <ul style="list-style-type: none"> <li>● an upgrade of the EDRMS to ensure its effective operation on APVMA mobile tablet devices</li> <li>● development of an online induction module to introduce new staff to APVMA information management practices</li> <li>● introduction of new modules into the internal portal to support efficient management of product data, actives data and finance data associated with agvet applications</li> <li>● introduction of new workload management features into the internal portal to support the management of tasks and milestones within the end-to-end registration process</li> <li>● improvements to the online services site, including <ul style="list-style-type: none"> <li>– annual return of actives reporting</li> <li>– agvet application status dashboard reporting</li> <li>– up-front payment options to include full fees</li> <li>– increased registration renewal options</li> <li>– a fast-track application system for certain application types</li> </ul> </li> <li>● commencement of work to redevelop our record authority in preparation for the digitisation of historic paper records.</li> </ul>

Key activity: Provide clear work instructions and management controls		
Performance measure	Source	Result against performance measure
Review internal work instructions within scheduled timeframes	<i>Operational plan 2016-17</i>	<p>This year:</p> <ul style="list-style-type: none"> <li>we implemented the IML, which contains guidelines, accountable authority instructions, policies, decision maps, process maps, work instructions, forms, notices, templates and reference material; these combine to outline the approved work practices for APVMA staff</li> <li>we reviewed and subsequently updated around 27% of our instructional material</li> <li>we conducted a number of major projects that will increase the efficiency and effectiveness of the work instruction review processes; the revision or creation of the IML documentation will reflect the project outcomes.</li> </ul> <p><b>See also</b> Key activity: <i>Ensure a high level of organisational health and financial viability.</i></p>
Key activity: Ensure business systems support the efficient operation of the agency		
Performance measure	Source	Result against performance measure
Reduction in number of legacy business systems	<i>Operational plan 2016-17</i>	<p>We are conducting a project to migrate and decommission legacy business systems by October 2018. This year:</p> <ul style="list-style-type: none"> <li>the project delivered new capability to support efficient management of product, actives and finance data; this has positioned the APVMA to decommission four legacy systems (iEARS, Agvet, NPRIS and the ATS Finance Module)</li> <li>the legacy records management system RecFind and the legacy corporate reporting tool Cambron were decommissioned.</li> </ul> <p>The project is tracking on schedule and budget.</p>

**Key activity:** Streamline the end-to-end registration process in line with the project plan deliverables

Performance measure	Source	Result against performance measure
Achieve key project milestones	<i>Operational plan 2016–17</i>	<p>This year:</p> <ul style="list-style-type: none"> <li>we reviewed the project on the end-to-end registration process, following the announcement of the APVMA relocation</li> <li>as part of the review, work on current and future state process mapping was accelerated and was delivered on time at the end of March 2017</li> <li>Phase 2 of the project started on 1 April 2017 to identify process inefficiencies and opportunities for improvements.</li> </ul> <p>The project is on track to be completed by end of August 2017 as per the project plan.</p>

**Key activity:** Complete the review of the good manufacturing practice (GMP) assessment programs

Performance measure	Source	Result against performance measure
Review completed	<i>Operational plan 2016–17</i>	<p>This year, we engaged external consultants to review the GMP programs and consider the APVMA approach to auditing and licensing, the approach of comparable international regulators, and possible improvements to increase program effectiveness. The completed review:</p> <ul style="list-style-type: none"> <li>recommended that we implement a second-party auditing model with a view to implementing a first-party auditing model within five years; this aims to improve international harmonisation of GMP for veterinary chemical products</li> <li>describes 10 key steps to achieve implementation that need to be considered by the APVMA and its stakeholders.</li> </ul> <p>We have commenced the initial consultation on these recommendations and proposed steps.</p>

<b>Key activity:</b> Implement the IT Strategic Plan to support information management, staff capability and service delivery		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Review completed	<i>Operational plan 2016-17</i>	<p>This year, the <i>ICT strategic plan 2016-19</i> was finalised and endorsed by the CEO and Executive Leadership Team. This plan included:</p> <ul style="list-style-type: none"> <li>• development of the <i>Information management strategic plan 2016-20</i>, to align the APVMA to the whole-of-government Digital Continuity 2020 strategic road map</li> <li>• development of an information management governance framework to ensure effective management of information across the agency.</li> </ul>
IT Strategic Plan milestones are met	<i>Operational plan 2016-17</i>	<p>Initiatives from the <i>ICT strategic plan 2016-19</i> and the <i>Information management strategic plan 2016-20</i> are now underway, with quarterly traffic light reports to be presented to the executive team from 2017-18.</p>
<b>Key activity:</b> Develop our digital strategy and capability		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Provide information systems that support the business	<i>Operational plan 2016-17</i>	<p>This year, we started to develop an APVMA Digital strategy to enable the operation of the APVMA from Armidale.</p> <p><b>See also</b> <i>Key activity: Ensure a high level of organisational health and financial viability</i> and <i>Key activity: Implement the IT Strategic Plan to support information management, staff capability and service delivery.</i></p>

<b>Key activity:</b> Implement recommendations from the Protective Security Policy Framework (PSPF) review		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
PSPF recommendations implemented	<i>Operational plan 2016–17</i>	<p>This year:</p> <ul style="list-style-type: none"> <li>• we continued to improve our performance as measured against the PSPF and the essential eight strategies for mitigating cyber incidents</li> <li>• we significantly improved APVMA security patching of desktop and server operating systems</li> <li>• we significantly reduced spam by implementing a reputation-based filter</li> <li>• we started monthly cyber incident reporting to the executive team.</li> </ul>
<b>Key activity:</b> Ensure organisational sustainability		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Ensure capability, culture and financial sustainability	<i>Operational plan 2016–17</i>	<p>This year:</p> <ul style="list-style-type: none"> <li>• the new <i>Enterprise Agreement 2017–20</i> was agreed to by staff</li> <li>• the people strategy and learning and development outcomes were implemented</li> <li>• flexible work arrangements for staff were supported</li> <li>• we developed and designed the Diploma of Government in Regulatory Science for launch in July 2017</li> <li>• we developed and are implementing our knowledge management strategy.</li> </ul> <p><b>See also</b> <i>Key activity: Ensure a high level of organisational health and financial viability.</i></p>

<b>Key activity: Implement the APVMA People Strategy</b>		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Improve workforce stability	<i>Operational plan 2016-17</i>	<p>A number of measures are being implemented to increase the stability of our current and future workforce, including:</p> <ul style="list-style-type: none"> <li>• a direct focus on retaining existing staff through the development of an APVMA retention policy</li> <li>• extending the <i>People Strategy 2016-19</i></li> <li>• undertaking workforce planning to identify current and future workforce needs</li> <li>• supporting staff by providing opportunities to participate in the accelerated science training program that is being implemented as part of the revised <i>Learning and Development Strategy</i></li> <li>• a contemporary, strategic recruitment strategy to identify future recruitment needs, appropriate candidate sources and new ways of attracting candidates to the APVMA.</li> </ul>
Staff engagement	<i>Operational plan 2016-17</i>	This year 93% of eligible APVMA staff voted in the March 2017 ballot for the enterprise agreement; of those that voted, 56% voted 'yes' to a new enterprise agreement.
No preventable work health and safety incidents requiring notification to the regulator/Comcare	<i>Operational plan 2016-17</i>	This year there were no incidents requiring notification to Comcare.

<b>Key activity:</b> Closely manage the APVMA budget		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Maintain equity reserve targets	<i>Operational plan 2016–17</i>	A cost base review commenced as a first step in identifying business costs to support the development of a revised cost recovery impact statement and to inform the future APVMA's equity target.
<b>Key activity:</b> Implement the <i>Learning and Development Strategy</i>		
<b>Performance measure</b>	<b>Source</b>	<b>Result against performance measure</b>
Strategy milestones are met	<i>Operational plan 2016–17</i>	<p>The APVMA <i>Learning and Development Strategy</i> was endorsed by the executive team in 2016 and refined in 2016–17 before the announcement that the APVMA would move to Armidale in 2019. This announcement has resulted in an organisational refocus for learning and development, with an increased focus on technical and scientific training.</p> <p><b>See also</b> Key activity: <i>Ensure a high level of organisational health and financial viability</i> and performance measure <i>Improve workforce stability</i> within Key activity: <i>Implement the APVMA people strategy</i>.</p>