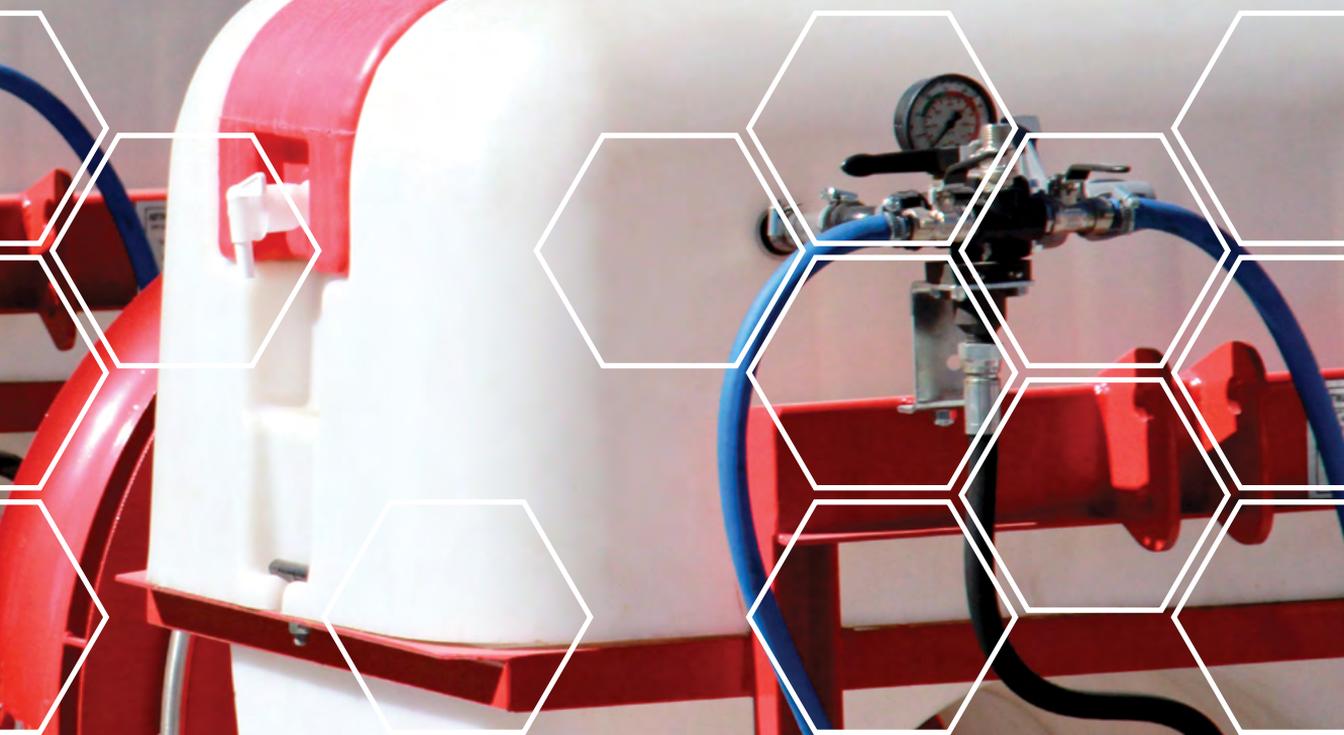




CHAPTER 3

Annual performance statement

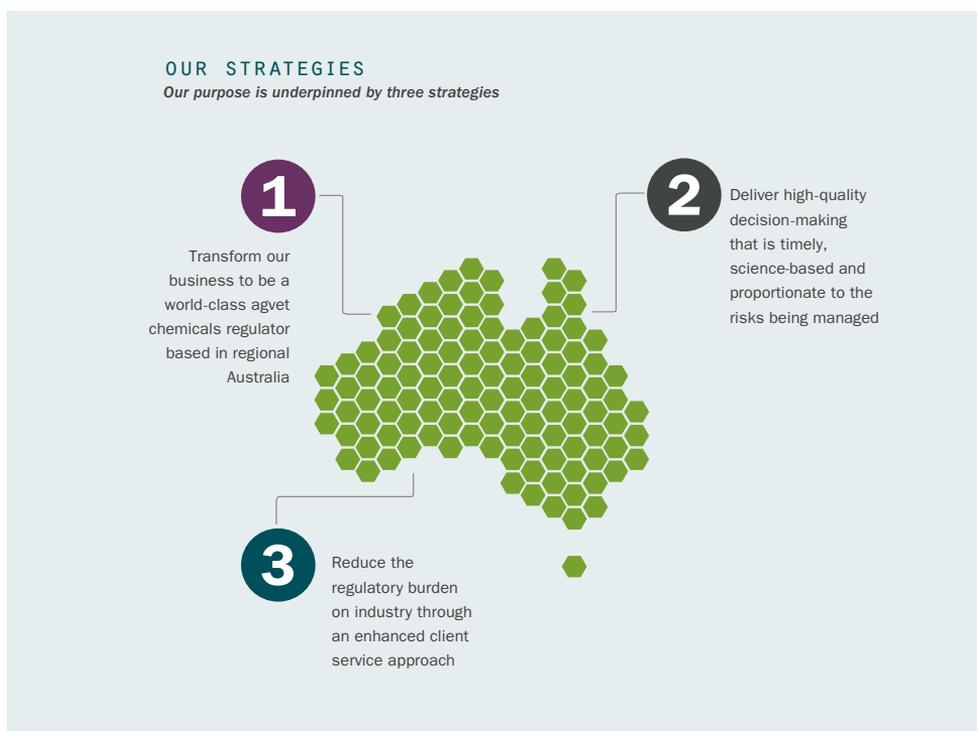


Strategic framework and reporting

The APVMA corporate strategies in 2017-18 reflect our aim to effectively manage our operations while implementing significant change in our business. Our strategies are contained in three key documents:

- The *Corporate plan 2017-18* outlines three strategies to deliver core assessment and registration of agvet chemicals, while transitioning our people, property and work practices to a new business model operating from regional Australia (Figure 2).
- The *Operational plan 2017-18* maps these strategies to activities and operational performance measures that enable the APVMA to achieve its purpose and regulatory functions.
- The *Regulator performance framework 2017-18* provides an additional lens through which the APVMA can assess regulatory performance against the Australian Government Deregulation Agenda. A self-assessment report against this framework is published each year on the APVMA website.

Figure 2: APVMA corporate strategies

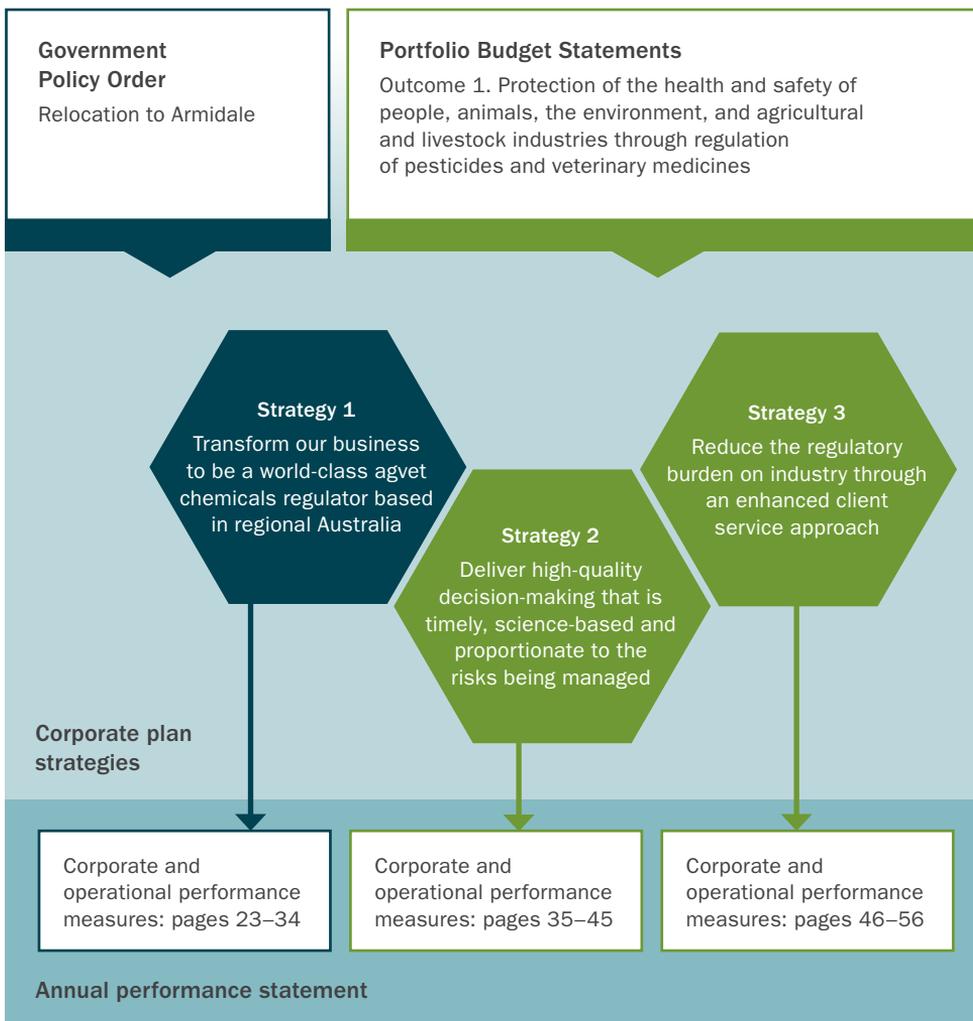


Measuring our performance

Our corporate strategies are interconnected. Our key performance indicators are therefore considered in a holistic way, focusing on four themes of legislative compliance, risk-based intervention, quality decision-making and stakeholder engagement. Successful delivery in one strategic area will reinforce and build success in all.

The relationship between our Portfolio Budget Statements, corporate plan and annual performance statement is shown in Figure 3.

Figure 3: Relationship between APVMA Portfolio Budget Statements, corporate plan and annual performance statement



Statement of preparation by the Chief Executive Officer

I, as the accountable authority of the APVMA, present the 2017-18 annual performance statement of the APVMA, as required under paragraph s. 39(1)(a) of the 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 s. 39(2) of the PGPA Act.

Dr Chris Parker
Chief Executive Officer
14 September 2018

Results against performance criterion

This chapter provides the results of our performance against:

- the *APVMA Portfolio Budget Statement (PBS)*
- measures in the *Corporate plan 2017-18*
- 12 focus areas listed in the *Operational plan 2017-18*.

Each focus area has at least one metric, as outlined in the *APVMA Operational plan 2017-18*. Results are presented in tables at the metric level, with one table for each performance strategy. A summary and explanation of performance against the strategy is provided at the beginning of each strategy.

Variation from the APVMA Portfolio Budget Statement

There have been no variations from the PBS in 2017-18.

Strategy 1

Transform our business to be a world-class agvet chemicals regulator based in regional Australia

Summary of performance

To achieve Strategy 1, we aim to:

- define, implement, embed and optimise the application of the new APVMA business model based in Armidale
- implement key changes across people (capability), process (workforce and workplace) and technology (ICT)
- define and implement business reform initiatives, including the *Agricultural competitiveness white paper* reform and agvet legislative reform
- improve stakeholder engagement
- create a sustainable and equitable funding base for the organisation.

We made significant progress this year on developing and implementing the new business model to support our relocation to Armidale. Construction of the permanent Armidale offices commenced and is expected to be completed mid-2019.

As part of the new business model, we examined our needs for digital technology and human resources. We developed a digital strategy, and the Australian Government allocated \$10.1 million over three years to deliver the enabling technology program of work. The APVMA employee retention policy provided incentives for our existing workforce to remain with the authority during the transition to Armidale. We also surveyed staff about their relocation plans to better understand our future staffing supply and profile. Access to regulatory science expertise was identified as a key risk so we explored recruitment efforts and teleworking arrangements to address this. Failure to fully mitigate this risk has required further measures, and the APVMA will retain a modest unit of specialist scientific and decision-making staff in a Canberra satellite office.

To further support staff, we developed a knowledge management strategy and framework. Changes to administrative process and workflows resulting from business improvements and projects undertaken through the *Agricultural competitiveness white paper* were documented to ensure consistent practice into the future as our staff and work change.

Engagement with industry and relevant international groups continued in an effort to share knowledge and ensure our information and processes continue to be world-class. This year we surveyed stakeholders to understand their satisfaction with APVMA information and consultative processes. The survey results were positive and we will use this feedback to continue to improve our engagement processes.

We have put in place a financial sustainability plan to return the APVMA to a sustainable position. We reviewed and updated our risk management framework and profile, in light of relocation activities to ensure that our risk management approach takes this important change into account.

Explanation of performance

The APVMA continues to make good progress towards our relocation goals. We achieved this by developing sound policies and strategies to target key areas, using expert staff skills and knowledge coupled with external input and consultancy services.

Focus area: Define, implement, embed and optimise the application of the new APVMA business model based in Armidale

Key activity: Define and commence implementation of the APVMA business model based in Armidale, by October 2017

Performance measure	Source	Result against performance measures
Published by October 2017	<i>Operational plan 2017-18</i>	Following extensive consultation with staff and stakeholders, the Armidale business model was finalised and published on our website in December 2017. The model informed work on potential teleworking arrangements, the digital strategy and priority recruitment for Armidale.
Progress made against the APVMA Armidale Relocation Strategy and program implementation	<i>Corporate plan 2017-18</i>	<p>We expanded our interim office in Armidale and appointed the Armidale Deputy CEO (DCEO). Executive responsibilities were also expanded to include another DCEO position; together the DCEOs oversee reforms, relocation and improved regulatory performance. We engaged external legal services and consolidated public affairs and parliamentary business teams.</p> <p>The APVMA Relocation Program Board governed relocation activities. The program of work was managed by the APVMA's relocation operations team, across three streams: people, place and digital. The Relocation Program Board reported directly to the CEO and the APVMA's executive. The Armidale Relocation Advisory Committee also provided strategic advice to the executive on major aspects of the relocation.</p>

Key activity: Maintain operations of the Armidale interim office while planning and designing the Armidale permanent premises

Performance measure	Source	Result against performance measure
Armidale office management and staffing managed in line with approved budget and policies	<i>Operational plan 2017-18</i>	<p>Relevant policies governing the Armidale office and workplace were in place during the year. All other general APVMA policies are in effect.</p> <p>The approved budget was controlled by APVMA line managers and reported in the normal course of business. All major expenditure proposals were reviewed by the Chief Finance Officer, and separate monthly relocation program reporting against the agreed budget was provided to the APVMA executive.</p> <p>We achieved a clear delineation between the APVMA 'business as usual' activities and those relating to the Armidale relocation through appropriate delegations.</p>
Progress made against the APVMA Armidale Relocation Strategy and Program Implementation	<i>Corporate plan 2017-18</i>	<p>Stirloch Group Pty Ltd was selected to construct and fit out our permanent office in Armidale. The building site at 102 Taylor and 91 Beardy St was unveiled in March 2018 by the Minister for Agriculture and Water Resources, the Hon. David Littleproud MP.</p> <p>Site clearance and excavation commenced in April 2018 and development remains on track, with the building to be delivered by mid-2019. A design working group, in consultation with APVMA staff, provided input on workstation design and requirements. Relocation activities were reported and monitored by the Relocation Program Board throughout 2017-18.</p>

Key activity: Develop and implement the recruitment strategy and workforce plan

Performance measure	Source	Result against performance measure
Recruitment strategy and workforce plan milestones met	<i>Operational plan 2017-18</i>	Following release of the APVMA's new business operating model in December 2017, an operational resourcing structure was established detailing the number and classification of employees by function required for the authority to fulfil its statutory obligations under the Agricultural and Veterinary Chemicals Code.
Progress made against the APVMA Armidale Relocation Strategy and Program Implementation	<i>Corporate plan 2017-18</i>	We increased our presence in Armidale through priority recruitment action, and reduced our Canberra presence through employee separations.
Improved workforce stability and reduced staff separation		<p>APVMA allocated staffing levels remained relatively stable throughout the year, with targeted recruitment keeping pace with separations.</p> <p>In February 2018, we surveyed staff intentions to relocate. The results of this survey informed the development of our priority recruitment schedule to ensure business continuity.</p>

Focus area: Implement key changes across people (capability), process (workforce and workplace) and technology (ICT)

Key activity: Define and implement a people strategy to support the new APVMA business model based in Armidale

Performance measure	Source	Result against performance measure
People strategies are in place by October 2017 and being implemented	<i>Operational plan 2017-18</i>	In October 2017, the transitional <i>People strategy 2017-18</i> was finalised and implementation commenced.
Improved workforce stability and reduced staff separation	<i>Corporate plan 2017-18</i>	See also <i>Key activity: Develop and implement the recruitment strategy and workforce plan.</i>

Key activity: Implement priority activities within the ICT Strategic Plan and Digital Strategy to support business modernisation, including the digitisation of files

Performance measure	Source	Result against performance measure
Progress against ICT Strategic Plan and Digital Strategy	<i>Operational plan 2017-18</i>	The ICT team met the agreed goals of the ICT Strategic Plan during 2017-18: improving service delivery, improving stability, improving collaboration with business and building a stronger ICT team.
Progress made against the APVMA Armidale Relocation Strategy and Program Implementation	<i>Corporate plan 2017-18</i>	<p>We improved system stability through increased performance monitoring to allow reactive and pre-emptive intervention. Collaboration improved across the authority through the deployment of Skype for Business messaging and video conferencing available to all staff. This enabled better working across multiple sites, whether in the office or remote.</p> <p>The APVMA digital strategy was published in May 2018, delivering on a key milestone of the preparatory phase outlined in the APVMA in Armidale Relocation Strategy. In May the Australian Government announced the allocation of \$10.1 million over three years to fund the digital strategy. Since May, the ICT teams worked towards achieving relocation strategy objectives through development of the Enabling technology program.</p>

Focus area: Define and implement business reform initiatives, including the Agricultural competitiveness white paper reforms and agvet legislative reform

Key activity: Review organisational capability and capacity requirements		
Performance measure	Source	Result against performance measure
Review completed	<i>Operational plan 2017-18</i>	See <i>Key activity: Develop and implement the recruitment strategy and workforce plan.</i>

Key activity: Implement the Enterprise Risk Framework		
Performance measure	Source	Result against performance measure
Risk governance in place and risk reporting mechanisms are maintained	<i>Operational plan 2017-18</i>	Our risk management framework was revised and implemented as a key deliverable in the APVMA's implementation of the 2014 agvet chemical legislative reforms. The framework helped staff to identify and manage enterprise risk. We developed operational and relocation risk registers, and improved our management of project risk by reporting monthly to the executive. A Major Projects Board was established to monitor implementation and progress of APVMA business reforms and white paper projects.
Delivery against project milestones and benefits realisation of <i>Agricultural competitiveness white paper reforms</i>	<i>Corporate plan 2017-18</i>	The APVMA executive reviewed and updated our strategic risks in light of relocation activities.
Risk management frameworks and policies are in place and regularly assessed	<i>Regulator performance framework—3.1</i>	In December 2017, we engaged a consultant to undertake assurance mapping for the agency. The work included analysis of the extent to which assurance activities are in place to address significant risks affecting our key operations. Following the appointment of the APVMA CEO in November 2017, we reviewed the authority's risk appetite and management practices. In May 2018, the executive endorsed the revised risk management approach and supporting documentation, including our risk governance and accountability matrix. These documents were agreed by the APVMA Audit Committee.

Key activity: Implement the knowledge management strategy

Performance measure	Source	Result against performance measure
Knowledge management strategy milestones met	<i>Operational plan 2017-18</i>	This year we conducted activities to understand and improve our knowledge environment to ensure that we are maintaining the knowledge that staff require to do their jobs. Building on the work commissioned with a consultant in 2016-17 to develop our knowledge management strategy, we launched a knowledge management project in 2018 to develop critical knowledge products, and design and implement a knowledge management framework to support the needs of the organisation into the future.
Delivery against project milestones and benefits realisation of <i>Agricultural competitiveness white paper reforms</i>	<i>Corporate plan 2017-18</i>	<p>By 30 June 2018, over 1000 pieces of instructional material had been reviewed, updated or developed to document key APVMA work practices. Changes to administrative process and workflows resulting from business improvements and white paper projects were made and documented to ensure consistent practice into the future as our staff and work change.</p> <p>Reports on progress of the APVMA knowledge management projects were provided monthly to the Relocation Program Board.</p>

Key activity: Contribute to the Department of Agriculture and Water Resources agvet chemical legislative reform

Performance measure	Source	Result against performance measure
Contributions are made	<i>Operational plan 2017-18</i>	APVMA continues to work cooperatively with the Australian Government Department of Agriculture and Water Resources to advance reform measures, provide advice on implications of various measures and contribute to stakeholder engagement activities.
Feedback is provided to inform the development or amendment of regulatory frameworks	<i>Regulator performance framework—6.2</i>	<p>The Operational Efficiency Bill was introduced to parliament on 25 October 2017, and we progressed planning in 2018 to prepare for implementation.</p> <p>The APVMA also provided feedback to the Department of Agriculture and Water Resources on an exposure draft of the Streamlining Regulation Bill.</p>

Focus area: Improve stakeholder engagement

Key activity: Improve the delivery of industry information sessions		
Performance measure	Source	Result against performance measure
Stakeholder feedback from APVMA information sessions is largely positive and suggested improvements are acted on for future events	<i>Operational plan 2017–18</i>	<p>Since 2015, the APVMA has conducted industry information sessions to facilitate engagement with clients and improve communication with stakeholders.</p> <p>To address feedback from the 2016 industry information sessions, in 2017 the APVMA:</p> <ul style="list-style-type: none"> • allocated more time for informal networking and improved access to APVMA staff during break-out times • implemented a question-and-answer function on social media, and scheduled panel discussions and question time within the program • provided training and support for presenters to improve presentation quality.
Stakeholder engagement and public confidence measured through the breadth and number of industry engagement activities delivered	<i>Corporate plan 2017–18</i>	<p>In September 2017, 157 regulated clients and stakeholders attended the APVMA information sessions held in Canberra. Feedback on the sessions was largely positive, with 81% of surveyed participants agreeing that the event was worthwhile and 95% agreeing that the quality of the APVMA speakers was very good or good.</p>
Demonstrated understanding of the operating environment of regulated entities	<i>Regulator performance framework—1.1, 2.3</i>	<p>Planning commenced for APVMA engagement and events in 2018 that will seek to address feedback collected from the 2017 event and the 2018 client and stakeholder survey.</p> <p>The APVMA consults on major changes to operational policy, guidelines and systems before they are finalised. This year:</p> <ul style="list-style-type: none"> • there were over 3100 unique visits to the public consultation pages of the APVMA website, indicating the strong visibility and accessibility of APVMA consultations • we consulted publicly on 49 regulatory decisions and proposed changes to operational policy and development of guidelines • we held three industry workshops in July 2017, November 2017 and March 2018, to user test improvements to tailored guidance material and module descriptors.

Key activity: Survey clients and stakeholders to inform development of the APVMA stakeholder engagement strategy

Performance measure	Source	Result against performance measure
An APVMA stakeholder survey is deployed	<i>Operational plan 2017-18</i>	In March we conducted a client and stakeholder survey to measure satisfaction with APVMA communication channels and engagement; 380 people responded to the survey, which has provided a benchmark for evaluating future improvements.
Stakeholder engagement and public confidence measured by surveying stakeholders to understand the level of satisfaction with APVMA information and consultative processes	<i>Corporate plan 2017-18</i>	<p>Satisfaction with APVMA’s consultative process was largely positive. More than two-thirds of respondents who had participated in stakeholder consultation (e.g. meetings, stakeholder forums, calls for submission) in the 12 months before the survey were either satisfied (48%) or very satisfied (19%) with APVMA’s efforts to engage and consult on regulatory and operational changes and amendments.</p> <p>Confidence in APVMA decision-making was strong, with 68% of respondents agreeing that our decisions are made in accordance with the relevant legislative framework, and 62% agreeing decisions are underpinned by science. Areas where respondents thought performance could be improved included timeliness and transparency of decisions, and appropriate understanding and management of risk.</p> <p>While we are very active in the international regulatory arena, the survey also revealed low levels of recognition of the APVMA’s reputation as a world-leader in agvet chemical regulation: 33% of respondents agreed that the APVMA keeps pace with international regulators.</p> <p>See also <i>Key activity: Continue engaging and harmonising with relevant international forums, including facilitating APVMA attendance at forums such as OECD and VICH.</i></p> <p>The survey provided insights into the preferred methods of communication and consultation for clients and stakeholders. These preferences were considered as part of the early development of the APVMA stakeholder engagement strategy.</p>
Level of stakeholder engagement in implementing regulatory frameworks	<i>Regulator performance framework—6.1</i>	

Key activity: Continue engaging and harmonising with relevant international forums, including facilitating APVMA attendance at forums such as the OECD and VICH

Performance measure	Source	Result against performance measure
APVMA attendance at least five international forums	<i>Operational plan 2017-18</i>	Our regulatory scientists participate in many international forums. This involvement ensures that our assessment staff are familiar with and implementing global best practice in the Australian context. APVMA contributed to 16 international forums in 2017-18 (see Table 7, page 68).
Stakeholder engagement and public confidence measured by surveying stakeholders to understand the level of satisfaction with APVMA information and consultative processes	<i>Corporate plan 2017-18</i>	<p>The APVMA also hosted delegations from Brazil in October 2017 and South Korea in June 2018, presenting on our communication, technology and approach to process improvement.</p> <p>See also <i>Key activity: Survey clients and stakeholders to inform development of the APVMA stakeholder engagement strategy.</i></p>
Demonstrated understanding of the operating environment of regulated entities	<i>Regulator performance framework—1.1</i>	

Focus area: Create a sustainable and equitable funding base for the organisation

Key activity: Investigate the impact of business improvements and lower regulatory approaches on the agency's cost base and model

Performance measure	Source	Result against performance measure
Financial modelling of business improvements completed and can inform the agency's cost base	<i>Operational plan 2017-18</i>	The PricewaterhouseCoopers (PwC) Stage 1 Revenue Modelling—Fees Analysis review of APVMA cost recovery arrangements is complete. The PwC review made a number of recommendations, including improving the current cost recovery practices and refining the modelling to assist with the development of an agreed future fee structure. These recommendations are informing the development of a Cost Recovery Implementation Statement, which will be developed and implemented in 2019-20.
Responsible financial management of agency operations, including maintenance of equity reserve targets	<i>Corporate plan 2017-18</i>	At 30 June 2018, the APVMA equity reserve was \$6.418 million. In 2017-18, the CEO approved a financial sustainability plan outlining measures to return the APVMA to the prescribed equity reserve balance over the next four years. This includes the development and implementation of a renewed Cost Recovery Implementation Statement in 2019-20 (see above) and interim measures to retain positive cash flows.

Strategy 2

Deliver high-quality decision-making that is timely, science-based and proportionate to the risks being managed

Summary of performance

To achieve Strategy 2, we aim to:

- maintain a strong focus on delivering APVMA's core regulatory responsibilities, while seeking to achieve improvements around application processing efficiency
- invest in the decision-making capability of staff
- continue engaging and harmonising with relevant international forums.

This year, the APVMA achieved overall performance rates of 73 per cent within timeframe, including 70 per cent for product registration (pesticides 63 per cent, veterinary medicines 81 per cent), 86 per cent for active approvals and 67 per cent for permits. More details are given in Table 2.

Table 2: Activities related to APVMA regulatory decisions

Types of regulatory decisions	Commenced	Finalised/ issued	In progress
Pre-application assistance	146	143	28
Product registration—pesticides	1151	1325	496
Product registration—veterinary medicines	864	965	288
Actives	729	747	357
Permits	483	545	165
Items 8L, 8M, 8P	658	639	36
Item 25	10	18	5
Notifiable variations	762	747	15
Import consents	740	779	14
Certificates of export	335	309	6

We invested in staff development and networks to support our work. This includes conducting the Accelerated Regulatory Science Training Program to develop regulatory science staff, with three intakes and one graduation to date. We helped shape the curriculum for a Graduate Certificate and Graduate Diploma in Science (Regulatory Science) at the University of New England (UNE), and established networks with UNE and CSIRO in Armidale. We drew on external expertise to strengthen and streamline our work; international assessments contributed to the assessment of 28 products this year.

Explanation of performance

The APVMA has continued to improve core business processes and sought to align improvements with the new business operating model to deliver efficiencies for staff and regulated industry in 2018.

An independent review of assessment performance considered internal and external influences, and confirmed that fluctuations and volatility in the assessment workload and the range in quality and complexity of applications received make it difficult to meet the legislated performance measure of 100 per cent on-time assessments. It also confirmed that multiple factors contribute to delays in assessment and outlined a plan for reform that will be implemented in forward years.

Focus area: Maintain a strong focus on delivering APVMA's core regulatory responsibilities, while seeking to achieve improvements around application processing efficiency

Key activity: Define and implement the regulatory science projects to inform regulatory frameworks

Performance measure	Source	Result against performance measure
Projects delivered in line with project milestones	<i>Operational plan 2017-18</i>	<p>We delivered a program of regulatory science projects aimed at improving the efficiency of finalising product registration applications:</p> <ul style="list-style-type: none"> • one project aims to elicit higher-quality submissions from product registration applicants. The APVMA also participates in international workshare arrangements with overseas regulatory agencies. Workshare offers a highly efficient program for product registrants to register their products in several countries concurrently, and has been well received by stakeholders • developing and documenting an approach to regulating agvet chemical products of emerging technologies. A draft report titled <i>Managing the registration of emerging technology agvet products</i> was tabled at the Science Quality Committee meeting on 7 February 2018 and comments returned in April. The comments indicated that a major revision of the draft report was required, and this was in progress at the end of the financial year • consulting and publishing a report on antimicrobial resistance. The Australian Government Department of Health, and the Department of Agriculture and Water Resources were consulted, and the report, titled <i>Antibiotic resistance in animals: a report for the APVMA</i>, was published to apvma.gov.au in August 2017. The author of the report, Emeritus Professor Mary Barton, subsequently presented a seminar on antimicrobial resistance in animals to staff from the APVMA and other Australian Government departments and agencies in February 2018. <p>We have continued to focus on improving our science quality. The Science Quality Committee considered and addressed issues related to the quality of scientific processes and regulatory outputs, and offered guidance to scientific evaluators.</p>

Performance measure	Source	Result against performance measure
Projects delivered in line with project milestones	<i>Operational plan 2017-18</i>	<p data-bbox="555 293 868 319"><i>(Continued from previous page)</i></p> <p data-bbox="555 344 1096 491">We are looking to advancements in science that may improve the ability of tests, models and assessment methods to better predict product safety issues. We completed several projects that directly improved product assessment methodology, including:</p> <ul data-bbox="565 515 1076 763" style="list-style-type: none"> <li data-bbox="565 515 1063 601">• a methodology to assess risks posed by imported live microorganisms intended for use in veterinary vaccines <li data-bbox="565 611 1076 696">• a framework to evaluate software models used to calculate components of risk associated with agvet chemical products <li data-bbox="565 706 1056 763">• a system to analyse risks to insect pollinators from pesticide use. <p data-bbox="555 788 955 814">In staff development and outreach, we:</p> <ul data-bbox="565 839 1137 1658" style="list-style-type: none"> <li data-bbox="565 839 1137 1134">• helped shape the UNE Regulatory Science curriculum. In 2017, UNE offered a Graduate Certificate and a Graduate Diploma in Science (Regulatory Science) for the first time. The curriculum was reviewed at the UNE Agricultural and Veterinary Chemicals Regulatory Science Advisory Board on 21 July 2017. The APVMA Chief Regulatory Scientist serves on this board and recommended the inclusion of core competencies in the course that would be relevant to the needs of the APVMA <li data-bbox="565 1144 1126 1315">• established networks in Armidale. We started to build long-term partnerships with UNE and other science research bodies. For example, we discussed partnership arrangements with the CSIRO Division of Agriculture and Food and with a private science research body in Armidale <li data-bbox="565 1325 1130 1506">• conducted an enHealth meeting and workshop. The Chief Regulatory Scientist presented on the APVMA's Accelerated Regulatory Science Training Program to a workshop hosted jointly by the Australasian College of Toxicology and Risk Assessment and enHealth in Melbourne on 10 November 2017 <li data-bbox="565 1515 1110 1658">• launched a new section of our website on 'Our science', which provides information on our regulatory framework, projects and collaborations. The section is rated as one of the 50 most popular APVMA pages online

Performance measure	Source	Result against performance measure
Projects delivered in line with project milestones	<i>Operational plan 2017-18</i>	<p data-bbox="556 297 865 316"><i>(Continued from previous page)</i></p> <ul style="list-style-type: none"> <li data-bbox="569 350 1107 399">• established a science seminar series with monthly presentations, including: <ul style="list-style-type: none"> <li data-bbox="583 415 1107 464">- Emeritus Professor Mary Barton—Antimicrobial resistance in animals <li data-bbox="583 479 1107 529">- Mr Mark Jenner—Human occupational exposure modelling: challenges and future direction <li data-bbox="583 544 1107 594">- Dr Les Davies—Neonicotinoids and the health of honey bees in Australia <li data-bbox="583 609 1107 658">- Dr Joe Smith—Reflections on what makes an effective regulator <li data-bbox="583 674 1146 761">- Professor David Dorman—Application of systematic review methods in an overall strategy for evaluating low-dose toxicity from endocrine active chemicals.

Performance against legislative timeframes

Performance measure	Source	Result against performance measure
<p>Performance against legislative timeframes:</p> <ul style="list-style-type: none"> • complete 70% of regulatory decisions within the statutory timeframes • finalise 50% of Emergency Permits within 14 days and 90% finalised in 28 days • 100% of chemical reconsiderations are finalised in accordance with the program schedule and meet legislative timeframes 	<p><i>Corporate plan 2017-18</i></p>	<p>In 2017–18:</p> <ul style="list-style-type: none"> • 73% of regulatory decisions for products, permits, and actives were completed within the statutory timeframe • 64% of emergency permits were completed within 14 days, and 88% were completed within 28 days • 15% of chemical reconsiderations were finalised in accordance with the program schedule. <p>Targeted effort reduced the number of overdue applications during the first half of the year, particularly within the pesticides stream, by realigning and rescheduling resources. We improved the monitoring and tracking of applications through the internal application management system, and streamlined the documentation of decisions.</p>
<p>Efficient and effective APVMA business processes</p>	<p><i>Regulator performance framework—1.3</i></p>	<p>The chemical reconsideration of Polihexanide and Macrolide antibiotics were finalised this year. Details of these reviews, including the final decisions can be found at apvma.gov.au/node/12691 and apvma.gov.au/node/12581 respectively.</p> <p>Substantial progress was made towards completing a further five reconsiderations, which are expected to progress to public consultation in 2018–19.</p> <p>In 2017–18, the Office of the Chief Regulatory Scientist was asked to review three applications and these reviews were completed.</p>

Key activity: Scrutinise options around processing timeframes to identify improvements through an independent review

Performance measure	Source	Result against performance measure
An independent review of agency timeframe performance completed	<i>Operational plan 2017-18</i>	In August 2017, the CEO commissioned the Independent review of assessment performance. The report was released in January 2018. We accepted all report recommendations, which will be implemented through a coordinated program of reform over the forward three years.

Focus area: Invest in the decision-making capability of staff

Key activity: Maintain and energise the Adverse Experience Reporting Program (AERP) to better inform current and future decisions

Performance measure	Source	Result against performance measure																				
AERP data entry and analysis outputs are achieved	<i>Operational plan 2017-18</i>	In 2017-18, the AERP team received more than 5000* adverse experience reports and classified 2841.																				
<table border="1"> <thead> <tr> <th>Classification</th> <th>Agricultural</th> <th>Veterinary</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Mandatory (non-serious)</td> <td></td> <td>2 1430</td> <td>1432</td> </tr> <tr> <td>Mandatory (serious)</td> <td>49</td> <td>1244</td> <td>1293</td> </tr> <tr> <td>Voluntary</td> <td>20</td> <td>96</td> <td>116</td> </tr> <tr> <td>Total</td> <td>71</td> <td>2770</td> <td>2841</td> </tr> </tbody> </table>			Classification	Agricultural	Veterinary	Total	Mandatory (non-serious)		2 1430	1432	Mandatory (serious)	49	1244	1293	Voluntary	20	96	116	Total	71	2770	2841
Classification	Agricultural	Veterinary	Total																			
Mandatory (non-serious)		2 1430	1432																			
Mandatory (serious)	49	1244	1293																			
Voluntary	20	96	116																			
Total	71	2770	2841																			

*one adverse incident may be reported multiple times (eg the vet, consumer and registrant may all report the same incident)

In addition to classifying and entering the data, we analyse the data and inform relevant APVMA areas of any findings warranting regulatory action. As a result of this analysis, regulatory action was taken on three product families to ensure that their ongoing use remains safe and efficacious.

Adjustments to registration requirements and the cancellation of registration for safety reasons flowing from the AERP

Corporate plan 2017-18

No safety issues were identified to warrant the cancellation of any product registrations. AERP data supported 10 applications or registrant-initiated label changes, and data was provided to inform four compliance issues. AERP data was used to inform four chemical review processes (second-generation anticoagulant rodenticides, macrolides, chlorpyrifos and methiocarb).

Key activities: Deliver the APVMA Accelerated Regulatory Science Training Program—Diploma of Government (Regulatory Science)

Performance measure	Source	Result against performance measure
Number of APVMA regulatory scientists undertaking the accelerated training	<i>Operational plan 2017–18</i>	We are conducting the Accelerated Regulatory Science Training Program to develop the skills of regulatory science staff. The program runs over 10 months and successful participants receive a Diploma of Government in regulatory science. Three intakes progressed study in 2017–18, including two in Canberra and one in Armidale. A total of 46 staff undertook the training. The first intake of 12 participants graduated on 5 June 2018 and the second and third intakes are expected to complete the program in August 2018.
A year-on-year reduction in the number of decisions that are referred to external bodies (i.e. court, the Ombudsman, the Administrative Appeals Tribunal [AAT]) for reviews that result in a reversal of the original decision	<i>Corporate plan 2017–18</i>	In 2016–17, four matters with the AAT were remitted to the APVMA for reconsideration. In 2017–18, one decision was set aside by the AAT. This decision was set aside in line with an agreement between the APVMA and the appellant. Under that agreement, the appellant was required to amend their application and the revised application was considered by the APVMA in accordance with the requirements of the Agvet Code.

Focus area: Continue engaging and harmonising with relevant international forums

Key activity: Implement and complete the *Agricultural competitiveness white paper* reforms to deliver improved business processes and quality decision-making through internal assessments and guidelines, and compliance and monitoring

Performance measure	Source	Result against performance measure
Delivery against project milestones and realising the benefits of <i>Agricultural competitiveness white paper</i> reforms	<i>Operational plan 2017–18</i>	Closure reports for white paper reform projects indicate that six of the nine projects were largely delivered, with the remaining ICT development and implementation due to be completed in 2018–19. <i>See Key activity: Finalise and embed business improvements in response to the 2017 ANAO report on the APVMA's implementation of agvet chemical reforms (2014).</i>

Measuring the impact of reduced regulatory approaches and alignment with risk

Performance measure	Source	Result against performance measure
<p>The impact of reducing regulatory approaches and aligning these approaches with risk, in particular:</p> <ul style="list-style-type: none"> the number of applications using data assessment, standards and decisions from comparable regulators industry awareness and rate of adoption of data guidelines, standards and international assessments used to reduce effort to register agvet chemicals the number of risk management frameworks and policies in place and regularly reassessed effective lower regulatory effort when applied to lower regulatory risk 	<p><i>Corporate plan 2017-18</i></p>	<p>In 2017-18, international assessments contributed to the assessment of 28 products. They also supported residues assessment of 19 minor use or emergency permits. International assessment web pages were updated, and consultations on the approach to timeframes with Animal Medicines Australia, CropLife Australia and the Veterinary Manufacturers and Distributors Association have been completed.</p> <p>The client and stakeholder survey conducted in March found that of the 365 respondents who had accessed the APVMA website in the 12 months preceding the survey, 45% had used the data guidelines, and 12% had viewed guidance on international assessments.</p> <p>Initial consultations on veterinary active guidelines were undertaken in November 2017 and comments from industry and stakeholders were considered before wider consultation was undertaken during February and March 2018. The chemistry risk assessment manual was circulated to industry groups for comment, which were considered before wider consultation between April and May 2018.</p>
<p>International data guidelines, standards and assessments adopted to reduce effort to register agvet chemicals</p>	<p><i>Regulator performance framework—1.2</i></p>	

Key activity: Continue to encourage the use of international assessments

Performance measure	Source	Result against performance measure
Opportunities to use data assessment, standards and decisions from comparable regulators are broadly communicated and client interest is measured through hits on the web and client enquiries	<i>Operational plan 2017–18</i>	<p>APVMA has promoted the use of international assessments to clients and stakeholders through various channels, including:</p> <ul style="list-style-type: none"> • using Twitter to reach 1443 followers • giving a presentation to 157 attendees at the 2017 APVMA Industry Information Session • adding a feature banner to the website to direct visitors to detailed guidance • providing regulatory update stories to 3517 subscribers.
International data guidelines, standards and assessments adopted to reduce effort to register agvet chemicals	<i>Regulator performance framework—1.2</i>	The web page for guidance on the use of international assessments received 860 unique visits in 2017–18.

Strategy 3

Reduce the regulatory burden on industry through an enhanced client service approach

Summary of performance

To achieve Strategy 3, we aim to:

- ensure consistency of registration, compliance and licensing activities with regulatory risk
- define, implement and streamline business reform initiatives in the APVMA (*Agricultural competitive white paper* reform and internal process reforms)
- implement legislative reform
- stabilise and build on the existing user experience.

In the 2016 Federal Budget, the APVMA was allocated \$7.3 million over four years to implement the APVMA's components of the *Agricultural competitiveness white paper* reforms. The aims of the white paper reforms are to:

- lower regulatory approaches to registration—to reduce regulatory effort
- enhance the user experiences—to improve client and stakeholder interactions
- implement more efficient business systems—to improve efficiency and transparency.

We implemented a range of projects and activities under the white paper reforms. For example, we developed tailored guidance material for the top 20 common application types, including fast track applications, revised the module descriptors and developed risk assessment manuals to improve the quality of applications. We provided pre-application assistance to clarify the nature and levels of assessment required before clients submit an application—a program that has been popular.

Compliance activities continued to focus on monitoring and education, and were effective in addressing noncompliance of both manufacturers and retailers.

Explanation of performance

The Independent review of assessment performance recommended that we:

- make better use of legislative instruments by modifying the training and guidance provided to staff
- explore earlier rejections of poor-quality applications
- improve the management of backlogs through resource management and scheduling
- assess opportunities to delegate sign-off of decisions to assessment teams.

By implementing these recommendations, together with white paper reforms, knowledge management, legislative reform and the digital strategy, we are moving to significantly improve our client services and reduce the burden on industry. These changes are supported by strengthened governance processes and leadership.

Focus area: Ensure consistency of registration, compliance and licensing activities with regulatory risk

Key activity: Improve the quality and consistency of decisions through effective engagement with internal advisory committees and concurrent incremental improvement of internal forms and templates

Performance measure	Source	Result against performance measure
Internal advisory committees report improvements in the consistency of APVMA decisions	<i>Operational plan 2017-18</i>	The Science Quality Committee met seven times. It reviewed OECD guidelines for adoption by the APVMA and provided scientific advice to evaluators to improve the quality and consistency of regulatory decisions. The Registration Quality Committee finalised issues pertaining to generic products and revised internal forms and templates for generic product applications. See also the <i>Governance</i> section.

Key activity: Investigate the applications of an improved data analytics capability in the Adverse Experience Reporting Program (AERP) that can better inform current and future decisions

Performance measure	Source	Result against performance measure
Number of business decisions informed and corrective actions taken as a result of improved AERP data and analysis	<i>Operational plan 2017-18</i>	See <i>Key activity: Maintain and energise the Adverse Experience Reporting Program (AERP) to better inform current and future decisions.</i>

Key activity: Continue efficacy and contestability projects

Performance measure	Source	Result against performance measure
Projects delivered	<i>Operational plan 2017-18</i>	The efficacy contestability pilot closed for submission of applications on 30 June 2018. A total of 30 applications were received for inclusion in the pilot. Of those, 13 have been finalised and the remainder are being evaluated.
Lower regulatory effort is applied to activities of lower regulatory risk	<i>Regulator performance framework—3.2</i>	

Key activity: Develop and implement the APVMA compliance plan

Performance measure	Source	Result against performance measure
Compliance activities are delivered	<i>Operational plan 2017-18</i>	The Compliance and Monitoring team: <ul style="list-style-type: none"> • investigated 230 new allegations of noncompliance and finalised 220 that led to: <ul style="list-style-type: none"> – one compulsory recall – six formal warnings – 17 infringement notices issued (totalling \$153 500) – one notice to produce – one enforceable undertaking – two investigation warrants • participated in Interpol-led Operation Pangea X • conducted containment screening of 48 agricultural chemical products, all of which were found to be compliant • collaborated with the Australian Border Force to monitor chemical imports into Australia • conducted audits of adherence to conditions of 10 permits and 15 agricultural chemical products; two were found to be noncompliant and action has been taken by the permit holders to remedy this noncompliance • delivered education campaigns targeting the supply of unregistered insect repellents, import and supply of unregistered veterinary chemical products for use in the greyhound racing industry, and import of unregistered chemical products through customs brokers.
Risk management frameworks and policies are in place and regularly assessed	<i>Regulator performance framework—3.1, 3.3, 4.1, 4.2, 4.3</i>	
Compliance and enforcement strategies are consistent with agreed risk management policies		
Monitoring and enforcement strategies allow for a range of regulatory responses		
Compliance activities respond to business needs and regulated entities where relevant		
Information requested from regulated entities is necessary and acted upon		
Targeted reductions in noncompliant behaviour as a result of implementing the APVMA compliance plan	<i>Operational plan 2017-18</i>	The APVMA conducted targeted monitoring of unregulated products in discount retail and rural supply stores. More than 55 retailers throughout Australia were inspected, with 15 unregistered agvet chemical products identified for sale. These products were removed from stores and tracked back to distributors, who agreed to cease distribution of the products.

Key activity: Administer requirements for veterinary manufacturing audits and licensing

Performance measure	Source	Result against performance measure
Audits completed and licensing managed as per the schedule, with longer audit intervals established for compliant operators	<i>Operational plan 2017-18</i>	82% of audits were completed within schedule and longer audit intervals are being applied to compliant operators.
Compliance and enforcement strategies are consistent with agreed risk management policies	<i>Regulator performance framework—3.2</i>	

Focus area: Define, implement and streamline the business reform initiatives in the APVMA

Key activity: Implement and complete *Agricultural competitiveness white paper* reforms to enhance the user experience, including improving registration pathways, transforming the user experience, delivering tailored guidance for the top 20 application types, and streamlining end-to-end registration

Performance measure	Source	Result against performance measure
Delivery against project milestones and realising the benefits of <i>Agricultural competitiveness white paper</i> reforms	<i>Operational plan 2017–18</i>	<p>The APVMA implemented several initiatives under the white paper reforms.</p> <p>In the area of registration pathways, we:</p> <ul style="list-style-type: none"> reviewed the fast-track pilot, and implemented the recommendations by changing online services, instructional material and guidance material on the website revised the module descriptors and consulted with industry in June 2018. The revisions, and additional website functionality to improve the usability of the descriptors, will be implemented in the first quarter of 2018–19 continued to work on the draft antifouling paint guideline. IT improvements to online services are being tested. The antifouling paint guideline will be published on the website in the first quarter of 2018–19.
Level of satisfaction with information and guidance materials	<i>Regulator performance framework—2.1, 2.3, 6.1</i>	<p>To transform the user experience, we:</p> <ul style="list-style-type: none"> completed the end-to-end registration project in August 2017; recommendations are being actioned through the business process improvement projects developed tailored guidance material. The first two application types were published in August 2017. A workshop was held with industry representatives in November 2017 to support drafting of content for the generic application types. A workshop was also held in March 2018 to help draft content for changes to formulations
Extent and satisfaction with APVMA consultative processes		
Level of stakeholder engagement in implementing regulatory frameworks		

Performance measure	Source	Result against performance measure
		<p>(Continued from previous page)</p> <ul style="list-style-type: none"> developed risk assessment manuals. A draft chemistry risk assessment manual for public consultation was published on our website in May 2018. The remaining manuals for environment, residues, toxicology, human health and efficacy are being progressed for consultation and publishing on the website in the first quarter of 2018–19 identified improvements to the content and usability of the current data guidelines, which will be implemented in the first quarter of 2018–19 The first phase of the archive website decommission was completed in December 2017. Further work was undertaken to transition the application summaries to the current website and complete the decommission in the first quarter of 2018–19. <p>All projects were monitored by the Major Projects Board.</p>

Key activities: Update the APVMA Client Service Charter and investigate internal reform to consolidate the monitoring and management of client feedback channels

Performance measure	Source	Result against performance measure
The revised client service charter implemented and feedback channels streamlined	<i>Operational plan 2017–18</i>	<p>A comprehensive review of the client service charter commenced in June 2018 and APVMA will undertake further consultation with industry clients and stakeholders next year.</p> <p>In June 2018, we introduced a complaint handling policy to improve our feedback systems and complaint management practices.</p> <p>See Key activity: Survey clients and stakeholders to inform development of the APVMA stakeholder engagement strategy.</p>
Client service standards met	<i>Corporate plan 2017–18</i>	The APVMA Case Management and Administration Unit received 6335 calls and 7684 emails. Phone messages and emails were checked daily and every effort was made to meet our client response performance timeframes (client service charter).
Level of satisfaction with the quality and timeliness of advice on decisions	<i>Regulator performance framework—2.2</i>	The APVMA Case Management and Administration Unit received 6335 calls and 7684 emails. Phone messages and emails were checked daily and every effort was made to meet our client response performance timeframes (client service charter).

Key activity: Improve information on the APVMA website through an audit and review process

Performance measure	Source	Result against performance measure
Increased positive and decreased negative feedback about the quality of online information	<i>Operational plan 2017-18</i>	<p>Via a feedback mechanism at the bottom of each web page, we received:</p> <ul style="list-style-type: none"> • 93 positive ratings – up 4% from last year • 105 negative ratings – up 19% from last year. Increased negative feedback is being investigated and addressed. • 14 neutral ratings – down 23% from last year.
Level of satisfaction with information and guidance materials	<i>Regulator performance framework—2.1</i>	<p>We received the following feedback reports through a form on the online services portal:</p> <ul style="list-style-type: none"> • 13 positive – up 9% from last year • 26 negative – down 12% from last year • 45 neutral – up 3% from last year. <p>Audit and review of the website:</p> <ul style="list-style-type: none"> • there are 4704 individual pages on the APVMA website. In 2017-18, 2053 pages were reviewed and 715 new pages were created.

Focus area: Implement legislative reform

Key activity: Finalise and embed business improvements in response to the 2017 ANAO report on the APVMA's implementation of agvet chemical reforms (2014)

Performance measure	Source	Result against performance measure
Business improvements are implemented	<i>Operational plan 2017-18</i>	<p>Progress against ANAO Recommendation 1— Internal quality framework</p> <p>We continued to improve our assessment process to increase efficiency and timeliness, all the while ensuring appropriate levels of risk management are applied. Improvements include:</p> <ul style="list-style-type: none"> • provision of pre-application assistance to clarify the nature and levels of assessment required before clients submit an application • evaluation planning at the commencement of evaluation, including requests for advice from expert areas • project planning for external scientific assessments, including providing guidance to reviewers on previous related decisions • peer review of science-based recommendations from both external and internal experts before these recommendations are accepted by the APVMA. Applicants are also given the opportunity to review these reports before a regulatory decision is made • public consultation as required by legislation for major applications (i.e. before the decision to register a product with a new active constituent or where the application is an extension of use to a new major food group). <p>The business model for the APVMA in Armidale embeds a Chief Regulatory Scientist. One of the key roles of this function is to further support quality decision-making across our regulatory functions. Planning commenced for an internal quality framework that will be implemented after our move to Armidale.</p>

Performance measure	Source	Result against performance measure
Business improvements are implemented	<i>Operational plan 2017–18</i>	<p data-bbox="676 253 1146 291"><i>(Continued from previous page)</i></p> <p data-bbox="676 310 1146 624">We continued to identify, monitor and respond to emerging regulatory issues. New technologies used in crop production and animal husbandry may require different regulatory frameworks and risk analysis approaches. The authority has been preparing for the regulation of products of nanotechnology and biotechnology in collaboration with international and national experts from industry, academia, research institutes and other regulatory agencies.</p> <p data-bbox="676 643 1146 900">APVMA scientists continued to work with other Australian Government regulatory agencies responsible for regulating chemicals and biological agents through the Regulatory Science Network (RSN). A key objective of the RSN is to help improve the performance of Australian Government regulatory agencies by bringing together senior scientists to discuss regulatory and technical issues.</p> <p data-bbox="676 919 1146 1205"><i>See also Key activity: Continue engaging and harmonising with relevant international forums, including facilitating APVMA attendance at forums such as the OECD and VICH; Key activity: Define and implement the regulatory science projects to inform regulatory frameworks; and Key activity: Deliver the APVMA Accelerated Regulatory Science Training Program—Diploma of Government (Regulatory Science).</i></p> <p data-bbox="676 1224 1146 1319">Progress against Recommendation 2—Measures and targets in improving effectiveness and efficiency</p> <p data-bbox="676 1328 1146 1462">The APVMA achieved overall performance rates of 73% within timeframe, including 70% for product registration (pesticides 63%, veterinary medicines 81%), 86% for active approvals and 67% for permits.</p> <p data-bbox="676 1481 1146 1723"><i>See Strategy 2—Deliver high-quality decision-making that is timely, science-based and proportionate to the risks being managed and Focus area: Maintain a strong focus on delivering APVMA’s core regulatory responsibilities, while seeking to achieve improvements around application processing efficiency.</i></p>

Performance measure	Source	Result against performance measure
Business improvements are implemented	<i>Operational plan 2017–18</i>	<p data-bbox="676 262 991 291"><i>(Continued from previous page)</i></p> <p data-bbox="676 316 1103 515">The Independent review of assessment performance delivered recommendations to improve regulatory efficiency of APVMA decision making in January 2018. All recommendations were accepted, with implementation to occur in the forward 3 years.</p> <p data-bbox="676 544 1139 630"><i>See Key activity: Scrutinise options around processing timeframes to identify improvements through an independent review.</i></p> <p data-bbox="676 654 959 740">Progress against ANAO Recommendation 3—Governance arrangements</p> <p data-bbox="676 752 1145 982">We improved arrangements for current and future change programs to strengthen governance and project management in line with best practice. Program and project boards were established to provide oversight, and dedicated project teams managed the implementation of the white paper reforms and the relocation to Armidale.</p> <p data-bbox="676 1011 1126 1271">The Major Projects Board membership was revised and it now oversees projects identified by the APVMA's executive leadership team as critical to the future success of the agency. The projects include those funded under the white paper, and other projects that relate to the APVMA's reform agenda (such as the response to the review of assessment performance).</p> <p data-bbox="676 1300 1145 1386"><i>See also Focus area: Define, implement, embed and optimise the application of the new APVMA business model based in Armidale.</i></p> <p data-bbox="676 1410 1067 1464">Progress against ANAO Recommendation 4—Business risks</p> <p data-bbox="676 1475 1103 1528"><i>See Key activity: Implement the Enterprise Risk Framework.</i></p>

Focus area: Stabilise and build on the existing user experience

Key activity: Continue to undertake application assessment forums and manage proactive engagement of clients

Performance measure	Source	Result against performance measure
Improved client engagement	<i>Operational plan 2017-18</i>	In our Proactive Stakeholder Engagement Program, regular face-to-face meetings or teleconferences were held with the 30 most frequent applicants to discuss the status and planning of current and future applications. These most frequent applicants account for about 50% of all major applications.
Feedback mechanisms are in place and used to improve service to regulated entities	<i>Regulator performance framework—5.2, 6.1</i>	
Level of stakeholder engagement in implementing regulatory frameworks		Pre-application assistance (PAA) provides technical advice to clients on the relevance or suitability of data, reports and international assessments before they submit applications. This year, PAA advice was provided for 135 applications, which included 44 PAA meetings.

Key activity: Continue to implement the APVMA ICT Strategic Plan and continue work on decommissioning legacy systems and improving application stability

Performance measure	Source	Result against performance measure
Reduced number of legacy business systems	<i>Operational plan 2017-18</i>	The last APVMA application using the Ingres database management system is scheduled for migration by the end of 2018. This will finalise the planned decommissioning of legacy platforms.
Effective and effective APVMA business processes	<i>Regulator performance framework—1.3</i>	We are also rationalising the number of servers maintained within our managed infrastructure in preparation for migration of the infrastructure to cloud-hosted arrangements that will be implemented under the Enabling technology program.

