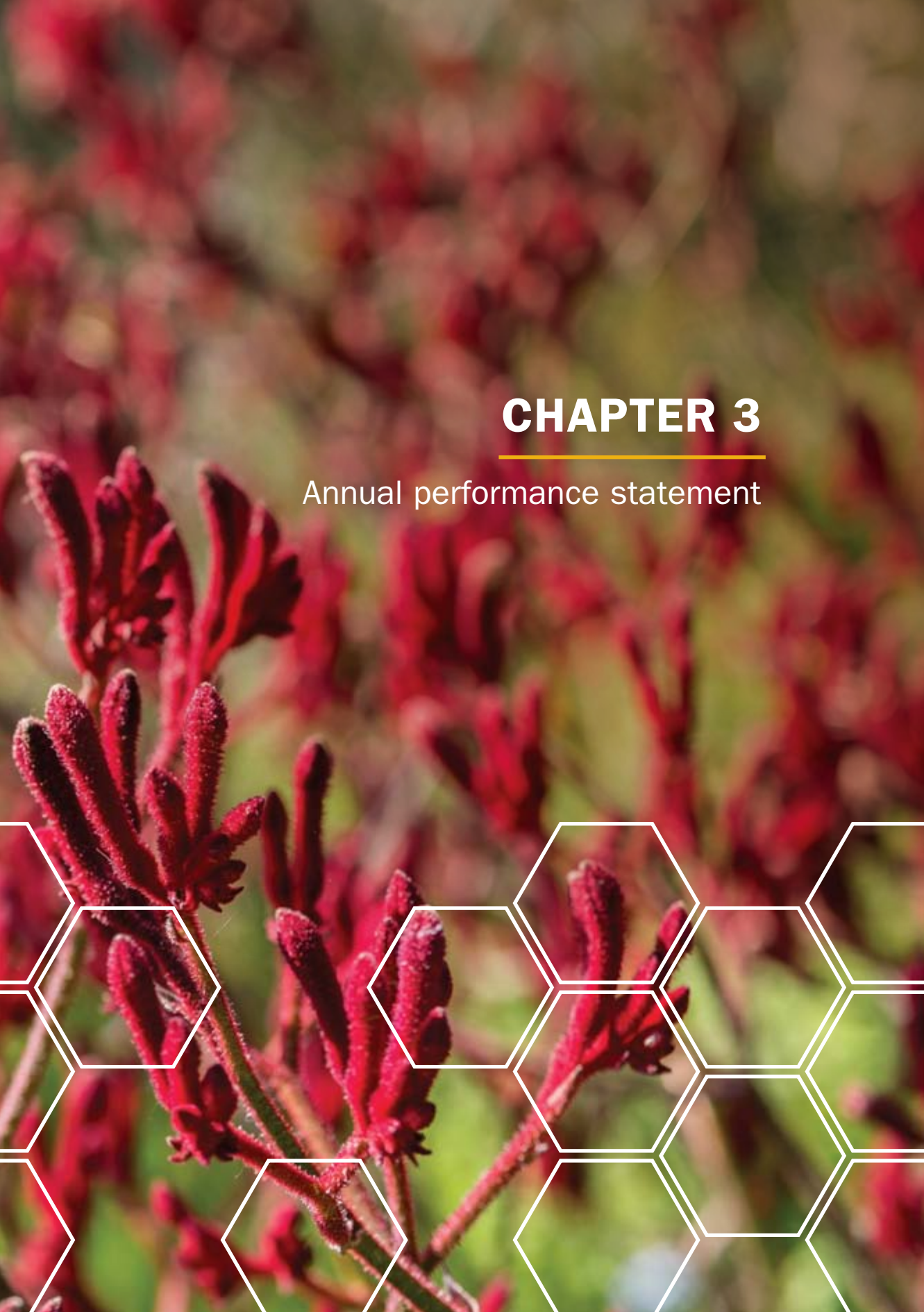

CHAPTER 3

Annual performance statement

Strategic framework and reporting

The APVMA *Corporate Plan 2018–19* and *Operational Plan 2018–19* have expressed three strategies to help the agency to achieve its vision and mission (Figure 1):

- **strategy one**—transform our business to provide world-class agvet chemical regulation from regional Australia
- **strategy two**—maintain regulatory science capability to deliver high-quality decision making that is timely, science based and proportionate to the risks being managed
- **strategy three**—improve regulatory service delivery and feedback systems to reduce the regulatory burden on industry.

Our corporate strategies are interconnected. Successful delivery in one strategic area will reinforce and build success in all.

Figure 1: APVMA strategies

Measuring our performance

Each of the three APVMA strategies have activities and performance measures. Through these, we aim to ensure that:

- regulatory service delivery matches client and stakeholder expectations of a modern regulator
- relocation risks are managed within allocated budget and timeframes
- decisions are timely, defensible and align with international best practice; regulatory intervention is aligned with regulatory risk.

Results against performance criteria

This chapter provides the results of our performance against:

- the APVMA Portfolio Budget Statement (PBS)
- nine focus areas listed in the *APVMA Operational Plan 2018–19*.

The *APVMA Operational Plan 2018–19* details performance measures for each strategy. Results against these measures are presented in tables, with one table for each strategy. A summary and explanation of the performance 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 2018–19.

Statement of preparation by the Chief Executive Officer

I, as the accountable authority of the APVMA, present the 2018–19 annual performance statement of the APVMA, as required under paragraph s. 39(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 ss. (39)(2) of the PGPA Act.

Dr Chris Parker
Chief Executive Officer
September 2019

Strategy one
Transform our business to provide world-class agvet chemical regulation from regional Australia

Summary and explanation of performance

We have completed the physical relocation to Armidale and made progress in developing the staff, information, office and ICT resources needed to continue and improve our business from regional Australia. This has been achieved through rigorous planning processes and sound management practices. We have put into place strong financial management structures to ensure our financial viability while we develop a renewed cost recovery implementation statement.

Focus areas and activities

Implement the APVMA Armidale business model:

- implement recruitment activities for Armidale in line with the APVMA recruitment strategy
- oversee construction of the permanent APVMA premises in Armidale
- implement the APVMA digital strategy
- put in place documented processes and practices for improved knowledge management
- establish and maintain a learning culture.

Modernise our ICT:

- manage procurement of ICT products and services that progress priority elements of the APVMA digital strategy through an Enabling Technology Program for
  - infrastructure services
  - unified communications and collaboration
  - digitisation of analogue records
  - ICT service management and support
- identify business requirements for the business application improvement project.

Ensure cost of operations are reflected in current fees, levies and charges:

- manage and monitor the APVMA financial sustainability plan in line with APVMA governance arrangements
- put in place arrangements to address the APVMA's operating loss
- commence review of the Cost Recovery Implementation Statement (CRIS).

Performance against corporate performance measures

Performance measure	Source	Result
Maintenance of average staffing levels within 5% of the budgeted target for each financial year	*Operational Plan 2018–19*	The budgeted average staffing level was 195. Our peak staffing level was 210 at June 2019 with a minimum staffing level of 175 at July 2018.
Yearly growth of the Armidale staffing and gradual reduction in Canberra full time equivalent (FTE); Armidale staffing target of 70 FTE	*Operational Plan 2018–19*	At 1 July 2018 there were 33.6 FTE located in Armidale, and 175.5 FTE located in Canberra. As at 30 June 2019, there were 105 staff located in Armidale, and 108 staff located in Canberra.
Maintenance of critical knowledge products	*Operational Plan 2018–19*	All instructional material within the APVMA was identified and reviewed for currency. Documents were reviewed, updated, or flagged for future updating or archiving from our knowledge base and Instructional Material Library (IML). Our knowledge management tools, including the IML and knowledge base, were redesigned to better support staff and a knowledge maintenance plan was developed to ensure the effective ongoing management of critical knowledge products.
Priority recruitment of positions mapped to the Armidale business model	*Operational Plan 2018–19*	During 2018–19 there were 48 priority recruitment activities undertaken across Armidale and Canberra. 86 individuals were recruited across the organisation from 1 July 2018 to 30 June 2019. 14 Canberra-based staff relocated to the Armidale office.
Construction of Armidale premises completed on time and within budget	*Operational Plan 2018–19*	Our Armidale premises were completed and a Certificate of Occupation was issued. Business-as-usual operations commenced in the new office in June 2019, ahead of schedule and within budget.

Performance measure	Source	Result
Delivery of products and services under the Enabling Technology Program and achievement of digital strategy objectives within allocated budget: • ICT back-end infrastructure successfully migrated to a cloud services arrangement • all APVMA staff (onsite and remote users) have access to consistent and reliable desktop collaboration and communication services • digitisation of analogue records is in progress; ad hoc user requests are completed within 3 business days.	*Operational Plan 2018–19*	Stage 1 of our move to managed services and cloud-based infrastructure is complete. ICT service desk functions were transferred to DXC Technology on 19 March 2019 and end-user services are in place; the design for cloud migration is complete and migration is in progress with completion scheduled for end November 2019. We awarded management of the APVMA electronic document and records management (eDRM) system to Objective Managed Services on 13 December 2018, and their services commenced on 16 January 2018. The eDRM was upgraded to the most recent version on 24 June 2019. The contract for the digitisation of physical records was awarded to ZircoDATA on 26 July 2018. Digitisation is in progress and digitised files are being automatically uploaded into the eDRM. Quality control processes are in place and a recent internal business review of electronic files has confirmed usability and utility of the digitised files. An agreement for provision of managed services for ongoing support and future improvement of the APVMA's core business applications was signed with DXC Technology on 1 July 2019. DXC is transitioning applications support services to their Digital Transformation Centre and has commenced an applications transformation project with an initial schedule for the first release of improved business systems in mid-2020.
Responsible financial management of APVMA operations, including maintenance of positive equity balance until the implementation of a renewed cost recovery fee structure can assist to return reserves to $7.0 million for future operation	*Operational Plan 2018–19*	In April 2019, the APVMA introduced a new financial management system, Technology One. This replaced our ageing financial management system and supports the future management of the APVMA by bringing our systems in line with the Department of Agriculture.

Strategy two

Maintain regulatory science capability to deliver high-quality decision making that is timely, science based and proportionate to the risks being managed

Summary and explanation of performance

In 2018–19 we improved our regulatory processes with 85 per cent of applications processed within statutory timeframes, and we finalised around 3000 applications. We processed 7126 adverse experience reports and took regulatory action on one product family to ensure that its use remains safe and efficacious. We also completed stage one of our chemical review into chlorpyrifos and have proposed to cancel its use in domestic and home garden settings, and in some public spaces.

Focus areas and activities

High-performing organisation:

- develop a learning and development strategy for on-boarding and capability development of new workforce
- establish the Office of the Chief Regulatory Scientist
- continue delivery of the APVMA accelerated regulatory science training program—Diploma of Government (Regulatory Science)
- deliver regulatory training
- renew online learning modules
- maintain and update procedures and material
- embed management practices for the enterprise risk framework.

Implement reforms and independent review recommendations:

- implement high-priority recommendations identified in the independent review
- monitor and report on benefits realised through the Agricultural Competitiveness White Paper
- work with the Department of Agriculture and Water Resources to pursue efficiencies through legislative reform, advocating recommendations made in the independent review.

Maintain alignment with international best practice:

- continue engaging and harmonising with relevant international forums
- periodically review and update APVMA risk assessment manuals and data guidelines to align with relevant international standards.

Performance against corporate performance measures

Performance measure	Source	Result
Maintaining a low number of regulatory decisions which are overturned by external bodies such as the Administrative Appeals Tribunal or Court	*Corporate Plan 2018–19*	In the 2018–19 year, the APVMA had 1 regulatory decision upheld (with minor amendments) by the Administrative Appeals Tribunal. This is an improvement on 1 decision overturned in 2017–18 and 4 decisions overturned in 2016–17.
Adjustments to registration requirements and the cancellation of registration for safety reasons flowing from the Adverse Experience Reporting Program (AERP)	*Operational Plan 2018–19*	In 2018–19, the APVMA processed more than 7126 adverse experience reports. One adverse incident may be reported multiple times (eg the vet, consumer and registrant may all report the same incident). The total number of reports received includes duplicate reports and reports classified as unrelated to the registered product. 951 classified reports have been classified as related to: • animal health—62.0% • efficacy—25.0% • human health—9.7% • crop health—0.8% • environment—2.4%. No safety issues were identified that warranted the cancellation of any product registrations; however, as a result of the receipt, classification and analysis of adverse experience reports received this year, the APVMA took regulatory action on 1 product family to ensure that its ongoing use remains safe and efficacious. Data from the AERP were also provided to inform registration and permit applications, compliance matters and chemical review processes.
APVMA contributions made to international forums	*Operational Plan 2018–19*	APVMA staff made presentations and attended several international forums during 2018–19 (see Table 8).

Performance measure	Source	Result
Maintaining a 24-month review cycle for APVMA risk assessment manuals and data guidelines	*Regulator performance framework*	The APVMA has published the following manuals: • Environment: apvma.gov.au/node/46416 • Chemistry and Manufacture: apvma.gov.au/node/45566 • Health: apvma.gov.au/node/45571 • Residues and Trade: apvma.gov.au/node/45576
Incremental improvement in operational performance against legislative timeframes: • 70% of regulatory decisions completed within statutory timeframes • 50% of emergency permits finalised within 14 days and 90% finalised within 28 days • 100% of chemical reconsiderations finalised in accordance with the program schedule.	*Operational Plan 2018–19*	• 85% of regulatory decisions for products, permits and active constituents were completed within statutory timeframe • 36% of emergency permits were completed within 14 days, and 67% were completed within 28 days • chemical reconsiderations finalised: – in August 2018 the methiocarb Proposed Regulatory Decisions report was published, for a consultation period of three months – in October 2018, in response to spray drift associated with 2,4 –D, product labels were suspended and new label instructions were issued at the same time to reduce the risk of spray drift – in June 2019, the chlorpyrifos review first stage (concerning home garden and domestic uses) was progressed. We made a proposed regulatory decision to suspend and cancel all home garden and domestic chlorpyrifos products, and to remove uses from certain public spaces.

Performance measure	Source	Result
Increased number of compliant manufacturing facilities that qualify for a reduced audit interval of up to 36 months	*Operational Plan 2018–19*	The APVMA continues to reduce the regulatory burden and cost of compliance for regulated entities by employing a risk-based approach for auditing manufacturers of veterinary medicines. Audit intervals are broken into 4 categories, and facilities are assigned to each category based on: • the non-conformance score obtained from the Good Manufacturing Practice audit • product-related factors (category of licence) to provide an overall risk valuation • the combined risk valuation of the subsequent audit interval • risk assessment matrix. At 30 June 2019, 54% of compliant manufacturing facilities qualified for an audit interval of 24 months or greater, with 6% qualifying for an audit interval of greater than 36 months.
Reduced burden and reduced cost for compliant manufacturers	*Operational Plan 2018–19*	In 2018–19: • 19 audits increased audit interval in comparison to previous intervals, resulting in a reduction in the burden to industry • 10 remained the same as the previous interval with no increase in burden.
Faster processing of nontechnical applications and minor variations	*Operational Plan 2018–19*	Non-technical assessments have assessment periods of 3 months or less and have no technical assessment The APVMA finalised non-technical assessments in an average of 2.4 months in 2018–19, down from an average of 2.6 months in 2017–18
The number of applications using data assessment, standards and decisions from comparable regulators	*Operational Plan 2018–19*	In 2018–19, international assessments contributed to the assessment of 16 products. They also supported residues assessment of 24 minor use or emergency permits
The average reduction in assessment time achieved for applications using international data	*Operational Plan 2018–19*	For the 2 products that were finished in the year which were substantively supported by international assessments and project plans agreed with the applicants, finalisation occurred 10 and 13 months before the statutory finalisation date

Strategy three

Improve regulatory service delivery and feedback systems to reduce the regulatory burden on industry

Summary and explanation of performance

We have reviewed and updated the APVMA website and finalised pathways and guidance materials for users. We are developing a new Stakeholder Engagement Framework and conducted 36 public consultations.

Focus areas and activities

Reduce the regulatory burden on industry:

- develop and implement a program of work to support the Australian Government agvet chemical legislative reforms.

Establish business intelligence and analysis capabilities:

- establish a centralised business intelligence capability
- develop a business intelligence and reporting framework.

Consolidate APVMA communication and service channels:

- improve currency, usability and accessibility of online information at apvma.gov.au
- set the framework for APVMA stakeholder engagement.

Performance against corporate performance measures

Performance measure	Source	Result
Implementation of legislative reforms and reporting on operational impacts and benefits for clients	*Corporate Plan 2018–19*	The Streamlining Regulation and Operational Efficiency Bills before Parliament in 2018 did not pass second readings before Parliament was dissolved, and therefore there were no new legislative reforms needing implementation.
The quality and breadth of industry engagement activities delivered each year that meet the needs and preferences of clients and stakeholders	*Regulator performance framework*	In 2018–19, the APVMA conducted 36 public consultations on a range of topics including chemical product approvals, trade advice notices, public release summaries, chemical reviews and revisions to the Australia New Zealand Food Standards Code. A new Stakeholder Engagement Framework is expected to be released in the 2019–20 financial year.

Performance measure	Source	Result
Annual survey of clients and stakeholders to monitor and track the level of satisfaction with APVMA online systems, interactions with clients and stakeholders, and regulatory information available online: • improve overall satisfaction with APVMA service performance (42% satisfied or very satisfied in 2018) • improve net promoter score (44 in 2018) • maintain satisfaction levels for clients interacting with APVMA staff (69% satisfied or very satisfied in 2018) • improved satisfaction of using online systems for small business and infrequent registrants • improve user satisfaction with apvma.gov.au (54% satisfied or very satisfied in 2018).	*Regulator performance framework*	The APVMA client and stakeholder survey was not conducted in 2018–19, with the next survey scheduled to occur in 2019–20. We have reviewed the APVMA website content. Website feedback has been largely positive. We received 277 positive, 189 negative and 5 neutral feedback messages for individual web pages.
Alignment with the APVMA service charter	*Corporate Plan 2018–19*	Web content and publications, including the *APVMA Gazette* and *Regulatory Update*, were published on schedule in accordance with the service charter. The APVMA Case Management and Administration Unit received over 5600 calls and 8100 emails in 2018–19. Phone messages and emails were checked daily and every effort was made to meet the requirements of our client service charter.