CHAPTER 2

PERFORMANCE AGAINST STRATEGIES

STRATEGIC FRAMEWORK AND REPORTING

The APVMA Corporate Plan 2012–15 identified four objectives:

- Objective 1—Deliver the benefits of more efficient regulation to business and the community
- Objective 2—Be transparent, consistent and predictable in delivering our regulatory services and decisions
- Objective 3—Focus efficiency and effectiveness measures on the protection of human, animal and plant health, the environment and trade
- Objective 4—Be respected and trusted for the regulatory decisions we take.

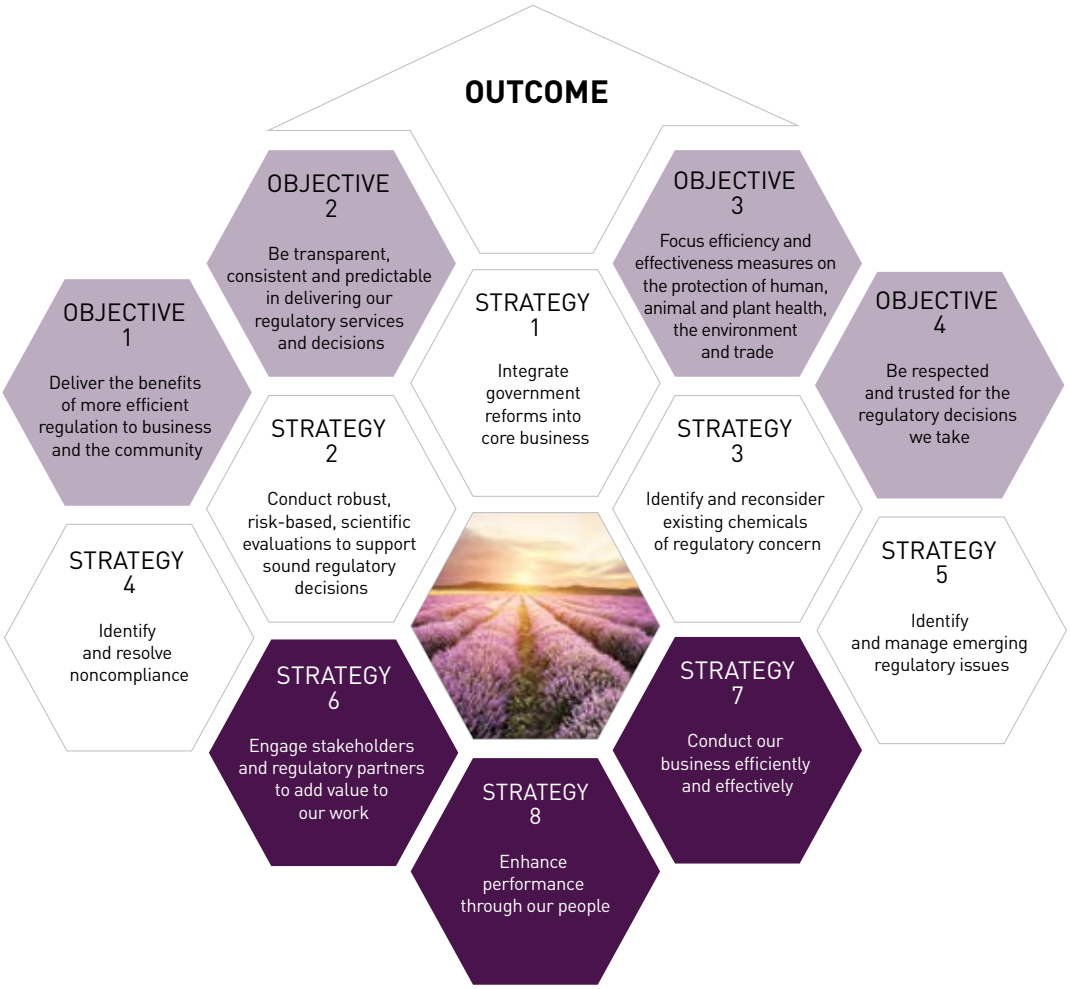
The APVMA *Operational plan 2014–15* identified eight strategies to achieve the corporate plan objectives and the APVMA's outcome (Figure 2):

- Strategy 1—Integrate government reforms into core business
- Strategy 2—Conduct robust, risk-based scientific evaluations to support sound regulatory decisions
- Strategy 3—Identify and reconsider existing chemicals of regulatory concern
- Strategy 4—Identify and resolve noncompliance
- Strategy 5—Identify and manage emerging regulatory issues
- Strategy 6—Engage stakeholders and regulatory partners to add value to our work
- Strategy 7—Conduct our business efficiently and effectively
- Strategy 8—Enhance performance through our people.

Strategies 1–5 are our core business strategies, and are supported and enabled by strategies 6–8.

FIGURE 2: APVMA OBJECTIVES AND STRATEGIES

'Protection of the health and safety of people, animals, the environment, and agricultural and livestock industries through regulation of pesticides and veterinary medicines.'



The APVMA Corporate Plan 2012–15 identified four objectives. The diagram above shows the relationship between these objectives, the eight strategies to achieve the objectives and the APVMA's outcome.

This report

This annual report assesses our performance against the eight strategies. Under each strategy are listed the initiatives and activities that are designed to achieve the strategy, and the performance measures for each. For example:

STRATEGY 1—INTEGRATE GOVERNMENT REFORMS INTO CORE BUSINESS

Initiative/activity—Embed revised APVMA regulatory guidelines into APVMA systems and processes

PERFORMANCE MEASURES	PROGRESS
Draft compendium in place by January 2014, for stakeholder consultation, awareness raising and education	
Compendium content finalised by April 2014 for further communication and training	

A summary table provides an overall assessment for each performance measure, and accompanying text provides detail.

Variation from the APVMA Portfolio Budget Statement

There have been no variations from the Portfolio Budget Statement in 2014–15.

SUMMARY OF PERFORMANCE AGAINST STRATEGIES

In 2014–15, the APVMA implemented widespread reform and change across all strategies. New business systems designed to complement and further increase the impact of the legislative reforms, as well as improvements to the way we manage and conduct our business, have provided a solid base for further improvement in coming years.

Also this year, the APVMA developed its first performance framework. The APVMA Regulator Performance Framework sets out how the APVMA intends to measure and report its performance each year, as part of an Australian Government requirement for all regulators. It contains performance measures against each key indicator and the evidence that will be collected to demonstrate performance. The first assessment period will be 2015–16.

Strategy 1—Integrate government reforms into core business. From 1 July 2014, legislative reforms aimed at improving the efficiency and effectiveness of agvet chemical registration and review processes were implemented. The APVMA has worked hard over the past few years to put new processes in place to support the reforms and to educate stakeholders about the changes. These processes have been supported by the launch of new online systems to allow applicants to submit and pay for their applications electronically, and a range of new internal processes, including a new case management system.

Building on more than 20 years experience in the regulation of agvet chemicals, the APVMA this year sought to identify classes of products for which the risks are well defined and therefore might be suitable for reduced regulatory effort. This includes considering where we can make greater use of international data, assessments, standards and decisions, in line with the government's Industry Innovation and Competitiveness Agenda.

Strategy 2—Conduct robust, risk-based scientific evaluations to support sound regulatory decisions. In 2014–15, we ran two registration systems in parallel as we transitioned to the new legislation: one for applications received before 1 July 2014 and one for applications received after 1 July 2014.

We received 2590 new applications in 2014–15 and finalised 3402. This includes pesticide, veterinary medicine and permit applications. Our overall performance for processing applications within statutory timeframes was below target, primarily because of the significant effort required to implement the new legislation and to run two registration systems in parallel. The process improvement initiatives we have implemented will continue to improve our ability to meet timeframe performance targets. We are also implementing new arrangements under the reform legislation for applicants to seek assistance before applying, which are designed to streamline the application process and improve the quality of applications.

Strategy 3—Identify and reconsider existing chemicals of regulatory concern. We validate our regulatory efforts and identify issues about particular chemicals through a range of sources, such as the Chemical Review Program, the AERP, and levels of compliance with the National Residue Survey.

To fulfil new legislative requirements, the APVMA prepared and published on its website work plans for all 18 current chemical reviews. These work plans provide greater transparency for our chemical review work by clearly setting out the scope of the remaining work, key milestones and the maximum legislative timeframe in which a decision will be made.

As a result of chemical reviews in 2014–15, the APVMA cancelled 3 active constituents, 11 products and 167 labels, and continued the suspension of 1 active constituent, 23 products and 46 labels. We also evaluated pesticide residue data for 80 applications for product registration and 95 applications for permits.

This year, we also consulted with the public to prioritise chemicals identified for review. We expect to publish a new order of priority by October 2015.

Strategy 4—Identify and resolve noncompliance. In 2014–15, we received 255 reports of alleged noncompliance and finalised 288 cases, including a number carried over from previous years. Through information and education campaigns, and monitoring of specific issues, such as label compliance, we have continued to assist companies to achieve voluntary compliance.

Strategy 5—Identify and manage emerging regulatory issues. We engage with other government agencies and our international counterparts to identify and mange emerging issues. This year, we examined the emerging use of nanomaterials in agvet chemicals, and methods for assessing the impact of agricultural chemicals on pollinators. The APVMA worked with international regulators and scientists to understand and explore these issues, and to develop regulatory guidance for Australian conditions.

Strategy 6—Engage stakeholders and regulatory partners to add value to our work. We established a significant program of ongoing engagement this year, with the first of six planned industry information and education sessions held in Sydney in June 2015. To better understand our future operating environment, the Advisory Board hosted a Future's Forum to hear from stakeholders from across the agricultural sector and from our regulatory partners. This year, the APVMA refreshed its Client Service Charter, including setting service standards and response times, and put in place simpler online feedback tools.

Strategy 7—Conduct our business efficiently and effectively. In 2014–15, we continued to focus on improving our external-facing information technology (IT) systems, particularly online product applications.

We began the transition to contemporary database technology in 2014–15, which will improve our future business intelligence and performance reporting capability. We also redeveloped the external-facing searchable chemicals database this year to make it easier to use and more accessible; rollout is scheduled for September 2015.

In 2014–15, we also developed the APVMA Corporate Plan 2015–19, which provides the road map for the agency's work in the second half of the decade.

Strategy 8—Enhance performance through our people. We had 172 full-time and part-time staff at 30 June 2015. We appointed Dr Phil Reeves to the new role of APVMA Chief Scientist and Mr Alan Norden as the Executive Director, Registration Management and Evaluation. An APVMA-wide capability review was undertaken to identify current and future skills gaps, which will continue in 2015–16. We developed new e-learning modules to increase staff awareness of the security, financial and behavioural expectations of public sector employees, and these are now part of the APVMA induction package. All staff undertook face-to-face training and completed online education on appropriate management of confidential commercial information.

AT A GLANCE—ACHIEVEMENTS 2014–15

		2014–15	2013–14
Pesticides	Applications received for product registration, variation to registration or label approval	1388	1942
	Applications finalised	1843	1870
	Percentage of applications finalised within the statutory timeframe	81%	96%
Veterinary medicines	Applications received for product registration, variation to registration or label approval	653	997
	Applications finalised	941	1187
	Percentage of applications finalised within the statutory timeframe	80%	90%
Permits	Applications received	549	668
	Applications finalised	618	590
	Percentage of applications finalised within the statutory timeframe	70%	90%
Registered chemicals	Review reports published	2	4
	Regulatory actions taken (2 affirm active constituent approvals, 3 cancel active constituent approvals, 11 cancel product registrations, 3 affirm label approvals, 101 vary label approvals, 167 cancel product labels)	287	438
	Regulatory decisions made (1 continue active constituent approval suspension, 23 continue product registration suspensions, 1 revokes product label suspension, 46 continue product label suspensions)	71	117
Adverse experience reports	Reports of suspected adverse experiences	5116	1821
Noncompliance	Allegations of noncompliance received	255	243
	Allegations finalised	288	156
	Recall actions taken	2	9
	Site visits conducted	68	49
Communication	International visits to the APVMA	4	3
	Attendance and presentations at conferences and meetings	39	16

Note: The 'applications finalised' performance measure has been updated since the *Annual report 2013–14* to include applications rejected or withdrawn at preliminary assessment. Although the APVMA does not evaluate these applications, they are regarded as finalised.

STRATEGY 1—INTEGRATE GOVERNMENT REFORMS INTO CORE BUSINESS

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* was implemented on 1 July 2014. The aim of the legislative reforms was to improve the efficiency and effectiveness of agvet chemical registration and review processes. The APVMA has worked on two main fronts to implement reform: improving APVMA processes, and communicating with and training stakeholders.

Reduce the administrative and regulatory burden on industry

PERFORMANCE MEASURES	PROGRESS
Developed a new, risk-based assessment framework that will allow the use of 'lighter touches' on chemicals of lower regulatory concern	In progress
Streamlined registration processes	Achieved
Recognised overseas data and studies, and developed opportunities to participate in global joint reviews (for both agricultural chemicals and veterinary medicines)	In progress
Developed an automated system for industry to report adverse experiences	Partly achieved
Developed a range of new IT tools to make it easier to transact with the APVMA	In progress

Assessment

The Risk Assessment Framework project aims to identify classes of products or types of applications where the risks are well defined and regulatory intervention can be reduced. Using information gathered from the Risk Assessment Framework Industry Working Group in March 2015, we are developing the selection criteria for such products and applications. A project webpage has been established, which will be made available once we have refined the decision-making criteria. It is anticipated that the first stage of the revised framework will be in operation by July 2016 (see Case study 1).

Registrations

In 2014–15, we began streamlining our registration processes, and integrated case management into the evaluation process to improve management of an application.

We established the Registration Management and Evaluation (RME) and Scientific Assessment and Chemical Review (SACR) programs, replacing the Pesticides Program and Veterinary Medicines Program. The RME program conducts the overall management of an application, including risk management. The SACR program conducts risk assessment in the key areas of chemistry, residues, environment, efficacy, target safety and human health. The new structure and case management allow us to improve the efficiency of our evaluation processes.

Some of the legislative reforms introduced this year either negate the need for registration of certain products or reduce the burden on industry to make changes to an existing registration. These include removing the need for certain stockfeeds and petfoods to be registered where they meet specific requirements for constituents, labelling, manufacturing and claims. Specified minor variations are now possible to some name, manufacturing and label details for registered products and active constituent approvals as notifiable variations or simplified applications.

Collaboration

The Organisation for Economic Co-operation and Development (OECD) Global Joint Review (GJR) program for pesticides continues, and the APVMA is participating in five GJRs. The first GJR-type application is under way for extension of use of a veterinary product. This is being conducted jointly with Canada and New Zealand. It is hoped that the experiences from this first exercise will be shared and refined for future veterinary product applications.

IT tools

A range of new web-based systems were launched during the reporting period. These will streamline the interaction between the APVMA and applicants, and have been designed to be flexible, allowing rapid modification, if needed.

IT systems for automated online feedback and interactive electronic label submissions have been developed, to improve and simplify interactions with the APVMA. Automation of AERP reports is currently under review.

The APVMA has begun planning to incorporate the Globally Harmonised Submission and Transport Standard, developed by the OECD, into the APVMA online application system. This will allow data to be submitted and generated in the internationally agreed standard format.

The AERP assesses reports of adverse experiences associated with the use of registered agvet chemical products. This provides the APVMA with valuable information on registered chemicals, which may trigger further investigation. In 2013–14, we launched an online reporting form for adverse experience reports. This tool facilitates more efficient reporting by stakeholders for single reports. A portal for online submission of applications was implemented, followed by the development of an online feedback system and online submission of the annual return of actives data. Several other systems are now being developed to further improve our service delivery and customer experience.

The majority of information received by the AERP is submitted by registration holders as periodic summary updates (PSUs). PSUs consolidate all the adverse experience feedback the holder has received for a product, typically in a 12-month cycle, including information about the holder's investigation and assessment of each incident. We currently accept PSUs in a range of forms. Reporting templates are available from the AERP pages of the APVMA website, and this information is usually provided to the APVMA electronically.

We are currently investigating options to support the automatic upload of this information to the APVMA's adverse experience database to improve our processing efficiency and reduce the time taken for us to assess each incident.

CASE STUDY 1

Risk Assessment Framework

The APVMA's Risk Assessment Framework project aims to define the appropriate level of regulatory effort needed to assess applications for approval of active constituents, registration of products or variations to existing products. The approach to regulating agvet chemicals arising from this project will ensure that regulation is only used where absolutely necessary and only to the extent needed to satisfy legislative criteria. In practice, this means that the level of regulatory intervention and associated requirements are commensurate with the risks posed by particular products.

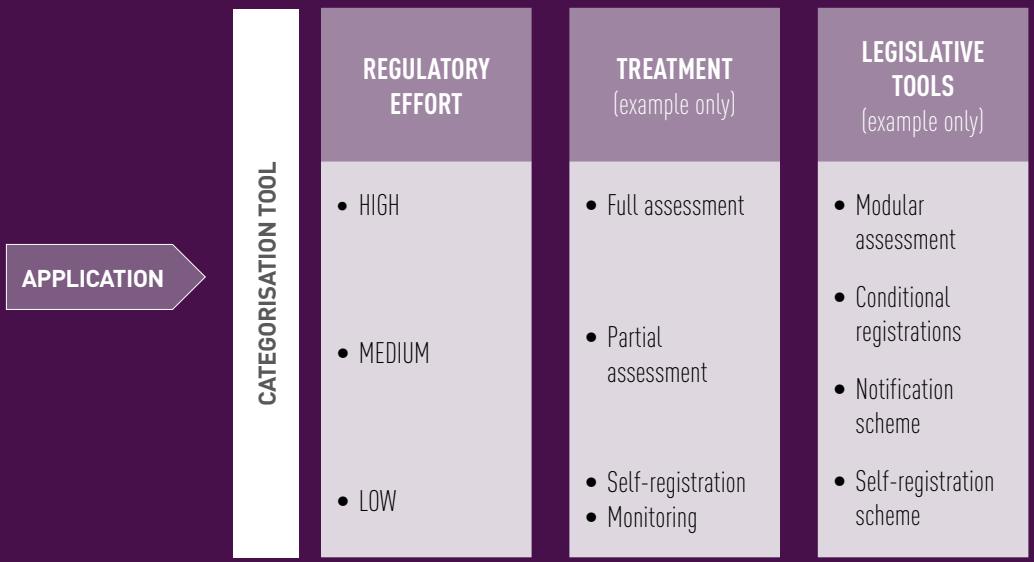
The agvet industries expect transparency and predictability from the work of the APVMA. Where information and assessments from other regulatory agencies are available and can be substituted for a national assessment, applicants also expect the APVMA to provide concessions in relation to timeframes and data requirements.

Using our more than 20 years experience in the regulation of agvet chemicals, through this project the APVMA is seeking to identify classes of products for which the risks are well defined and therefore could be suitable for reduced regulatory intervention. Through further alignment of the APVMA's regulatory practices with those of other key regulators, as well as greater use of international data, assessments, standards and decisions, the APVMA will ensure that Australian-specific requirements are justifiable and that there is no duplication of effort as a result of the APVMA's requirements. These are the principles set out in the government's Industry Innovation and Competitiveness Agenda, which underpin the Regulator Performance Framework.

In the first stage of this project, the APVMA is working with the University of Melbourne to develop a categorisation tool for applications (Figure 3). A Risk Assessment Framework Industry Working Group was established this year with representatives from diverse sectors of the agvet industries. Using information and feedback from this group, we have identified additional treatment options to further refine the tool.

This work has also helped us to identify other areas where reduced regulatory intervention could be considered. The categorisation tool is expected to provide a transparent and predictable categorisation of an application. It will be driven by the 'risks we know' and 'risks we don't know' approach, with requirements proportioned appropriately to the level of knowledge. Some of the options being considered will build on approaches used by other regulators for products of low regulatory concern.

FIGURE 3: RISK-BASED ASSESSMENT FRAMEWORK CONCEPT



Support the Australian Government's minor use project, to improve access to minor use permits by the agricultural industry

PERFORMANCE MEASURES	PROGRESS
Engaged and participated in the planning, development and implementation of the initiative	In progress

In 2014–15, the APVMA worked with the Australian Government Department of Agriculture and the Rural Industries Research and Development Corporation (RIRDC) to improve chemical access for users. We participated in several forums conducted by the RIRDC to establish a cross-industry collaborative forum for identifying and prioritising chemical access needs of users.

With input and funding from the Department of Agriculture, we have also established two projects around minor use.

The first project will establish a list of crop groups (eg pome fruits, stone fruits, cereal grains, bulb vegetables) and identify representative commodities for each group for which research data and assessments can be extrapolated to other group members, and which are deemed to satisfy efficacy and safety criteria without the need for further data or assessment. This project is scheduled for completion in 2015–16.

The second project will review around 750 minor use permits currently issued in livestock and agricultural crops to determine their suitability for transition to full label registration without further data or assessment. The project will be conducted between July 2015 and December 2017.

Continue to improve the transparency of APVMA operational practices, policies and guidelines

PERFORMANCE MEASURES	PROGRESS
Published all relevant regulatory guidance and operational information in user-friendly formats and in a timely manner	Achieved

The implementation of legislative reforms has highlighted the importance of clear communication with our stakeholders. Our flagship communication product is the APVMA website, which provides a range of regulatory guidance and operational information, and information on our programs and projects.

A web governance policy delivered this year establishes clear processes for managing new and updated content for the website. The policy ensures that regulatory information published on the website is both timely and accurate.

Government website accessibility standards were substantially met this year. A planned usability review in 2015–16 will be used to improve the user experience of the website, and our online application and transaction tools.

Support industry readiness to comply with the new regulatory framework

PERFORMANCE MEASURES	PROGRESS
Implemented case management system from 1 July 2014	Achieved
Conducted refresher training for industry on new requirements	Achieved

Case management

The APVMA has implemented a new case management system to support the implementation of the legislative reforms. The new system is designed to deliver more efficient management of applications and enquiries.

The case management system incorporates tracking, administration and management of applications from submission to completion. The system also provides a single point of contact for clients for pre-application assistance, email correspondence and telephone enquiries. Our case managers in the newly formed Case Management and Administration Unit monitor workflow, coordinate timeframes, and are the communication link between applicants and technical areas.

Industry training

Along with updates to our website, we have worked directly with stakeholders to communicate what the legislative changes mean for them.

In June 2015, we started a series of stakeholder information education sessions that will be completed in November 2016. Events will be held in Canberra, Melbourne and Sydney, complemented by one-day CEO visits to Perth and Brisbane.

The focus of the series is on quality regulatory decision making, with a mix of general information sessions, computer-based training, and coverage of specific topics of interest. The program was developed in consultation with industry, and takes into account results from an industry survey and feedback from industry following previous information and training sessions.

The first session, on 1 June 2015 in Sydney, was attended by around 150 people. Feedback from the day indicated that all sessions were positively received, with people commenting that they could see real and positive change in the APVMA's approach.

STRATEGY 2—CONDUCT ROBUST, RISK-BASED SCIENTIFIC EVALUATIONS TO SUPPORT SOUND REGULATORY DECISIONS

Our scientific evaluations are based on robust, risk-based methods. We keep in contact with relevant organisations to ensure that these methods reflect international best practice. We also review the latest science and regulatory information to inform our decisions and processes. We help applicants to navigate the regulatory processes, and support them with a range of information materials and training.

Make quality, timely decisions on registration, active approval and permit applications

PERFORMANCE MEASURES	PROGRESS
Met timeframe performance targets for applications received before commencement of new legislation:	Not achieved
• 90% of product registrations	74%
• 60% of active approvals	44%
• 85% of permits	65%
Met timeframe performance targets for applications received after commencement of new legislation:	Not achieved
• 100% of product registrations	88%
• 100% of active approvals	84%
• 100% of permits	76%
Further improved regulatory guidelines, including new technical manuals	In progress
Developed criteria to be used to determine whether efficacy is a relevant consideration in assessing an application	Achieved

Applications are made to the APVMA to approve, register or vary active products, constituents or labels. Applications must be supported by information that allows us to determine whether the product meets the applicable safety, trade, efficacy and labelling criteria.

Timeframe performance targets were not met in 2014–15. The considerable effort required to implement the new legislation meant that the assessment of new applications fell behind the performance targets. The drop in performance was a result of a concerted effort to minimise the number of applications that would transition to the new legislation, by finalising applications received before 1 July 2014 that were already outside timeframes at the beginning of the period.

New regulatory guidelines were developed and delivered by 1 July 2014 to coincide with the commencement of the legislative reforms. This followed extensive consultation with industry in the lead-up to 1 July 2014.

We began a new program to review and update all existing data guidelines, to convert them to a more accessible and consistent format. Through this work, we have identified a number of international data guidelines that will be adopted in 2015–16. We also developed a technical manual for chemistry, which will be released for consultation in late 2015.

In 2014–15, we developed tools to reduce the administrative burden relating to efficacy. This included a list of product types for which no efficacy data are required, and industry guidance on the type of data that may be provided in an application to address the efficacy criterion.

Pesticides

Product applications

We received 1388 applications for product registration, variation to registration or label approval for pesticide products in 2014–15. This is 29 per cent less than in the previous year (Table 1).

There were 89 pesticide product applications transitioned to the new legislation in July 2015.

TABLE 1: APPLICATIONS FOR PESTICIDE PRODUCT REGISTRATION OR VARIATION, 2014–15

Applications	2013–14	2014–15	% change
Applications in progress at beginning of period	1039	1107	6% more
Applications received	1942	1388	29% less
Applications finalised	1870	1843	2% less
Applications in progress at end of period	1107	657	41% less

Product finalisations

In 2014–15, we completed 651 applications within the statutory timeframe for applications received before 1 July 2014 (74 per cent compared with a target of 90 per cent), and completed 844 applications within the statutory timeframe for applications received after 1 July 2014 (88 per cent compared with a target of 100 per cent; Table 2).

TABLE 2: PESTICIDE PRODUCT FINALISATIONS, 2014–15

	2013–14	2014–15		
Applications	Total finalised	Total finalised	Finalised in timeframe	Finalised in timeframe (%)
Received before 1 July 2014	1870	883	651	74
Received after 1 July 2014	0	960	844	88
Total	1870	1843	1495	81

Permits

In 2014–15, we received 418 permit applications and finalised 456 permits, of which 70 per cent were completed within the statutory timeframe. Of the permit applications finalised, approximately 46 per cent were for minor use, 30 per cent were for reissue of a previous permit, 2 per cent were for export use, 7 per cent were for emergency use and 14 per cent were for other use (eg research).

Active constituent approvals

The focus this year was to finalise as many applications as possible that were already in progress on 1 July 2014, to reduce the number of applications that would need to be transitioned to new arrangements on 1 July 2015. The timeframe statistics for these older applications was 44 per cent within the timeframe, compared with 80 per cent last year. This change reflects the significant additional work required to finalise legacy applications under the previous system. For applications received after 1 July 2014, 84 per cent of active constituent approvals were completed within the timeframe, compared with the target of 100 per cent.

Veterinary medicines

Product applications

We received 653 applications for product registration, variation to registration or label approval for veterinary medicine products in 2014–15. This is 35 per cent less than in the previous year (Table 3).

There were 93 veterinary medicine applications transitioned to the new legislation in July 2015.

TABLE 3: APPLICATIONS FOR VETERINARY MEDICINE PRODUCT REGISTRATION OR VARIATION, 2014–15

Applications	2013–14	2014–15	% change
Applications in progress at beginning of period	828	640	23% less
Applications received	997	653	35% less
Applications finalised	1187	941	21% less
Applications in progress at end of period	640	372	42% less

Product finalisations

In 2014–15, we completed 376 applications within the statutory timeframe for applications received before 1 July 2014 (73 per cent compared with a target of 90 per cent), and completed 377 applications within the statutory timeframe for applications received after 1 July 2014 (88 per cent compared with a target of 100 per cent; Table 4).

TABLE 4: VETERINARY MEDICINE PRODUCT FINALISATIONS, 2014–15

	2013–14	2014–15		
Applications	Total finalised	Total finalised	Finalised in timeframe	Finalised in timeframe (%)
Received before 1 July 2014	1187	514	376	73
Received after 1 July 2014	0	427	377	88
Total	1187	941	753	80

Permits

In 2014–15, we received 131 permit applications and finalised 162 permits, of which 71 per cent were completed within the statutory timeframe.

Of the permit applications finalised, approximately 11 per cent were for minor use, 37 per cent were for reissue of a previous permit, 13 per cent were for export use, 2 per cent were for emergency use and 37 per cent were for other use (eg research).

Support provision of high-quality applications

PERFORMANCE MEASURES	PROGRESS
Launched new IT tools to allow online submission of applications and data	Achieved
Conducted two courses for applicants and consultants on application preparation	Achieved
Implemented pre-submission meetings from 1 July 2014	Achieved

See also Strategy 1.

IT tools

In 2014–15, a new online application system replaced paper-based applications. This means that the information and payments that must accompany applications (including permits) can be provided at the time the application is submitted. The online application system guides applicants to the correct application pathway, and enables submission of applications and payment of fees online.

A purpose-built decision-tree tool leads applicants through a series of questions to identity the correct item number and fee for the proposed application. Online training tools and several face-to-face training sessions delivered in 2014–15 provided applicants and consultants with information about how to use the new online application and payment system. The schedule of future improvements to these systems is published on the APVMA website. An online feedback system means that users can easily report issues and make suggestions for improvement.

A new secure facility for the distribution of work to supporting government agencies was also launched during the year.

Pre-application assistance

On 1 July 2014, new arrangements were introduced as part of the reforms to allow applicants to seek assistance before submitting an application to register, vary or seek a permit for a pesticide or veterinary medicine product. This is designed to help potential applicants understand how to prepare and make an application, and seek advice, to ensure that applicants present relevant information with their application. Applicants are charged a fee for pre-application assistance (PAA).

In 2014–15, there were 191 PAA applications. Of these, 95 received written correspondence, 9 met with APVMA staff, 31 are still in progress, and 56 were refunded and reclassified as either enquiries or technical assessments.

Following feedback from industry and stakeholders, we undertook an independent review of the implementation and operation of PAA arrangements. The review highlighted that the PAA did not meet the standards required by our clients, and that we did not have adequate systems and processes in place to support it effectively.

We are committed to implementing all the recommendations from the review and to redesigning the entire PAA process to meet clients' needs. Significant improvements to the system have already been made. Over the medium to long term, we will engage with industry to co-design a system that works for the people who use it. The new PAA system is expected to be implemented in October 2015.

Enhance quality assurance

PERFORMANCE MEASURES	PROGRESS
Developed new internal quality assurance systems to provide confidence that individual decisions are sound and consistent with statutory obligations	Achieved
Developed processes to give assurance of the quality of external advice provided as part of the registration process	In progress

We have established two new committees to examine the quality of scientific risk assessment and risk management: the Science Quality Committee and the Registration Quality Committee. These committees are chaired by senior executives of the APVMA. Membership includes APVMA specialist staff and specialists from other regulatory agencies, as necessary.

The Science Quality Committee is responsible for approving proposals for development and adoption of scientific methodologies, testing guidelines and guidance documents produced by the APVMA and partner agencies, providing a forum for open debate of scientific issues, providing advice on complex assessments relevant to registration or chemical review decisions, and overseeing the development of the science strategy of the APVMA.

The Registration Quality Committee is responsible for providing advice on APVMA frameworks to foster excellence in decision making; overseeing quality assurance and the administration of decision making on registrations to ensure that decisions are consistent, timely, transparent and predictable; considering trends in feedback, complaints and adverse experience reports; and identifying, where appropriate, changes to registration processes to address the trends and improve the underlying business processes for registrations.

Two new positions in the scientific assessment program—Health Assessment Coordinator and Environment Assessment Coordinator—were established to review the quality of reports from external service providers. Quality checks of reports received from the Australian Government departments of Health and the Environment were also conducted, with more detailed peer review when required.

Implement streamlined application assessment processes

PERFORMANCE MEASURES	PROGRESS
Designed and implemented a single, integrated, end-to-end process for registration and compliance to ensure better alignment, visibility and coordination	Partly achieved
Implemented a case management system to manage the case load of applications through the registration process, and provide proactive communication and defined points of contact for applicants	Partly achieved

See also Strategy 1.

The APVMA aims to ensure that registration decisions have a sound legal basis, and that compliance activities, if required, can be achieved and upheld. Processes for registration and compliance are therefore continually reviewed and improved.

For example, as part of the legislative reform changes and to support APVMA processes, we are developing new systems to improve the application process.

The APVMA implemented a case management system on 1 July 2014. The new Case Management and Administration Unit tracks, administers and manages applications from lodgement to finalisation. Case managers from the unit are assigned applications, and track and coordinate the progress of their applications through to finalisation. The case managers provide a single point of contact for the applicant, and liaise between technical areas and the applicant.

The new case management system has delivered more efficient management of both applications and enquiries. Improvements to IT systems will further streamline the application assessment process during 2015–16. This will help the APVMA to meet its new legislative timeframes.

A new management system has been partially developed and is in use for internal management of applications. We expect the system to be fully functional in 2015–16.

Improve the use of overseas data, assessment and decisions to reduce regulatory burden

PERFORMANCE MEASURES	PROGRESS
Designed and implemented a framework for increasing the use of data, assessments and decisions from comparable regulators, and for deciding when data generated overseas can be used to support an Australian application	In progress
Analysed relevant international guidelines to determine their suitability for adoption in Australia	Achieved
Harmonised data requirements with international regulatory partners for chemistry to reduce the regulatory burden on applicants	In progress
Developed a model to enable international experience to be used to help resolve scientific issues	Achieved

Regulatory agencies around the world are dealing with similar issues. The APVMA is therefore not seeking to 'reinvent the wheel', but to draw on international best practice and guidelines to inform our work.

International assessments

In line with the government's Industry Innovation and Competitiveness Agenda, a policy document was published: *APVMA's approach to the use of international data, assessments, standards and decisions*. The document was published for consultation in April 2015, and workshops were held with interested stakeholders to develop detailed criteria on the use of assessments from comparable overseas regulators. Based on the submissions received, we will develop and consult on a set of detailed criteria, which we expect to publish by the end of 2015.

International guidelines and expertise

The APVMA keeps up to date with international developments in assessment of pesticides and veterinary medicines. A program of identifying new data guidelines for adoption, and revising existing guidelines, began this year, with a dedicated officer working internally with the expert areas. Many data guidelines that were previously available are being revised and prepared for consultation before implementation.

The work program of the OECD Working Group on Pesticides includes a new initiative to develop harmonised data requirements for chemistry among OECD members. The aim of the initiative is to use the learnings from GJR activities to achieve a single chemistry assessment that all OECD members would accept. An APVMA representative is a member of the chemistry group.

This year, we have targeted a number of overseas tools that may help in our work.

In 2012, the United States Environment Protection Agency released a significantly revised crop re-entry risk calculator, which estimates the likelihood of transfer of pesticides from sprayed crops to workers re-entering the crop. The APVMA reviewed this publication during the year to establish its suitability for Australian use. The calculator was adopted for use as an exposure assessment tool for Australian conditions from 1 May 2015.

We are also examining the suitability of the North American Agricultural Handlers Exposure Database as an assessment tool to estimate worker exposure to pesticides under Australian conditions.

The APVMA began evaluating an electronic tool known as Metapath, which is being developed by the OECD Working Group on Pesticides. It displays metabolism pathways and relevant data on pesticide metabolites obtained from regulatory studies. It is envisaged that Metapath will promote harmonisation of study reporting and facilitate exchange of data on pesticide metabolism to help regulators in their assessments of metabolism and residue studies.

Develop a regulatory framework to support spray drift policy

PERFORMANCE MEASURES	PROGRESS
Commenced public consultation by 30 January 2015	In progress
Completed public consultation and review of proposal by 30 June 2015	In progress

The possibility of spray drift to nontarget crops during the application of pesticides is a concern to both the community and the agricultural industry. Industry is constantly challenged to find ways to minimise spray drift more effectively. The APVMA is responsible for ensuring that nontarget pesticide spray drift does not harm human health, the environment or Australia's international trade.

We have completed several aspects of the spray drift project, including:

- improving spray drift modelling for ground-boom applications through the validation of a model under Australian conditions from the work of the National Working Party on Pesticide Applications; this will be a world first, and allows consideration of a much larger range of nozzles and other methods of reducing spray drift than has previously been possible
- updating the modelling used for aerial application to an improved version that has been validated and used by overseas agencies
- adopting modelling used by the German Government for vertical sprayers (typically orchard/vineyard equipment, but may also include similar equipment used in trellis tomatoes, forestry and ornamentals); this modelling has been used as a reference for the approval of almost 300 drift reduction technologies in Germany
- improving risk assessments through greater use of real-world data inputs
- developing clearer labelling instructions to remove uncertainty for chemical users.

A new drift management tool is being developed to assist users by calculating refined buffer distances, based on their use pattern, application equipment and weather patterns.

The APVMA expects to consult on the framework and finalise it in 2015–16.

Improve international engagement

PERFORMANCE MEASURES	PROGRESS
Developed a new international engagement strategy that enables the APVMA to share information, identify emerging trends, and solve common regulatory issues with our international regulatory partners	In progress

To achieve effective regulation and maintain a contemporary scientific knowledge base, the APVMA engages with regulatory counterparts in other countries, adopts international guidelines when they are suitable for an Australian context and explores formal partnership arrangements with comparable overseas regulatory agencies. The APVMA has active working relationships with many international agencies and overseas regulators. We work collaboratively on various projects and shared initiatives, and actively participate in international forums on key regulatory matters and emerging issues (see Case study 2).

This year, we reviewed our international engagement in the context of our strategic goals to better understand where our regulatory efforts should be directed—this will complement our work in making better use of international data assessments, standards and decisions. An international engagement strategy is now being developed, which will establish clear priorities and goals for 2015–17.

Specific international cooperative activities include:

- harmonising data requirements, risk assessment methodologies and risk management approaches—for example, with the OECD and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)
- contributing to the development of international standards through participation in expert committees and working groups for the national interest—for example, the Joint Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO) Meeting on Pesticide Residues, and the Joint Expert Committee on Food Additives (JECFA) (with regard to veterinary drugs)
- participating in global joint reviews of pesticides and veterinary medicines
- sharing data, including the use of overseas assessment reports to assist our decision making
- regional engagement and capacity building and training on compliance, risk assessment and registration processes
- managing emerging issues, including risks at the international level, for active constituents and agvet chemical products
- building regulatory networks with counterpart agencies in other countries and developing supportive agreements for working together.

The APVMA operates in a global regulatory environment and has various obligations to the national interest. The APVMA's obligations are valuable opportunities to build and improve its work. Examples of current commitments include:

- participation in meetings of the Codex Alimentarius Commission, the OECD and VICH
- contributing to the development of international standards through participation in expert committees and working groups for the national interest (eg Joint FAO/WHO Meeting on Pesticide Residues and JECFA)
- treaty-related activities under the Mutual Recognition Agreement on Conformity Assessment between Australia and the European Community to ensure that such agreements remain effective
- international treaty obligations under the Stockholm Convention on Persistent Organic Pollutants and the Rotterdam Convention, through providing advice to the Australian Government departments of Agriculture and the Environment.

CASE STUDY 2

Estimating exposures of agricultural workers who mix, load and use pesticides

In Australia, evaluations of occupational exposure to pesticides have used the United Kingdom's Predictive Operator Exposure Model and the United States's Pesticide Handlers Exposure Database (PHED). Recent analyses have highlighted the need to extend the datasets underlying some of the PHED pesticide-use scenarios. The APVMA has been liaising with the North American Agricultural Handler Exposure Task Force about accessing its Agricultural Handler Exposure Database and its underlying proprietary data, with the initial aim of evaluating its suitability for use in Australian cropping scenarios before considering its possible adoption as an assessment tool to estimate exposures for different crop uses.

As part of this work, APVMA's Principal Scientist, Pesticides, was invited to be the opening presenter at a symposium, 'Global approaches to assessment of bystander and agricultural worker exposure and risk' at the Congress of Pesticide Chemistry of the International Union of Pure and Applied Chemistry in San Francisco in August 2014. Regulators from Brazil, California, India, Japan and the United States also contributed formal presentations, followed by discussions between a wider range of participants.

Build and maintain a quality scientific assessment capability

PERFORMANCE MEASURES	PROGRESS
Established new memorandums of understanding with advising agencies to provide expert advice to support APVMA decision making	Not achieved
Finalised a tender process for additional providers of external scientific assessment services	Achieved

The APVMA receives registration and reconsideration advice from the Australian Government departments of Health and the Environment on matters concerning human health and the environment. Where the departments do not have the scientific expertise or the capacity to provide such advice, external scientific reviewers are contracted.

The APVMA's aim for any new departmental agreements is to ensure that they provide value for money, and that the services provided by the departments are timely, efficient and effective.

This year we conducted and finalised an open tender process to appoint suitably qualified and experienced individuals or organisations to a multi-use panel for scientific disciplines. The panel contains eight scientific disciplines: antimicrobial resistance, chemistry, efficacy, environment, immunobiologicals, residues, toxicology, and work health and safety.

In 2014–15, the APVMA contracted 23 human health assessment reports (approximately 25 per cent of human health assessments received by the APVMA during this period) and 56 environment assessment reports (approximately 50 per cent of environmental assessments received during this period).

Given the increased use of external assessors, the APVMA suspended the development of the memorandums of understanding with the Department of Health and the Department of the Environment. It is expected that this will be revisited in 2015–16.

Implement outcomes from the Joint Expert Committee on Food Additives methodology for setting maximum residue levels (MRLs) for veterinary medicines

PERFORMANCE MEASURES	PROGRESS
Implemented outcomes by 1 January 2015	Not achieved

In December 2013, a meeting was held at the APVMA to review the APVMA's application of the JECFA approach to recommending MRLs for veterinary medicines. The recommendations are in four key areas: workflows, evaluating risk, communicating risk and resources.

The workflow and resource recommendations were addressed in the APVMA's organisational restructure in October 2014. A single team is now responsible for assessment of pesticide and veterinary medicine residues.

Our approach to evaluating and communicating risk associated with MRLs for veterinary chemicals is being considered as part of the APVMA's broader approach to improving our risk assessment capability.

STRATEGY 3—IDENTIFY AND RECONSIDER EXISTING CHEMICALS OF REGULATORY CONCERN

The APVMA can reconsider registered products, approved active constituents or labels if new information raises concerns about the chemical's safety or efficacy. This process is called a 'chemical review'.

We also identify chemicals of regulatory concern through our AERP and through compliance with the MRLs we set.

Implement new chemical review work plans and enhanced stakeholder engagement with review activities

PERFORMANCE MEASURES	PROGRESS
Implemented an improved website for chemical reviews	Achieved
Established work plans by 30 June 2015	Achieved
Reviewed the existing Priority Candidate Review List by December 2014	Achieved
Conducted a feasibility study into the development of a dynamic (near-real-time) online publication system for AERP reports	In progress

Stakeholders and the general public provide valuable information that feeds into chemical reviews. The APVMA supports stakeholder and community engagement, and ensures that chemical reviews are efficient and effective.

An improved website for chemical reviews was implemented on 1 July 2014, and we made improvements throughout the year (see Case study 3). The new layout provides greater transparency by showing the nine phases of the work plan for each review, and the current status of each. This means that people can more easily see where the review of a particular chemical is up to, the reason for its nomination and the current regulatory position.

To fulfil new legislative requirements, the APVMA has prepared and published work plans for all 18 current chemical reviews. These set out the scope of the remaining work, key milestones and the maximum legislative timeframe in which a decision will be made.

The APVMA, in collaboration with the advisory agencies and the states and territories, has reviewed the 39 chemicals on the Priority Candidate Review List (to ensure that it is targeting the highest-risk chemicals). A two-day workshop was held in Canberra in November 2014 with the Australian Government Department of Agriculture, the Australian Government Department of the Environment, the Office of Chemical Safety, Food Standards Australia New Zealand, and the states and territories to decide on a revised list of high-priority chemicals. Twenty-five chemicals from the Priority Candidate Review List were reconfirmed for review.

From 31 March to 30 June 2015, we consulted with the public to seek additional information to help prioritise the chemicals for review and determine the approach that may be taken in conducting the review. Following the evaluation of public submissions, the APVMA expects to publish the new priority order by October 2015.

CASE STUDY 3

Redesigning chemical review webpages

The high profile of chemical review decisions and their potential impact on end users, industry and the community mean that accurate, up-to-date and accessible website information is needed. Redesigning the APVMA's chemical review webpages to meet these requirements is challenging, because chemical reviews can be complex and are highly variable—no two reviews are the same. The Chemical Review Program has run for more than 20 years and has accumulated an assortment of process information, technical assessment reports and communications in relation to almost 150 different chemicals.

Because chemical reviews incorporate legislative, scientific and administrative processes, the design concept for the webpages has been built around the following key elements:

- legislation—new legislation relevant to the conduct of chemical reviews was implemented in 2014–15
- scientific assessment—all chemical review decision are based on a comprehensive risk assessment
- project management and communication—including stakeholder engagement.

For each chemical review (both completed and current reviews), the new chemical review webpages were designed around the nine phases of a review:

1. Nomination—new information raises human health and/or environmental concerns in relation to an existing chemical.
2. Prioritisation—based on the scientific case, the review is prioritised.
3. Scoping and work plan—the scope of the review is defined (public health, worker safety, environment, trade, target crop or animal safety, chemistry, residues and trade), and a work plan is prepared, as required by legislation.
4. Notice of reconsideration—notices are sent to holders of approvals and registrations requiring them to submit data relevant to the scope of the review.
5. Assessment—risks associated with uses of the chemical are scientifically examined.
6. Draft regulatory measure—risk management decisions are proposed, including affirming the approval or registration, varying product labels, or suspending or cancelling products.
7. Consultation—a period of public consultation takes place.
8. Regulatory decision—the APVMA makes the final decision on the future use of the chemical.
9. Implementation—changes are made to product labels, or products are phased out.

Select and take action on registered chemicals when concerns are identified and validated by the APVMA

PERFORMANCE MEASURES	PROGRESS
Met the target of less than 1% of AERP reports requiring significant regulatory action	Achieved
Achieved 99% compliance with MRLs for agvet chemicals in food commodities (as reported in the random monitoring programs of the National Residue Survey)	Achieved
Completed at least six chemical review decisions	Achieved

We validate our regulatory efforts and identify issues through a range of sources, such as the AERP, levels of compliance with the National Residue Survey on MRLs, and the Chemical Review Program.

Adverse Experience Reporting Program

The AERP collects, assesses and reports annual data received about adverse experiences associated with the use of registered agvet chemical products. Reports are published on the APVMA website to give stakeholders and the general public access to the information.

The APVMA is currently exploring how adverse experience data could be published as assessments are completed.

In 2014–15, the APVMA received 5116 adverse experience reports: 3450 related to animal health, 405 related to product efficacy, 85 related to human health, 16 related to the environment and none related to crop health. No regulatory action was taken by the APVMA in relation to adverse experience reports. Reports continue to provide valuable information to support decision making in relation to registration, chemical review, compliance and manufacturer licensing.

Compliance with maximum residue limits

The APVMA sets MRLs for agvet chemicals in agricultural produce, particularly produce entering the food chain. MRLs are set at levels that are not likely to be exceeded if the agvet chemicals are used in accordance with approved label instructions. At the time the MRLs are set, the APVMA undertakes a dietary exposure evaluation to ensure that the levels do not pose an undue hazard to human health. The National Residue Survey conducts comprehensive testing for all Australian crops every year.

In 2014–15, the target of 99 per cent compliance with MRLs in food commodities for pesticides and veterinary medicines was achieved (99.37 per cent). This means that 99 per cent of the food commodities tested did not exceed the MRL and that instructions for use of chemical products, set by the APVMA, are working as intended—that is, to protect human health.

We evaluated pesticide residue data for 80 applications for product registration and 95 applications for permits. Including variations resulting from chemical review activity, we made 845 variations to the APVMA MRL standard. We also made 8 amendments to the Australia New Zealand Food Standards Code, resulting in 323 MRL variations, 214 of which were associated with uses approved under permit.

We also continued to implement harmonisation initiatives with other Australian Government and international agencies. The Japanese Positive List is a project initiated in 2006–07 by the Australian Government Department of Agriculture, with support from relevant industry organisations. The project has provided information to the Japanese Ministry of Health, Labour and Welfare to support the establishment of MRLs in Japan, based on Australian use patterns and registrations. In 2014–15, we provided information to Japanese authorities regarding MRLs for 21 pesticides and veterinary medicines.

Chemical review regulatory action

The possible regulatory decisions at the completion of a review are:

- no changes (affirm)
- changes to approval or registration (vary)
- no further approval or registration (cancel).

Any or all of these actions are possible for any one review.

The APVMA undertook 284 regulatory actions for chemical reviews in 2014–15 (Table 5).

TABLE 5: REGULATORY ACTIONS FOLLOWING CHEMICAL REVIEW, 2014–15

	Actives			Products			Labels			
Chemical	Affirm	Vary	Cancel	Affirm	Vary	Cancel	Affirm	Vary	Cancel	Total
2,4-D			3							
Azinphos-methyl	1							2		
Dichlorvos						3		3		
Fenthion			1			8			13	
Haloxyfop									10	
Profenofos								4	1	
Sheep ectoparasiticides							2	92	141	
Total	1		4			11	2	101	165	284

At any time, either within or outside the review process, the APVMA can suspend approvals or registrations for a specified period. At the same time, instructions for use (where appropriate) are issued when there is an immediate concern that can be managed in the short term. Suspensions can also be put in place to allow for relevant trial work to generate results needed for consideration or to provide additional information within specific timeframes.

There were 71 regulatory decisions made in 2014–15 (Table 6).

TABLE 6: SUSPENSIONS FOLLOWING CHEMICAL REVIEW, 2014–15

	Actives			Products			Labels			
Chemical	Suspend	Revoke suspension	Continue suspension	Suspend	Revoke suspension	Continue suspension	Suspend	Revoke suspension	Continue suspension	Total
Dimethoate					1	13			24	
Quintozene			1			10			22	
Total			1		1	23			46	71

Chemical review outcomes

2,4-D	In January 2015, the APVMA cancelled three 2,4-D active constituent approvals because of failure to provide information about the levels of dioxins. The formal review of 2,4-D is continuing.
Azinphos-methyl	In March 2015, the APVMA concluded the review of azinphos-methyl and published the *Azinphos-methyl* review regulatory decisions report. The key outcome of the review is that registered products containing azinphos-methyl can continue to be supplied and used in Australia. In finalising the review, the APVMA added new label instructions to address worker safety and environmental risks. We then affirmed one active constituent approval and two product registrations.
Dichlorvos	In January 2015, the APVMA took action to remove the grain protection use of dichlorvos from suspended product labels because our concerns regarding the potential risk to workers (which led to the initial suspension of grain protection uses in March 2013) had not been addressed. Three product registrations were cancelled, and a further three products received label variations that enabled continued registration for these products with reduced uses. The grain protection use was permitted for a short phase-out period to 2 March 2015, to coincide with the end of the 2014–15 grain harvest season.
Dimethoate	In October 2014, the APVMA continued the suspension of 13 products to manage dietary risks. In March 2015, we revoked the suspension of one dimethoate product to enable the approval of a new label that is consistent with the dimethoate suspension instructions.
Fenthion	In October 2015, the APVMA finalised the review of fenthion and published the *Final review findings and regulatory decision for the reconsideration of fenthion*. Assessment of available data concluded that the use of products containing fenthion may, in most situations, pose undue risks to human health (via dietary and occupational exposure) and the environment. On this basis, the APVMA cancelled 6 products and their 10 labels. Following the finalisation of the fenthion review, the active constituent was cancelled at the request of the holder on 3 November 2014. Consequently, the registrations of all remaining products were also cancelled.
Haloxyfop	In October 2014, the APVMA cancelled 10 labels for 9 registered products, because the previously approved labels no longer met the labelling criteria. The APVMA issued new instructions for use to 48 registered products to enable the continued registration of these products.
Quintozene	The suspension of a single quintozene active constituent approval and 10 quintozene-containing product registrations was extended from 14 February 2015 until 13 November 2015 because of the potential presence of undeclared dioxin impurities.
Profenofos	In August 2014, the APVMA cancelled one and varied four product labels to ensure that, if profenofos products were to be resupplied in Australia, they would contain adequate instructions to protect workers.

Sheep ectoparasiticides	The APVMA implemented the findings of the review of 13 selected sheep ectoparasiticides (94 registered products), which was finalised in June 2014. We concluded that the risks associated with chemical residues on treated wool could be managed by making changes to product labels; we affirmed 2 product labels, cancelled 141 product labels and varied 92 product labels.

Voluntary cancellations

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* allows a holder to voluntarily cancel an approval or registration by way of a written notice to the APVMA. If the APVMA is satisfied that there are no valid reasons why it should not agree to the request, it must cancel the approval or registration and provide written notice of its decision.

In 2014–15, the APVMA cancelled 6 active constituent approvals, 13 product registrations and 39 product label approvals at the request of the holder.

Ongoing reviews

Eighteen chemicals remain under review:

- 2,4-D low-volatile esters
- chlorpyrifos
- diazinon
- dimethoate
- diquat
- fenamiphos
- fenitrothion
- fipronil
- macrolide antibiotics
- maldison (malathion)
- methidathion
- methiocarb
- molinate
- neomycin
- omethoate
- paraquat
- polihexanide
- procymidone.

Engage effectively with the states and territories on the management of the National Registration Scheme, including increasing the involvement of the states and territories in chemical review processes

PERFORMANCE MEASURES	PROGRESS
Held two Registration Liaison Committee meetings by June 2015	Not achieved
Provided updates on suspension and reconsideration activities to the Agvet Chemical Regulation Committee twice a year	Achieved
Completed review into state and territory involvement in chemical reviews by January 2015	Achieved

Committees

The Registration Liaison Committee did not formally meet in 2014–15 as a result of a focus on more timely and appropriate operational engagement with our state and territory regulatory counterparts.

Anticipated APVMA chemical review and prioritisation activities were reported through the Agvet Chemical Task Group (formerly the Agvet Chemical Regulation Committee) to the Agriculture Senior Officials Committee, and are part of a public consultation process.

State and territory involvement

In 2014–15, state and territory engagement continued for operational and strategic matters. In particular, we engage with:

- the network of state and territory coordinators in relation to enforceability of label statements, residues management and permits for use of agvet chemical products
- compliance managers in relevant state and territory departments, as part of our compliance and enforcement activities.

State and territory departments participate in APVMA activities associated with chemical review decisions and reconsideration of chemicals in the market, and were consulted in the reprioritisation process for future reviews. State and territory representatives attended the APVMA Advisory Board Futures Forum in November 2014, which discussed the strategic direction for regulation of agvet chemicals.

In 2014–15, a review into state and territory involvement in chemical reviews identified opportunities for more targeted participation in the prioritisation, planning and implementation phases. The review also identified the importance of clearer communication around timelines and recommended that a consultative forum be established to discuss chemical review matters. To this end, the following initiatives were implemented:

- The APVMA convened a two-day workshop with the states and territories in November 2014 to review the current list of chemicals nominated for review. This workshop was a major engagement opportunity on the Chemical Review Program, and is the forerunner to an annual chemical review workshop with the states and territories.
- The APVMA prepared work plans for all current reviews that set out clear timelines for what will happen. These work plans will be published on our website from 1 July 2015.
- Ongoing updates on proposed suspension or cancellation activities have been provided to the states and territories through the Agvet Chemical Task Group.

Inform and engage with stakeholders about regulatory activity on registered chemicals

PERFORMANCE MEASURES	PROGRESS
Participated in, or delivered, review-related stakeholder forums	Achieved

We were active in a range of review-related forums in 2014–15, including:

- two formal submissions to, and attendance at, the inquiry by the Senate Rural and Regional Affairs and Transport References Committee into the implications of the use of fenthion on Australia's horticultural industry (July 2014)
- conduct of a two-day workshop in Canberra with the Australian Government Department of Agriculture, the Australian Government Department of the Environment, the Office of Chemical Safety, Food Standards Australia New Zealand, and the states and territories to review the Priority Candidate Review List (November 2014)
- attendance of the Director of the Chemical Review Program at the Pesticide Working Group in Townsville (November 2014)
- presentation by the Executive Director of Scientific Assessment and Chemical Review at an industry forum in Canberra on the Chemical Review Program (April 2015)
- presentation by the Director of the Chemical Review Program at the Sydney industry and education information session on improvements to the program, including more targeted prioritisation and earlier stakeholder engagement (June 2015).

STRATEGY 4—IDENTIFY AND RESOLVE NONCOMPLIANCE

Noncompliance with the Agvet Code Act may relate to unregistered products, supply of restricted chemical products to unauthorised users, unapproved labels, unfounded claims in advertising or other media, or active constituents that do not conform to APVMA standards. We actively monitor advertising, retail and online supplies to assess compliance, and encourage industry and the public to report potential noncompliance. APVMA compliance assessments aim to determine the likelihood that a breach of the legislation has occurred, and to assess its seriousness and likely consequences. The APVMA acts to prevent noncompliance, where possible, and to encourage ongoing and future compliance.

Develop a 2015–17 Compliance and Enforcement Strategy

PERFORMANCE MEASURES	PROGRESS
Developed strategy by June 2015	In progress
Implemented communications strategy to support the Compliance and Enforcement Strategy by 30 June 2015	In progress

This year, the APVMA began developing a new Compliance and Enforcement Strategy. The strategy outlines our objectives and approach to compliance and enforcement through to 30 June 2017. Following a period of industry consultation, we will publish the final strategy by the end of 2015.

Annual compliance plans will set out the yearly focus areas for education and compliance activity, supported by communication.

Manage our systems, practices and procedures to support a proactive, risk-based compliance and enforcement regime

PERFORMANCE MEASURES	PROGRESS
Processed 90% of consents to import within 14 days of receipt	Not achieved
Reviewed approved analysts and laboratories by December 2014	Achieved
Established procurement processes for analytical testing services by 30 June 2015	Achieved
Reviewed standard conditions of approval for all authorisations by 30 June 2015	Achieved
Conducted at least two 'intelligence-led' operations	Achieved

Consents to import

The APVMA issues consent to import unregistered or unapproved chemicals for specific reasons, including conduct of research or chemical trials, or for veterinary prescribing purposes. In 2014–15, 683 applications for consent to import were received by the APVMA, and 619 consents were issued. Of these, 414 were to allow small-scale trials or research, 62 were issued with specific permit applications, 131 were issued to veterinarians, 12 pre-registration permits issued, and 74 were either not approved or found to be unnecessary. This year, 79 per cent of consent-to-import applications were processed within 14 days of receipt, and 92 per cent were processed within 31 days.

Analysts and laboratories

The review of APVMA-approved analysts and laboratories was undertaken to ensure that the approved list was contemporary and up to date. Information was sent out to analysts on the APVMA's list of approved analysts asking them to indicate whether they wished to remain on the list.

In April 2015, we implemented a new process to allow submission of expressions of interest against set criteria for the approval of analysts.

The criteria for appointment were posted to the APVMA website to allow analysts to consider their situation before submitting an expression of interest to gain APVMA approval. Two analysts were added to the list of approved analysts as a result of this new process.

Conditions of approval

The approval of an active constituent, label or permit, a manufacturing licence, an agvet product registration or an import consent can be subject to conditions set out in the Agvet Code Regulations or imposed by the APVMA.

In 2014–15, we reviewed the conditions of approval for a range of approval types to identify areas for improvement. This included looking at where we can provide better guidance for APVMA staff when drafting legally enforceable conditions that also improve accessibility and understanding for holders and chemical users. The intention is to achieve greater overall compliance by setting conditions that can be enforced and are easily understood.

Intelligence-led operations

APVMA compliance and enforcement investigations increasingly used operational intelligence to guide compliance activities. Operational intelligence reports are routinely prepared to support education and awareness, and investigative activities. These assessments may consider the geographical distribution of chemical products and the turnover, volume of sales or import histories for chemicals.

Intelligence analysis from a variety of sources was used to support decisions and compliance activities for compliance cases and activities throughout the year. One assessment considered the business operations of a small manufacturer and supplier that restructured its company following regulatory action in 2014. The assessment recommended the approach to future investigative actions.

Undertake effective risk-based enforcement

PERFORMANCE MEASURES	PROGRESS
Assessed and prioritised 100% of allegations of noncompliance risk within five days	Achieved
Investigated 100% of identified high-priority allegations in accordance with APVMA compliance and enforcement policy	Achieved
Implemented new enforcement powers flowing from reform legislation	Achieved
Undertook six significant regulatory actions due to noncompliance with registration requirements	Achieved

When allegations of noncompliance are received, they are assessed and prioritised according to the associated risks. In 2014–15, the APVMA received 255 allegations of noncompliance (Table 7). As of 30 June 2015, the APVMA had 78 cases under consideration.

TABLE 7: ALLEGATIONS BY RISK CATEGORY, 2014–15

Risk category	Allegations	Open allegations
High	14	7
Medium	35	23
Low	43	17
Very low	163	31
Total	255	78

Compliance action on the investigated high-risk cases included a variety of responses, depending on the circumstances of the case. For example, the APVMA undertook a successful criminal prosecution of a company for supplying potentially dangerous veterinary products. We also provided guidance for individuals who had inadvertently contravened the law but were willing to return to a satisfactory level of compliance (see Case study 4).

Around 50 per cent of allegations relate to cross-border, national and international supply of chemical products. Of the remaining allegations, New South Wales and Victoria have a higher number of allegations, followed by Queensland and Western Australia (Table 8).

TABLE 8: GEOGRAPHICAL LOCATION OF ALLEGATIONS, 2014–15

Region	Allegations	Open allegations
All states	121	32
New South Wales	39	8
Northern Territory	1	0
Queensland	22	10
South Australia	2	1
Victoria	35	9
Western Australia	20	10
International	15	8
Total	255	78

Regulatory actions

The APVMA undertook enforcement action against companies in relation to a number of high-risk cases. A Perth-based company, Holistic Animal Medicines Pty Ltd, a manufacturer and supplier of homeopathic animal remedies, was prosecuted and convicted in the Perth Magistrates Court of five offences under the *Agricultural and Veterinary Chemicals Code (Western Australia) Act 1995* and fined $17 000. The offences related to the possession of unregistered veterinary chemical products with intent to supply, supply of unregistered veterinary products and advertisement of unregistered products.

This year we ran a pilot project to monitor compliance of product labelling with the APVMA-approved instructions for use and 'relevant particulars'. The label compliance audit focused on registered agricultural chemical products containing carbendazim, diuron or dichlorvos. Our audit examined 108 products marketed by 63 companies.

We found a good rate of compliance, although 60 per cent of the labels that we examined had minor issues with wording. We assisted those companies to correct the labels and return to compliance with the labelling requirements. Recall notices were issued for two products that did not contain any of the required changes to their labels, with the stocks required to be recalled and relabelled. This program of label auditing was very effective, and the APVMA will continue routine monitoring of marketed product labels next year.

New powers

The legislative reform gave us significant new tools for gathering information, monitoring compliance and enforcing agvet laws, including:

- notices to produce or attend
- substantiation notices
- monitoring warrants
- formal warnings
- infringement notices
- enforceable undertakings
- enforceable directions.

In 2014–15, APVMA inspectors used a range of these new powers, including monitoring and investigative warrants, infringements and statutory notices.

During the year, the first monitoring warrant was used to check on the compliance of a New South Wales–based company. Compliance inspectors conducted other site inspections with the consent of the occupiers, which meant that a monitoring warrant from a magistrate was not required.

The first investigative warrant was obtained and executed in Victoria to obtain evidence relating to alleged contraventions of the Agvet Code. The evidence obtained under the investigative warrant supported the issuing of the first infringement notices under the Agvet Code.

CASE STUDY 4

Awareness campaigns

As well as enforcement action, our compliance activities included education of the agvet chemical industry and users to build awareness.

In 2014–15, we ran awareness-raising campaigns for pool and spa chemicals, and dairy sanitisers.

Pool and spa chemicals

- The swimming pool campaign was run proactively. It included attending a pool and spa industry trade show to gain a better understanding of the sector, as well as providing information about the agvet legislation.
- We sent out fact sheets and guidance materials to around 435 pool and spa stores nationally. The message was further distributed in industry association communication products.
- In March 2015, we inspected a number of retail premises in Queensland and Western Australia. The retailers inspected showed a high level of compliance. We are continuing to work with a small number of retailers and suppliers on minor labelling issues.

Dairy sanitisers

- In late 2014, the APVMA became aware of concern in the industry about the possible substitution of active constituents in some sanitiser products.
- Our awareness-raising activities focused on holders of dairy sanitiser products. We wrote to holders to remind them of the importance of keeping their registration and label particulars accurate and up to date, and followed up on minor issues to assist them to return to voluntary compliance.
- We also investigated complaints received about dairy sanitisers.
- As a result of one investigation, the APVMA issued two infringement notices for the supply of a product with constituents that varied. We have continued to monitor the marketplace and take action as required.

Undertake effective inspection, auditing and enforcement activities for good manufacturing practice (GMP) and the Manufacturers' Licensing Scheme

PERFORMANCE MEASURES	PROGRESS
Developed new IT systems to better support GMP work practices	Postponed
Conducted GMP audit program to schedule	Achieved
Trialled in-house capacity to support domestic GMP audits	In progress
Implemented more transparent risk-based audit schedule	In progress
Developed guidelines for the release of toll manufactured and imported products	In progress
Undertook necessary actions for the APVMA to be recognised by the European Union to audit export manufacturers	In progress
Reviewed mutual recognition with national and international agencies to build confidence in collaborative arrangements	In progress

IT system

Development of a new IT system for GMP has been rescheduled to 2015–16. Major processes have already been mapped out, and process analysis is now under way.

GMP audits

The APVMA established the Manufacturers' Licensing Scheme in 1994 to assure, and build confidence in, the quality of veterinary medicines manufactured and supplied in Australia. To obtain and maintain a licence under the scheme, manufacturers must demonstrate adherence with the manufacturing standards set out by the APVMA, including the Manufacturing Principles and the *Australian code of good manufacturing practice for veterinary chemical products*.

In 2014–15, APVMA-authorised auditors conducted 71 audits of licensed Australian veterinary manufacturers, the Therapeutic Goods Administration (TGA) conducted 33 inspections, and the National Association of Testing Authorities (NATA) conducted 3 inspections on behalf of the APVMA. In testing our in-house capacity to support domestic GMP audits, one joint audit occurred with an APVMA-authorised auditor. The APVMA also attended a TGA inspection of a veterinary manufacturer as an observer.

The total number of audits conducted (107) is comparable to last year (103) and meets the annual target of 100–110 audits. Registrants of veterinary medicine products manufactured overseas must provide assurance that their products comply with manufacturing standards that are comparable to the APVMA requirements applying to Australian-based manufacturers. We recognise certificates of GMP compliance from a number of overseas authorities that are considered to have manufacturing standards and enforcement processes equivalent to those in Australia. In other cases, overseas manufacturing sites are audited by APVMA-authorised auditors.

APVMA-authorised auditors conducted 32 audits of foreign manufacturers who manufacture veterinary medicines for the Australian marketplace. We reviewed all audit reports, monitored progress with corrective actions, and finalised 174 audits after corrective actions were deemed satisfactory.

Evidence of GMP compliance was assessed as part of the product registration process for 349 manufacturing sites.

To facilitate export of Australian-manufactured veterinary medicines, 99 export certificates were issued with the GMP compliance statement, and 7 certificates were issued by the APVMA under the mutual recognition agreement between Australia and the European community.

As at 30 June 2015, 191 veterinary manufacturers were licensed by the APVMA or had applications pending, which is comparable to recent years (Table 9).

TABLE 9: VETERINARY MANUFACTURERS LICENSED OR BEING ASSESSED FOR A LICENCE, BY CATEGORY, AS AT 30 JUNE 2015

Category	Number of manufacturers
Category 1: Sterile and immunobiological products	37
Category 2: Nonsterile medicines other than categories 3 and 4	57
Category 3: Ectoparasiticides	5
Category 4: Feed supplements and premixes	19
Category 6: Single-step manufacturers (including packaging and labelling, analysis and testing)	73
Total	191

Note: Category 5 was reserved at the commencement of the scheme and is not currently used.

In 2014–15, we issued 37 notices of intent to suspend or cancel licences, refuse applications or impose conditions for manufacturers. Many of these notices were issued for overdue fees.

The proposal for implementation of the risk-based audit schedule has been further revised in line with the Regulator Performance Framework. Public consultation is expected to occur in early 2015–16.

Guidelines

Guidelines are being developed to assist industry with the release-for-supply process, where products are manufactured (in part or whole) by one manufacturer and then released for supply by another. Internal consideration and endorsement are in progress before further public consultation.

Other agencies

We are currently liaising with government departments to investigate recognition of the APVMA by the European Union to audit export manufacturers. Under the mutual recognition agreement, the TGA is currently recognised as the authorised inspection body, while the APVMA is the authorised certification body. Collaboration with the TGA is ongoing.

We are also reviewing mutual recognition agreements with national and international agencies. The national agencies are the TGA and NATA, and the international agency is from New Zealand.

Improve compliance and enforcement governance

PERFORMANCE MEASURES	PROGRESS
Held at least 10 Enforcement Committee meetings annually to integrate compliance and enforcement into APVMA business processes	Achieved
Undertook six significant regulatory actions due to noncompliance with registration requirements	Achieved

Enforcement Committee

The APVMA's Enforcement Committee oversees compliance and enforcement activities to ensure that they are consistent and accountable. The Enforcement Committee provides strategic oversight of cases and compliance trends to ensure a coordinated approach to compliance and enforcement activities in the agency, effective commitment of resources, and conduct of investigations is in accordance with the Australian Government Investigations Standards.

In 2014–15, the committee met 10 times and considered 38 matters.

After-action reviews

Enforcement action can encompass taking no further action, voluntary compliance action, administrative resolution, use of new compliance tools and criminal prosecution.

Regular verbal debriefs occur following use of an enforcement power. In December 2014, APVMA staff involved in the prosecution of Holistic Animal Medicines Pty Ltd (see above) undertook a formal case debriefing following the conclusion of legal proceedings. The lessons learned from the case were identified, and areas of improvement were noted for ongoing development of APVMA skills and processes. Improvements that could be made included reviewing exhibit and witness management, and appropriate resourcing of investigations at the outset of the operation.

STRATEGY 5—IDENTIFY AND MANAGE EMERGING REGULATORY ISSUES

The APVMA engages with other government agencies and its international counterparts to identify emerging issues, and to ensure that we develop appropriate policies and processes to manage them.

Assess and manage significant emerging regulatory issues

PERFORMANCE MEASURES	PROGRESS
Developed effective relationships with national and international regulatory counterparts, and established relevant agreements with national and international counterparts	Achieved
Participated in the Regulatory Science Network to promote consistent approaches to the management of emerging issues	Achieved
Effectively managed strategic issues, and coordinated input to ministerials, briefs and other government processes that represented a whole-of-APVMA position	Achieved

National and international relationships

The APVMA has active working relationships with many international regulators, including the Canadian Pest Management Regulatory Agency, the New Zealand Ministry for Primary Industries, the United Kingdom Veterinary Medicines Directorate, and the United States Food and Drug Administration. The APVMA also has seven current memorandums of understanding with regulators in other countries, which define our approach to sharing information and enable us to develop opportunities for further formal relationships with overseas counterparts. The APVMA also works with the Regulatory Science Network (RSN; see Case study 5).

The APVMA received a number of international visits this year, including the following:

- a Regulation and Assurance Principal Adviser from the New Zealand Ministry for Primary Industries visited the APVMA to provide insight on how the New Zealand regulatory system works (7 November 2014).
- an Indian delegation from various departments of the Indian Government visited the APVMA to learn about regulatory operations (3 December 2014).
- members of the National Academy of Agricultural Science, Rural Development Administration, in the Republic of Korea visited the APVMA to discuss good laboratory practice data requirements for residues trials and MRL setting (4 December 2014).
- a trainee from the Agricultural Chemicals Inspection Service in Japan's Ministry of Agriculture, Forestry and Fisheries spent eight weeks at the APVMA to learn about residues and dietary exposure risk assessments.

Input into other government processes

The APVMA has introduced a new procedure for handling ministerials, briefs and other government processes. These are now handled by a centralised unit, which coordinates and tracks any input. This process ensures that all outgoing correspondence, briefs and other documents present a whole-of-APVMA position to the minister, industry and other stakeholders.

Members of the National Academy of Science, Rural Development Administration, Republic of Korea, visited staff from the APVMA and the National Residue Survey. Left to right: Jason Lutze, Sun Young Lee, Geun-Hwan Gil, Raj Bhula, Karina Budd, Kyeong-Ae Son, Chris Williams

Working with CSIRO on interference RNA and nanopesticides

RNA interference (RNAi) is a biological process in which small RNA molecules inhibit gene expression, typically by causing the destruction of specific messenger RNA (mRNA) molecules. Scientific papers reporting on elements of this biological mechanism started appearing in the literature in 1990.

In cooperation with researchers at the Commonwealth Scientific and Industrial Research Organisation (CSIRO), the APVMA has started to consider the issues that may need to be taken into account in considering applications for pesticides and veterinary medicines based on RNAi, by contributing to a range of activities, including:

- a CSIRO workshop on 'RNAi: impediments to genetically based pest management control options', which was held in Canberra on 29–30 July 2014
- a seminar presented by CSIRO at the APVMA on 'RNA interference—an emerging technology for controlling pests and diseases in animals and plants' on 15 May 2015; this was followed by a discussion about regulatory issues that might need to be considered in the development of new agvet chemical products based on RNAi
- helping with the development of the program for a CSIRO workshop on 'Nanopesticides: technologies for improved delivery of pesticides and RNAi', which was held in Canberra on 15–16 June 2015; the APVMA's Chief Scientist and Principal Scientist, Pesticides, gave presentations on regulatory issues to be considered in the use of nanotechnology in agvet chemical formulations and delivery mechanisms, and on the regulation of pesticides using RNAi to control pests in plants.

CASE STUDY 5

The Regulatory Science Network

Including the APVMA, nine government agencies and departments are responsible for the regulation of chemicals and biological agents in Australia. The RSN was established in 2011 to help forge closer ties between these bodies. The RSN provides a forum for scientists and technical staff to discuss regulatory scientific issues and improve interagency cooperation.

On 28 November 2014, the APVMA contributed to an RSN symposium on 'Doing more with less: how science can contribute to smart regulation'. Representatives from Australian Government regulatory agencies shared information about improvements they had made in their technical work.

This follows a key theme of RSN knowledge sharing: risk analysis. Risk analysis is the cornerstone for regulatory decisions; however, agencies take diverse approaches to risk analysis, which are mainly attributable to differences in the legislative frameworks and regulatory contexts in which the agencies operate. Communicating these differences has enabled regulatory scientists to better understand risk analysis principles.

Dr Chris Schyvens, APVMA

The APVMA presentation covered the following areas: a project looking to better align regulatory risk with product risk; participation in global joint reviews of pesticides; memorandums of understanding with equivalent regulatory agencies overseas; internationally harmonised regulatory requirements and guidance being developed through VICH and the World Association for the Advancement of Veterinary Parasitology; establishment of the APVMA Office of the Chief Scientist, and the use of science to support pragmatic and fact-based regulation; refinement of spray drift policy; and increased international harmonisation.

The APVMA shared the lessons learned from the operation of the RSN as a possible model for similar international agency liaison on regulatory science issues through a poster presented at the 13th Congress of Pesticide Chemistry of the International Union of Pure and Applied Chemistry in San Francisco on 14 August 2014.

Mr David Rumbold, APVMA

Contribute to high-level forums relating to regulation of agricultural and veterinary chemicals

PERFORMANCE MEASURES	PROGRESS
Contributed to the Regulators' Forum, the Regulatory Science Network, the Agvet Chemical Regulation Committee and other relevant forums	Achieved

Liaison with national and international organisations and forums is important to informing APVMA processes and decisions.

The APVMA is an active member of the Regulators' Forum, which comprises the heads of the APVMA, the Australian Government Department of Agriculture, the Australian Radiation Protection and Nuclear Safety Agency, Food Standards Australia New Zealand, the National Industrial Chemicals Notification and Assessment Scheme, the Office of the Gene Technology Regulator and the TGA. The forum meets quarterly, with a focus on risk assessment, workforce planning, public awareness and confidence, and addressing cross-agency issues. The APMVA CEO is an observer on the Agvet Chemical Task Group (formerly the Agvet Chemical Regulation Committee).

Support Department of Agriculture initiatives on quality assurance of imported chemicals

PERFORMANCE MEASURES	PROGRESS
Completed stage 2 of the Agrochemical Intelligence Project by December 2014	Achieved

The APVMA Agrochemical Intelligence Project aimed to collect information to increase understanding of the supply of illegal agricultural chemicals to Australia, to enable the strategic allocation of compliance resources in the future.

The first phase of the project has been finalised, with the development of a price-based model for assessing chemical importations. The findings of the project were presented to the Australian Government Department of Agriculture in October and November 2014, and to APVMA staff in December 2014.

During the year, APVMA inspectors received intelligence about the potential import of an unregistered chemical product in Western Australia. Liaison with the Australian Customs and Border Protection Service (Customs; now the Australian Border Force) enabled verification of the contents of the shipping containers on the vessel, demonstrating the close working relationship between the APVMA and Customs. The APVMA also cooperated with Customs in Operation Pangea (see Case study 6).

To improve our field-based identification of chemical substances, the APVMA purchased a handheld Raman spectrometer during the year, with financial assistance from the Australian Government Department of Agriculture. Use of this portable device means that APVMA inspectors can conduct immediate tests that can identify more than 11 000 chemicals on the spot. This in-field analysis saves time and costly laboratory analysis, and helps the APVMA to take swifter regulatory action to protect the safety of people, animals, crops and the environment.

The Raman spectrometer also helps inspectors to manage their workplace safety when dealing with unknown chemicals. All inspectors are trained in how to use the device before they use it in the field.

CASE STUDY 6

Operation Pangea VIII

In June 2015, the APVMA participated in the Interpol-coordinated Operation Pangea VIII. Operation Pangea is an annual global week of action targeting trade and online sales of unregistered and counterfeit medicines, including veterinary medicines. This year, the APVMA joined staff from Customs (now the Australian Border Force) and the TGA in the operation. APVMA inspectors were deployed to Brisbane and Perth, where they helped to examine international mail items.

During the operation, 9 packages with 361 individual doses were identified as unregistered veterinary chemicals being imported into Australia. Compliance inspectors have engaged with the importers to gather more information and educate the importers of their obligations under the agvet chemical laws.

Our participation in Operation Pangea:

- improved our understanding of Customs processes at border control points
- provided us with new intelligence about the import of veterinary chemical products into Australia
- enabled us to update staff from Customs, the TGA, the Australian Government Department of Agriculture and Australia Post about our new compliance and enforcement powers following 2014 legislative amendments
- gained media exposure for the APVMA to promote the safety message to consumers about the risks of buying and using unregistered veterinary products.

The APVMA's new Raman spectrometer being used by a compliance inspector during a field inspection to identify a chemical product.

Lead work on implications of nanotechnology for the regulation of agricultural and veterinary chemicals

PERFORMANCE MEASURES	PROGRESS
Held interagency symposium by December 2014	Achieved
Reported on regulatory considerations for agvet nanotechnology by December 2014	In progress

Nanotechnology is an emerging technology for the formulation and delivery of active ingredients, and the development of new active ingredients (see Case study 7). The risks associated with this technology are being carefully evaluated by the APVMA and other regulatory agencies.

The APVMA has developed a report, *Regulatory considerations for nanopesticides and veterinary nanomedicines*, which is the first of its kind in the world. The report aims to inform and stimulate discussion about nanotechnology and highlights the key regulatory considerations for agvet chemical nanomaterials based on the current state of knowledge. It systematically explores the opportunities and risks of these substances in Australian agriculture and animal husbandry, and reviews the published work relevant to the registration of nanoscale agvet chemicals.

The general consensus is that, for the foreseeable future, existing regulatory frameworks will be used to regulate nanomaterials. Over time, however, the framework will evolve as new information becomes available.

Implement regulatory action that may be required to protect pollinator health from the use of agricultural chemicals

PERFORMANCE MEASURES	PROGRESS
Worked with partner agencies to update technical assessment manuals	Achieved
Developed additional label advice and applied it as necessary	Achieved

The APVMA has developed an Australian guidance document for conducting risk assessments for the effects of plant protection products on bees and other insect pollinators, for use by the APVMA, the Department of the Environment and external advisers. The document is based on North American guidelines (jointly developed by the United States Environmental Protection Agency, the Canadian Pest Management Regulatory Agency and the California Department of Pesticide Regulation) and European guidelines (developed by the European Food Safety Authority). The guidance document has been released for public comment on our website.

The pollinator guidance document includes guidance on the application of appropriate label statements and warnings relating to protecting insect pollinators. In considering registrations of new products that may present a risk to bees, in addition to using standard label statements to protect insect pollinators, the APVMA is adding label advice about bee safety on a case-by-case basis.

The APVMA's Principal Scientist, Pesticides, was an expert reviewer for a draft chapter on 'Thematic assessment of pollinators, pollination and food production' for the Intergovernmental Platform on Biodiversity and Ecosystem Services. The platform was established in April 2012 as an independent intergovernmental body that is open to all member countries of the United Nations.

CASE STUDY 7

Nanotechnology Regulation Symposium

The APVMA held a Nanotechnology Regulation Symposium in Canberra on 28 October 2014, which was attended by around 130 stakeholders from industry, academia, regulatory agencies and nongovernment organisations. Discussions at the symposium were guided by the draft report, and presentations by experts were followed by audience discussion. Deliberations on the day were captured and will be considered for inclusion in the final APVMA report on the regulatory considerations for nanopesticides and veterinary nanomedicines.

The MC, speakers and panellists at the APVMA Nanotechnology Regulation Symposium: (front row, left to right) Mr John Hughes, Dr Phil Reeves, Professor Terry Turney, Ms Kareena Arthy (APVMA CEO), Dr Norman Swan (MC); (back row, left to right) Dr Glen Walker, Dr Rai Kookana, Professor Mike Roberts, Dr Graeme Batley, Professor Brian Priestly and Dr Andrew Bartholomaeus

STRATEGY 6—ENGAGE STAKEHOLDERS AND REGULATORY PARTNERS TO ADD VALUE TO OUR WORK

Engagement with our stakeholders and regulatory partners is essential to meeting their needs and developing best-practice processes. Our communication efforts are designed to be two way—soliciting information from our stakeholders and partners, as well as disseminating information about our processes and decisions. In this way, we aim to build a regulatory partnership of mutual benefit.

Implement communications activities to support the strategic direction of the APVMA

PERFORMANCE MEASURES	PROGRESS
Published Chief Regulatory Scientist's *Our science* page on website	Achieved
Developed regulatory science news items of public interest for website publication	Achieved
Developed and implemented a refreshed visual identity	Achieved
Undertook a review of APVMA channels to ensure consistency in external-facing products, such as letters, notices, information and web content, and alignment with the Client Service Charter	Achieved

The APVMA developed an overarching communications strategy in 2014–15, which outlines key communications activities to support our corporate goals.

The strategy has been developed based on stakeholder views, expectations and needs, which have been drawn from submissions to various Senate committees, feedback at APVMA information and training sessions, and face-to-face engagement.

As a result of the collective feedback and information gathering, the following key themes have been identified as central to the expectations our stakeholders have of the APVMA. These themes will guide our communication efforts:

- predictable and timely decision making
- efficient systems and processes
- client service, relationships and engagement
- security and protection of information.

The CEO regularly engages with industry bodies, conducts industry forums, and facilitates events such as the APVMA Advisory Board's Futures Forum. In addition, the APVMA's senior leaders regularly attend corporate, industry and government forums (see Case study 8).

CASE STUDY 8

Reaching out through forums

In late 2014, the APVMA Advisory Board hosted a Futures Forum with the theme of 'Building a regulator for the future'. The forum created an opportunity to bring together all stakeholders to discuss and better understand the current environment in which the APVMA operates, identify the longer-term trends that may affect the future of the regulator and provide advice on what the APVMA should do over the next 3–5 years to position itself as a contemporary, world-class regulator. Attendees included representatives from the chemical and agricultural industries, consumer representatives, government and research organisations.

During the forum, national and international speakers presented on stakeholder perspectives, changing views and trends that will affect the environment in which the APVMA operates. This included farmers' perspectives, consumer attitudes to food, future directions of crop protection products, Australia's competitiveness and veterinary medicines. A case study on nanotechnology as a new and emerging technology was also presented.

Key themes that emerged were the importance of a balance between facilitating innovation and protecting consumers and the environment, placing the unique requirements of our Australian system in the global regulatory environment, a proportionate response to risk that is transparent and repeatable, and future directions in science and the resulting impact on agvet chemical regulation in Australia. These themes were explored, with participants considering the role of the APVMA in a range of possible future regulatory and social environments.

In all of the settings, the primary role of the regulator was seen as focusing on a reasonable level of safety to users, consumers and others exposed to agvet chemical products, and ensuring that there would be no unacceptable impact on the environment. Participants reflected a continued expectation that the regulator be technically competent, efficient, transparent and consistent, and that decisions reflect the real level of risk posed by a product. The key components identified for building a regulator of the future were regulatory and scientific excellence in decision making, strong international connections, community confidence, and dynamic and efficient business processes.

The outcomes from the forum fed into development of strategic priorities for 2015–16 and the framework for the APVMA Corporate Plan 2015–19. They also informed the Advisory Board in its role of providing advice to the CEO on strategic matters.

Website content

The APVMA released an *Our science* webpage in May 2015 to communicate regulatory science items that may be of public interest. The webpage provides an overview of the role of the APVMA's Office of the Chief Scientist, lists the APVMA's Science Fellows and specialist subject advisers, provides information about the RSN, defines 'regulatory science', provides the risk analysis framework that underpins our risk assessment methodology, and sets out the principles of good regulatory science practice.

Other news and information items posted on our website in 2014–15 included:

- the use of the 2012–13 United States Environment Protection Agency crop re-entry risk calculator
- explanatory information to help people understand the risk of the herbicide glyphosate, following an assessment by the International Agency for Research on Cancer and classification of the herbicide as 'probably carcinogenic to humans'; the information provides assurance that, based on the current risk assessment, the label instructions on all glyphosate products—when followed—provide adequate protection for users
- an information page developed specifically for farmers and people working in agricultural industries, which outlines the APVMA's role in making sure that what farmers buy from suppliers is safe and effective for crops and animals; the information focuses on raising awareness in key areas such as using chemicals according to label instructions, and the online database and iPhone app are useful resources for people in the field—this page has received positive feedback from users
- detailed information developed to address community concerns about the Hendra virus vaccine; the information addressed permit and product registration issues, safety, health, side effects, and adverse reactions and how to report them, and provided links to useful information developed by state and territory agencies.

Visual identity

As part of the commencement of the new legislation on 1 July 2014 and the development of new regulatory guidelines, a new APVMA website was built and launched, including an update of our visual appearance. All corporate and external products have been updated during 2014–15 to reflect a new and contemporary look and feel for the APVMA, which can be adapted for multiple purposes.

Correspondence review

An audit and review of our external operational products revealed around 380 items, including letters, emails and legal notices, that potentially require improvement. A project to redevelop these products will be rolled out in 2015–16. It will take a phased approach to improving high-volume items as a priority, as well as looking for opportunities to integrate with business and IT systems, where possible.

Conferences

APVMA staff are involved in a range of national and international conferences (Table 10), which are important in building networks, and collecting and disseminating information.

TABLE 10: CONFERENCES ATTENDED AND PRESENTATIONS GIVEN BY APVMA STAFF, 2014–15

Date	Event and location	APVMA representative	Presentation or attendance
4 July 2014	South Australian Ground Sprayers industry day, Adelaide	Mr David Rumbold, Spray Drift Project Manager	'Update from the national regulator' (presentation)
30 July 2014	CSIRO workshop, 'RNAi: impediments to genetically based pest management control options', Canberra	Dr Les Davies, Principal Scientist	'RNAi technology: regulatory perspectives' (presentation)
10–14 August 2014	13th IUPAC International Congress of Pesticide Chemistry, 'Global approaches to assessment of bystander and agricultural worker exposure and risk', San Francisco	Dr Les Davies, Principal Scientist	'Operator exposure challenges in Australia' (presentation)
		Dr Phil Reeves, Chief Scientist	'Regulation of nanopesticides' (presentation)
		Dr Phil Reeves, Chief Scientist, and Dr Les Davies, Principal Scientist	'Finding common ground: establishment of an Australian regulatory science network' (poster)
13–14 August 2014	Sunraysia Wine Grape Grower update, Swan Hill and Mildura	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)
15 August 2014	Australian Ground Sprayers Association annual meeting, Melbourne	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)
21 August 2014	Veterinary Manufacturers and Distributors Association annual general meeting, Sydney	Dr Allen Bryce, Executive Director, Registration Management and Evaluation; and Mr Bruce Johnson, Manager, Manufacturing and Licensing	'Update on APVMA reform and update of the MQL section and impact of reform' (presentation)
3–4 September 2014	AgVet Chemical Conference/Registered Trainers Workshop	Dr Jason Lutze, Director, Residues and Trade	'Off-label use approval, risk management techniques, buffer zone management' (presentation)
8–12 September 2014	United States IR-4 Project, Food Use Workshop and Bacterial Disease Mini-Summit, Atlanta	Mr Alan Norden, Executive Director, Registration Management and Evaluation	Attended
9 September 2014	Australian Wine Research Institute Webinar Series	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)
16–25 September 2014	Joint FAO/WHO Meeting on Pesticide Residues, FAO residues/toxicology panels, Rome	Dr Matt O'Mullane, Director, Chemical Review; and Mr Sam Margerison, Senior Evaluator, Pesticides Residues	Participation on the panels for pesticide toxicology and pesticide residues

Date	Event and location	APVMA representative	Presentation or attendance
19–20 September 2014	NSW Ground Sprayers Conference, Dubbo	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation) 'Legal framework within Australia' (presentation)
13 October 2014	Lectures to fifth-year Doctor of Veterinary Medicine students, University of Adelaide	Dr Phil Reeves, Chief Scientist	'Chemical residues in foods of animal origin' (presentation)
24 October 2014	Lecture to third-year undergraduate and masters students, Australian National University	Dr Les Davies, Principal Scientist	'The APVMA: its biosecurity role' (presentation)
5 November 2014	APVMA Advisory Board Futures Forum 2014	Dr Phil Reeves, Chief Scientist	'Case study: nanotechnology' (presentation)
19–20 November 2014	Priority Candidate Review List review, two-day workshop with Australian Government departments of Agriculture and the Environment, Office of Chemical Safety, Food Standards Australia New Zealand, and states and territories, APVMA, Canberra	APVMA staff	Workshop
24 November 2014	National Working Party on Pesticide Applications executive meeting, Canberra	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)
27 November 2014	Pesticide Working Group, Townsville	Dr Matt O'Mullane, Director, Chemical Review Program	Attended
28 November 2014	Regulatory Science Network annual meeting, Canberra	Dr Chris Schyvens, Health Assessment Coordinator; and Mr David Rumbold, Spray Drift Project Manager	'Doing more with less: how science can contribute to smart regulation' (presentation)
1–5 December 2014	OIE regional workshop for focal points for veterinary products, Tokyo	Ms Susan Hanns, Senior Risk Manager	Attended
8–12 December 2014	OECD Risk Reduction Steering Group meeting and seminar on nonprofessional uses, Registration Steering Group meeting, Paris	Mr Alan Norden, Executive Director, Registration Management and Evaluation	Attended

Date	Event and location	APVMA representative	Presentation or attendance
12–15 January 2015	'Spray drift: research, management and modelling in pesticide application' workshop, North Platte, Nebraska	Mr David Rumbold, Spray Drift Project Manager	'APVMA spray drift regulatory framework' (presentation) 'DRT schemes: linking research data and models—an Australian approach' (presentation)
12–13 February 2015	Joint meeting of APVMA and New Zealand Environmental Protection Authority, Canberra	Mr David Rumbold, Spray Drift Project Manager	'Spray drift management in Australia' (presentation)
23–26 February 2015	31st VICH Steering Committee meeting, Washington	Dr Phil Reeves, Chief Scientist	Attended
12 March 2015	Aerial Agricultural Association of Australia board meeting, Canberra	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)
30–31 March 2015	OECD Network on Illegal Trade of Pesticides, third meeting, Paris	Ms Kareena Arthy, APVMA CEO; and Ms Stef Janiec, Executive Director, Legal and Compliance	Attended via video link
13–18 April 2015	47th Session of Codex Committee on Pesticide Residues, China	Dr Raj Bhula, Executive Director, Scientific Assessment and Review	Attended
22 April 2015	Industry forum, Canberra	Dr Raj Bhula, Executive Director, Scientific Assessment and Review	'The APVMA's Chemical Review Program' (presentation) 'Use of international data, assessments, standards and decisions and the risk framework project' (presentation)
27 April – 1 May 2015	22nd Session of Codex Committee on Residues of Veterinary Drugs in Food, San José, Costa Rica	Dr Jason Lutze, Director, Residues and Trade	Attended
6 May 2015	CeBIT e-government conference, Sydney	Mr Tony de la Fosse, Executive Director, Corporate Services, and Chief Operating Officer	Attended
7 May 2015	Joint meeting on spray drift between APVMA and United Kingdom Chemical Regulation Directorate, York, United Kingdom	Mr David Rumbold, Spray Drift Project Manager	'Legal framework within Australia' (presentation)

Date	Event and location	APVMA representative	Presentation or attendance
12 May 2015	Joint meeting on spray drift between APVMA, the Julius Kühn-Institute, and the German Federal Office of Consumer Protection and Food Safety, Braunschweig, Germany	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)
18–22 May 2015	OECD Working Group on Pesticides, 30th meeting, and Biopesticides Steering Group meeting and seminar, Paris	Ms Kareena Arthy, APVMA CEO	Attended
21 May 2015	National Working Party on Pesticide Applications annual meeting, Canberra	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)
22 May 2015	OECD Electronic Exchange of Pesticide Data, Paris	Ms Connie Warburton, Acting Director, Application Development	Presented via video link
28 May 2015	AusChem training webconference	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)
1 June 2015	Industry information and education session, Sydney	Dr Phil Reeves, Chief Scientist; and Dr Les Davies, Principal Scientist	'Regulatory science at the APVMA' (presentation)
15–16 June 2015	CSIRO workshop, 'Nanopesticides: technologies for improved delivery of pesticides and RNAi', Canberra	Dr Les Davies, Principal Scientist	'Regulatory considerations for RNAi technology in plant protection applications' (presentation)
		Dr Phil Reeves, Chief Scientist	'Regulatory considerations for nanopesticides' (presentation)
16–17 June 2015	National Working Party on Grain Protection workshop, Melbourne	Dr Raj Bhula, Executive Director, Scientific Assessment and Review	'APVMA update: Codex MRLs and JMPR—how does it all work' (presentation)
		Dr Jason Lutze, Director, Residues and Trade	'Australian MRLs: how are they established?' (presentation)
24 June 2015	NSW SMARTtrain Masterclass webconference	Mr David Rumbold, Spray Drift Project Manager	'Spray drift project update' (presentation)

Codex = Codex Alimentarius Commission; CSIRO = Commonwealth Scientific and Industrial Research Organisation; FAO = Food and Agriculture Organization of the United Nations; IUPAC = International Union of Pure and Applied Chemistry; OECD = Organisation for Economic Co-operation and Development; OIE = World Organisation for Animal Health; VICH = International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; WHO = World Health Organization

Develop a new Client Service Charter

PERFORMANCE MEASURES	PROGRESS
Developed a new Client Service Charter that provides guidance to staff and stakeholders on the experience to be expected from engagement with the APVMA by December 2014	Achieved

In early 2015, we revised our Client Service Charter to set out expectations and standards for APVMA response times. We have implemented a new online system that allows individuals to submit complaints, compliments, comments and suggestions, and the time taken to respond to these is actively monitored by senior management. Reporting of these and other metrics will be integrated into our new Regulator Performance Framework. The APVMA is also implementing a ticketed enquiry system so that we can track enquiry response times against charter standards. A series of internal training events have been held to raise awareness among APVMA staff of the importance of client service.

We have also made it easier for stakeholders to provide feedback—an online feedback mechanism was set up to enable users to report problems, suggest improvements, lodge complaints and provide feedback from the APVMA website.

Redevelop the APVMA website

PERFORMANCE MEASURES	PROGRESS
Launched the new website on 1 July 2014	Achieved
Launched the new website on 1 July 2014	Achieved

See also Strategy 1.

The APVMA has worked to redevelop our website to meet stakeholder needs and present APVMA information as clearly as possible.

The new APVMA website was launched on 1 July 2014. More than 3 million words of new or migrated content were published into a new structure, which was built to conform with government online and accessibility standards. The APVMA website now runs a sophisticated web content management system that allows continuous improvement of the website, including usability enhancements such as 'content last reviewed' dates and assignment of responsibility for the completion of content review.

The final report on the Web Accessibility National Transition Strategy was submitted to the Australian Government Department of Finance in January 2015. The new APVMA website substantially conforms with accessibility standards. Some legacy PDFs migrated from the old website will be retired or updated over time. A formal assessment of accessibility and usability will be undertaken in 2015–16.

Seek input on strategic issues from the APVMA's Advisory Board

PERFORMANCE MEASURES	PROGRESS
Held four Advisory Board meetings by June 2015	Achieved

APVMA Advisory Board meetings were held on 25 August and 5 November 2014, and 11 February and 23 April 2015 (see Appendix A). The board provided advice to the CEO regarding the APVMA's:

- progress with implementing the legislative reforms and business re-engineering
- new 2015–19 corporate plan
- Regulator Performance Framework
- development of a risk-based decision assessment framework
- policy on use of international data, standards, decisions and assessments
- consultation on the revised Priority Candidate Review List
- new Client Service Charter
- communication activities, particularly with the agricultural sector, and in relation to clarifying the roles and responsibilities of the APVMA.

Implement new industry consultative committee arrangements, including the use of special-purpose working groups

PERFORMANCE MEASURES	PROGRESS
Undertook at least two industry forums	Achieved
Ensured that stakeholders are satisfied with consultative arrangements	In progress

See also Strategy 1.

The Advisory Board hosted a Futures Forum on 5 and 6 November 2014 with the theme of 'Building a regulator for the future', which discussed strategic direction for the regulation of agvet chemicals (see Case study 8). An industry forum focusing on the APVMA's priorities for 2015 was held for all key stakeholder groups on 22 April 2015.

The CEO attended a range of peak body meetings during the year. A program of targeted events and training is being developed to be held in various locations throughout Australia in 2015–16. Consultation on the Regulator Performance Framework and new corporate plan occurred in March and April 2015.

Work effectively with the Department of Agriculture on agvet chemical issues of mutual interest

PERFORMANCE MEASURES	PROGRESS
Ensured satisfaction with level and quality of engagement	Achieved

The APVMA works collaboratively with the Australian Government Department of Agriculture, and consultation regularly occurs across all levels of both organisations. A more centralised approach to engagement with the department has allowed the APVMA to provide consistent whole-of-APVMA input to proposals for further reform of the regulation of agvet chemicals, where those proposals are relevant to the roles and responsibilities of the APVMA.

In late 2014, the European Union released an online consultation to help European regulators develop regulatory criteria to define endocrine disruptors. In view of the potential impact of any new regulations on Australia's international trade, the Australian Government Department of Foreign Affairs and Trade (DFAT) coordinated a whole-of-government response to the questionnaire. The APVMA provided detailed technical comments to DFAT through the Department of Agriculture.

Improve staff capability in science communication

PERFORMANCE MEASURES	PROGRESS
Trained staff in communication skills for scientists	Achieved

A workshop was held for APVMA staff on 25 March 2015 on 'Getting heard: writing for the media'. The workshop introduced participants to techniques for structuring written information for media and web content. The course showed participants how to take the key elements of scientific information and reports, and craft that material into key points and storylines that can be used to inform the community about the work of the APVMA.

STRATEGY 7—CONDUCT OUR BUSINESS EFFICIENTLY AND EFFECTIVELY

Our business systems, including resource and financial management, reporting, and IT, provide essential support to APVMA processes and staff. We continuously seek to improve our systems. In 2014–15, we developed a new corporate plan, and we are currently developing a new approach to quality management.

Enhance information technology systems to improve service delivery

PERFORMANCE MEASURES	PROGRESS
Implemented iPos electronic procurement system	In progress
Redesigned the APVMA chemicals database search interface to improve usability and launched it by 30 August 2014	In progress
Implemented automated workflow that is integrated with the electronic records management system for all critical business processes	In progress
Extended agency e-Portal, including existing work tracking systems	In progress
Implemented new IT systems to support the Manufacturers' Licensing Scheme by October 2014	Postponed
Implemented AERP phase 2 (near-real-time online reporting and improved internal systems) by 30 June 2015	Under review
Replaced the import consents access system with a portal interface by June 2015	Postponed
Implemented a new business intelligence system	Achieved
Developed and implemented a system to collect data on antibiotic sales	Postponed

See also Strategy 2.

In 2014–15, we focused on IT systems to support the implementation of reforms to the Agvet Code—in particular, systems to support online applications for product registration and active approval.

Our priority was to improve our outward-facing IT systems to support stakeholders to make applications. As a result, full delivery of some planned enhancements to systems was delayed.

An electronic procurement system was rolled out to the finance and human resources teams, and wider delivery is planned for 2015–16.

The public interface of the APVMA's chemicals database, which contains information about all agvet chemical registered products and active constituents approved for use in Australia, was redeveloped and improved this year. The new web interface, which is optimised for use on both desktops and mobile devices, will make it easier for people to access information from wherever they are; expected release is late 2015.

As part of implementing a new electronic records management system, we successfully completed a pilot to automate document workflow and approval, to streamline our registration and compliance processes. Automated workflow for critical business processes will continue to be rolled out in 2015–16.

A secure online system was also implemented to manage the allocation of assessment tasks for applications, both inside the APVMA and to external specialists such as the Australian Government Department of Health. This means that, as documents and data move through the evaluation process, we can better manage timeframes and guarantee the security of information at all points in the process.

The development of an IT system to support the Manufacturers' Licensing Scheme was deferred subject to a review of the business processes and procedures for MQL. The requirements will be reassessed once the review is complete.

Work to improve adverse experiences reporting was deferred because of the focus on ongoing enhancements to the online registration systems. This work will be rescoped in 2015–16 following a review of our business processes for the AERP.

The transition to contemporary database technology this year lays the foundation for increasing our business intelligence capability and will improve our ability to report performance with regard to registration timeframes. In 2015–16, we will be regularly reporting and publishing performance against timeframes on our website—this is in line with our commitment to meet key performance indicators in our Regulator Performance Framework.

Replacement of existing systems for applications for import consent and for the collection of antibiotic sales data was deferred to 2015–16 to enable continued focus on our registration systems.

Develop a new corporate plan with new key performance measures

PERFORMANCE MEASURES	PROGRESS
Developed a new corporate plan for 2015–19 to support the APVMA in its goal of being a contemporary world-class regulator	Achieved
Developed new key performance measures to provide an accurate reflection of overall performance	Achieved

The APVMA Corporate Plan 2015–19 was developed this year. It includes a refined vision and mission for the APVMA, with four key strategies:

- Deliver regulatory decisions that are timely, science based and proportionate to the risks being managed.
- Reduce the burden on industry in complying with regulatory requirements.
- Build a client-focused approach to service delivery committed to continuous improvement.
- Operate as a contemporary, high-performing and efficient organisation.

The new corporate plan will be the basis for next year's operational plan and subsequent annual reports.

In 2014–15, the APVMA developed its response to the new Regulator Performance Framework. The APVMA Performance Framework sets out how the APVMA intends to measure and report its performance against the Regulator Performance Framework. It contains performance measures against each of the six key indicators, as well as the evidence that will be collected to demonstrate performance. The six indicators against which the APVMA will measure its performance are as follows:

- Regulators do not unnecessarily impede the efficient operation of regulated entities.
- Communication with regulated entities is clear, targeted and effective.
- Actions undertaken by regulators are proportionate to the regulatory risk being managed.

- Compliance and monitoring approaches are streamlined and coordinated.
- Regulators are open and transparent in dealing with regulated entities.
- Regulators actively contribute to the continuous improvement of regulatory frameworks.

This is the first APVMA Performance Framework, and it is anticipated that it will be refined in the initial years to better target performance measures and evidence.

Enhance the APVMA's mobile device capability to improve access to APVMA systems for mobile users

PERFORMANCE MEASURES	PROGRESS
Implemented a secure, platform-independent system to facilitate BYOD (bring your own device) for mobile devices by December 2014	Achieved

The new mobility platform has been developed and deployed. It is now operating in both corporately provided and privately owned devices, allowing these devices to securely connect to the APVMA network.

Complete redevelopment of the APVMA's core agvet chemicals database

PERFORMANCE MEASURES	PROGRESS
Migrated data to new database by 30 June 2015	Partly achieved

Migration of data from legacy systems into new systems has started. It will be finalised during 2015–16 to allow decommission of legacy systems.

Protect and manage information resources

PERFORMANCE MEASURES	PROGRESS
Maintained IT system up-time of 97% or greater	Achieved
Met the target of no significant security incidents	Achieved
Defeated cyber intrusions before damage occurred	Achieved
Defeated virus attacks before damage occurred	Achieved
Undertook penetration testing of IT systems and achieved sound report	Achieved
Migrated from hard-copy to digital for application data by July 2014	Achieved
Transitioned from hard-copy to digital library by 30 June 2015	Achieved
Implemented a real-time corporate data backup solution by February 2015	Achieved
Developed IT risk management plans for all critical business systems by June 2015	Partly achieved

In 2014–15, there were no IT network security breaches. All APVMA IT systems were operational and secure. IT risk assessments were conducted for human resource, finance and mobility platforms, and did not identify any significant risks. To improve business continuity capability and provide off-site corporate backup, the IT infrastructure was relocated to a secure commercial data centre. Penetration testing of our IT systems indicated that the systems are secure.

The migration from hard-copy to digital data has been completed successfully. This included the delivery of an objective electronic document and records management system, which now manages our substantial volume of digital information.

Implement IT, physical, personnel and governance security policies to align to the Protective Security Policy Framework

PERFORMANCE MEASURES	PROGRESS
Continued compliance with the Protective Security Policy Framework	In progress
Reviewed the APVMA's physical and information security environment	Achieved
Implemented online IT security training module	Achieved

The APVMA was compliant with the Protective Security Policy Framework, and a revised information security policy was developed. We also implemented an online suite of security training, including physical, personnel and information security.

Maintain and enhance an efficient quality system

PERFORMANCE MEASURES	PROGRESS
Met the target of no significant ISO audit findings	Not achieved
Resolved procedure amendment requests within six months	Not achieved
Revised quality management procedures to reflect changes arising from reforms	In progress

The system was previously accredited against International Organization for Standardization (ISO) standard AS/NZS ISO 9001:2008. A review of this system revealed that it was no longer meeting business needs, and accreditation was allowed to lapse in August 2014. A new approach to quality management was developed and will be implemented in 2015–16.

Instructional material has been revised to reflect changes arising from legislative reforms and internal changes. Eighty obsolete documents have been decommissioned from the quality management system and replaced with updated material. The work is ongoing and scheduled to be completed by 30 September 2015.

Comply with government reporting requirements, legislation and standards

PERFORMANCE MEASURES	PROGRESS
Audited financial statements cleared by due date	Achieved
Submitted input to Portfolio Budget Statement by due date	Achieved
Met the target of no significant findings from internal and external audits	Achieved
Completed transition from FMA Act to PGPA Act	Achieved
Delivered responses to government surveys, questions on notice, ministerial correspondence and related material on time and to a high quality	Achieved

See also Strategy 5.

The APVMA exercises due diligence with regard to all aspects of its reporting requirements. All reporting requirements were complied with during 2014–15. Audited financial statements were cleared by the due date with no significant findings; nor were there any significant findings from other internal and external audits. Input to the Portfolio Budget Statement of the Australian Government Department of Agriculture was provided by the due date.

The PGPA Act replaced the *Financial Management and Accountability Act 1997* (FMA Act) on 1 July 2014. The APVMA successfully completed its transition from an FMA Act agency to become a corporate Commonwealth entity under the PGPA Act during 2014–15.

In 2014–15, a centralised unit was set up to handle ministerial correspondence, questions on notice, responses to government surveys and related material. We will continue to refine this process and seek feedback from relevant stakeholders.

Enhance access to information

PERFORMANCE MEASURES	PROGRESS
Adhered to Information Publication Scheme requirements according to the APVMA agency plan	Achieved
Complied with statutory timeframes for freedom of information requests	Achieved

The APVMA publishes an agency Information Publication Scheme (IPS) plan, which sets out how the APVMA intends to administer and comply with the IPS.

The APVMA managed its IPS entry through regular review and updating of the content, as well as improving the manner in which published information can be accessed and understood by the public.

Relevant APVMA programs ensure that the APVMA continues to meet its objective of maintaining a compliant IPS entry that is a valuable source of information for the public.

All freedom of information requests have been processed in accordance with the statutory timeframes set out in the *Freedom of Information Act 1982* (FOI Act; see also Appendix B). Where extensions of time have been required to process any requests, the relevant statutory power has been relied on within the FOI Act.

Implement new accountability framework for business processes

PERFORMANCE MEASURES	PROGRESS
Built specific accountability for business processes into the organisational structure to ensure that decision making is supported by efficient and effective business systems	Achieved

A revised organisational structure was implemented on 1 October 2014 to improve alignment with, and accountability for, business processes. This new structure strengthens the governance model to oversee all business processes and activities.

The APVMA's new structure comprises the following sections:

- Registration Management and Evaluation—processes and evaluates applications to register products, permits and active constituents, and manages the interface with clients
- Scientific Assessment and Chemical Review—provides scientific assessments that underpin registration decisions and reviews chemicals of concern
- Legal and Compliance—ensures the integrity of the regulatory framework through compliance, audit and monitoring, coordination, and sound legal advice
- Corporate Services—provides systems and support to all operations
- Chief Scientist—Dr Phil Reeves was appointed to the new role of APVMA Chief Scientist (see Case study 9).

The APVMA's governance committee structure was also reviewed to align it with the new structure and the goals of the agency. The new committee structure comprises:

- external committees
  - APVMA Advisory Board
  - Audit Committee
- internal committees
  - Executive Leadership Team
  - Senior Leadership Team
  - Staff Consultative Committee
  - Work Health and Safety Committee
  - Enforcement Committee
  - Business Technology and Systems Committee
  - Registration Quality Committee
  - Science Quality Committee.

CASE STUDY 9

Establishment of the APVMA's Office of the Chief Scientist

On 3 December 2014, the APVMA announced the appointment of Dr Phil Reeves to the new role of APVMA Chief Scientist.

APVMA's Office of the Chief Scientist was established to help ensure that our regulatory science frameworks and standards continue to meet appropriate national and international standards. Through engagement with national and international scientific and regulatory networks, the office will identify issues and trends that may affect the integrity of our regulatory science frameworks and standards, and develop appropriate projects and initiatives to enhance our scientific capability.

The office will also provide the CEO and senior staff with independent, expert advice on regulatory decisions and scientific aspects of the APVMA's regulatory framework, and will manage special projects.

Dr Reeves has a Bachelor of Veterinary Science (Honours) degree from the University of Queensland and a PhD in pharmacology from the University of Western Australia. He is a Fellow of the Australian and New Zealand College of Veterinary Scientists in veterinary industrial pharmacology.

He comes to this role with both private and public sector experience; he spent a number of years as a practising vet before undertaking research in molecular pharmacology and toxicology. Since 1992, he has held a number of positions at the APVMA, including as Principal Scientist and most recently as Chief Regulatory Scientist, Veterinary Medicines.

Dr Reeves has represented Australia at major international forums, including OECD, FAO/WHO and VICH working groups. He has presented more than 100 invited lectures in Australia and overseas, and has published numerous scientific journal articles and book chapters.

Dr Phil Reeves, APVMA

Ensure that cost-recovery arrangements reflect APVMA operating requirements

PERFORMANCE MEASURES	PROGRESS
Provided support to the first-principles review of the APVMA's cost-recovery arrangements being conducted by the Department of Agriculture	Achieved
Facilitated input by partner agencies into cost-recovery arrangements	Not achieved

See also Chapter 1.

APVMA costs are recovered from the agvet chemical industry through a system of application fees, annual fees and levies calculated on the value of sales. The Australian Government Department of Agriculture is conducting a 'first-principles review' of this system, and will make recommendations on options to strengthen the financial sustainability, transparency and accountability of the arrangements. We have provided the department with support and assistance in relation to the review.

The delay in completing the first-principles review has led to a delay in implementing a new cost-recovery impact statement, including facilitating input by partner agencies. This will now be completed during 2015–16 for commencement from 1 July 2016, and will update our existing fees and charges.

STRATEGY 8—ENHANCE PERFORMANCE THROUGH OUR PEOPLE

In 2014–15, the APVMA focused on developing our staff through support and training to improve both core and specific capabilities. Our investment in a skilled, diverse and healthy workforce reiterates our commitment to regulatory excellence, and acknowledges the pride and commitment demonstrated by our staff.

Staff profile

Tables 11–14 provide details of Australian Public Service (APS) employees who were employed at the APVMA under the *Public Service Act 1999* in 2014–15.

We had 144 full-time and part-time ongoing staff at 30 June 2015. There were also 28 non-ongoing or casual staff, bringing the total number of staff to 172 (99 female, 73 male). No staff identify as being Indigenous. Staff are located in Canberra, other than one staff member who is in Perth. Table 11 shows a breakdown by position level, Table 12 shows a breakdown by employment agreement, and Table 13 shows the salary level of different positions. Staff movements, including recruitments, resignations, terminations and retirements (excluding internal transfers and promotions), are shown in Table 14.

In 2014–15, the separation rate for ongoing staff was 11.8 per cent, which is an increase from the 5.56 per cent separation rate of the previous year.

TABLE 11: APVMA STAFFING, AT 30 JUNE 2015

Classification	Full time (ongoing)	Part time (ongoing)	Non-ongoing and casual	Total
CEO			1	1
Senior Executive Officer	4			4
Principal Scientist	2			2
EL2	22	1	3	26
EL1	37	6	6	49
APS 6	34	5	8	47
APS 5	8	4	3	15
APS 4	10	1	4	15
APS 3	8	2	3	13
APS 2	0	0	0	0
Trainee	0	0	0	0
Total	125	19	28	172

APS = Australian Public Service; CEO = Chief Executive Officer; EL = executive level

TABLE 12: NUMBER OF STAFF EMPLOYED UNDER COMMON LAW ARRANGEMENT AND ENTERPRISE AGREEMENT, AT 30 JUNE 2015

Classification	AWA	CLA	CA	Total
SES		6		6
Non-SES	0	0	166	166

AWA = Australian Workplace Agreement; CA = Commonwealth agreement; CLA = common law arrangement; SES = senior executive service

Note: The Chief Executive Officer is outside the above arrangements.

TABLE 13: SALARY RANGE BY CLASSIFICATION, AT 30 JUNE 2015

Classification	Minimum	Maximum
EL2	119 015	149 521
EL1	101 410	114 197
APS 6	83 807	93 557
APS 5	73 721	85 040
APS 4	64 918	80 990
APS 3	57 213	64 463
APS 2	0	0
Trainee	0	0

APS = Australian Public Service; EL = executive level

TABLE 14: STAFF MOVEMENTS AT APVMA, 2014–15

Classification	Ongoing separated	Non-ongoing separated	Ongoing recruited	Non-ongoing recruited
CEO	0	0	0	0
Senior Executive Officer	1	0	0	0
Principal Scientist	0	0	0	0
EL2	4	0	2	1
EL1	4	1	4	2
APS 6	5	4	4	5
APS 5	1	2	0	3
APS 4	1	4	2	3
APS 3	1	0	0	2
APS 2	0	0	0	0
Trainee	0	0	0	0
Total	17	11	12	16

APS = Australian Public Service; CEO = Chief Executive Officer; EL = executive level

Provide a safe, supportive and fair workplace

PERFORMANCE MEASURES	PROGRESS
Reviewed work health and safety management arrangements to ensure compliance with relevant codes of practice and best-practice incident reporting procedures	Achieved
Met target of no preventable health and safety incidents requiring notification to the regulator, Comcare	Achieved
Provided an accurate and timely remuneration service (100%)	Achieved

As part of work health and safety (WHS) arrangements, the APVMA:

- promotes and develops arrangements to ensure employees' health, safety and wellbeing at work, in accordance with the *Work Health and Safety Act 2011*
- provides operational guidelines for the operation of the Health and Safety Committee
- provides mechanisms for reviewing, varying, and informing employees about WHS arrangements, and for dealing with disputes during consultation.

Employees may raise WHS concerns via their health and safety representative or directly with the Health and Safety Committee.

The committee meets regularly and deals with a variety of matters out of session. The APVMA supports the training of up to two health and safety representatives, who ensure that the APVMA work group is consulted about, and informed of, relevant WHS matters. The representatives also conduct quarterly workplace inspections. No high-risk potential hazards were identified in 2014–15.

Four reports of potential hazards, injuries or illnesses to staff from work-related incidents were received in 2014–15. No reported incidents resulted in recorded days lost as a result of injuries. Following review and action, all incidents were found to be relatively minor and have been fully resolved. One incident necessitated a review of the APVMA's practices in handling suspicious mail items to ensure that relevant staff are aware of correct procedures and options to maintain their own safety and that of their colleagues. No incidents required notification to Comcare.

All staff were offered ergonomic workstation assessments to support the relocation or amalgamation of teams and individuals as a result of the organisational restructure.

Health and wellbeing initiatives

In 2014–15, we continued our tradition of supporting initiatives to help staff manage their health and wellbeing at work and at home. We provided free influenza vaccinations for staff, facilitated corporate gym memberships, and invited staff to undertake on-site fitness and general health assessments with qualified health practitioners.

Additionally, the APVMA held information sessions for staff throughout the year on subjects such as the benefits of our employee assistance program to general employee wellbeing, and a webinar series run by the NewAccess program that provided staff with information about seeking support for symptoms of depression and anxiety.

Remuneration

We achieved our target of 100 per cent accuracy and timeliness in our remuneration service. In addition, in line with the APVMA's movement towards a fully electronic record-keeping environment, we continued to improve our payroll management and employee self-service systems. These improvements facilitate better access to electronic application for entitlements and documentary evidence, and improve reporting capabilities and the ability to generate payment summaries electronically.

Disability reporting

Since 1994, Australian Government departments and agencies have reported on their performance as policy adviser, purchaser, employer, regulator and provider under the Commonwealth Disability Strategy. In 2007–08, reporting on the employer role was transferred to the Australian Public Service Commission's *State of the service report* and the *Australian Public Service Statistical Bulletin*. These reports are available at www.apsc.gov.au. Since 2010–11, departments and agencies have not been required to report on these functions.

The Commonwealth Disability Strategy has been overtaken by the new National Disability Strategy 2010–20, which sets out a 10-year national policy framework to improve the lives of people with disability, promote participation and create a more inclusive society. A high-level two-yearly report tracks progress against each of the six outcome areas of the strategy and presents a picture of how people with disability are faring.

Align people policies with legislation and best practice

PERFORMANCE MEASURES	PROGRESS
Reviewed all people policies and legislative requirements annually	Achieved
Implemented changes arising from the finalised enterprise agreement	In progress

We aim to support, develop and motivate our people to grow and adapt, to assist with meeting our corporate objectives. Our performance management framework seeks to:

- change APVMA culture from one focused on outputs to one focused on outcomes
- set a consistent and equitable basis for improving performance and rewarding excellence
- link rewards and remuneration to outcomes achieved
- simplify rating scales, with improved definitions capturing the Australian Public Service Commission's integrated leadership capabilities
- encourage a collaborative culture
- ensure transparency in performance management.

Support for the performance management system continued to be strong, with all staff participating during the year.

In addition to regular and ongoing review of the accuracy and currency of APVMA policies, all human resources and associated policies were reviewed in 2014–15 to ensure compliance with relevant legislative amendments. These include the translation of the Information Privacy Principles to the Australian Privacy Principles under the *Privacy Act 1988*.

Enhance the effectiveness and performance of our people

PERFORMANCE MEASURES	PROGRESS
Implemented a foundation leadership skills program to develop emerging leaders for APS-level staff	Achieved
Continued implementation of a leadership program for executive-level staff	Achieved
Met target of 100% participation in performance management	Achieved
Met target of 80% of recruitment processes completed within 45 days	Not achieved
Implemented new online recruitment portal	Achieved

We aim to recruit quality staff and to develop the skills of staff members at all levels.

Our commitment to developing our leaders continues through our new Management 101 program. This program includes topics such as recruitment, performance management and WHS arrangements. The program started in June 2015 and is open to all Executive Level 1 managers.

For individuals, each staff member is required to establish a Mutually Agreed Achievement Plan (MAAP) with their manager to enable performance appraisal and determine development priorities for the next year. All staff participated in the MAAP system in 2014–15.

Table 15 provides details of our recruitment activities in 2014–15. Following the organisational restructure and to prepare to meet future capability requirements identified through the capability review (see below), the APVMA sought to fill vacancies with suitable staff in accordance with the interim arrangements for APS recruitment. The APVMA undertook 41 external recruitment processes during 2014–15; 9 of these did not progress to selection because of the limited field of APS employee candidates. In response to this, permission to open four vacancies to all members of the Australian community was sought and granted by the Australian Public Service Commissioner. This allowed suitably qualified scientific staff from outside the APS to seek employment and bring additional scientific capability to the APVMA.

The APVMA's recruitment activities during 2014–15 were supported by an internally developed and supported online recruitment tool. This tool has been specifically designed to meet the APVMA's electronic recruitment needs. Costs have been reduced because an external licensed product is no longer required to perform the function.

TABLE 15: RECRUITMENT ACTIVITIES, 2014–15

Activity	Number
External recruitment advertisements	30
Expressions of interest (APS employees only)	11
Applications received	535
Average time from gazette close to offer date	68 days
Recruitment campaigns cancelled	9
Recruitment decisions (gazetted notifications)	12
Processes completed within 45 days	3
Internal recruitment advertisements	11
External recruitment in progress (as at 30 June 2015)	10
Recruitment rounds (total internal and external)	52

APS = Australian Public Service

Ensure that our people have the skills they need to do their job

PERFORMANCE MEASURES	PROGRESS
Undertook a capability review to identify current and future staff capability requirements by June 2015	Achieved
Continued implementation of the Learning and Development Strategy	Achieved

An APVMA-wide capability review was held in 2014–15. The review aimed to identify current and future skills gaps to support the APVMA's implementation of legislative reform, and to ensure that the APVMA is able to perform its regulatory role effectively now and in the future. The review has informed immediate and expected recruitment needs. It has also developed internal measurement tools that the APVMA can use to assess progress in capability development, and the needs of both technical and more generic roles across the agency.

Training

We aim to ensure that staff are equipped with the knowledge, practical skills and motivation they need to carry out their duties. In 2014–15, the human resources team worked with senior leaders to determine training needs for technical and nontechnical skills, and knowledge requirements (see Case study 10).

The 2013–15 Learning and Development Strategy aims to reinforce the APVMA's commitment to enhancing performance through our people. It was developed to define training and development priorities. During 2014–15, the human resources team continued to implement the priorities highlighted in the strategy—namely, development of scientific, leadership, administrative and managerial skills for our staff through an in-house suite of face-to-face programs and e-learning modules.

Specific training held during the year included:

- face-to-face training aimed at improving our specialised writing skills, including writing for the media, preparing Senate Estimates briefs, plain-English business writing, minute taking and preparing Statements of Reasons
- Whole Brain Thinking® workshops, where individual and team profiles were provided to assist staff to better understand the diversity of our organisation and how to work more effectively within it
- client service workshops for all staff that coincided with the launch of the APVMA's new Client Service Charter; each team developed its own group strategies for improving client service, both internally and externally, which will be displayed for all staff on our intranet
- an APVMA-sponsored Certificate IV in Training and Assessment for five staff members, which developed important capabilities that the staff members can apply to their role, and increased the capability of the APVMA to develop and deliver quality formal and informal learning and development initiatives.

The Study Encouragement Scheme continues to support staff to gain relevant tertiary qualifications, to expand individual and organisational capabilities. Five staff members are currently using the scheme to obtain qualifications in veterinary science, finance, business administration, human resource management and government investigation.

Our Learning and Development team produced a large suite of e-learning modules designed to promote and increase staff awareness of the security, financial and behavioural expectations of public sector employees. Modules included bullying and harassment; IT, physical and personnel security; fraud awareness; managing official information; and resource management. Completion of these modules was made mandatory for all APVMA staff, and the modules are also key components of the APVMA induction package.

CASE STUDY 10:

APVMA leadership program

A comprehensive 18-month leadership program was introduced in April 2013 and completed in October 2014. The program was delivered to two groups: the executive and the senior leaders. The program aimed to encourage APVMA senior leaders to realise their full potential in this ever-changing regulatory environment.

The program started with an insight centre to prepare the participants for the changed management skills required to deliver the APVMA's regulatory change agenda. This led to face-to-face workshops, group coaching sessions, a mentoring program and one-on-one sessions. Participants completed questionnaires before and after the program; these confirmed development growth, as did the observable change within the senior leaders.

Foster values and behaviours that support a robust, accountable public sector agency

PERFORMANCE MEASURES	PROGRESS
Met target of an absenteeism rate at or below APS average	Achieved
Ensured adherence to the code of conduct	Achieved

The APVMA is committed to the APS employment principles—in particular, we expect effective performance from all staff, and aim to provide a flexible, safe and rewarding workplace that promotes health and wellbeing. We aim to ensure that staff demonstrate APVMA values and behaviours through their work and interaction with stakeholders. In 2014–15, there was an increased emphasis on client service skills and adherence to the APS Code of Conduct. We make these values explicit in staff induction and management.

We ensure that any potential conflicts of interest (real or perceived) are declared by all staff in an annual process. The APVMA is committed to maintaining an accountable and ethical culture. Ensuring that private interests of staff and their families are declared openly and transparently ensures that potential conflicts of interest can be addressed.

Develop a new enterprise agreement

PERFORMANCE MEASURES	PROGRESS
Developed a new enterprise agreement consistent with the APS bargaining framework	In progress

The APVMA continued to negotiate collaboratively with staff and their nominated representatives on the next enterprise agreement for APS-level and executive-level staff. Negotiations are being undertaken in good faith and in accordance with the principles of the Australian Government Public Sector Workplace Bargaining Policy.