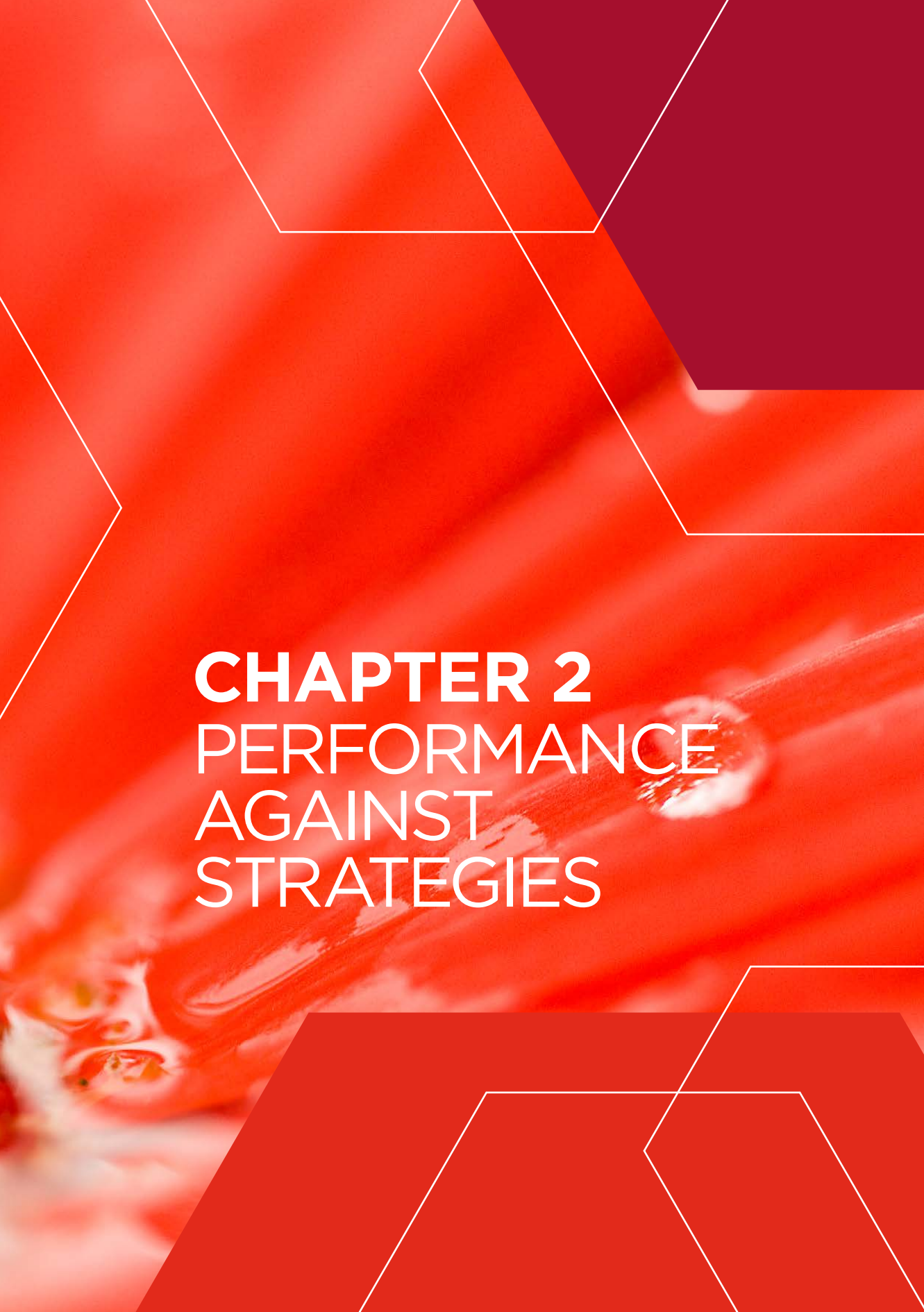


CHAPTER 2
PERFORMANCE AGAINST STRATEGIES

STRATEGIC FRAMEWORK AND REPORTING

The *APVMA corporate plan 2012–15* identifies 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 2013–14* 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, while Strategies 6–8 are supportive enabling strategies.

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

Figure 2 APVMA objectives and strategies

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:
>
> - 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 to the Portfolio Budget Statement in 2013–14.

SUMMARY OF PERFORMANCE AGAINST STRATEGIES

The APVMA is a client-focused service agency. In 2013–14, we worked to prepare industry for the impacts of legislative reform, and continued to improve our processes to ensure that we are a contemporary and world-class regulator.

Strategy 1—Integrate government reforms into core business. The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* will commence on 1 July 2014. The legislative reforms aim to increase the efficiency and effectiveness of the APVMA, and to make chemical assessment and review more predictable. In 2013–14, the APVMA worked to prepare the organisation and its stakeholders for implementation of the reforms. We have developed draft regulatory guidelines in consultation with industry, and have developed and delivered comprehensive training and communications to industry and APVMA staff.

Strategy 2—Conduct robust, risk-based, scientific evaluations to support sound regulatory decisions. Before pesticides and veterinary medicines can be registered for sale and use, we evaluate them to ensure that they can be used safely and effectively. In 2013–14, we approved and registered a large number of pesticides and veterinary medicines, and we have adhered to statutory timelines in our processes. We received 1942 and finalised 1870 applications for pesticide products (96 per cent within the statutory time frame), and received 997 and finalised 1187 applications for veterinary medicine products (90 per cent within the statutory time frame).

In December 2013, we reviewed the APVMA's application of the Joint Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) Expert Committee on Food Additives (JECFA) approach to recommending maximum residue limits (MRLs) for veterinary medicines, with the help of four internationally renowned experts.

The experts made recommendations aimed at strengthening the APVMA's evaluation of veterinary medicine residues; implementation of these recommendations will begin later in 2014.

Strategy 3—Identify and reconsider existing chemicals of regulatory concern. The APVMA reviews and reconsiders approved active constituents, registered products, or labels of pesticides and veterinary medicines if credible new data suggest that current use may pose previously unknown risks to human health, animal or crop safety, the environment or trade, or suggest product ineffectiveness. Chemical reviews in 2013–14 included 2,4-D high-volatile esters, diazinon, dichlorvos, dimethoate, fenthion, molinate and sheep ectoparasiticides. As a result of reviews, the APVMA undertook 261 regulatory actions; cancelled 2 active constituent approvals, 11 product registrations and 118 product labels; and varied 130 label approvals.

We also investigate reports of adverse events associated with registered pesticides or veterinary medicines. These adverse events can include threats to human or animal health, nontarget crop or plant damage, environmental damage or lack of efficacy. In 2013–14, we assessed and classified 2138 reports of suspected adverse events, none of which required significant regulatory action.

Strategy 4—Identify and resolve noncompliance. Noncompliance with the *Agricultural and Veterinary Chemicals Code Act 1994* 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. We also license and audit veterinary manufacturers to ensure adherence to APVMA-prescribed manufacturing standards. In 2013–14, APVMA-authorised auditors audited 103 licensed Australian veterinary manufacturers.

In 2013–14, we received 243 reports of alleged noncompliance and continued to investigate a number of cases from 2012–13. We finalised 156 allegations and 9 recall events. One brief of evidence has been submitted and accepted for prosecution by the Commonwealth Director of Public Prosecutions. We conducted field investigations, including Operation Catch in 2013—a nationwide sampling of 2,4-D chemical products and active constituents from formulators, manufacturers and retail stores. Results of the operation were generally satisfactory.

Strategy 5—Identify and manage emerging regulatory issues. International regulatory science is continually updated by new findings, processes and policies. We engage with other government agencies and our international counterparts to identify emerging issues and inform our decision-making. We collaborate on international projects and participate in expert groups such as the Joint Meeting on Pesticide Residues (administered by the FAO and WHO) and JECFA (on veterinary drugs).

In 2013–14, we examined a range of regulatory issues. Following consultation with stakeholders, we completed and published a review of the use of neonicotinoid insecticides in Australia and whether they present more of a risk to bee health than other pesticides. We also published a review of glyphosate and birth defects, organised a symposium on endocrine-disrupting chemicals, and commissioned a review of pesticides and Parkinson's disease. We are also examining the issue of nanopesticides and veterinary nanomedicines.

We are nearing completion of a report of regulatory considerations applicable to agricultural and veterinary nanomaterials, and are part of a project being conducted by the International Union of Pure and Applied Chemistry to develop guiding principles for a globally harmonised ecological risk assessment methodology for nanopesticides.

Strategy 6—Engage stakeholders and regulatory partners to add value to our work. We aim to involve stakeholders in our decision-making and promote confidence in our decisions. Our stakeholders include our regulatory partners, registrants and manufacturers of pesticides and veterinary medicines, farmers, veterinary practitioners, researchers, educators and the general public. Communication activities during 2013–14 focused on informing and educating industry about the legislative reforms and their application. We produced web-based and printed information for a range of audiences, and conducted training sessions on the impact of the reforms. More than 400 people attended information sessions in Adelaide, Brisbane, Canberra, Melbourne, Perth and Sydney during February and March 2014, and an industry workshop was held on 29 April 2014. We also held a Science Communication Symposium so that staff from the member agencies of the Regulatory Science Network, including APVMA staff, could learn more about science communication.

A major project in 2013–14 has been the redevelopment of our website. More than 3000 web pages and around 10 000 downloadable documents were analysed for migration, review, deletion or archive. The new website, including the regulatory guidelines, will be launched on 1 July 2014.

Advisory Board meetings were held in July, September and December 2013, and February and April 2014. An industry workshop for all key stakeholder groups was held in April 2014 to prepare for the implementation of legislative reforms and to discuss strategic issues relating to changes to APVMA business processes.

Strategy 7—Conduct our business efficiently and effectively. We aim to maintain a high standard of operation for all our business systems, including reporting, resource and financial management, and information and communication technologies (ICT). Our quality management system regularly audits our performance and processes to look for ways to improve them.

In 2013–14, we developed a new web-based portal, which includes an online application system to guide applicants through the application process for registering pesticides and veterinary medicines. We also launched an online tool to assist applicants and registrants to submit their product labels. New internal systems were launched, including a web-based application management portal, and an electronic document and records management system. These systems will allow electronic applications to be processed more efficiently, providing fewer opportunities for error and reducing administrative delays.

Strategy 8—Enhance performance through our people. We had 167 staff at 30 June 2014. We aim to increase the capability of our staff through support and training. Our Learning and Development Strategy links learning and development activities with business needs by engaging staff in the design of internal training. In 2013–14, a full-time Learning and Development Manager was engaged to implement the strategy. We also value and support staff health, safety and wellbeing, and conduct a number of health and wellbeing initiatives throughout the year.

At a glance

	2012–13	2013–14
Pesticides		
Applications received for product registration, variation to registration	2062	1942
Applications finalised (excludes those withdrawn at preliminary assessment)	1864	1622
Percentage of applications finalised within the statutory time frame (target 90%)	95%	96%
Veterinary medicines		
Applications received for product registration, variation to registration or label approval	913	997
Applications finalised (excludes those withdrawn at preliminary assessment)	782	981
Percentage of applications finalised within the statutory time frame (target 90%)	89%	90%
Registered chemicals		
Review reports published	7	4
a compromises of regulatory actions taken—0 affirm active constituent approvals, 2 cancel active constituent approvals, 0 affirm product registrations, 11 cancel product registrations, 222 vary label approvals, 203 cancel product labels	167	438
b compromises of regulatory decisions made—4 suspend active constituent approvals, 1 continue active constituent approval suspension, 1 revoke active constituent approval suspension, 2 suspend product registrations, 34 continue product registration suspensions, 10 revoke product registration suspensions, 0 suspend product labels, 56 continue product label suspensions, 9 revoke product label suspensions	66	117
Adverse experience reports		
Reports of suspected adverse experiences assessed and classified	2935	1821
Reports finalised within 90 days from date of receipt	27%	90%
Noncompliance		
Allegations of noncompliance received	241	243
Allegations finalised	179	156
Recall actions taken	16	9
Monitoring visits conducted	56	49
Communication		
International visits to APVMA	5	3
Attendance and presentations at conferences and meetings	20	16

STRATEGY 1—INTEGRATE GOVERNMENT REFORMS INTO CORE BUSINESS

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* received royal assent on 29 June 2013, for commencement on 1 July 2014. The main aim of the reforms captured in the legislation is to improve the efficiency and effectiveness of registration and review processes.

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	Achieved
Compendium content finalised by April 2014 for further communication and training	Achieved (in May, to allow further industry consultation)

The APVMA developed new guidance material, business processes and information technology systems to embed the new legislative requirements into our systems, and provide greater predictability and transparency for applicants.

The APVMA's regulatory guidelines provide details of how the relevant agricultural and veterinary chemicals legislation is enacted by the APVMA, and how pesticides and veterinary medicines can be registered in Australia. The guidelines, which are designed as a web-based resource, were published in January 2014 for public consultation. The consultation period was to close at the end of March 2014, but was extended into April 2014 at the request of industry. As a result, and to allow sufficient time to properly take into account feedback from industry, the APVMA delayed release of the updated version of the guidelines until May 2014.

The regulatory guidelines are supported by eight legislative instruments, which were developed in consultation with industry from April 2014 to June 2014. The legislative instruments cover requirements for obtaining pre-application assistance and submitting an application, as well as efficacy and specific product standards.

Work instructions for APVMA staff, based on the regulatory guidelines, were developed and implemented. A range of external and internal information technology systems were developed to support the online submission and management of applications. A centralised point of contact for all enquiries was established, and a new case management system was designed and implemented in preparation for 1 July 2014.

ENHANCE TRANSPARENCY OF APVMA OPERATIONAL PRACTICES, POLICIES AND GUIDELINES

Performance measures	Progress
All relevant operational information published under the Information Publication Scheme according to the APVMA agency plan	Achieved
Relevant guidelines (including the Risk Compendium) published online to improve transparency of APVMA policies and procedures for stakeholders	Achieved

The APVMA ensures that all information we publish is accurate and up to date at the time of publication, and endeavours to review the accuracy of the register of information in accordance with the agency plan for the implementation of the Information Publication Scheme.

The regulatory guidelines were published online in May 2014 following public consultation (see above). The new guidelines are designed as a web-based product to facilitate their ongoing review and improvement.

SUPPORT INDUSTRY READINESS TO COMPLY WITH NEW REGULATORY FRAMEWORKS

Performance measures	Progress
Reform communication strategy developed by end July 2013, and activities undertaken in accordance with the strategy	Achieved
Detailed industry support material in place and seminars conducted with relevant stakeholders before commencement of new legislation	Achieved
New case management system developed and piloted, ready for full implementation by 1 July 2014	Achieved

The APVMA developed and delivered a comprehensive training and communication strategy to help industry to prepare for the implementation of the legislative reforms (see case study).

A new case management system was developed and piloted during 2013–14. The new system and processes were ready for implementation on 1 July 2014 and will be further developed in 2014–15. Case management will deliver an efficient means of tracking, administering and managing applications from submission to completion, to ensure that legislative time frames are achieved. The case management system also encompasses a single point of contact for clients for email correspondence or telephone enquiries.

IMPLEMENT CHANGES ARISING FROM THE 2013 AMENDMENTS TO THE APVMA'S GOVERNING LEGISLATION IN PREPARATION FOR COMMENCEMENT ON 1 JULY 2014

Performance measures	Progress
Reforms implemented in accordance with time frames	Achieved

Throughout 2013–14, the APVMA implemented the necessary changes to guidance material, business processes and information technology systems to give effect to the legislative reforms commencing on 1 July 2014. This included engaging with industry and relevant government agencies at national, and state and territory levels.

ENSURE STAFF ARE AWARE OF CHANGES AND ARE CAPABLE OF DELIVERING THE REFORM OBJECTIVES

Performance measures	Progress
All staff trained before the commencement of the new legislation	Achieved

Staff development has been a key priority for the APVMA during 2013–14, to ensure that the organisation is prepared for implementation of the legislative reforms (see case study).

CASE STUDY

Training for reform

Training for industry has been a critical learning and development project in the implementation of the legislative reforms. The Learning and Development area has actively worked with line managers and subject matter experts to develop training options that are tailored to the needs of our external stakeholders.

More than 400 people attended information sessions held in Adelaide, Brisbane, Canberra, Melbourne, Perth and Sydney during February and March 2014. APVMA staff presented an overview of the changes in key areas and then took questions from the audience. The format, deliberately designed to allow plenty of time for questions, was positively received by participants.

Feedback from these sessions was used to develop and implement a training program, which aimed to ensure that all key stakeholders are confident and informed about the changes taking place in the operation of the APVMA.

Detailed industry support material was developed and used for industry training on the new reforms, which was conducted on 2–3 June and again on 12–13 June. The feedback received from participants in this training was very positive, with 93.75 per cent of participants confirming that the training improved their readiness for the upcoming legislative changes.

Training topics covered were:

- application processes
- evaluation and determination
- fees and charges
- permits
- adverse experience reporting
- noncompliance powers
- using the portal.

The training workshops are supported by a suite of e-learning modules, which are available through the APVMA website. The first of these modules is pre-application assistance.

Staff development was also a key priority for the APVMA during 2013–14, to ensure that the organisation is prepared for implementation of the legislative reforms. Our Legislative Reform Training suite has been implemented using a three-tier approach: T1—high-level overview of key changes and processes, T2—exploring and understanding new technical processes, and T3—on-the-job training in new practices and procedures. Nontechnical subjects were also incorporated, to help staff manage their work more efficiently, balance work–life commitments and develop themselves as leaders.

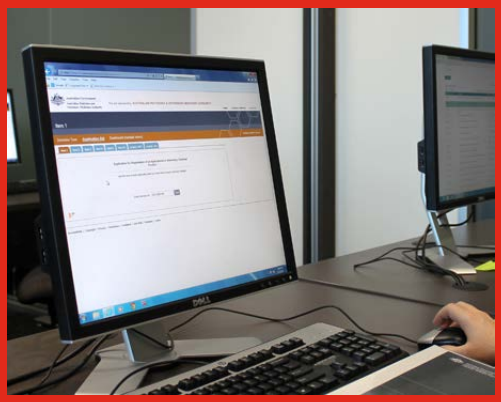
An online learning management system was implemented across the organisation to support the rollout of the Legislative Reform Training, as well as security awareness and other nontechnical topics. Ongoing development and improvement of online offerings will continue to be a priority in 2014–15.

All compliance staff attended APVMA in-house training on the changes in compliance and enforcement provisions arising from the legislative reforms. Compliance training packages were developed and delivered to a broad range of APVMA staff in relation to condition setting, resolving noncompliance and compliance powers. A majority of APVMA staff participated in introductory training sessions relating to APVMA compliance.

Training was also provided to our partner agencies, the Australian Government Department of Health and Department of the Environment, on 26 May 2014, to ensure that they were also prepared for the new legislation.

A range of new e-learning modules will be released in 2014–15.

Industry training held in Canberra



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

Our scientific evaluations are based on robust, risk-based methods. Registrations and approvals of pesticides and veterinary medicines are only granted if we are satisfied that the evidence indicates that these chemicals can be used safely and effectively. We review the latest international science and regulatory information to inform our decisions. We also help applicants to navigate the regulatory processes, and work to improve our internal processes to support decision-making.

We have two separate evaluation programs: the Pesticides Program and the Veterinary Medicines Program. Activities in these programs are supported by the development of information materials, new business processes and training.

MAKE QUALITY, TIMELY DECISIONS ON REGISTRATION, ACTIVE APPROVAL AND PERMIT APPLICATIONS

Performance measures	Progress
Time frame performance met for applications received before commencement of new legislation:	Achieved
• 90% of product registrations	94%
• 60% of active approvals	80%
• 85% of permits	90%
Work practices reviewed to ensure alignment with legislative requirements, and staff trained appropriately	Achieved
Enhanced peer-review processes implemented	Achieved

Our pesticides and veterinary medicines evaluation programs ensure that chemicals intended for sale in Australia are safe and effective (see 'Highlights: new products for agricultural and animal health'). We generate quarterly performance statistics for the programs, which are analysed for trends such as the number of applications received, the number in progress and the percentage finalised within statutory time frames. When trends are negative with respect to our targets, we investigate and take action to address the causes. Quarterly statistics are summarised on the APVMA website.

Work practices continued to be reviewed and developed to ensure that they are aligned with the legislative reforms. Staff training on the new legislative framework and practices has been under way since early 2014.

Two new positions—Health Assessment Coordinator and Environmental Assessment Coordinator—were created. The Health Assessment Coordinator provides technical oversight of toxicology, and work health and safety assessments, which are generally done by the Office of Chemical Safety in the Australian Government Department of Health The Environmental Assessment Coordinator provides technical oversight of

environmental assessments, which are generally done by the Chemical Assessments Section in the Australian Government Department of the Environment. These positions have played an important role by peer-reviewing assessments conducted for the APVMA, especially those with more difficult or contentious issues.

Pesticides evaluation

Product applications

We received 1942 applications for product registration, variation to registration or label approval for pesticide products in 2013–14. This is 5.8 per cent less than in the previous year (Table 1). By the end of 2013–14, approximately 6.5 per cent more applications were still in progress than at the end of the previous year.

Table 1 Applications for pesticide product registration or variation, 2013–14

Applications	2012–13	2013–14	% change
Number of applications in progress at beginning of period	1028	1039	1.8
Applications received	2062	1942	–5.8
Applications finalised	2054	1870	–9.0
Number of applications in progress at end of period	1039	1107	6.5

Note: Statistics include 248 applications received that were, in screening, either withdrawn by the applicant, treated as withdrawn or rejected. Although the APVMA did not accept these applications for evaluation, they are regarded as finalised.

Product finalisations

Our target in 2013–14 was to finalise 90 per cent of applications for pesticide products within the statutory time frame. We completed 1870 applications, 96 per cent within the statutory time frame (Table 2).

The average elapsed time for the 20 finalised applications falling into the 13–15-month category is reported as 35.6 months. This figure is heavily influenced by applications for new products that required the generation of additional data during the course of assessment.

Table 2 Pesticide product finalisations, 2013–14

Class of application	2012–13	2013–14				
	Total finalised	Total finalised	Finalised in time frame	Finalised in time frame (%)	Average clock time to finalise (months)	Average elapsed time to finalise (months)
Modular	1	17	17	100	NA	3.7
2–3 months	1490	1241	1223	99	1.6	3.7
5 months	186	209	189	90	4.6	11.3
6–8 months	86	78	71	91	6.5	12.8
9–12 months	80	57	48	84	9.3	19.4
13–15 months	17	20	13	68	16.1	32.3
Total	1864	1622	1561	96	NA	NA

modular = no fixed time frame or fee; NA = not applicable

Note: Statistics do not include 248 applications received that were, in screening, either withdrawn by the applicant, treated as withdrawn or rejected. Although the APVMA did not accept these applications for evaluation, they are regarded as finalised.

Permits and minor use

Permits may be considered by the APVMA for four purposes:

- minor use—applies to situations usually involving low acreage, small portions of high-acreage crops, or animal species that are not covered by the product label
- emergency use—for situations such as outbreaks of exotic pests and diseases
- research—allows chemical products to be used in research trials of varying sizes for scientific purposes, such as determining the suitability of a product for a new use or generating data necessary to register a product
- export—allows the permit holder to possess and supply an unregistered chemical product or an unapproved active constituent for export purposes only.

In 2013–14, we received 487 applications and finalised 438 permits, of which 90 per cent were completed within the statutory time frame. Of the permits finalised, approximately 42 per cent were for minor use, 13 per cent were for research purposes, 3 per cent were for emergency uses, and the remaining 42 per cent were for export purposes and renewal of existing permits.

Of the minor use and emergency use permits issued during the year, horticultural crops remained the largest sector seeking approvals (71 per cent of all issued permits). Vegetables made up 35 per cent of total permits issued; fruits and nuts, 29 per cent; and non–food producing crops, such as ornamentals, nursery stock, turf, essential oils, pyrethrum and poppies, 7 per cent.

Other sectors and purposes that were issued minor use permits included broadacre crops (10 per cent), environmental and noxious weeds (10 per cent), invertebrate pests (5 per cent), vertebrate pests (2 per cent) and plantation forestry (2 per cent).

Veterinary medicines evaluation

Product applications

We received 997 applications for product registration, variation to registration or label approval for veterinary medicine products in 2013–14. This is 9.2 per cent more than in the previous year (Table 3). By the end of 2013–14, 2.1 per cent more applications were still in progress than at the end of the previous year. This is the result of more complex applications requiring technical assessment: although there was a 13 per cent reduction in the number of applications finalised with short (2–3 month) time frames, from 564 to 491, the number of more complex (5+ months) applications finalised increased by 24 per cent, from 233 to 289.

Table 3 Applications for veterinary medicine product registration or variation, 2013–14

Applications	2012–13	2013–14	% change
Number of applications in progress at beginning of period	811	828	2.1
Applications received	913	997	9.2
Applications finalised	782	1187	51.8
Number of applications in progress at end of period	828	640	–22.7

Note: Statistics include 206 applications received that were, in screening, either withdrawn by the applicant, treated as withdrawn or rejected. Although the APVMA did not accept these applications for evaluation, they are regarded as finalised.

Product finalisations

Our target in 2013–14 was to finalise 90 per cent of applications for veterinary medicines within the statutory time frame. We finalised 1187 applications, 52 per cent more than for the previous year, with 90 per cent of these within the statutory time frame (Table 4).

The average elapsed time for the 19 finalised applications in the 13–15-month category is reported as 40.6 months. This figure is heavily influenced by the finalisation of some longstanding applications.

Table 4 Veterinary medicine product finalisations, 2013–14

Class of application	2012–13	2013–14				
	Total finalised	Total finalised	Finalised in time frame	Finalised in time frame (%)	Average clock time to finalise (months)	Average elapsed time to finalise (months)
Modular	0	0	NA	NA	NA	NA
2–3 months	491	696	668	96	1.1	5.6
5 months	170	173	155	90	4.9	11.7
6–8 months	44	55	24	44	10.1	22.2
9–12 months	49	38	25	66	10.9	27.4
13–15 months	26	19	12	63	20.7	40.6
Total	782	981	884	90	NA	NA

modular = no fixed time frame or fee; NA = not applicable

Note: Statistics do not include 206 applications received that were, in screening, either withdrawn by the applicant, treated as withdrawn, or rejected. Although the APVMA did not accept these applications for evaluation, they are regarded as finalised.

Permits and minor use

In 2013–14, we received 181 permit applications and finalised 152 permits, of which 91 per cent were completed within the statutory time frame.

Permit renewals accounted for 43 per cent of permits issued. The largest proportion (39 per cent) of the new permits issued were for research purposes. Export permits accounted for 11 per cent, and minor use permits 7 per cent.

HIGHLIGHTS

New products for agriculture and animal health

This year has seen a significant number of approvals and registrations for new pesticides and veterinary medicines, and major extensions of use (Table A). These new products have significantly expanded the range of products available to farmers and veterinary practitioners to reduce pests, and to prevent and treat disease.

The data on 13–18-month assessments are an indicator of innovative products for which there is new chemistry.

New products for agriculture

New pesticides and major extensions for agriculture approved this year include:

- a herbicide containing the active constituent terbuthylazine for control and suppression of weeds in wheat, barley and oats
- a herbicide containing the active constituent prosulfocarb in combination with metolachlor for control of grass and broadleaf weeds in potatoes
- an insecticide containing the active constituent sulfoxaflor for control of insect pests in broadacre, vegetable and fruit crops
- an insecticide containing the active constituent cyromazine for use in mushroom production
- an insecticide containing the active constituent emamectin to control insect pests in pulses
- an insecticide containing the active constituent cyantraniliprole in combination with thiamethoxam for control of Argentine stem weevil larvae, scarab beetle larvae, and armyworm and cutworm caterpillars in turf
- an insecticide containing the active constituent spinetoram for control of insect pests in sweet corn
- the insecticide deltamethrin incorporated within netting material for use in bed nets for the control of mosquitoes
- a fungicide containing the active constituent tebuconazole for use as a pruning wound dressing on apple and cherry trees.

New products for animal health

New products for animal health registered this year, based on active constituents not previously registered in veterinary medicines in Australia, included:

- a vaccine for pigs to aid in prevention of infection with porcine circovirus type 2 (PCV-2), viraemia and PCV-2 transmission, and in the control of PCV-associated disease
- a vaccine to aid in control of reproductive losses, including abortions, due to *Campylobacter* infection in sheep
- a product to treat hyperthyroidism and hyperthyroidism-associated clinical signs in cats
- a product to aid in management of overweight and obesity in adult dogs.

Table A Number of 13–18-month finalisations, 2009–14

	2009–10	2010–11	2011–12	2012–13	2013–14
Pesticides	11	13	23	17	20
Veterinary medicines	8	5	18	26	19
Total	19	18	41	43	39

SUPPORT PROVISION OF HIGH-QUALITY APPLICATIONS

Performance measures	Progress
Tools developed to promote online submission of applications and data	Achieved
Current electronic application and registration system replaced with a web-based system	Achieved
Examination undertaken of new models to better support minor use	Deferred
Processes implemented to provide formalised pre-application assistance to applicants	Achieved
Two courses run for applicants and consultants on application preparation	Achieved

During 2013–14, a range of new application tools were developed to support industry and assist in its application processes.

We implemented a new electronic decision-support tool, which will enable potential applicants to determine whether their agricultural chemical product requires registration. This system is already available for veterinary medicines applications but is now being extended to agricultural chemical applications.

A new web-based portal was developed to provide a 'one stop shop' for applicants and others who need to interact with the APVMA. The portal contains a new decision tree and online application system that will allow applications to be submitted electronically in accordance with the new legislation.

The decision tree will guide applicants through the application process and the choices they need to make about their application. The online application system will allow applicants to easily lodge their applications and supporting data. The new e-lodgement process will be more efficient, provide fewer opportunities for errors, reduce delays in the receipt of applications and improve APVMA administrative processes. Applicants will also be provided with a range of real-time information on the status of their applications through a new interface called My Portal. The new system will integrate with the new regulatory guidelines. A new e-label facility will allow applicants to submit their draft labels electronically. These new systems were developed and tested in 2013–14, and will be launched on 1 July 2014.

We also developed a new secure web-based agency portal that will allow application data to be securely shared with the Australian Government Department of the Environment and the Office of Chemical Safety within the Department of Health, for the purposes of assessment.

A new electronic document and records management system was successfully implemented in April 2014. The new system is key to the APVMA's move to electronic submissions, allowing the very large amounts of data the APVMA processes each year to be managed digitally.

In 2013–14, we redeveloped our public information search facility (called PubCRIS). The previous web-based form has been improved and now scales to the mobile device from which it is accessed. Additional product information for stopped, cancelled and expired products is now included. Search results can be downloaded and manipulated in software such as Excel. A new search interface for PubCRIS will be developed in early 2014–15.

New internal information and communication technology systems are being progressively rolled out that will allow electronic applications to be processed more efficiently, providing fewer opportunities for error and reducing administrative delays. A new internal portal has been developed and will offer new functionality, such as case management (see 'Support industry readiness to comply with new regulatory frameworks' in Strategy 1). The move to digital information will facilitate a range of further productivity improvements across the APVMA.

The Australian Government has committed $8.0 million over four years to help farmers improve their access to minor uses of agricultural and veterinary chemicals from 2014–15. The program, to be led by the Department of Agriculture, aims to develop tools and processes to help farmers access agvet chemicals, while still ensuring the protection of human health and the environment. The APVMA deferred internal work on minor use to ensure that it aligns with this new initiative.

ADOPT ENHANCED REGULATORY STANDARDS AND FRAMEWORKS FOR EVALUATIONS

Performance measures	Progress
Analysis of VICH international guidelines undertaken to determine their suitability for adoption in Australia, and at least two guidelines adopted	Achieved
Expert panels established and used for at least two science quality issues	Achieved
New arrangements put in place to register biological products independently of biosecurity requirements	Achieved
Ensure changes to regulatory frameworks and standards are applied across the APVMA and advisory agencies	Achieved

In 2013–14, we adopted 14 guidelines from the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) and 12 guidelines from the World Association for the Advancement of Veterinary Parasitology.

We have established and worked with expert panels on the APVMA's application of the JECFA approach to recommending MRLs for veterinary medicines (see case study below), and on nanopesticides (see case study in Strategy 5).

A new process has been implemented to enable finalisation of registrations and permits for applications that are deficient only because an Agriculture Biosecurity permit has not yet been granted. In such cases, registrations may be granted or permits issued with a condition that the product may only be supplied once the Agriculture Biosecurity permit has been granted. This change has improved the efficiency of the APVMA assessment process and will mean faster registrations or issuance of permits for affected products.

In 2013–14, we implemented a new regulatory framework and standards that reflect the legislative reforms. (See 'Embed revised APVMA regulatory guidelines into APVMA systems and processes' in Strategy 1).

DEVELOP REGULATORY FRAMEWORK TO SUPPORT SPRAY DRIFT POLICY

Performance measures	Progress
Draft consultation framework published by January 2014	Not achieved
Consultation completed by June 2014	Not achieved

The spray drift project commenced in mid-September 2013. The milestones for the project were adjusted so that the scientific aspects of the review could be addressed first, to guide communication strategy requirements. As a result, the framework is not expected to be finalised for consultation until 2014–15.

In December 2013, we formed a working group of technical experts from national, state and territory government agencies to collaborate and discuss the regulatory implications of scientific advances in spray drift research. We also engaged with expert international spray drift regulators and researchers, culminating in a workshop in Brisbane run by the National Working Party on Pesticide Application in June 2014.

FINALISE ARRANGEMENTS FOR CONTROL OF LABELS IN THE MARKETPLACE

Performance measures	Progress
Revised arrangements for control of market labels in place by June 2014	Achieved

The regulation of product labels is an important part of our work, ensuring that accurate use and safety information is provided to chemical users. The APVMA approves product labels as part of the product registration process. In June 2014, we launched an online tool to assist applicants and registrants to maintain their product labels. The tool simplifies the application process into an online form that has much of the content preformatted. Labels are complex and consist of multiple parts; an applicant is now able to highlight just the parts of the label proposed for change. This saves time for the applicant, and will make assessment of label applications easier and more efficient for APVMA staff.

REVIEW APPLICATION OF JOINT EXPERT COMMITTEE ON FOOD ADDITIVES METHODOLOGY FOR SETTING MAXIMUM RESIDUE LEVELS FOR VETERINARY MEDICINES

Performance measures	Progress
Review undertaken by March 2014	Achieved

A meeting was held at the APVMA on 10–11 December 2013 to review the APVMA's application of the JECFA approach to recommending MRLs for veterinary medicines (see case study). The meeting also considered certain matters relating to veterinary medicine residues that fall outside the scope of JECFA's work, including the assignment of slaughter withholding periods and export slaughter intervals. In addition, practical measures to inform the development of best practice in Australia for the regulation of veterinary chemicals used in food-producing species were discussed. A meeting report and recommendations, and phased implementation of the program will occur in 2014–15.

CASE STUDY

Striving for best practice in the evaluation of veterinary medicine residues in food

The regulation of pesticides and veterinary medicines in Australia has a long history. By 1945, all states had legislation in place requiring pesticides and veterinary medicines to be registered before sale. The determination of maximum residue limits (MRLs) for pesticides and veterinary medicines for use in Australia commenced in 1961. (The MRL is the maximum concentration of a residue resulting from the registered use of an agricultural or veterinary chemical that is legally permitted or recognised as acceptable in or on food.) In 2006, Australia aligned with international practice when the APVMA decided to adopt the Joint FAO/WHO Expert Committee on Food Additives (JECFA) approach for determining MRLs for veterinary medicines.

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. Four experts participated in the meeting as independent expert advisers: Dr Dieter Arnold from Germany, Professor Alan Boobis from the United Kingdom, Dr Art Craigmill from the United States and Emeritus Professor Jock McLean from Australia. All are internationally renowned for their expertise in the fields of toxicology and/or residues of veterinary medicines in animal-derived foods.

Animal Medicines Australia Limited (formerly Animal Health Alliance [Australia]) and the Veterinary Manufacturers and Distributors Association were invited to lodge submissions for consideration by the experts; one submission was received. In addition, representatives of four animal health companies accepted invitations from the APVMA to discuss their concerns relating to the current Australian system directly with the panel.

The visiting experts made recommendations aimed at strengthening the APVMA's evaluation of veterinary medicine residues. The recommendations involve four areas: workflows, evaluating risk, communicating risk, and resources. A report describing the meeting's conclusions and recommendations will be published in 2014–15.

During their visit, the experts also presented a training session to staff from the APVMA, the Office of Chemical Safety and Food Standards Australia New Zealand. The training addressed issues at the cutting edge of toxicology and residues of veterinary medicines in food, including physiological-based pharmacokinetics, population pharmacokinetics, and a new approach for assessing dietary exposure to veterinary medicines in food, as trialled at the 78th meeting of JECFA held in November 2013.

Implementation of the recommendations and the training will assist the APVMA as it strives for best practice in the evaluation of veterinary medicine residues in food.

CONTINUOUS IMPROVEMENT OF RISK MANAGEMENT FRAMEWORKS UNDERPINNING DECISION-MAKING

Performance measures	Progress
Research undertaken into best-practice risk management approaches by science-based regulators	Ongoing
Risk assessment practices and procedures reviewed to ensure best practice	Ongoing

The APVMA contributed to a Food Standards Australia New Zealand workshop on risk management, at which each agency considered regulatory approaches to the management of risk.

The United States Environmental Protection Agency 2012 crop re-entry calculator (for safe re-entry of workers into pesticide-treated crops) was assessed for its validity to Australian pesticide use situations; it was deemed suitable to replace the previous re-entry calculator (the 2000 version).

Also in 2013–14, international experts reviewed the APVMA's application of the JECFA approach for determining MRLs for veterinary medicines (see case study above).

HIGHLIGHTS

of APVMA risk management research

Environmental exposure modelling

We have continued work on a project to develop catchment-specific environmental exposure methods.

Traditionally, simple models have been used to estimate pesticide levels that might occur in water bodies as a result of run-off or spray drift. In recent years, Australian state government agencies have made catchment-specific environmental datasets (rainfall, stream and river flows, landform slopes, etc.) freely available on the internet. It is now possible to use these data to conduct more complex regulatory environmental risk assessments that better reflect real-world conditions.

To develop these assessment methods, we have compiled datasets and developed methodology for run-off risk calculations and buffer zone determinations for pesticide use in dryland cropping regions of Australia. The methodology has been discussed with the Australian Government Department of the Environment, and with state and territory representatives on the Registration Liaison Committee. The next step is to publish the methodology on our website and seek comment from the regulated industry and the public on technical issues, before considering further development of the methodology as a regulatory tool in environmental risk assessment.

Pesticide Handler Exposure Database

We are investigating ways to better estimate exposure of workers when they handle and use pesticides. The aim of this project is to improve estimates of exposure of pesticide users when actual exposure data are not available from measurements made during a scientific trial.

The Office of Chemical Safety (OCS) in the Australian Government Department of Health (which conducts public and work health and safety assessments on pesticides and veterinary medicines for the APVMA) uses a database called P-HED (Pesticide Handler Exposure Database) to estimate worker exposure to pesticides for a range of mixing and application practices. A United States taskforce is currently measuring dermal and inhalation exposure of agricultural workers applying pesticides by different methods to a range of crops. Once generated, these new data will replace or extend older datasets in P-HED in an exposure dataset called the Agricultural Handler Exposure Database (A-HED).

The Chief Regulatory Scientist, Pesticides, has been liaising with representatives of the chemical crop protection industry to work out the best way for the Australian regulatory system to access and use proprietary data in A-HED as the data become available.

Crop re-entry calculator

We are updating the re-entry calculator for workers re-entering pesticide-treated crops.

The OCS has been using the 2000 version of the United States Environmental Protection Agency re-entry risk calculator to estimate the likely transfer of pesticides from sprayed crops to workers re-entering the crop. An updated version of the calculator was published in 2012.

We have reviewed the changes made in the calculator and established its suitability for Australian use, and chemical registrants are now submitting re-entry calculations based on the 2012 calculator.

STRATEGY 3—IDENTIFY AND RECONSIDER EXISTING CHEMICALS OF REGULATORY CONCERN

We review existing chemicals to assess any new information that raises concerns about the use of the chemicals, and take regulatory action to mitigate identified risks.

MONITOR REGULATORY AND SCIENTIFIC DEVELOPMENTS AND ADVERSE EXPERIENCES, AND INITIATE REVIEWS WHEN WARRANTED

Performance measures	Progress
Issues identified and considered; responses developed and reported as needed	Achieved
Annual summary of adverse experience reports published	Not achieved

In 2013–14, we have researched and liaised with other regulatory agencies about a range of current issues (see 'Highlights of APMVA research').

Adverse Experience Reporting Program

The APVMA's Adverse Experience Reporting Program (AERP) assesses reports of adverse events associated with registered pesticides or veterinary medicines when used according to the approved label directions. An adverse event can be any undesirable experience—such as damage to human or animal health, or the environment—that arises from the use of the chemical. The AERP facilitates regulatory action that may be necessary to ensure the continued safety, quality and effectiveness of registered products. The AERP has two components: the AERP Vet for registered veterinary medicines and the AERP Ag for registered agricultural chemicals.

Under s. 161 of the Agvet Code, product registrants have a legal obligation to report to the APVMA any adverse events from the use of their registered product. In addition, anyone can voluntarily report an adverse experience to the APVMA, including veterinarians, animal owners, farmers, gardeners, agronomists, health workers, state and territory authorities, and members of the public.

The AERP assesses and classifies adverse experience reports relating to:

- human health, including users or members of the public
- animal health
- nontarget crop or plant damage
- lack of efficacy
- residue violations
- environmental damage.

HIGHLIGHTS

of APVMA research

Neonicotinoid insecticides and bees

A regulatory stakeholder workshop—to consider bee protection goals, testing requirements for insecticides with respect to possible effects on bees, and label warnings and use instructions—was held at the APVMA on 24 July 2013. Following this workshop and consultation with a range of stakeholders, we completed a review of the use of neonicotinoid insecticides in Australia and whether they present more of a risk to bee health than other pesticides. This review was published on our website on 19 February 2014 (archive.apvma.gov.au/news_media/chemicals/bee_and_neonicotinoids.php). It summarised the current state of research on neonicotinoids and their regulatory status in other jurisdictions, made recommendations to increase our understanding of bee health issues in Australia and reduce the risks to bees from the use of these insecticides, and outlined options available to the APVMA if new information suggests that further regulatory action to reduce the environmental risks of neonicotinoids is warranted.

Following publication of this report, the Chief Regulatory Scientist, Pesticides, and the Chief Executive Officer were invited to appear before the Canadian Senate's Standing Committee on Agriculture and Forestry, which is examining the importance of bees and bee health in the production of honey, food and seed in Canada. This took place via a video link on 7 May 2014.

A national symposium, Neonicotinoids and Other Insecticides: Research and Stewardship, was held on 9 April 2014. This symposium was initiated by the APVMA and organised by Plant Health Australia (PHA), with sponsorship from the APVMA, the Grains Research and Development Corporation, and the Rural Industries Research and Development Corporation. Speaker presentations were published on the PHA website (planthealthaustralia.com.au/about-us/events/neonicotinoids-and-other-insecticides).

Endocrine-disrupting chemicals

The subject of endocrine-disrupting chemicals and their regulation is a contested area of regulatory science, and the APVMA is conducting an ongoing investigation into the regulation of these chemicals.

A successful symposium, Endocrine-Disrupting Chemicals: Science and Regulation, was held in Canberra on 16 October 2013. The scientific program, which included national and international speakers, was largely organised by the APVMA's Chief Regulatory Scientist, Pesticides, with input from members of the Regulatory Science Network. The symposium was well attended, with participants from government regulatory agencies, consultancy firms, universities and the agvet chemical industry. Speaker presentations were published on the Australasian College of Toxicology and Risk Assessment website.

Glyphosate and birth defects

A 2011 review published by Earth Open Source (EOS), a not-for-profit organisation, asserted that the herbicide glyphosate shows reproductive and developmental toxicity at concentrations lower than those used in studies compliant with standards of the Organisation for Economic Co-operation and Development and good laboratory practice standards, as assessed by various regulatory agencies worldwide. In addition, it was suggested that glyphosate has genotoxic, carcinogenic, neurotoxic and endocrine-disrupting potential. On 6 August 2013, we published a detailed review of the EOS report, relevant archived data and new studies (archive.apvma.gov.au/news_media/chemicals/glyphosate.php). The available evidence suggests that glyphosate products are safe to use and that there is no risk from residues in foodstuffs.

The APVMA may take various actions in response to its assessment and classification of an adverse experience report. These actions include:

- suspending and/or cancelling the registration of a product
- amending the conditions of a product registration, such as requiring changes to label instructions or warnings
- reviewing the active constituent of a product under the APVMA's Chemical Review Program
- referring the matter to state control-of-use authorities for action
- undertaking educational and promotional activities.

In 2013–14, we assessed and classified 2138 reports of suspected adverse experiences relating to pesticides and veterinary medicines:

- AERP Ag—We assessed 74 adverse experience reports relating to pesticides; 38 per cent involved impacts on crops or target areas, 3 per cent involved lack of effect, 5 per cent involved environmental or nontarget effects, and 54 per cent involved human health issues.
- AERP Vet—We assessed 2064 adverse experience reports relating to veterinary medicines; 81 per cent involved animal safety, 15 per cent involved lack of efficacy and 4 per cent involved human health issues. Numerous enquiries were also received from veterinarians and members of the public.

Based on these reports and assessments, the AERP provided feedback to various areas of the APVMA and relevant state agencies to assist them in making compliance, quality assurance, registration, review and licensing decisions. In 2013–14, no adverse experience reports required significant regulatory action.

We also launched a new online reporting system to facilitate more effective reporting by stakeholders. This upgrade has improved our data-gathering potential, the quality of reports and user satisfaction.

SELECT AND TAKE ACTION ON REGISTERED CHEMICALS WHEN CONCERNS ARE IDENTIFIED AND VALIDATED BY THE APVMA

Performance measures	Progress
At least six chemical review decisions completed	Achieved
Number of Adverse Experience Reporting Program reports requiring significant regulatory action less than 1%	Achieved
99% compliance with maximum residue limits of agvet chemicals in food commodities (as reported in the National Residue Survey)	Achieved

Regulatory decisions

The APVMA has the authority to reconsider approved active constituents (the component of the pesticide or veterinary medicine product that is responsible for its physiological or pharmacological action), registered products or labels if credible new data suggest that current use may pose previously unknown risks to human health, animal or crop

safety, the environment or trade, or suggest product ineffectiveness. If this happens, the APVMA can initiate a reconsideration process to assess the identified risk and determine whether changes are needed to ensure that the product can continue to be used safely and effectively. Chemicals prioritised for review are listed in the priority candidate review list (apvma.gov.au/node/10876). The possible regulatory decisions at the completion of a review are no changes (affirmation), changes to approval or registration (variation), or no further approval or registration (cancellation).

The APVMA undertook 438 regulatory actions following chemical reviews in 2013–14. These were:

- affirm active constituent approvals (0)
- cancel active constituent approvals (2)
- affirm product registrations (0)
- cancel product registrations (11)
- vary label approvals (222)
- cancel product labels (203).

The APVMA also has the authority to suspend registrations or approvals for a specified period. Instructions for use 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 time frames. In 2013–14, 117 regulatory decisions were made. These were:

- suspend active constituent approvals (4)
- continue active constituent approval suspensions (1)
- revoke active constituent approval suspensions (1)
- suspend product registration (2)
- continue product registration suspensions (34)
- revoke product registration suspensions (10)
- suspend product labels (0)
- continue product label suspensions (56)
- revoke product label suspensions (9).

Chemical review outcomes

The outcomes of chemical reviews in 2013–14 include the following:

- 2,4-D high-volatile esters (HVE)—In August 2013, the APVMA cancelled selected 2,4-D HVE active constituent approvals, product registrations and associated label approvals (2 active constituent approval cancellations, 4 active constituent approval suspensions, 14 active constituent approval voluntary cancellations, revocation of the suspension of 1 active constituent approval, 11 product registration cancellations, 82 label approval cancellations, 111 new product label approvals). This completed part 1 of the review of 2,4-D following the publication in July 2013 of the annex to the APVMA's *Preliminary review findings (environment) part 1: 2,4-D esters volume 1: review summary*.

- Diazinon—In October 2013, the APVMA suspended the registration of the product Southern Cross Gold OP Spray-on Off-Shears Sheep Lice Treatment and its associated label approval.
- Dichlorvos—In September 2013, the APVMA revoked the suspension of one product for the purpose of approving a new label as part of an application to vary the instructions for use of the product. The new label is consistent with the regulatory decisions made in the dichlorvos final review report and regulatory decision, published in March 2011. In October 2013, the APVMA continued the suspension of the registrations and label approvals of six dichlorvos products used for grain protection.
- Dimethoate—In September 2013, the suspension of certain dimethoate products was continued until 5 October 2014 (continuation of 16 product registration suspensions, continuation of 48 label approval suspensions, revocation of 9 product registration suspensions, 9 new product label approvals, 27 label approval cancellations, 3 voluntary label approval cancellations).
- Fenthion—In October 2013, the suspension of fenthion home garden and horticultural products and labels was continued until October 2014. In May 2014, the fenthion preliminary review findings were published for a three-month public consultation phase, along with the environmental, updated work health and safety, and veterinary residues assessment reports.
- Molinate—In January 2014, the APVMA released the molinate preliminary review findings report for a three-month public consultation phase.
- Sheep ectoparasiticides (multiple active constituents)—In June 2014, the APVMA published the review findings report for sheep ectoparasiticides and finalised the review (94 product label approval cancellations, 94 new product label approvals).

Other chemical outcomes include:

- Naphthalene—In 2013–14, the registration of one mothball product containing naphthalene and its accompanying label were voluntarily cancelled.
- Quintozene—In 2013–14, the suspension of 1 quintozene active constituent approval and 10 product registrations was continued, pending the provision of chemistry data on the concentration of dioxins in the active constituent.

Ongoing reviews

Nineteen chemicals remain under review:

- 2,4-D low-volatile esters
- chlorpyrifos
- diazinon
- dimethoate
- diquat
- fenamiphos
- fenitrothion
- fenthion
- fipronil

- macrolide antibiotics
- maldison (malathion)
- methidathion
- methiocarb
- molinate
- neomycin
- omethoate
- paraquat
- polihexanide
- procymidone.

Maximum residue limits of agvet chemicals in food commodities

The Portfolio Budget Statement target of 99 per cent compliance with MRLs in food commodities for pesticides and veterinary medicines has been achieved. Compliance is monitored and reported by the National Residue Survey section of the Australian Government Department of Agriculture.

In 2013–14, we evaluated pesticide residue data for 37 applications for product registration and 130 applications for permits. Including variations resulting from chemical review activity, we made 698 variations to the APVMA MRL standard. For veterinary medicines, we evaluated residue data for 13 applications for product registration and 4 applications for permits. We made 4 variations to the APVMA MRL standard. We also made 12 amendments to the Australia New Zealand Food Standards Code, resulting in 436 MRL variations, 310 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 2013–14, we provided information to Japanese authorities regarding MRLs for 16 pesticides and veterinary medicines.

INFORM STAKEHOLDERS OF REGULATORY ACTIVITY ON REGISTERED CHEMICALS

Performance measures	Progress
Participation in, or delivery of, review-related stakeholder forums	Achieved

It is important that we communicate with the chemical industry and chemical users about our decision-making, both to ensure that they are up to date with any changes and to receive input to our decisions. In 2013–14, we conducted an extensive program of stakeholder engagement:

- July 2013—We held various stakeholder meetings to discuss the 2,4-D review and particularly the issue around dioxins; stakeholders included CropLife, the National Farmers' Federation and product registrants.

- September 2013—The Chemical Review Manager gave a presentation to the NSW Groundsprayers Association annual conference in Dubbo on the Chemical Review Program and the AERP.
- October 2013—The Registration Liaison Committee was updated on the latest developments within the Chemical Review Program. A specific update was provided on the progress of the fenthion review, including the proposed extension of the current suspension, removal of use of fenthion on stone fruit (with the exception of cherries, plums and nectarines) and changes to withholding periods in light of new residues data.
- October 2013—The Chemical Review Manager gave a presentation at a workshop on consumer product risk assessment that was organised by the Australian Competition and Consumer Commission. The presentation focused on the risk analysis tools used in the postmarket surveillance of pesticides and veterinary medicines, and covered chemical review, the AERP and compliance.
- October 2013—We held teleconferences with grower groups regarding the continuation of the suspension of certain fenthion products and the removal of uses on stone fruit.
- January 2014—We met with approval holders and product registrants to discuss the paraquat review.
- February and March 2014—We met with stakeholders to discuss the molinate review.
- February 2014—We met with approval holders and product registrants to discuss the maldison review.
- February 2014—The Chemical Review Manager gave a presentation to a ChemCert accreditation workshop in Port Macquarie.
- March 2014—Staff from the chemical review team gave a presentation on chemical reviews at the Pesticide Working Group Meeting in Townsville.

MORE PROACTIVE PLANNING OF CHEMICAL REVIEWS

Performance measures	Progress
Work plans developed and published for chemicals under review, from January 2014	Deferred

Because of the significant number of active reviews that the APVMA is progressing, we did not start any new reviews in 2013–14. We will prepare work plans for any new reviews started after 1 July 2014.

Transitional arrangements in place until the end of 2014–15 will require the preparation of work plans for any of the above active chemical reviews that have not been completed by 1 July 2015. States and territories are being updated each quarter on the progress and estimated milestone completion periods for all active chemical reviews.

STRATEGY 4—IDENTIFY AND RESOLVE NONCOMPLIANCE

Noncompliance with the *Agricultural and Veterinary Chemicals Code Act 1994* 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.

All reports and detections of potential breaches of the agvet legislation are subject to an initial assessment to ascertain their priority for further compliance and enforcement action. This assessment typically includes a preliminary examination and analysis of the noncompliance report or allegation to determine the likelihood that a breach of the legislation has occurred, and to assess its seriousness and likely consequences. If possible, the APVMA acts to prevent noncompliance and encourage ongoing and future compliance.

Based on the outcome of the initial assessment and the legislation, we determine the appropriate level of intervention, if any. Depending on the results of the initial assessment, we may elect to:

- not pursue the matter further
- seek more information from the person or company that reported the noncompliance, as well as the marketplace or the entity that the noncompliance report relates to
- proceed with a detailed investigative action.

IMPLEMENT A RISK-BASED STRATEGY FOR COMPLIANCE

Performance measures	Progress
Strategy developed by June 2014	Achieved
New powers from reforms ready to implement	Achieved
Intelligence-led approach integrated into compliance activities by December 2013	Achieved

The APVMA has been preparing for administration of a significantly different compliance and enforcement regime as part of the legislative reforms. Our risk-based strategy to compliance and enforcement was developed as part of the new regulatory guidelines, and launched with their publication in January 2014.

In 2013–14, we developed the regulatory guidelines and guidance materials for our staff, and delivered training to ensure that all APVMA inspectors are ready to deliver our risk-based compliance strategy (see 'Embed revised APVMA regulatory guidelines into APVMA systems and processes' in Strategy 1).

See 'Support Department of Agriculture initiatives on quality assurance of imported chemicals' in Strategy 5 for a report on the APVMA Agrochemical Intelligence Project.

MANAGE OUR SYSTEMS, PRACTICES AND PROCEDURES TO SUPPORT A PROACTIVE COMPLIANCE AND ENFORCEMENT REGIME

Performance measures	Progress
90% of consents to import processed within 14 days of receipt	Achieved
Upgrade of compliance systems completed by December 2013	Achieved
Permit audit strategy developed and implemented by June 2014	Achieved

Consents to import unregistered or unapproved chemicals may be issued by the APVMA when a legitimate reason exists for a person or a company to have possession of the chemicals in Australia. Common reasons for needing to import unregistered chemical products include for research or chemical trials, and for special veterinary applications such as in zoos. In 2013–14, we assessed 777 applications and issued 739 consents to import. Of these, 526 were issued to allow importation for use under an APVMA small-scale trial permit, 71 were associated with specific permit applications, four were issued for products pending registration, 138 were issued to veterinarians, and 42 were either not approved or found to be unnecessary.

In 2013–14, 95 per cent of applications were processed (issued) within 14 days of receipt. The average time taken to issue consent was five days.

Following testing of a new case management system last year, all compliance administrative and case work is now managed within the new APVMA electronic document and records management system (see 'Support provision of high-quality applications' in Strategy 2).

Permit audits now form part of our risk-based compliance strategy. Audits help to evaluate whether APVMA-imposed conditions are effective in their role of protecting human and animal health, agriculture, the environment and trade. In 2013–14, we developed communication materials and internal guidance documents for the conduct of compliance audits; these are available on our website (apvma.gov.au/node/11021). We undertook four audits to check compliance with APVMA-issued permits. Our initial focus was on permits issued within the previous 12 months. Audits were desk based and involved examination of documentary information. The audit process informs us about the level of compliance with APVMA conditions, the quality of our conditions with regard to ease of comprehension and enforceability, and the systems in place to measure and improve regulatory compliance.

All APVMA investigative staff hold qualifications and have relevant work experience that accords with the Australian Government Investigations Standards (2011). In 2013–14, two staff members completed a Certificate IV in statutory compliance qualification. Compliance staff also attended training in administrative law and interviewing techniques.

TARGET COMMUNICATION ACTIVITIES TO SIGNIFICANT EMERGING NONCOMPLIANCE ISSUES

Performance measures	Progress
A new communication strategy finalised by September 2013 and activities delivered according to the strategy	Achieved
Increased stakeholder awareness of identified issues	Achieved

In 2013–14, we prepared a communication strategy about how we will inform industry and the general public about what is required to comply with the requirements of the Agvet Code. A key part of the strategy involves the proactive use of information activities, to disseminate information to industry members and the community.

We monitor allegations of noncompliance to determine where campaign responses may be appropriate, looking at the number of complaints received about a particular product type or activity, and the number of noncompliant entities that are likely to be engaging in that behaviour. Our monitoring of the market (the physical market and internet trade) provides supporting data to guide these activities.

In 2013–14, we took numerous opportunities to raise awareness of the work that we do. Staff made presentations to foreign visitors, industry and overseas regulators. We also worked with our co-regulators in the fields of environment and health, undertaking site inspections, product recalls and enforcement actions.

We updated publicly available information to assist stakeholders to comply with current and new legislation. We clarified the ongoing responsibilities of parties who hold approvals, registrations, permits and licences, as part of the information about legislative reforms (apvma.gov.au/node/67). We also provided updated information about permit auditing and updated advice about our response to advertising complaints.

IMPROVE VOLUNTARY COMPLIANCE AND DETER NONCOMPLIANCE

Performance measures	Progress
Establish baseline level awareness of compliance responsibilities by December 2013 as the basis of future surveys	Deferred

Our implementation activities associated with the legislative reforms that commence on 1 July 2014 included information on the compliance responsibilities of product registrants. We deferred our intended baseline survey of registrants' awareness to align with the start of the new legislation, to obtain a more meaningful baseline result that could be used over a number of years.

UNDERTAKE EFFECTIVE RISK-BASED ENFORCEMENT

Performance measures	Progress
100% of allegations of noncompliance risk-assessed and prioritised	Achieved
100% of identified high-priority allegations investigated	Achieved
Field investigations validate accuracy of risk assessment and prioritisation process	Ongoing
Six significant regulatory actions undertaken due to noncompliance with registration requirements	Five undertaken

Matters are risk-assessed upon receipt. Risk assessments may be reviewed throughout investigation of a matter as further information becomes available.

In 2013–14, we received 243 reports of alleged noncompliance and continued to investigate a number of cases from 2012–13. We finalised 156 allegations and 9 recall events. One brief of evidence has been submitted and accepted for prosecution by the Commonwealth Director of Public Prosecutions. This matter is currently before the courts and is not expected to conclude until later in 2014. At the close of business on 30 June 2014, 62 matters remained subject to compliance action, and 6 voluntary recalls were in progress.

In early 2013–14, the APVMA finalised monitoring of a voluntary recall of an unregistered insecticide product that was being distributed nationally through two major retailers. The APVMA negotiated for the removal of the product from retail sale with the supplier of the product. The two retailers ensured the removal of approximately 1300 packets of this unregistered chemical product from about 230 stores nationally.

In early 2014, we assisted the Australian Customs and Border Protection Service in Perth to identify of a chemical substance suspected of being an agricultural chemical product. The chemical product had been detected during routine Customs screening, and there was concern that it may pose safety risks if delivered to the importer. The substance was described by the importer as a luminous powder or pigment, which originated from China. The APVMA sampled the substance and submitted it for testing, the results of which indicated that it was not an agricultural chemical product and did not pose a safety risk. As a result, Customs released the chemical substance to the importer.

In mid-2014, an APVMA inspector participated in a major operation with the Western Australian Police, the Australian Federal Police and other law enforcement authorities. Although no contraventions of the agvet laws were detected, our inspector provided assistance and advice in relation to chemical products stored at various premises.

The APVMA also continued to build its intelligence links with other national and international regulators. In response to information about the potential importation of an unregistered agricultural chemical, the APVMA issued an information notice to other government regulators, resulting in information being obtained that is assisting further enquiries.

In 2013–14, the APVMA undertook a number of field inspections relating to alleged contraventions of the agvet laws. Inspectors used these opportunities to provide up-to-date information about the agvet reforms to the various people with whom they engaged.

An APVMA good manufacturing practice (GMP) audit led to concerns that some manufacturing steps were being performed by a third party who did not hold an APVMA manufacturing licence. Monitoring visits were conducted to review documentation at all involved premises. This led to the recommendation for a further audit of the APVMA licence holder and compliance action with respect to the third party.

In late 2013, the APVMA undertook Operation Catch, a nationwide sampling of 2,4-D chemical products and active constituents from formulators, manufacturers and retail stores. Field teams were directed to specific sites to conduct sampling based on analysis of available intelligence. Analysis focused on examination of active levels in chemical products and the presence of dioxin impurities. Samples were analysed at the National Measurement Institute. As a result of the targeted sampling, 48 samples relating to 28 products and 8 approved active constituents were analysed. Records were also requested from approval holders and registrants. The results were provided to the Chemical Review Program in support of the current review of 2,4-D.

UNDERTAKE EFFECTIVE INSPECTION, AUDITING AND ENFORCEMENT ACTIVITIES FOR GOOD MANUFACTURING PRACTICE AND THE MANUFACTURERS' LICENSING SCHEME

Performance measures	Progress
100% of GMP noncompliance assessed and prioritised	Achieved

The Manufacturers' Licensing Scheme was established 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 APVMA-prescribed manufacturing standards, including the *Australian code of good manufacturing practice for veterinary chemical products*.

We authorise auditors, including auditors from other specified authorities (in particular, the Therapeutic Goods Administration—TGA), to periodically audit manufacturers to confirm compliance with APVMA guidelines.

Registrants of veterinary medicine products manufactured overseas must provide assurance that their products comply with manufacturing standards that are comparable to the APVMA GMP requirements applying to Australian-based manufacturers. We recognise certificates 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.

In 2013–14, APVMA-authorised auditors conducted 103 audits of licensed Australian veterinary manufacturers, meeting the annual target of 100–110 for combined APVMA and TGA audits. The TGA conducted 29 of these audits on behalf of the APVMA. APVMA-authorised auditors conducted 27 audits of foreign manufacturers who manufacture veterinary medicines for the Australian marketplace. We reviewed all audit reports, monitored progress with corrective actions, and finalised 149 audits after corrective actions were deemed satisfactory.

Evidence of GMP compliance was assessed as part of the product registration process for 755 manufacturing sites. This is an increase of 15 per cent from the previous year, and an increase of 50 per cent from 2011–12. As at 30 June 2014, 204 veterinary manufacturers were licensed by the APVMA or had applications pending, which is comparable to recent years. Single-step manufacturers represented the largest percentage of manufacturers by category of product (Table 5).

Table 5 Veterinary manufacturers licensed or being assessed for a licence, by category, as at 30 June 2014

Category	Percentage of manufacturers
Category 1: Sterile and immunobiological products	40
Category 2: Nonsterile medicines other than categories 3 and 4	64
Category 3: Ectoparasiticides	6
Category 4: Feed supplements and premixes	20
Category 6: Single-step manufacturers (including packaging and labelling, analysis and testing)	74

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

We impose conditions on all new licences, and may vary conditions on existing licences, for veterinary medicine manufacturers to aid compliance and overcome delays in responding to identified noncompliances. In 2013–14, we issued 54 notices of intent to suspend or cancel licences, refuse applications or impose conditions for manufacturers. Annual licence fees increased on 1 July 2013, which led to a large number of notices of intent to cancel being issued for overdue fee payments.

The APVMA continued to facilitate the export of veterinary chemical products through the issue of certificates for GMP compliance. Thirty-seven export certificates were issued with the GMP compliance statement (ss. 69D and 70 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*), and five certificates were issued by the APVMA under the Mutual Recognition Agreement on Conformity Assessment between Australia and the European Community.

IMPROVE DECISION-MAKING ON THE APPLICATION OF COERCIVE POWERS THROUGH A NEW ENFORCEMENT COMMITTEE

Performance measures	Progress
Committee established and operating effectively	Achieved
Level of enforcement action considered appropriate during after-action reviews	Achieved

In 2013–14, we established an Enforcement Committee that provides senior executive oversight of critical decisions on compliance and enforcement matters. The committee enables strategic consideration of cases, promotes the effective allocation of resources, and supports a coordinated approach to compliance and enforcement across all APVMA program areas.

The committee comprises APVMA executive directors, an independent member from the National Industrial Chemicals Notification and Assessment Scheme, and representatives from the APVMA Public Affairs and Legal programs. Meetings involve consideration of minutes prepared by case officers that summarise investigative actions and recommend further actions for all compliance cases. A summary of received and closed allegations is also tabled for the committee's information. In 2013–14, the committee met six times and was consulted about 11 investigative matters for consideration; 5 matters were taken to the Enforcement Committee multiple times to ensure continuity of oversight through the life of the compliance actions.

All enforcement actions were endorsed as appropriate by the Enforcement Committee.

STRATEGY 5—IDENTIFY AND MANAGE EMERGING REGULATORY ISSUES

We proactively manage emerging regulatory issues that may affect our policies and processes. We engage with other government agencies and our international counterparts to identify emerging issues, and support our implementation of international best practice in risk assessment of pesticides and veterinary medicines.

ASSESS AND MANAGE SIGNIFICANT EMERGING REGULATORY ISSUES

Performance measures	Progress
Regulatory Strategy Group meets quarterly to identify emerging issues and oversee work to address issues	Not achieved
Effective relationships with national and international regulatory counterparts and relevant agreements in place with national and international counterparts	Achieved
Stakeholder satisfaction for issues management initiatives	Achieved

The Regulatory Strategy Group was disbanded following establishment of the Enforcement Committee and revised operation of the executive leadership team.

The APVMA currently has active working relationships with many international agencies and overseas regulators. We participate in international forums on key regulatory matters and emerging issues, and monitor regulatory actions in other jurisdictions and consider their relevance for Australia.

We work collaboratively on various international projects and activities, including:

- global joint reviews of pesticides and veterinary medicines
- expert meetings such as the Codex Alimentarius Commission, the Organisation for Economic Co-operation and Development, and the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products)
- developing international standards through participation in expert committees, such as the FAO/WHO Joint Meeting on Pesticide Residues and JECFA (on veterinary drugs)
- treaty-related activities under the Mutual Recognition Agreement on Conformity Assessment between Australia and the European Community
- Stockholm and Rotterdam international treaty obligations (through providing advice to the Australian Government Department of Agriculture and Department of the Environment)
- international activities on development and harmonisation of data requirements, risk assessment methodologies and risk management approaches, such as the VICH
- regional capacity building and training on compliance, risk assessment and registration processes.

The APVMA has memoranda of understanding with global regulatory counterparts, including:

- United States Food and Drug Administration
- European Commission
- New Zealand Ministry for Primary Industries
- New Zealand Food Safety Authority
- Pest Management Regulatory Agency in Health Canada
- Taiwan Food and Drug Administration
- Veterinary Drugs Directorate of the Veterinary Program of Health Canada
- United Kingdom Veterinary Medicines Directorate
- United Kingdom Chemicals Regulation Directorate.

The chief regulatory scientists also maintain contact with regulatory staff in the United States Environmental Protection Agency, the United States Food and Drug Administration's Centre for Veterinary Medicine, the European Quality Nano Regulatory Expert Group, the Canadian Pest Management Regulatory Agency, the European Medicines Agency, the German Federal Institute for Risk Assessment, and the New Zealand Environmental Protection Authority.

We received a number of international visits in 2013–14, including:

- international experts from Germany, the United Kingdom and the United States for the review of the APVMA's use of the JECFA approach to recommending MRLs for veterinary medicines (10–11 December 2013)
- an Indian delegation from the Department of Animal Husbandry, Dairying and Fisheries to discuss the APVMA's GMP compliance assessment schemes (15 January 2014)
- a representative from ASTM International (previously known as the American Society for Testing and Materials) to discuss the assessment of adjuvants for spray drift reduction (5 May 2014).

APVMA executive and staff participated in a range of national and international conferences and meetings (Table 6).

In 2013–14, the APVMA pursued a range of issues management initiatives. Many of these are outlined elsewhere in this report (eg legislative reform in Strategy 1, chemical review outcomes in Strategy 3). We engaged with stakeholders to ensure that their views were considered in regulatory decision-making.

Table 6 Conferences and meetings, 2013–14

Date	Event and location	Presentation or participation	Who
6–8 August 2013	5-day series of government and public meetings, Taiwan	Presented 'The APVMA's approach and management solutions for minor uses', at the invitation of the China Productivity Centre and the Chinese Bureau of Animal and Plant Health Inspection and Quarantine	Manager, Minor Use Pesticides
24–30 August 2013	Codex Committee on Residues of Veterinary Drugs in Food, United States	Participated	Manager, Residues Veterinary Medicines
27 August 2013	University of Sydney, Sydney	Presented 'Chemical residues in food production animals' (two lectures)	Chief Regulatory Scientist, Veterinary Medicines
2 September 2013	University of Adelaide, Adelaide	Presented 'Residues of veterinary drugs'	Chief Regulatory Scientist, Veterinary Medicines
12 September 2013	7th Annual Conference of the Society for Risk Analysis, Canberra	Presented 'Finding common ground: establishment of a Regulatory Science Network'	Chief Regulatory Scientist, Veterinary Medicines
17–26 September 2013	WHO/FAO JMPR Residues and Toxicology panels, Geneva, Switzerland	Participated	Manager, Chemical Review; Senior Evaluator, Pesticides Residues
4 October 2013	Charles Sturt University, Wagga Wagga	Presented 'Chemical residues in foods of animal origin' (two lectures)	Chief Regulatory Scientist, Veterinary Medicines
7–11 October 2013	OECD Registration Steering Group and Risk Reduction Steering Group Joint Meeting, Paris	Participated	Executive Director, Pesticides; Manager, Minor Use Pesticides
16 October 2013	Endocrine-Disrupting Chemicals: Science and Regulation, Canberra	Presented the introductory talk and chaired the meeting	Chief Regulatory Scientist, Pesticides
24–25 October 2013	1st Frontier Industrial Forum, China	Chaired 'Frontier of nanoscience and nanotechnology'; presented 'Nanopesticides and veterinary nanomedicines —the possibilities and challenges'	Chief Regulatory Scientist, Veterinary Medicines
10–15 November 2013	29th VICH Steering Committee meeting, Auckland	Participated	Executive Director, Veterinary Medicines

Date	Event and location	Presentation or participation	Who
19 November 2013	PharmPro Production Group, Sydney	Presented 'Reform update and scheduling audits'	Manager, Manufacturing Quality and Licensing
26 November 2013	Regulatory Science Network: Science Communication Symposium, Canberra	Chair and introductory speaker	Chief Regulatory Scientist, Veterinary Medicines
		Presented on communicating science at the APVMA	Chief Regulatory Scientist, Pesticides
19 March 2014	Pet Food Industry Association of Australia General Meeting, Canberra	Presented 'APVMA auditing and AS 5812'	Manager, Manufacturing Quality and Licensing
1 April 2014	Biopesticides Working Group, Paris	Participated	CEO; Executive Director, Pesticides
2 April 2014	Feed Ingredients and Additives Association of Australia General Meeting, Canberra	Presented 'Manufacturing standards required by FIAAA, FAMI-QS and the APVMA'	Manager, Manufacturing Quality and Licensing
2–3 April 2014	OECD Working Group on Pesticides, Paris	Participated	CEO; Executive Director, Pesticides
9 April 2014	Neonicotinoids and Other Insecticides: Research and Stewardship Symposium	Presented 'Risks to bees from neonicotinoid insecticides'	Chief Regulatory Scientist, Pesticides
5–10 May 2014	46th Codex Committee on Pesticide Residues, China	Participated	Executive Director, Pesticides
7 May 2014	Canadian Senate Standing Committee on Agriculture and Forestry	Questioned in regard to bee health and the use of neonicotinoid insecticides in Australia	Chief Regulatory Scientist, Pesticides; CEO
20 June 2014	FSANZ Workshop on Risk Management	Participated and presented 'Approaches to risk management at the APVMA'	Chief Regulatory Scientist, Pesticides
23–27 June 2014	30th VICH Steering Committee meeting, Brussels	Participated	Executive Director, Veterinary Medicines

CEO = Chief Executive Officer; FAO = Food and Agriculture Organization of the United Nations; FSANZ = Food Standards Australia New Zealand; JMPR = Joint Meeting on Pesticide Residues; OECD = Organisation for Economic Co-operation and Development; VICH = International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; WHO = World Health Organization

CONTRIBUTE TO HIGH-LEVEL FORUMS RELATING TO REGULATION OF AGRICULTURAL AND VETERINARY CHEMICALS

Performance measures	Progress
Contributions made to the Regulatory Science Network, the Regulators' Forum, the Agvet Chemical Regulation Committee and other relevant forums	Achieved

The APVMA works closely with other regulatory agencies in Australia, especially through regular meetings and activities of the Regulatory Science Network (see 'Highlight: what is the Regulatory Science Network?'). The network provides a forum at which the APVMA can hear about risk management approaches in other science-based Australian regulatory agencies. The APVMA plays a significant role in driving this initiative.

The APVMA is also active in the Regulators' Forum, which is made up of the heads of seven agencies: 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 Therapeutic Goods Administration. The forum meets quarterly, with a focus on risk assessment, workforce planning, public awareness and confidence, and addressing cross-agency issues. The APVMA Chief Executive Officer is an observer on the Agvet Chemical Regulation Committee.

As a member of the Regulatory Science Network, the APVMA participated in a Science Communication Symposium, which provided an opportunity for staff from the APVMA and other member agencies to learn from science and communication specialists about how to effectively communicate with colleagues about risk, and how to communicate regulatory science decisions to the general public (see case study).

HIGHLIGHT

What is the Regulatory Science Network?

The Regulatory Science Network (RSN), which was formed in 2011, involves scientists and technical staff from nine Australian Government agencies and departments responsible for regulating chemicals and biological agents.

What are its objectives?

The overarching objective of the RSN is to help improve the performance of Australian Government regulatory agencies by strengthening evidence-based decision-making. It seeks to do this by:

- improving the quality and consistency of regulatory science
- fostering collaboration and sharing of scientific knowledge and experience between agencies
- contributing to regulatory science issues, including regulatory science advocacy.

How are the objectives achieved?

To achieve these objectives, the RSN has:

- established a cooperative forum that provides opportunities for the sharing of information relating to regulatory science
- convened regulatory science seminars, workshops and conferences to promote staff professional development and training
- supported activities of the Regulators' Forum.

How does it operate?

Members of the RSN meet at least four times each year to plan a range of activities in accordance with the RSN Charter.

The inaugural Chair was Dr Phil Reeves (APVMA), and the Vice-Chair was Dr Paul Keese (Office of the Gene Technology Regulator). At present, the APVMA provides secretariat support and reports to the Regulators' Forum.

What has the RSN achieved to date?

Risk analysis is the cornerstone of regulatory decisions and provides a unifying theme for RSN activities, which include:

- a series of joint agency seminars
- four interagency workshops on risk analysis, risk communication and nanotechnology
- a symposium on Assessing Emerging Chemical and Biological Risks for the 2012 World Congress on Risk in Sydney
- a presentation to the 2013 conference of the Society for Risk Analysis—Australia and New Zealand.

Who are the members?

- APVMA, Australian Government Department of Agriculture and Department of the Environment, Australian Radiation Protection and Nuclear Safety Agency, Food Standards Australia New Zealand, National Industrial Chemicals Notification and Assessment Scheme, Office of Chemicals Safety, Office of the Gene Technology Regulator, Therapeutic Goods Administration.

CASE STUDY

Regulatory Science Network's Science Communication Symposium

In 2013, staff within the Regulatory Science Network (RSN) member agencies expressed a strong desire to gain a better understanding of how to communicate regulatory science. The RSN responded by hosting a Science Communication Symposium in Canberra; 130 people from Australia and New Zealand attended the event. The symposium provided an opportunity for agency staff to learn more about science communication from both scientists and communication specialists.

One of the keynote speakers was Professor Mark Burgman from the University of Melbourne, who gave an enthralling presentation titled 'Uncertainty in expert judgement: implications for risk communication'. As a result of Professor Burgman's presentation, options are now being explored for the RSN agencies to undertake tailored training in expert group consultation and decision-making methods so that these tools might be applied to regulatory science.

The other keynote speaker was Ms Donna Edman from the Strategic Counsel, who presented 'The case for engaging: why regulatory agencies have a duty to communicate beyond technical audiences'. A key message from the presentation was that regulatory agencies that ignore the need to effectively communicate their science to external audiences do so at their peril.

Speakers and panellists—from the APVMA, the Australian Government Department of Agriculture and Department of the Environment, 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 Therapeutic Goods Administration—addressed issues relating to communication of science both within and external to regulatory agencies.

The feedback received from attendees indicated that the symposium was a resounding success.

Professor Mark Burgman

Donna Edman

Dr Phil Reeves

SUPPORT DEPARTMENT OF AGRICULTURE INITIATIVES ON QUALITY ASSURANCE OF IMPORTED CHEMICALS

Performance measures	Progress
Substandard Agrochemical Intelligence Project completed	Achieved

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

In particular, the project aimed to:

- identify risk areas, and develop a series of import risk profiles that can be used for establishing alerts for enforcement action at the border or immediately post-border
- proactively engage with international partners to reduce and restrict illegal chemical production and trade to Australia
- establish processes, tools and templates, and undertake capacity building for a new intelligence function within the APVMA.

The project is complete and a report has been prepared. The key output of the project has been the development of a methodology that will augment our ability to detect shipments of concern. A secondary project will continue to test and validate the methodology throughout 2014–15. The project reviewed a number of previous compliance case studies to identify areas of compliance concern and provide a useful picture of agrochemical supply chains.

The APVMA strengthened its intelligence-led approach to operations, such as the targeting and delivery of Operation Catch at the end of 2013 (see 'Undertake effective risk-based enforcement' in Strategy 4). We also developed a valuation-based method, based on our ongoing assessment of Customs import data.

We have increased our liaison and engagement with Australian and international partner agencies to share information relating to any known or suspected importation of illegal agricultural chemicals. International partners are also committing resources to pursuing proactive approaches to identify, reduce and restrict the illegal trade in agricultural chemicals.

All noncompliance reports are risk-assessed by the APVMA. We use information from within the APVMA and from other government agencies to inform further actions. The APVMA has put in place a range of measures to improve our ability to detect illegal chemicals.

A number of intelligence briefings for law enforcement personnel have been compiled and distributed to APVMA and partner regulatory staff. Targeted at inspectors and authorised officers, these briefings provide the current status of issues and further information to assist partner agencies to work with APVMA inspectors. Sharing of such information with partner agencies has garnered positive comments.

LEAD WORK ON IMPLICATIONS OF NANOTECHNOLOGY ON THE REGULATION OF AGRICULTURAL AND VETERINARY CHEMICALS

Performance measures	Progress
Interagency symposium held by March 2014	To be held October 2014
Report on regulatory considerations for agvet nanotechnology by June 2014	Not achieved

Nanotechnology is the manipulation of matter on an atomic or molecular scale to develop new chemical products. Nanotechnology holds enormous promise for the agricultural and animal husbandry sectors. However, there are some concerns about the potential safety risks of nanomaterials to human health and the environment. It is important, therefore, that the regulatory framework for nanopesticides and veterinary nanomedicines ensures that these materials can be responsibly introduced into Australian agriculture and animal husbandry.

The existing regulatory framework for conventional chemicals is expected to be used in the regulation of nanomaterials for the foreseeable future. Over time, however, the framework will evolve as new information on limitations in current risk assessments becomes available.

We are nearing completion of a report on regulatory considerations applicable to nanomaterials intended for use in Australian agriculture and animal husbandry. Chapters of the report address the reformed legislative environment; technical aspects, including physicochemical characteristics and manufacture; and the potential impact of nanomaterials on human health and the environment.

Consultation on a final draft report is scheduled to commence in September 2014, and will culminate at a nanotechnology symposium in late October 2014. The report (which will be available in early 2015) and symposium will heighten awareness of nanotechnology and its regulation in the agricultural and animal husbandry sectors. They represent major milestones of a project that will inform the development of a rational regulatory framework for nanopesticides and veterinary nanomedicines in Australia.

CASE STUDY

Assessing the ecological risks of nanopesticides

Nanotechnology is emerging as a useful tool in the formulation and delivery of pesticides. The novel properties of nanoparticles may deliver increased efficacy or a reduced environmental footprint, or both. However, it is currently not clear how nanopesticide behaviour and environmental impact will differ from those of conventionally formulated pesticide active ingredients. There is a need to understand the potential risks associated with nanopesticides in a harmonised and scientifically sound manner.

In late 2012, the International Union of Pure and Applied Chemistry (IUPAC) approved funding for a project to develop guiding principles for a globally harmonised ecological risk assessment methodology for nanopesticides. The APVMA subsequently contributed funds to the project, which is led by APVMA Science Fellow Dr Rai Kookana. A project team comprising representatives of regulatory agencies and international experts drawn from the agrochemical industry and academia attended a workshop at the University of York in the United Kingdom in May 2013. The APVMA is represented on the project by Dr Phil Reeves, Chief Regulatory Scientist, Veterinary Medicines.

The output of the workshop has been published in the *Journal of Agricultural and Food Chemistry*. The main focus of the paper is on assessing whether nanoformulation introduces differences in ecological risk assessments compared with conventional active ingredients. The paper also proposes changes to test methodologies and research priorities; its recommendations, if adopted, would facilitate the development of regulatory approaches and a regulatory framework for nanopesticides.

Five members of the project team, including Dr Kookana and Dr Reeves, will present the findings of the project at a symposium titled 'Fate, effects, and risks of nanopesticides' at the 13th IUPAC Congress of Pesticide Chemistry in San Francisco in August 2014. The specialist presentations and discussions during the symposium will address some of the knowledge gaps identified by the 2013 workshop in York. The work will also be considered at an APVMA symposium on nanotechnology to be held in Canberra in late 2014.

Dr Rai Kookana and Dr Phil Reeves

INVESTIGATE THE REGULATION OF ENDOCRINE-DISRUPTING CHEMICALS BY OTHER REGULATORS

Performance measures	Progress
Symposium held by October 2013	Achieved
Outcomes and APVMA response published by December 2013	Achieved

A successful symposium, Endocrine-Disrupting Chemicals: Science and Regulation, was held in Canberra on 16 October 2013 (see 'Highlights of APVMA research' in Strategy 3).

INVESTIGATE WHAT REGULATORY ACTION MAY BE REQUIRED TO PROTECT POLLINATOR HEALTH FROM USE OF AGRICULTURAL CHEMICALS

Performance measures	Progress
Workshops for regulatory stakeholders and broader stakeholder consultation held by September 2013	Achieved
Outcomes reported by December 2013	Ongoing

In 2013–14, we held a stakeholder workshop on bees and neonicotinoid insecticides (see 'Highlights of APVMA research' in Strategy 3).

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

We aim to involve stakeholders in our decision-making, and promote confidence in our processes and decisions. Our stakeholders include our regulatory partners, registrants and manufacturers of pesticides and veterinary medicines, farmers, veterinary practitioners, researchers, educators and the general public.

DEVELOP AND IMPLEMENT NEW COMMUNICATIONS STRATEGY, INCLUDING STAKEHOLDER ENGAGEMENT MODEL AND IMPLEMENTATION OF REFORMS

Performance measures	Progress
Strategy developed by September 2013 and activities undertaken in accordance with strategy	Achieved

Communication activities during 2013–14 were intensive. They focused on informing and educating industry about the legislative reforms, and assisting industry to prepare for application of the reforms.

As part of the reform communication strategy, a stakeholder engagement model was developed to inform our approach. We proactively engaged with industry and government stakeholders and our own staff to provide timely, accurate and accessible information about the reforms.

Some of the highly successful activities that were implemented for stakeholders were as follows:

- We reviewed our entire suite of regulatory guidance material to bring it into line with the new laws, and increase its accessibility and ease of use by providing it as online content. This included a period of industry consultation on the information, and testing of the online resource.
- Face-to-face information sessions were held in early 2014 in Melbourne, Adelaide, Perth, Brisbane, Sydney and Canberra. These were attended by more than 400 stakeholders, who took the opportunity to find out more about the legislative reforms.
- Two training workshops were held in Canberra in June 2014 to give practical assistance to industry before the commencement of the reforms. The workshops were attended by 190 stakeholders.

We produced regular web-based and printed information for a range of audiences. We also conducted detailed briefings, face-to-face forums and meetings to ensure that the following key stakeholders were kept informed:

- the Australian Minister for Agriculture
- the Australian Government Department of Agriculture
- partner agencies under the National Registration Scheme
- the APVMA Advisory Board
- industry representative bodies.

DEVELOP AND DEPLOY SUITABLE TOOLS AND RESOURCES TO ALLOW STAFF TO COMMUNICATE MORE CONSISTENTLY AND EFFICIENTLY WITH STAKEHOLDERS

Performance measures	Progress
Web-based content management system implemented	Achieved
New intranet in place	Achieved
Visual identity and language style guides updated	Achieved

The APVMA implemented the Drupal content management system with the launch of a new intranet in October 2013. This allows a more efficient publishing process, increased communication between staff, and more robust management of content to ensure consistency and accuracy. The same content management system has been used for the new APVMA website, which will be launched on 1 July 2014.

We updated our visual identity in 2013. Our key corporate products, including the regulatory guidelines website and the *Operational plan 2012–13*, carry the new identity. The language and style guide was updated and published in December 2013.

DEVELOP NEW CASE MANAGEMENT SYSTEM AND CLIENT SERVICE CHARTER

Performance measures	Progress
New system and charter in place by June 2014	Partly achieved

The new case management system and processes are ready for implementation on 1 July 2014 (see 'Support industry readiness to comply with new regulatory frameworks' in Strategy 1).

A new charter will be developed in line with the new client service model, which created the concept of the first point of contact. The new service charter will be developed in the first half of 2014–15.

REDEVELOP WEBSITE WITH AN ONLINE PRESENCE FOR THE RISK COMPENDIUM

Performance measures	Progress
New website launched in early 2014	Due July 2014
Website meets relevant government online and accessibility standards	Achieved

The APVMA website redevelopment project reached a key milestone on 29 January 2014 with the publication of the new website for the regulatory guidelines (previously known as the Risk Compendium). The regulatory guidelines website is a subsite of the APVMA's general website, accessible by a link from the home page (apvma.gov.au) until the launch of the new website on 1 July 2014.

The content and website for the regulatory guidelines were open for public consultation from 29 January to 11 April 2014. Submissions on the regulatory guidelines were invited to address:

- comprehensiveness—level of detail and information provided
- usability—including navigation, information design, content structure, user experience and system responsiveness
- readability—ease of reading and understanding
- errors—factual errors, grammatical/typographical errors and incorrect links.

We received 19 submissions from agricultural and veterinary medicine industry associations, chemical companies, regulatory consultants and product users. In response to these, significant improvements were made to the navigation and usability of the website, and a new version went live on 19 May 2014.

Redevelopment of the general website commenced in earnest in February 2014 with a comprehensive content audit. More than 3000 web pages and around 10 000 downloadable documents were analysed for migration, review, deletion or archive. The new website, incorporating the regulatory guidelines, will be launched on 1 July 2014.

The new website conforms substantially to the web content accessibility guidelines. Although a small number of accessibility issues are yet to be addressed, the APVMA has committed to fully conforming by December 2014.

SEEK INPUT ON STRATEGIC ISSUES FROM THE APVMA ADVISORY BOARD

Performance measures	Progress
Four Advisory Board meetings held by June 2014	Achieved

See Appendix A for details of the APVMA Advisory Board and issues considered at meetings in 2013–14.

IMPLEMENT NEW INDUSTRY CONSULTATIVE COMMITTEE ARRANGEMENTS, INCLUDING THE USE OF SPECIAL-PURPOSE WORKING GROUPS

Performance measures	Progress
At least two industry forums undertaken	Achieved
Stakeholders satisfied with consultative arrangements	Achieved

The APVMA continues to engage with industry through targeted consultation and meetings on a range of matters, including the Manufacturers' Licensing Scheme, to ensure input to APVMA corporate planning activities, and consideration of current or emerging strategic issues. We are also considering how we will approach our formalised industry consultative arrangements in the future.

We held an industry workshop for all key stakeholder groups on 29 April 2014. The main areas of focus were preparation for implementation of legislative reforms with effect from 1 July 2014 and business re-engineering to support the strategic direction of the APVMA over the next three years.

The new web-based IT systems underwent extensive testing by a small group of 'super-users', and a wider group of registrants and applicants. Feedback from these two groups provided invaluable information on the usability of the new systems, and how the new applications should be designed to most effectively support the applicants who will use the systems.

The APVMA also contributed to symposiums on neonicotinoids and endocrine-disrupting chemicals (see 'Highlights of APVMA research' in Strategy 3).

ENGAGE EFFECTIVELY WITH THE STATES AND TERRITORIES ON THE MANAGEMENT OF THE NATIONAL REGISTRATION SCHEME, INCLUDING INCREASED INVOLVEMENT OF STATES AND TERRITORIES IN CHEMICAL REVIEW PROCESSES

Performance measures	Progress
Two Registration Liaison Committee meetings held by June 2014	Achieved
Update on suspension and reconsideration activities provided to the Agvet Chemical Regulation Committee twice a year	Achieved
Risk Compendium provided to states and territories for discussion	Achieved

See Appendix B for details of the Registration Liaison Committee and matters considered at meetings in 2013–14. Committee meetings were held in October 2013 and March 2014.

The APVMA has provided quarterly updates to the Agvet Chemical Regulation Committee. These updates have included information on the progress of all active chemical reviews, including estimated timelines for the completion of component risk assessments, any suspensions or cancellations, significant stakeholder issues and review finalisation.

The draft regulatory guidelines (previously known as the Risk Compendium) were published in January 2014 to provide for a period of consultation, including with states and territories (see 'Embed revised APVMA regulatory guidelines into APVMA systems and processes' in Strategy 1).

ESTABLISH REVISED ARRANGEMENTS FOR THE PROVISION OF ADVICE FROM ADVISING AGENCIES

Performance measures	Progress
New arrangements in place by June 2014	Not achieved

The APVMA has developed a draft memorandum of understanding with partner Australian Government agencies for the provision of technical advice services; the draft is still under negotiation. The memorandum reflects a whole-of-government approach to procurement of technical and scientific advice.

In addition to developing new funding arrangements with our partner agencies, we also conducted an open tender for the provision of technical advice services to the APVMA. This has developed a pool of technical personnel from which we and our partners can draw for assistance in evaluating of applications.

WORK EFFECTIVELY WITH THE DEPARTMENT OF AGRICULTURE ON AGVET CHEMICAL ISSUES OF MUTUAL INTEREST

Performance measures	Progress
Satisfaction with level and quality of engagement	Achieved

The APVMA works collaboratively with the Australian Government Department of Agriculture to consider proposals for further reforms to the regulation of agvet chemicals, where these proposals are relevant to the roles and responsibilities of the APVMA. The APVMA has introduced a more centralised approach to engaging with the department to support the development of closer working relationships and improve consistency in the support provided.

STRATEGY 7—CONDUCT OUR BUSINESS EFFICIENTLY AND EFFECTIVELY

We aim to maintain a high standard of operation for all our business systems, including reporting, resource and financial management, and ICT. Our quality management system regularly audits the performance and processes of systems and sections to look for ways to improve them and our business performance.

In 2013–14, the APVMA commissioned a review into its internal business processes. The review canvassed a range of possible changes to our business processes, including the development of a risk-based decision framework that might allow regulatory risk to be better aligned with regulatory effort, more streamlined processes for registration and further improvements to the APVMA's internal quality assurance programs. The review's recommendations are currently being considered by APVMA management.

ENHANCE INFORMATION TECHNOLOGY SYSTEMS TO IMPROVE SERVICE DELIVERY

Performance measures	Progress
New payment module launched	Achieved
PubCRIS relaunched to cater for mobile device users	Achieved
An online annual returns submission facility developed by 30 June 2014	Ongoing
An online electronic registered label particulars facility launched by June 2014	Achieved

We developed a new web-based portal for applicants and relaunched PubCRIS (see 'Support provision of high-quality applications' in Strategy 2).

DEVELOP OR MODIFY ICT SYSTEM TO SUPPORT CHANGES REQUIRED FROM THE LEGISLATIVE AND BUSINESS REFORMS

Performance measures	Progress
Legacy ICT systems redeveloped to incorporate changes arising from reform legislation	Achieved

We have developed new systems to support legislative reforms (see 'Support provision of high-quality applications' in Strategy 2).

FINALISE THE ROLLOUT OF THE ELECTRONIC DOCUMENT AND RECORDS MANAGEMENT SYSTEM

Performance measures	Progress
APVMA-wide implementation by February 2014	Achieved

We implemented a new electronic document and records management system (see 'Support provision of high-quality applications' in Strategy 2).

COMMENCE REDEVELOPMENT OF THE APVMA'S CORE AGVET CHEMICAL DATABASE

Performance measures	Progress
Migration of data to new database under way by June 2014	Achieved

The migration of data from the APVMA's existing database to the new database is well under way. It is expected that the project will be completed in 2014–15.

PROTECT AND MANAGE INFORMATION RESOURCES

Performance measures	Progress
Maintain ICT system up-time of 97% or greater	Achieved
No significant security incidents	Achieved
Cyber intrusions defeated before damage occurs	Achieved
Virus attacks defeated before damage occurs	Achieved
Penetration testing of ICT systems undertaken and sound report achieved	Partly achieved

Information and communication technologies

The APVMA ICT section provides security; development of business applications for internal and external stakeholders; web services; customised solutions for mobile access and secure interactions; design, maintenance and support of network infrastructure; business continuity and disaster recovery planning; support for the electronic document and records management system; and help desk support for the desktop fleet, and for voice, smartphone, video conferencing and tablets.

In 2013–14, ICT system up-time was maintained above 97 per cent, and there were no significant security incidents. Penetration testing conducted during the reporting year indicated that staff would benefit from further training in 'social engineering'–based attacks. We are now developing online training to increase IT security awareness across the organisation.

Information Services

Information Services manages the APVMA's administrative files, including the archiving and destruction of records in accordance with standards issued by the National Archives of Australia, AS ISO 15489 1–2, the Protective Security Policy Framework (PSPF) and other Australian Government legislation. We have put in place information security requirements, including activities that will ensure compliance with the PSPF.

Information Services also provides library and research services to the organisation. We have implemented a discovery service that searches all databases and journals to which the APVMA subscribes, and have moved further towards an electronic library, replacing traditional hard-copy books with their electronic alternatives.

Information Services is also responsible for legal deposits. In 2013–14, the APVMA fulfilled its parliamentary reporting obligations and participated in Australian Government surveys, as requested.

IMPLEMENT IT, PHYSICAL, PERSONNEL AND GOVERNANCE SECURITY POLICIES TO ALIGN TO THE PROTECTIVE SECURITY POLICY FRAMEWORK

Performance measures	Progress
Compliance with Protective Security Policy Framework	Achieved
Data loss prevention strategy implemented, and the APVMA's physical and information security environment hardened	Achieved

The APVMA is compliant with the PSPF. A data loss prevention strategy was implemented during 2013–14.

MAINTAIN AND ENHANCE EFFICIENT QUALITY SYSTEM

Performance measures	Progress
No significant ISO audit findings	Achieved
Procedure amendment requests resolved within six months	Not achieved
Quality management procedures revised to reflect changes arising from reforms	Achieved
New document governance framework implemented by December 2013	Achieved

There were no significant International Organization for Standardization audit findings in 2013–14. Three requests, from internal staff who act as voluntary auditors, for procedure amendment were not finalised within the six-month target time frame. Quality management procedures (now called work instructions) were reviewed to reflect the changes arising from the legislative reforms. We implemented a new document governance framework, which will be further refined in 2014–15.

COMPLY WITH GOVERNMENT REPORTING REQUIREMENTS, LEGISLATION AND STANDARDS

Performance measures	Progress
Audited financial statements cleared by due date	Achieved
Input to Portfolio Budget Statements submitted by due date	Achieved
Responses to government surveys, questions on notice, ministerial correspondence and related material delivered on time and to a high quality	Achieved
No significant findings from internal and external audits	Achieved

In 2013–14, the APVMA complied with all reporting requirements, legislation and standards (see Chapter 4). Audited financial statements were cleared by the due date. We also provided input to Portfolio Budget Statements by the due date. Responses to government surveys, questions on notice, ministerial correspondence and related material were delivered on time and to a high quality, and there were no significant findings from internal and external audits.

ENHANCE ACCESS TO INFORMATION

Performance measures	Progress
Adhere to Information Publication Scheme requirements according to the APVMA agency plan	Achieved
Comply with statutory timeframes for freedom-of-information requests	Achieved

All freedom-of-information requests have been processed in accordance with the statutory time frames in the *Freedom of Information Act 1982* (FOI Act). Where extensions of time have been required to process any requests, the relevant statutory power has been relied on within the FOI Act.

LAUNCH A SECURE EXTRANET FOR REGISTRANTS TO LODGE THEIR DOCUMENTATION ONLINE

Performance measures	Progress
Secure extranet developed and lodgements available to registered users by June 2014	Achieved

We developed a new web-based portal for applicants, including a decision tree, an online application system and an e-label submission facility, which will allow applicants to easily lodge their applications and supporting data (see 'Support provision of high-quality applications' in Strategy 2).

ENSURE THAT COST-RECOVERY ARRANGEMENTS REFLECT APVMA OPERATING REQUIREMENTS

Performance measures	Progress
Implement a new cost-recovery impact statement	Achieved
Support provided to the first-principles review of the APVMA's cost-recovery arrangements being conducted by the Department of Agriculture	Achieved

In 2013–14, the APVMA implemented a number of changes to its cost-recovery framework, which flowed from the 2012 Cost-Recovery Impact Statement. We also provided support to the Australian Government Department of Agriculture's first-principles review of the APVMA's cost-recovery arrangements, which is expected to be finalised in 2014–15.

STRATEGY 8—ENHANCE PERFORMANCE THROUGH OUR PEOPLE

We recognise the importance of investing in a skilled, diverse and healthy workforce. We aim to increase the capability of our people through support and training so that they can carry out their duties to the best of their ability. We also value and support their health, safety and wellbeing.

We aim to ensure that staff demonstrate APVMA values and behaviours through their work and interaction with stakeholders, as well as adherence to the Australian Public Service (APS) Code of Conduct. We therefore make these values explicit in staff induction and management.

Staff profile

Tables 7–10 provide details of APS employees who were employed at the APVMA under the *Public Service Act 1999* in 2013–14.

We had 144 full-time and part-time staff at 30 June 2014. There were also 23 non-ongoing or casual staff, bringing the total number of staff to 167 (96 female, 71 male). Staff are located in Canberra, other than one staff member who is in Perth, Western Australia. Table 7 shows a breakdown by position level, Table 8 shows a breakdown by employment agreement, and Table 9 shows the salary level of different positions. Staff movements, including recruitments, resignations, terminations and retirements (excluding internal transfers and promotions), are shown in Table 10.

In 2013–14, the separation rate for ongoing staff was 5.56 per cent, which is a decrease on the 9.92 per cent separation rate of the previous year.

Table 7 Staff by position level and status, 2013–14

Classification	Full-time (ongoing)	Part-time (ongoing)	Non-ongoing and casual	Total
CEO	0	0	1	1
Senior executive officer	4	0	0	4
Principal scientist	2	0	0	2
EL 2	22	0	3	25
EL 1	33	4	5	42
APS 6	38	6	7	51
APS 5	10	3	0	13
APS 4	9	2	3	14
APS 3	10	1	4	15
APS 2	0	0	0	0
Trainee	0	0	0	0
Total	128	16	23	167

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

Table 8 Staff employed under common law arrangement and enterprise agreement at 30 June 2013

Classification	Australian workplace agreements	Common law arrangement	Commonwealth agreement	Total
SES	0	4	0	4
Non-SES	0	2	161	163

SES = senior executive service

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

Table 9 Salary range by classification at 30 June 2013

Classification	Minimum ($)	Maximum ($)
EL 2	119 015	156 393
EL 1	101 410	114 197
APS 6	83 807	93 557
APS 5	80 990	85 040
APS 4	64 918	71 520
APS 3	59 050	64 463
APS 2	0	0
Trainee	0	0

APS = Australian Public Service; EL = executive level

Note: Aggregate performance-linked bonus payments to staff during 2013–14 for 106 APS2–EL2 staff were $120 765.

Table 10 Staff movements, 2013–14

Classification	Ongoing separated	Non-ongoing separated	Ongoing recruited	Non-ongoing recruited
CEO	0	0	0	0
Senior executive officer	1	0	0	0
Chief research scientist, grade 1	0	0	0	0
EL 2	3	1	4	3
EL 1	0	1	0	4
APS 6	3	4	2	2
APS 5	2	2	0	1
APS 4	0	2	0	0
APS 3	0	2	0	0
APS 2	0	0	0	0
Trainee	0	0	0	0
Total	9	12	6	10

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

PROVIDE A SAFE, SUPPORTIVE AND FAIR WORKPLACE

Performance measures	Progress
Average reportable work, health and safety incidents at or below APS average	Achieved
Accurate and timely remuneration service (100%)	Achieved

Work health and safety

As part of the 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 requirements of 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 arrangements, and for dealing with disputes during consultation.

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

The Health and Safety Committee meets regularly and deals with a variety of matters out of session. Two health and safety representatives ensure that the APVMA work group is consulted and informed regarding WHS matters. They also conduct quarterly workplace inspections. No high-risk potential hazards were identified in 2013–14 from these inspections.

Eleven reports of potential hazards, injuries or illnesses to staff from work-related incidents were received in 2013–14, resulting in a total of two days lost due to injuries associated with the incidents. All were relatively minor in nature and have been fully resolved. There were no incidents requiring notification to Comcare (as the WHS regulator); however, one incident has resulted in a claim being accepted by Comcare.

Health and wellbeing initiatives

The APVMA continued the tradition of supporting Health Week initiatives to assist staff in the management of their health and wellbeing at work and at home. Staff were invited 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 skin cancer awareness and prevention, provided free influenza vaccinations for interested staff, and actively promoted and supported staff participation in lunchtime exercise activities.

Remuneration services

We provided accurate remuneration services throughout the year. Continued improvements to the payroll management and employee self-service systems provided staff with better access to electronic application for entitlements and improved reporting capabilities.

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 APS Commission's *State of the service report and the Australian Public Service statistical bulletin*. These reports are available at 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 will track progress against each of the six outcome areas of the strategy and present a picture of how people with disability are faring. The first of these reports will be available in late 2014 at dss.gov.au.

ALIGN PEOPLE POLICIES WITH LEGISLATION AND BEST PRACTICE

Performance measures	Progress
All people policies and legislative requirements reviewed annually	Achieved
Implement changes arising from 2013 amendments to the *Public Service Act 1999*	Achieved

In addition to regular and ongoing review of policy accuracy and currency, all human resources and associated policies were reviewed to ensure compliance with the legislative amendments to the *Public Service Act 1999* that came into effect on 1 July 2013. New procedures and guidelines regarding the application of Code of Conduct investigations and the setting of sanctions were published, and specific guidance relating to the use and disclosure of personal information was developed. The latter has now been superseded by the APVMA Privacy Policy, published in March 2014, which articulates APVMA practices supporting the Australian Privacy Principles.

The APVMA's workplace bullying and harassment policy was updated to ensure that staff were aware of changes implemented in January 2014, which enable individuals to report incidents of workplace bullying and harassment directly to the Fair Work Ombudsman. The APVMA's Public Interest Disclosure Procedures were published online in early 2014 and describe APVMA practices for handling disclosures made under the Public Interest Disclosure Scheme, which came into effect on 15 January 2014.

ENHANCE THE EFFECTIVENESS AND PERFORMANCE OF OUR PEOPLE

Performance measures	Progress
100% participation in performance management	Achieved
80% of recruitment processes completed within 45 days	Not achieved
A tailored executive leadership program implemented by December 2013	Achieved
Participate in relevant training offered by other regulatory agencies	Achieved

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
- increase senior executive involvement to calibrate ratings across the organisation
- simplify rating scales, with improved definitions capturing the APS Commission's integrated leadership capabilities
- encourage a collaborative culture
- ensure transparency in the performance management process.

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

Table 11 provides details of our recruitment activities in 2013–14. The year was challenging with regard to recruitment activities because of the interim arrangements for APS recruitment. For 33 per cent of positions, recruitment was finalised within 45 days of applications closing.

Table 11 Recruitment activities, 2013–14

Activity	Number
External recruitment advertisements	20
Applications received	358
Average time from gazette close to offer date	54 days
Recruitment campaigns cancelled	12
Recruitment decisions (gazetted notifications)	12
Processes completed within 45 days	33%
Internal recruitment advertisements	15
Recruitment rounds	35

ENSURE OUR PEOPLE HAVE THE SKILLS THEY NEED TO DO THEIR JOB

Performance measures	Progress
A range of online training modules delivered, including: • science risk • accountable and ethical decision-making • procurement • security	Achieved
New learning and development framework developed by September 2013	Achieved

We are committed to the ongoing professional development of all staff members, and aim to provide our staff with the necessary skills to progress in their role using a variety of approaches. Our Learning and Development Strategy links learning and development activities systematically with business needs by engaging staff in the design of internal training.

We are constantly working to improve our learning and development offerings. In 2013–14, a dedicated Learning and Development Manager was engaged as a full-time resource to manage and promote the increasing emphasis and importance the APVMA has placed on learning and development. The key role of this position is to ensure that the value of the Learning and Development Strategy is fully achieved.

The APVMA continued to support a system of mandatory induction training for incoming staff, and requires full participation in our performance management scheme, which also identifies individual training needs for staff. All staff participated in the scheme in 2013–14. The Study Encouragement Scheme continues to support staff in gaining relevant tertiary qualifications to expand individual and organisational capabilities. We focus on developing training delivery skills throughout the APVMA through actions such as 'train the trainer' courses and supporting staff in undertaking an APVMA-tailored Certificate IV in Training and Assessment.

In 2013–14, we have concentrated on preparing staff for legislative reform (see case study in Strategy 1).

FOSTER VALUES AND BEHAVIOURS THAT SUPPORT A ROBUST, ACCOUNTABLE PUBLIC SECTOR AGENCY

Performance management	Progress
Absenteeism rate at or below APS average	Achieved
Staff at or below 40-day annual leave cap by 31 December 2013	Achieved
Adherence to the APS Code of Conduct	Not achieved

No formal grievances or reviews of action were lodged in 2013–14.

New staff are fully briefed on the APVMA's expectations with regard to appropriate behaviours and actions, and adherence to the APS Code of Conduct, to protect our reputation within the APS and with our external stakeholders. Breaches of APVMA values and the Code of Conduct are treated seriously, in line with agreed internal policies and the enterprise agreement. In 2013–14, one breach of the Code of Conduct was determined following investigation, and a sanction was applied. No other investigations into potential breaches were undertaken in 2013–14.

DEVELOP A NEW ENTERPRISE AGREEMENT

Performance management	Progress
New enterprise agreement developed, consistent with the APS bargaining framework	In progress

Following release of the Australian Government Public Sector Workplace Bargaining Policy, the APVMA has started preparing for the next round of bargaining. The APVMA will work collaboratively with bargaining representatives to ensure that the next agreement meets the needs of APVMA staff and management, in accordance with the principles of the policy.