



Australian Government  
Australian Pesticides and  
Veterinary Medicines Authority

# ANNUAL REPORT

2014–15







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# LETTER OF TRANSMITTAL



Australian Government  
Australian Pesticides and  
Veterinary Medicines Authority

7 October 2015

The Hon Barnaby Joyce MP  
Minister for Agriculture  
Parliament House  
Canberra ACT 2600

Dear Minister Joyce

I am pleased to submit the Australian Pesticides and Veterinary Medicines Authority (APVMA) annual report for the year ending 30 June 2015 for your agreement to table.

The APVMA is required by the *Agricultural and Veterinary Chemicals (Administration) Act 1992* to provide an annual report on its operations for the preceding financial year. Among other things, the report must contain the financial statements required by s 42 of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and an audit report on those statements under s 43 of the PGPA Act. I confirm that this annual report complies with these requirements.

Also, in accordance with the *Commonwealth fraud control guidelines*, I certify that the APVMA has prepared a fraud risk assessment and a Fraud Control Plan, and has in place appropriate fraud prevention, detection, investigation, reporting and data collection procedures.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'K. Arthy'.

Kareena Arthy  
Chief Executive Officer

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# VISION AND MISSION

## VISION

Australians have confidence that agricultural and veterinary chemicals are safe to use.

## MISSION

To protect the health and safety of Australia—its people, animals and environment—and support Australian agriculture by taking a scientific and risk-based approach to regulating agricultural and veterinary chemicals.

*Taken from the APVMA Corporate Plan 2015-19.*



# CHIEF EXECUTIVE OFFICER'S REPORT AND OUTLOOK

During 2014–15, we implemented the most comprehensive legislative reform the agency has seen since its inception, and began an ambitious program of organisational change and business systems improvement.

Legislative changes that came into effect on 1 July 2014 overhauled processes for product registration and approval of active constituents. This required substantial effort on the part of both industry and the APVMA to maintain the flow of applications, registration of new products and active approvals.

Restructure of our registration and scientific assessment teams has improved the efficiency of our evaluation process, and performance against statutory timeframes improved during the year—providing a robust base from which to further improve our timeframe performance in the coming year.

To improve our focus on performance matters, a new Client Service Charter was developed, and formal feedback mechanisms are now in place that improve our ability to monitor the health of our systems and make timely improvements.

Our commitment to face-to-face engagement with industry continued with the establishment of a series of industry information and education sessions. The first of six planned events was held in Sydney in June 2015. We continued to contribute to the development of international standards and consistency in global regulation of agricultural and veterinary chemicals through our participation in expert committees and working groups.

Strong operational relationships continued with our partner agencies, and state and territory departments on matters such as chemical reviews, human health and safety, residues and trade, and control of use.

The Chemical Review Program was revamped, and information on the website now clearly sets out where each review is up to—detailed work plans now provide even greater transparency for the community and industry.

Compliance activity continued to be risk based. Two awareness-raising campaigns focused on assisting people to return to voluntary compliance through education, and a pilot project to monitor labelling code compliance for a small number of products revealed widespread minor noncompliance. Routine monitoring will continue next year.

Our focus on regulatory science was further strengthened this year with the appointment of a Chief Scientist, and the delivery of the nanotechnology regulation symposium and report, which marked the culmination of four years of APVMA-led research, consultation and collaboration.

Major consultation with industry this year means that our partnership project with the University of Melbourne to establish a sophisticated risk assessment framework, and our own review of guidelines on international data requirements, are on track to deliver better access to chemicals and further reduce the regulatory burden for industry.

This year marked a refocus of our strategic direction, and refinement of our vision and mission in the APVMA Corporate Plan 2015–19. We have an ambitious agenda of change and innovation ahead of us, which has at its heart the pursuit of scientific excellence and appropriate risk management, client service delivery and continuous improvement in everything we do.

I am pleased to present this annual report of our work in 2014–15.

Kareena Arthy  
Chief Executive Officer  
September 2015





# CHAPTER 1

## ORGANISATION OVERVIEW



## CORPORATE PROFILE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent statutory authority responsible for the assessment, registration and regulation of agricultural and veterinary (agvet) chemicals in Australia.

Before agvet chemical products can be legally sold, supplied or used in Australia, they must be evaluated and registered by the APVMA through the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS).

More than 11 000 pesticide and veterinary medicine products are currently registered in Australia, including products for treating crop and garden diseases and pests, and medicines for treating agricultural and companion animals.

The APVMA takes a systematic, scientific, evidence-based approach to decision making and operations. We evaluate the safety and performance of chemicals intended for sale in Australia, to ensure that the health and safety of people, animals, crops and the environment are protected. Registered products must also not unduly jeopardise Australia's trade with other countries.

Our work supports primary industries—agriculture, forestry, horticulture and aquaculture—by allowing the supply of safe, effective animal health and crop protection products. Our work also supports consumers, by ensuring that household and garden pesticides, and pet products are safe to use.

Our role extends beyond registration of pesticides and veterinary medicines to encompass a range of activities aimed at protecting Australians and ensuring that products are safe. We license and audit veterinary manufacturers to ensure adherence to APVMA-prescribed manufacturing standards. We manage an Adverse Experience Reporting Program (AERP) that is designed to ensure early detection of unforeseen problems with registered chemicals. We also monitor the market for compliance, and review and take regulatory action on registered pesticides and veterinary medicines when concerns are identified.

The APVMA is a portfolio agency of the Minister for Agriculture, the Hon Barnaby Joyce MP.

## LEGISLATIVE FRAMEWORK

The APVMA is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act). The Administration Act sets out the role of the APVMA to undertake the responsibilities conferred on it by the states and territories under the NRS.

Functions and powers are conferred on the APVMA by the Administration Act, the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code Act) and the Agricultural and Veterinary Chemicals Code (Agvet Code). The Agvet Code provides for the evaluation, registration and control of agricultural chemicals and veterinary medicines, and related matters.

The APVMA is a corporate Commonwealth entity under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). A corporate Commonwealth entity is a Commonwealth entity that is a body corporate and is legally separate from the Commonwealth.

# FUNCTIONS AND POWERS

The APVMA is responsible for assessing and registering pesticide and veterinary medicine products proposed for supply and use in Australia, and for controlling them up to the point of retail sale. It also oversees the import and export of these chemicals and medicines that contain them. The states and territories are responsible for regulating and managing the use of pesticides and veterinary medicines once they are sold.

The functions of the APVMA, set out in s. 7 of the Administration Act, are to:

- assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, registered chemical products, and labels for containers for chemical products
- provide information to the Australian Government and its agencies, and the states and territories, about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for such products, and cooperate with Australian Government agencies on matters relating to the management and control of chemical products
- keep records and statistics of approvals and registrations it has granted, and permits and licences it has issued under the Agvet Code
- evaluate the effects of the use of chemical products in the states and participating territories
- cooperate with the Australian Government and its agencies, and the states and participating territories, to facilitate a consistent approach to the assessment and control of chemicals
- cooperate with the Australian Government and its agencies, and the states and participating territories, to develop codes of practice, standards and guidelines for, and to recommend precautions to be taken in connection with, the manufacture, export, import, sale, handling, possession, storage, disposal and use of chemical products
- collect, interpret, disseminate and publish information relating to chemical products and their use
- encourage and facilitate the application and use of results of evaluation and testing of chemical products
- exchange information relating to chemical products and their use with overseas and international bodies that have similar functions to those of the APVMA
- when requested by the minister, or on its own initiative, report to or advise the minister on any matter relating to chemical products or arising in the course of the performance of the APVMA's functions
- encourage and facilitate the introduction of uniform national procedures for controlling the use of pesticides and veterinary medicines
- fund and cooperate in a program designed to ensure that active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products comply with the Agvet Code, and the Agricultural and Veterinary Chemicals Code Regulations 1995.

In accordance with s. 10 of the Administration Act, the Australian Government minister responsible for administering pesticide and veterinary medicine legislation may direct the APVMA (in writing) in relation to its functions or powers under Australian, state or territory laws. The APVMA must comply with any such direction. No such direction was given in 2014–15.



## FUNDING

The APVMA is a cost-recovered agency. Registrants pay application fees to register new products and active constituents, amend a current registration or apply for a permit. An annual fee is payable each year to renew the registration of a product. Product owners also pay an annual levy, based on the sales of their registered products.

Levies are imposed under the *Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994*, the *Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994* and the *Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994*. Levies are collected under the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*, and the levy rates are prescribed in the Regulations to the Act.

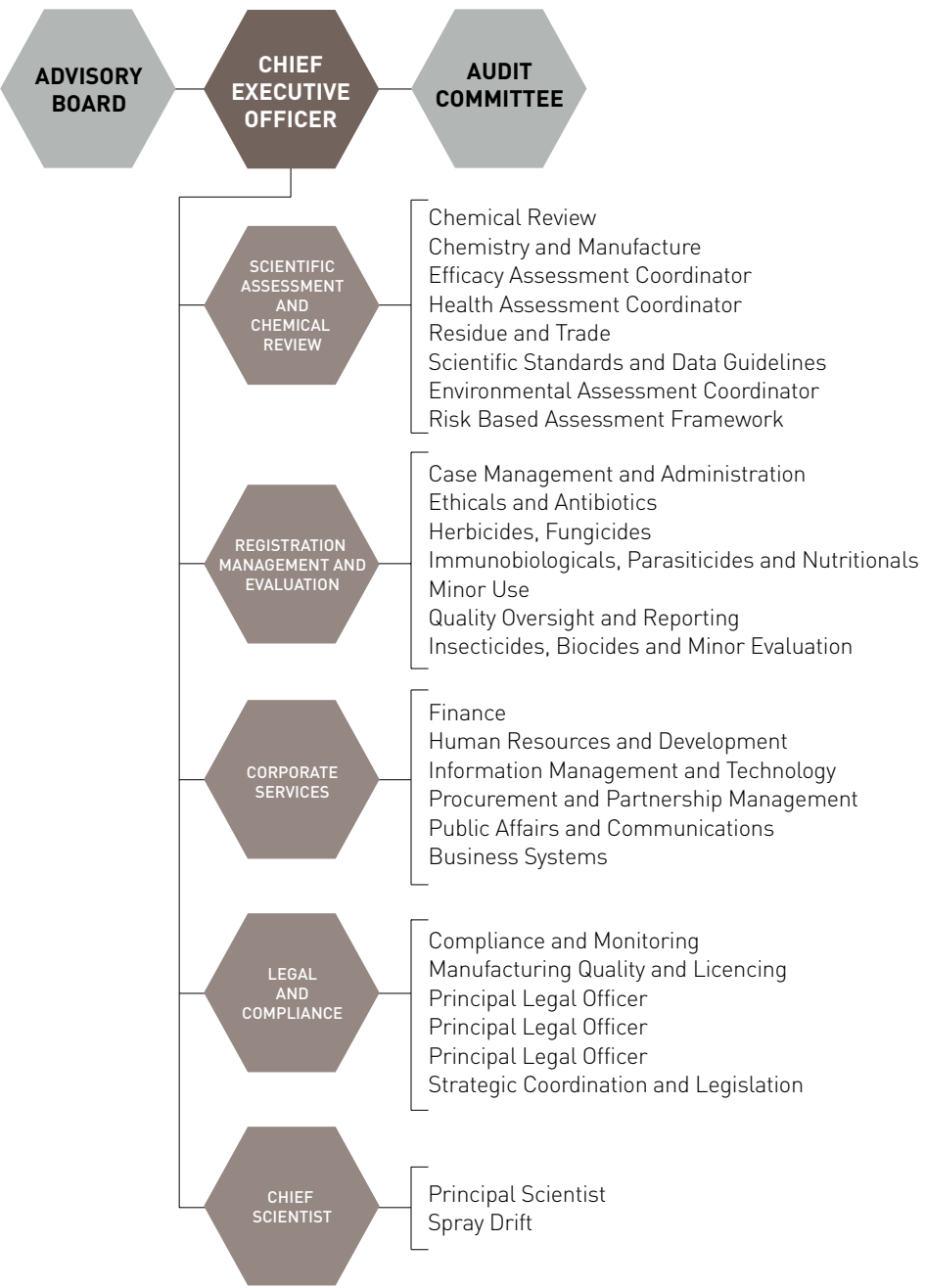
The Australian Government Department of Agriculture is currently conducting a first-principles review of the APVMA's cost-recovery arrangements.

The APVMA's income for 2014–15 was \$29.741 million, an increase of \$1.466 million (5.18 per cent) from 2013–14. The APVMA's equity at year end increased to \$10.490 million following a one-off accounting adjustment (see Chapter 4).

# EXECUTIVE MANAGEMENT AND STRUCTURE

The APVMA management structure (Figure 1) supports effective operation, communication and strategic understanding at all levels of the organisation.

FIGURE 1: ORGANISATION STRUCTURE, AS AT 30 JUNE 2015



The APVMA executive team is responsible for business and compliance performance. It oversees the development of key corporate plans and strategies, monitors and reviews organisational performance and risk, and ensures that the APVMA meets its regulatory obligations. The collective skills and experience of the executive and APVMA staff are used to develop and consider strategic initiatives and operational issues.



## **Ms Kareena Arthy**

### **Chief Executive Officer**

The Chief Executive Officer (CEO) is responsible for APVMA governance and management, including the exercise of the APVMA's powers and functions. The CEO consults with the Advisory Board and key stakeholders to set the organisation's vision, objectives and strategies to meet its legislative responsibilities. The CEO approves the APVMA's strategic, financial and operational plans and budgets; monitors financial and operational performance; and oversees program performance. The CEO leads the agency's engagement efforts, particularly its engagement with key international agencies.



## **Mr Tony de la Fosse BA GradDipHRM MBA GAICD**

### **Executive Director, Corporate Services, and Chief Operating Officer**

The Executive Director, Corporate Services, manages finance and administration, human resources, public affairs and communications, information technology (including operations, security, information services and application development), procurement and business systems. Key responsibilities include providing timely and accurate financial data, and preparing financial plans, budgets and strategies that maximise the APVMA's ability to deliver quality services with the funds available. The position is also responsible for risk management, records management, physical and personnel security, and e-commerce.



## **Dr Raj Bhula BSc(Hons) PhD**

### **Executive Director, Scientific Assessment and Chemical Review**

The Executive Director, Scientific Assessment and Chemical Review, manages the expert assessment areas of the APVMA and the Chemical Review Program. This includes the chemistry and manufacture team, the residues team, and the assessment coordinators for health, environment and efficacy. Responsibilities include determining whether registered chemicals continue to meet contemporary standards, and continuously improving data guidelines and the quality of the assessments contributing to registration and review processes.



## **Mr Alan Norden**

### **Executive Director, Registration Management and Evaluation**

The Executive Director, Registration Management and Evaluation, manages the evaluation and registration of pesticides and veterinary medicines. Responsibilities include granting permits, certificates of export and import consents; and managing applications and enquiries for pesticides and veterinary medicines.



## **Ms Stefanie Janiec BCom (Acctg&BusLaw) LLB LLM**

### **Executive Director, Legal and Compliance, and General Counsel**

The Executive Director, Legal and Compliance, and General Counsel provides, and oversees the provision of, legal advice and support to the CEO and the staff on all aspects of the APVMA's regulatory, administrative and corporate functions. Responsibilities include delivering the APVMA's regulatory compliance operations and coordinating advice, briefings and reports regarding policy development, regulatory matters and operational issues from a whole-of-agency perspective for the minister, the CEO and the broader agency.



## **Dr Phil Reeves BVSc(Hons) PhD FANZCVS**

### **Chief Scientist**

The Chief Scientist ensures that the APVMA's regulatory science frameworks and standards meet appropriate national and international standards. Through engagement with national and international scientific and regulatory networks, the Chief Scientist identifies issues and trends that may affect the integrity of the APVMA's regulatory science frameworks and standards, and develops appropriate projects and initiatives to improve the APVMA's scientific capability. Responsibilities also include providing the CEO and senior staff with independent, expert advice on regulatory decisions and scientific aspects of the APVMA's regulatory framework, and managing the APVMA's principal scientists and special projects.

## **Advisory Board and Audit Committee**

The APVMA CEO is supported by an Advisory Board that provides advice and recommendations on issues relevant to the functions of the APVMA (see Appendix A). Board members are appointed by the Minister for Agriculture for their experience in areas associated with the APVMA's stakeholders. Advice is also provided by the APVMA Audit Committee in relation to the risk control and compliance framework, the APVMA's financial and management responsibilities, and its external accountability responsibilities (see Appendix A).



## AT A GLANCE—APVMA ACTIVITIES

**Registration management:** Agvet chemical products must be registered before they can be legally sold, supplied or used in Australia. Applications are made to the APVMA to approve, register or vary active products, constituents or labels. Applications must be supported by information that allows us to determine whether we are satisfied that the product meets the applicable safety, trade, efficacy and labelling criteria.

**Scientific assessment:** The APVMA assesses chemistry, manufacture, active constituents, formulated products and residues in food, based on international best practice and robust methodology. In addition, assessment coordinators for human health, environment and efficacy work with assessors at the Australian Government departments of Health and the Environment, as well as with external consultants, to ensure that health, environmental and efficacy assessments are of a high standard.

**Compliance and enforcement:** Noncompliance with the Agvet Code Act may relate to unregistered products, supply of restricted chemical products to unauthorised users, unapproved labels, unfounded claims in advertising or other media, or active constituents that do not conform to APVMA standards. We actively monitor advertising, retail and online supplies to assess compliance, and encourage industry and the public to report potential noncompliance. All reports and detections of potential breaches of the legislation are assessed before the APVMA acts, to prevent noncompliance, and encourage ongoing and future compliance.

**Manufacturers' Licensing Scheme:** Chemical manufacturers must be licensed to ensure that they adhere to APVMA-prescribed manufacturing standards, including the Manufacturing Principles and the *Australian code of good manufacturing practice for veterinary chemical products*. Registrants of products manufactured overseas must provide assurance that their products comply with manufacturing standards that are comparable to the APVMA requirements.

**Chemical review:** The APVMA reviews existing chemicals to assess any new information that raises concerns about the use of the chemicals, and takes regulatory action to mitigate identified risks. The review can investigate previously unknown risks or product ineffectiveness, and can cover approved active constituents, registered products or approved labels. We assess the identified risk to determine whether changes are needed to ensure that the product can continue to be used safely and effectively. 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).

**Adverse Experience Reporting Program:** The APVMA assesses reports of adverse experiences associated with the use of registered agvet chemical products. This provides us with valuable information on registered chemicals, which may trigger further investigation.

**Service delivery:** The APVMA operates a range of web-based systems to streamline interaction between the APVMA and applicants, including a decision guide to ensure that applicants take the correct application path, a smart online application process for more efficient data collection, context-aware application forms, and a system to allow creation and submission of product labels. We have a case management unit that manages applications, and is the first point of contact for enquiries and applicants. A Client Service Charter sets out the standards of service that people can expect to receive when transacting or engaging with the APVMA.





# CHAPTER 2

## PERFORMANCE AGAINST STRATEGIES



# STRATEGIC FRAMEWORK AND REPORTING

The APVMA Corporate Plan 2012–15 identified four objectives:

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

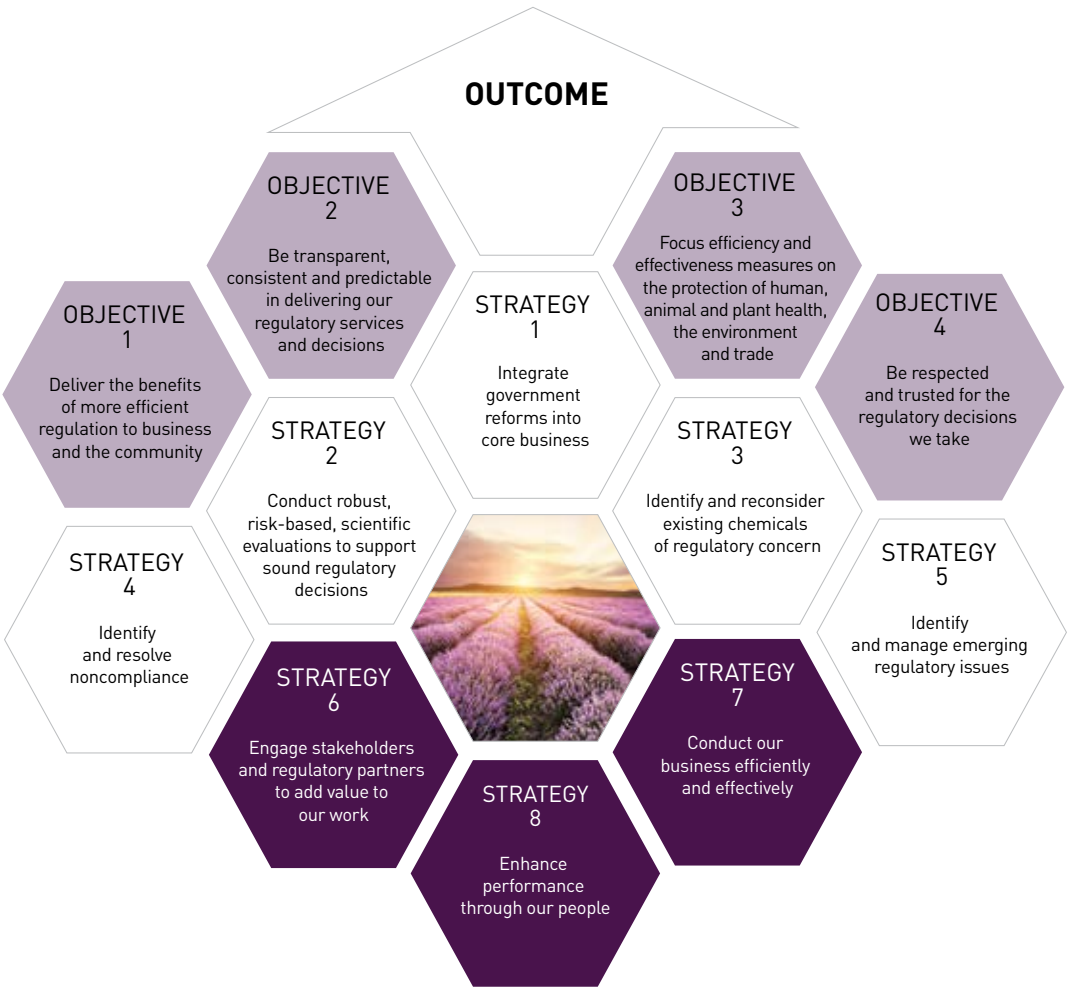
The APVMA *Operational plan 2014–15* identified eight strategies to achieve the corporate plan objectives and the APVMA's outcome (Figure 2):

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

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

FIGURE 2: APVMA OBJECTIVES AND STRATEGIES

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



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



## This report

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

### STRATEGY 1—INTEGRATE GOVERNMENT REFORMS INTO CORE BUSINESS

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

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

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

### Variation from the APVMA Portfolio Budget Statement

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

## SUMMARY OF PERFORMANCE AGAINST STRATEGIES

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

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

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

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

**Strategy 2—Conduct robust, risk-based scientific evaluations to support sound regulatory**

**decisions.** In 2014–15, we ran two registration systems in parallel as we transitioned to the new legislation: one for applications received before 1 July 2014 and one for applications received after 1 July 2014.

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

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

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

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

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

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

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

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

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

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

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

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

## AT A GLANCE—ACHIEVEMENTS 2014–15

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

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

# STRATEGY 1—INTEGRATE GOVERNMENT REFORMS INTO CORE BUSINESS

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

## Reduce the administrative and regulatory burden on industry

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

### Assessment

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

### Registrations

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

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

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

## Collaboration

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

## IT tools

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

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

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

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

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

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



# CASE STUDY 1

## Risk Assessment Framework

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

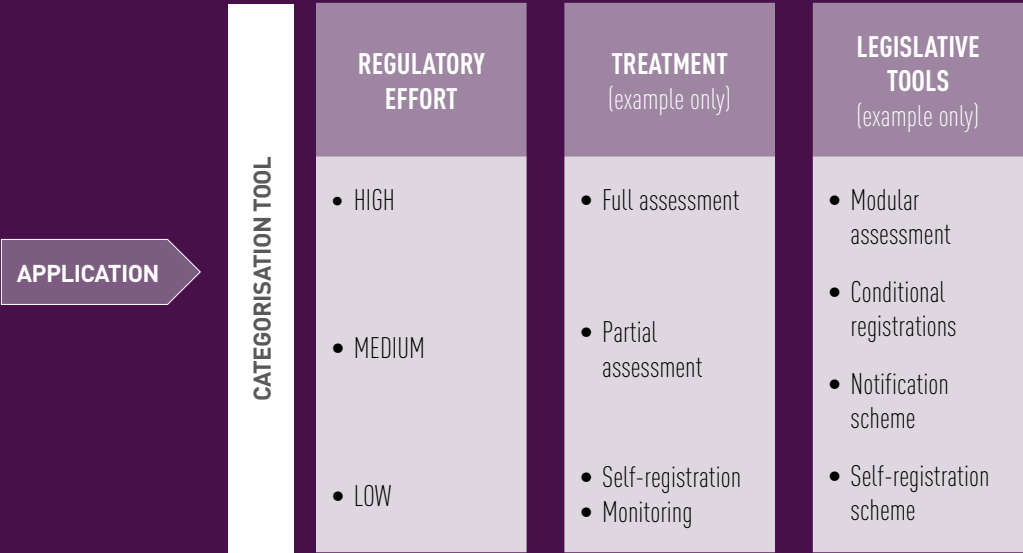
The agvet industries expect transparency and predictability from the work of the APVMA. Where information and assessments from other regulatory agencies are available and can be substituted for a national assessment, applicants also expect the APVMA to provide concessions in relation to timeframes and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

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

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

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

FIGURE 3: RISK-BASED ASSESSMENT FRAMEWORK CONCEPT



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

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

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

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

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

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

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

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

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

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

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

## Support industry readiness to comply with the new regulatory framework

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

### Case management

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

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

### Industry training

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

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

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

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

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

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

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

PERFORMANCE MEASURES	PROGRESS
Met timeframe performance targets for applications received before commencement of new legislation: <ul style="list-style-type: none"> <li>90% of product registrations</li> <li>60% of active approvals</li> <li>85% of permits</li> </ul>	Not achieved 74% 44% 65%
Met timeframe performance targets for applications received after commencement of new legislation: <ul style="list-style-type: none"> <li>100% of product registrations</li> <li>100% of active approvals</li> <li>100% of permits</li> </ul>	Not achieved 88% 84% 76%
Further improved regulatory guidelines, including new technical manuals	In progress
Developed criteria to be used to determine whether efficacy is a relevant consideration in assessing an application	Achieved

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

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

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

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

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

## Pesticides

### *Product applications*

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

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

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

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

### *Product finalisations*

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

**TABLE 2: PESTICIDE PRODUCT FINALISATIONS, 2014–15**

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

### *Permits*

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



Active constituent approvals

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

Veterinary medicines

Product applications

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

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

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

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

Product finalisations

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

TABLE 4: VETERINARY MEDICINE PRODUCT FINALISATIONS, 2014–15

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

Permits

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

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

## Support provision of high-quality applications

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

See also Strategy 1.

### IT tools

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

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

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

### Pre-application assistance

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

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

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

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

## Enhance quality assurance

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

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

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

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

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

## Implement streamlined application assessment processes

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

*See also Strategy 1.*

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

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

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

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

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

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

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

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

### International assessments

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

### International guidelines and expertise

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

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

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

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

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

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

## Develop a regulatory framework to support spray drift policy

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

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

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

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



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

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

## Improve international engagement

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

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

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

Specific international cooperative activities include:

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

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

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

## CASE STUDY 2

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

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

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

## Build and maintain a quality scientific assessment capability

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

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

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

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

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

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

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

PERFORMANCE MEASURES	PROGRESS
Implemented outcomes by 1 January 2015	Not achieved

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

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

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

## STRATEGY 3—IDENTIFY AND RECONSIDER EXISTING CHEMICALS OF REGULATORY CONCERN

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

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

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

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

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

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

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

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

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

## CASE STUDY 3

### Redesigning chemical review webpages

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

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

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

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

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



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

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

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

### Adverse Experience Reporting Program

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

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

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

### Compliance with maximum residue limits

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

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

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

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

### Chemical review regulatory action

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

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

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

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

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

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

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

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

**TABLE 6: SUSPENSIONS FOLLOWING CHEMICAL REVIEW, 2014–15**

Chemical	Actives			Products			Labels			Total
	Sus-pend	Revoke suspen-sion	Continue suspen-sion	Sus-pend	Revoke suspen-sion	Continue suspen-sion	Sus-pend	Revoke suspen-sion	Continue suspen-sion	
Dimethoate					1	13				24
Quintozene			1			10				22
Total			1		1	23			46	71

## Chemical review outcomes

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

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

### Voluntary cancellations

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

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

### Ongoing reviews

Eighteen chemicals remain under review:

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

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

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

### Committees

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

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

### State and territory involvement

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

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

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

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

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



Inform and engage with stakeholders about regulatory activity on registered chemicals

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

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

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

## STRATEGY 4—IDENTIFY AND RESOLVE NONCOMPLIANCE

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

### Develop a 2015–17 Compliance and Enforcement Strategy

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

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

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

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

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

#### Consents to import

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

## Analysts and laboratories

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

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

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

## Conditions of approval

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

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

## Intelligence-led operations

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

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

## Undertake effective risk-based enforcement

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

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

TABLE 7: ALLEGATIONS BY RISK CATEGORY, 2014-15

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

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

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

TABLE 8: GEOGRAPHICAL LOCATION OF ALLEGATIONS, 2014-15

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

## Regulatory actions

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

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

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

## New powers

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

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

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

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

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



## CASE STUDY 4

### Awareness campaigns

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

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

#### Pool and spa chemicals

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

#### Dairy sanitisers

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

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

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

### IT system

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

### GMP audits

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

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

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

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

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

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

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

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

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

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

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

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

### Guidelines

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

### Other agencies

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

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

## Improve compliance and enforcement governance

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

### Enforcement Committee

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

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

### After-action reviews

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

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

## STRATEGY 5—IDENTIFY AND MANAGE EMERGING REGULATORY ISSUES

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

### Assess and manage significant emerging regulatory issues

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

### National and international relationships

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

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

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

### Input into other government processes

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



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

### **Working with CSIRO on interference RNA and nanopesticides**

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

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

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



## CASE STUDY 5

### The Regulatory Science Network

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

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

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



*Dr Chris Schyvens, APVMA*

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

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



*Mr David Rumbold, APVMA*

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

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

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

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

## Support Department of Agriculture initiatives on quality assurance of imported chemicals

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

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

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

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

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

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

## CASE STUDY 6

### Operation Pangea VIII

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

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

Our participation in Operation Pangea:

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



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

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

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

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

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

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

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

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

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

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

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

## CASE STUDY 7

### Nanotechnology Regulation Symposium

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



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

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

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

### Implement communications activities to support the strategic direction of the APVMA

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

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

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

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

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

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



## CASE STUDY 8

### Reaching out through forums

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

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

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

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

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

## Website content

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

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

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

## Visual identity

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

## Correspondence review

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

## Conferences

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

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

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

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

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

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

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

## Develop a new Client Service Charter

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

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

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

## Redevelop the APVMA website

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

*See also Strategy 1.*

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

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

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



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

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

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

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

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

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

*See also Strategy 1.*

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

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

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

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

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

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

Improve staff capability in science communication

PERFORMANCE MEASURES	PROGRESS
Trained staff in communication skills for scientists	Achieved

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

## STRATEGY 7—CONDUCT OUR BUSINESS EFFICIENTLY AND EFFECTIVELY

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

### Enhance information technology systems to improve service delivery

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

*See also Strategy 2.*

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

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

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

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

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

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

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

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

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

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

## Develop a new corporate plan with new key performance measures

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

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

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

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

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

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

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

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

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

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

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

## Complete redevelopment of the APVMA's core agvet chemicals database

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

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

## Protect and manage information resources

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

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

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

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

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

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

## Maintain and enhance an efficient quality system

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

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

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

## Comply with government reporting requirements, legislation and standards

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

See also Strategy 5.

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

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

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

## Enhance access to information

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

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

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

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

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



## Implement new accountability framework for business processes

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

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

The APVMA's new structure comprises the following sections:

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

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

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

## CASE STUDY 9

### Establishment of the APVMA's Office of the Chief Scientist

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

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

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

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

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

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



*Dr Phil Reeves, APVMA*

Ensure that cost-recovery arrangements reflect APVMA operating requirements

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

See also Chapter 1.

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

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

## STRATEGY 8—ENHANCE PERFORMANCE THROUGH OUR PEOPLE

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

### Staff profile

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

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

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

**TABLE 11: APVMA STAFFING, AT 30 JUNE 2015**

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

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

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

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

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

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

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

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

APS = Australian Public Service; EL = executive level

**TABLE 14: STAFF MOVEMENTS AT APVMA, 2014-15**

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

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

## Provide a safe, supportive and fair workplace

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

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

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

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

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

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

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

### **Health and wellbeing initiatives**

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

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

### **Remuneration**

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

### **Disability reporting**

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

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



## Align people policies with legislation and best practice

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

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

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

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

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

## Enhance the effectiveness and performance of our people

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

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

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

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

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

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

**TABLE 15: RECRUITMENT ACTIVITIES, 2014–15**

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

APS = Australian Public Service

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

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

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

## Training

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

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

Specific training held during the year included:

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

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

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

## CASE STUDY 10:

### APVMA leadership program

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

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

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

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

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

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

### Develop a new enterprise agreement

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

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





# CHAPTER 3

## MANAGEMENT FRAMEWORK



## CORPORATE GOVERNANCE

Until 2014, the APVMA was a prescribed agency under the FMA Act. The PGPA Act replaced the FMA Act on 1 July 2014, and the APVMA completed its transition from an FMA Act agency to a corporate Commonwealth entity under the PGPA Act during 2014–15.

The APVMA is a body corporate with a separate legal identity from the Commonwealth of Australia. The APVMA CEO is responsible for the governance and management of the APVMA, with the support of the executive team (see Chapter 1), the Advisory Board and the Audit Committee (see Appendix A).

## PLANNING

### Corporate and operational plans

As an independent statutory authority, the APVMA is required to conduct rigorous corporate planning and reporting. Our planning and reporting requirements are set out in the Administration Act.

Our central planning document is the corporate plan, which defines the principal objectives of the APVMA and gives a broad outline of the strategies to achieve these objectives. Each corporate plan has a life of four years. This year, we developed the **APVMA Corporate Plan 2015–19**. The corporate plan is aligned with the APVMA Regulator Performance Framework, which outlines key performance measures for the APVMA.

In addition, each year an operational plan is developed that sets out the actions needed to achieve the objectives in the corporate plan. Our operational effectiveness is measured each year through the performance indicators set out in the operational plan and the Portfolio Budget Statement.

### Input to decision making

Our stakeholders are an integral part of our business, and it is essential that we meet their needs. It is also essential that our processes reflect best international practice and the latest science.

We place a high priority on interaction and consultation with our stakeholders and with other regulatory agencies. Stakeholders from industry, chemical users, government and the community all provide input and are involved in our decision making, and development of guidelines and operational policy.

We have established committees and processes to facilitate this involvement (see Appendix A). We also conduct public consultation to inform proposals, and form internal and external working groups and reference groups to address specific issues.

## ACCOUNTABILITY

### Internal accountability structures

#### Corporate risk management

The methodology used to assess risk at the APVMA is consistent with the International Risk Management Standard and best practice. A comprehensive Risk Management Plan is in place.

Risks are reviewed by the APVMA's Senior Leadership Team on a regular basis, to ensure that all risks facing the organisation are identified. Risks are assessed and scored, with consensus sought on the likelihood of the risk occurring and the possible consequences. For high and unacceptable risks, treatments are then developed and controls are documented. The risk treatments are regularly monitored to ensure that they are implemented.



A Risk Register is maintained to document the risks. The Risk Register is constantly updated to ensure that it reflects the current risks facing the organisation.

The APVMA Audit Committee regularly reviews this framework and the Risk Register.

### Quality management systems

The APVMA is currently developing a new approach to quality management. This will be presented to the APVMA Senior Leadership Team in July 2015, before presentation for approval to the Executive Leadership Team. The new approach will align the APVMA with industry best practice for quality management and is scheduled to be implemented by the end of 2015–16.

### Fraud control

The APVMA has a fraud risk assessment and a Fraud Control Plan in place that comply with the *Commonwealth fraud control guidelines*. The plan includes fraud prevention, detection, investigation, reporting and data collection procedures. This year, a new Fraud Control Plan was developed for 2014–16.

There were no cases of fraud during the reporting period.

## External accountability structures

### Reporting

Our performance is publicly reported in an annual report that is prepared according to the *Requirements for annual reports for non-corporate Commonwealth entities subject to the PGPA Act*, issued by the Australian Government Department of the Prime Minister and Cabinet.

The *APVMA Gazette* lists all APVMA notices and decisions required under the Agvet Code, including registrations, reviews and changes to registration status. The gazette is published fortnightly and is available from the APVMA website.

### APVMA service charter

We aim to provide the highest quality service to all our stakeholders. The APVMA Client Service Charter outlines the standards of service that external audiences can expect when interacting with the APVMA. The charter applies to all stakeholders, including the chemicals industry that the APVMA regulates, other government agencies, chemical users and the community.

In early 2015, we revised the charter to set out mutual expectations and APVMA response time standards. Client service workshops were held for all staff to coincide with the launch of the new charter.

### Parliamentary committees and other reviews

The APVMA made a supplementary submission to the Senate Rural and Regional Affairs and Transport References Committee inquiry into the implications of the use of fenthion by Australia's horticulture industry. The APVMA CEO (Kareena Arthy), Executive Director, Scientific Assessment and Chemical Review (Dr Raj Bhula), and Director, Chemical Review (Dr Matthew O'Mullane), gave evidence at a public hearing of the committee on 7 July 2014.

The APVMA appeared before the Senate Estimates Rural and Regional Affairs and Transport Legislation Committee hearings on 20 November 2014 (supplementary), 23 February 2015 (additional) and 25 May 2015 (budget).

## Auditor-General's reports

The APVMA was not audited by the Australian National Audit Office in 2014–15, other than the audit of the APVMA 2013–14 financial statements.

## Ombudsman

During 2014–15, there were no reports to parliament or investigations by the Commonwealth Ombudsman about the APVMA.

## Courts and tribunals

During 2014–15, the APVMA was notified of two matters before the Administrative Appeals Tribunal (AAT) and one matter before the Federal Court. One of the AAT matters has been withdrawn, and the other matters are ongoing.

Five AAT matters were carried over from the previous year. Four of these matters have been withdrawn, and one is ongoing.

## Office of the Australian Information Commissioner reviews

During 2014–15, the APVMA did not receive any notifications of reviews or complaints from the Office of the Australian Information Commissioner (OAIC).

One complaint about how the APVMA handled a freedom of information internal review was carried over from the previous year. The OAIC decided not to investigate the complaint.

## Privacy

The APVMA adheres to the *Privacy Act 1988*. The APVMA's privacy policy is located on the APVMA website. Our operations were not subject to any report or determinations by the Privacy Commissioner.

## Environmental performance

The APVMA has adopted an environmental management system, in accordance with requirements of s. 516A of the *Environment Protection and Biodiversity Conservation Act 1999*, the Agvet Code and the Greening of Government program. This enables the APVMA to minimise the impact of its activities on the environment, in alignment with the principles of ecologically sustainable development and environmental management. The environmental management system uses ISO 14001:2004 as its framework.

The APVMA works to reduce its environmental impact by:

- recycling paper, plastic and kitchen waste to reduce its impact on landfill
- maintaining water tanks for watering gardens at the APVMA's premises in Canberra
- meeting the whole-of-government Energy Efficiency in Government Operations target for energy use of 7500 megajoules per person
- purchasing 100 per cent recycled paper
- using environmental criteria guidelines to ensure that environmental impacts are considered for all purchases
- using VM Ware computer hardware to reduce electricity consumption
- using high-efficiency T5 lighting and movement-activated lighting
- using videoconferencing facilities to minimise travel

- using multifunction-device printers that reduce paper waste by secure release, and authenticate all print, copy, scan and fax jobs
- maintaining on-site worm farms to process waste food collected from APVMA kitchens, thus reducing waste going to landfill.

We strive to continually improve our environment management systems. Our new electronic document and records management system will help reduce our paper and printer consumables.







# CHAPTER 4

## FINANCIAL PERFORMANCE



## SUMMARY OF FINANCIAL PERFORMANCE

Tables 16 and 17 provide an overview of APVMA financial performance for 2014–15. Full details are in the audited financial statements on the following pages.

### Income

Our total income for this financial year was \$29.741 million (Table 16), an increase of \$1.466 million (5.18 per cent) from the previous year. This increase is largely due to the lower than normal result in 2013–14 when \$2.0 million was returned to the budget as part of the Better Regulations reform funding agreement.

**TABLE 16: INCOME 2014–15**

Income source	Income (\$'000)	%
Receipts from industry		
Application fees	5 554	18.68
Levies	16 263	54.68
Annual fees (renewal fees)	4 703	15.81
Other receipts from industry	1 921	6.46
Parliamentary appropriation	743	2.50
Other revenue	557	1.87
<b>Total income</b>	<b>29 741</b>	<b>100.00</b>

### Expenditure

Total operating expenses for 2014–15 were \$33.204 million (Table 17), an increase of \$1.207 million (3.77 per cent) from the previous year.

**TABLE 17: EXPENDITURE, 2014–15 (INCLUDING COMPARISON WITH PORTFOLIO BUDGET STATEMENT)**

	2014–15 actual expenditure (\$'000)	% of expenditure	2014–15 budget (per PBS) (\$'000)
Employee benefits	22 113	66.60	21 063
Supplier expenses	9 861	29.70	10 012
Depreciation	1 203	3.62	1 107
Other	27	0.08	–
<b>Total expenditure</b>	<b>33 204</b>	<b>100.00</b>	<b>32 182</b>

– = nil; PBS = Portfolio Budget Statement



Further details on the comparison of the APVMA's actual results for 2014–15 with the budget can be found in note 18 of the audited financial statements.

## Introduction of the PGPA Act

The PGPA Act was introduced on 1 July 2014, replacing both the FMA Act and the *Commonwealth Authorities and Companies Act 1997*. The APVMA was one of a small number of government entities that was reclassified from an FMA Act agency to a corporate Commonwealth entity. This reclassification resulted in a change to the way the APVMA accounts for industry fees and charges. This category of income is now recorded when money is received rather than when it was earned.

## 2014–15 result and equity balance

The APVMA recorded a net operating deficit of \$3.463 million for 2014–15. However, following the reclassification to a corporate Commonwealth entity, the APVMA was required to account for an additional \$5.155 million as an equity injection, being industry fees and charges treated as unearned income in 2013–14. This inclusion of the equity injection led to an overall result of a \$1.692 million surplus.

The equity balance at 30 June 2015 was \$10.490 million.

## Audit results

The APVMA achieved an unqualified audit result, and there were no adverse findings.

## Financial reserve

Revenue can vary significantly from year to year as a result of fluctuations in sales of pesticides and veterinary medicines, because of changing environmental conditions. To manage this, the APVMA aims to hold a financial reserve (which forms part of equity).

The financial reserve is based on three months of operating expenses and is currently set at \$7.0 million.

## Advertising and market research

No advertising or market research was conducted during 2014–15.

## Consultancies

In 2014–15, 23 new consultancy contracts were entered into, involving total actual expenditure (including capitalisation) of \$440 000. In addition, 28 ongoing consultancy contracts were active this year, involving total actual expenditure of \$802 000.

Selection processes are described in terms drawn from the Commonwealth procurement guidelines. 'Direct sourcing' refers to a selection process in which neither a tender nor a panel was used. In these situations, multiple quotes were obtained, with the number of quotes depending on the value of the procurement. APVMA Finance Procedure 4, 'Purchasing', outlines the number of quotes required:

- |                              |                      |                      |
|------------------------------|----------------------|----------------------|
| • Purchase of goods/services | to \$2000            | One quote            |
| • Purchase of goods/services | \$2001 to \$10 000   | Two written quotes   |
| • Purchase of goods/services | \$10 001 to \$80 000 | Three written quotes |
| • Purchase of goods/services | \$80 000 and over    | Tender               |

Exemptions to these requirements may be approved in some circumstances.





## INDEPENDENT AUDITOR'S REPORT

### To the Minister for Agriculture

I have audited the accompanying annual financial statements of the Australian Pesticides and Veterinary Medicines Authority for the year ended 30 June 2015, which comprise:

- Statement by the Accountable Authority and the Chief Financial Officer;
- Statement of Comprehensive Income;
- Statement of Financial Position;
- Statement of Changes in Equity;
- Cash Flow Statement;
- Schedule of Commitments; and
- Notes to and forming part of the financial statements comprising a Summary of Significant Accounting Policies and other explanatory information.

### *Chief Executive's Responsibility for the Financial Statements*

The Chief Executive of the Australian Pesticides and Veterinary Medicines Authority is responsible under the *Public Governance, Performance and Accountability Act 2013* for the preparation and fair presentation of annual financial statements that comply with Australian Accounting Standards and the rules made under that Act. The Chief Executive is also responsible for such internal control as is necessary to enable the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

### *Auditor's Responsibility*

My responsibility is to express an opinion on the financial statements based on my audit. I have conducted my audit in accordance with the Australian National Audit Office Auditing Standards, which incorporate the Australian Auditing Standards. These auditing standards require that I comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made by the Accountable Authority of the entity, as well as evaluating the overall presentation of the financial statements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my audit opinion.

#### *Independence*

In conducting my audit, I have followed the independence requirements of the Australian National Audit Office, which incorporate the requirements of the Australian accounting profession.

#### *Opinion*

In my opinion, the financial statements of the Australian Pesticides and Veterinary Medicines Authority:

- (a) comply with Australian Accounting Standards and the *Public Governance, Performance and Accountability/Financial Reporting Rule 2013*, and
- (b) present fairly the financial position of the Australian Pesticides and Veterinary Medicines Authority as at 30 June 2015 and its financial performance and cash flows for the year then ended.

Australian National Audit Office



Peter Kerr  
Executive Director  
Delegate of the Auditor-General  
Canberra  
10 September 2015



**Australian Government**  
**Australian Pesticides and  
 Veterinary Medicines Authority**

**STATEMENT BY THE ACCOUNTABLE AUTHORITY AND THE CHIEF FINANCIAL OFFICER**

In our opinion, the attached financial statements for the year ended 30 June 2015 comply with subsection 42(2) of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), and are based on properly maintained financial records as per subsection 41(2) of the PGPA Act.

In our opinion, at the date of this statement, there are reasonable grounds to believe that the Australian Pesticides and Veterinary Medicines Authority will be able to pay its debts as and when they fall due.

Signed  .....

Kareena Arthy  
 Chief Executive Officer

10 September 2015

Signed  .....

Dan Webb  
 Chief Financial Officer

10 September 2015

## Australian Pesticides and Veterinary Medicines Authority

### STATEMENT OF COMPREHENSIVE INCOME

for the year ended 30 June 2015

	Notes	2015 \$'000	2014 \$'000
<b>NET COST OF SERVICE</b>			
<b>Expenses</b>			
Employee benefits	3A	22 113	21 441
Suppliers	3B	9 861	9 691
Depreciation and amortisation	3C	1 203	841
Finance costs		17	16
Losses from asset sales	3D	10	8
<b>Total Expenses</b>		<b>33 204</b>	<b>31 997</b>
 <b>Own-Source Income</b>			
<b>Own-source revenue</b>			
Other revenue	4A	557	324
<b>Total own-source revenue</b>		<b>557</b>	<b>324</b>
<b>Total Own-Source Income</b>		<b>557</b>	<b>324</b>
 <b>Net Cost of Services</b>		<b>32 647</b>	<b>31 673</b>
 Revenue from Government	4B	29 184	27 951
<b>Surplus/(Deficit) Attributable to the Australian Government</b>		<b>(3 463)</b>	<b>(3 722)</b>
 <b>OTHER COMPREHENSIVE INCOME</b>			
<b>Items not subject to subsequent reclassification to profit and loss</b>			
Equity injection following restructure to a corporate Commonwealth entity		5 155	-
<b>Total other comprehensive income</b>		<b>5 155</b>	<b>-</b>
<b>Total Comprehensive Income/(Loss) Attributable to the Australian Government</b>		<b>1 692</b>	<b>(3 722)</b>

The above statement should be read in conjunction with the accompanying notes.

# Australian Pesticides and Veterinary Medicines Authority

## STATEMENT OF FINANCIAL POSITION

as at 30 June 2015

	Notes	2015 \$'000	2014 \$'000
<b>ASSETS</b>			
<b>Financial Assets</b>			
Cash and cash equivalents	6A	1 289	13 633
Trade and other receivables	6B	13 666	563
<b>Total financial assets</b>		<b>14 955</b>	<b>14 196</b>
<b>Non-Financial Assets</b>			
Land and buildings	7A,C	1 769	2 121
Property, plant and equipment	7B,C	761	845
Intangibles	7D,E	4 292	3 062
Other non-financial assets	7F	283	306
<b>Total non-financial assets</b>		<b>7 105</b>	<b>6 334</b>
<b>Total Assets</b>		<b>22 060</b>	<b>20 530</b>
<b>LIABILITIES</b>			
<b>Payables</b>			
Suppliers	8A	3 848	3 900
Other payables	8B	1 689	1 642
<b>Total payables</b>		<b>5 537</b>	<b>5 542</b>
<b>Provisions</b>			
Employee provisions	9A	5 578	5 752
Other provisions	9B	455	438
<b>Total provisions</b>		<b>6 033</b>	<b>6 190</b>
<b>Total Liabilities</b>		<b>11 570</b>	<b>11 732</b>
<b>Net Assets</b>		<b>10 490</b>	<b>8 798</b>
<b>EQUITY</b>			
Contributed equity		5 528	373
Reserves		1 123	1 123
Retained surplus		3 839	7 302
<b>Total Equity</b>		<b>10 490</b>	<b>8 798</b>

The above statement should be read in conjunction with the accompanying notes.

**Australian Pesticides and Veterinary Medicines Authority**

**STATEMENT OF CHANGES IN EQUITY**  
*for the year ended 30 June 2015*

	Asset				Contributed Equity/capital		Total Equity	
	Retained Earnings		Revaluation Reserves		2015		2014	
	2015	2014	2015	2014	2015	2014	2015	2014
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
<b>Opening Balance</b>								
Balance carried forward from previous period	7 302	11 024	1 123	1 123	373	373	8 798	12 520
<b>Adjusted opening balance</b>	<b>7 302</b>	<b>11 024</b>	<b>1 123</b>	<b>1 123</b>	<b>373</b>	<b>373</b>	<b>8 798</b>	<b>12 520</b>
<b>Comprehensive income</b>								
Surplus/(Loss) for the period	(3 463)	(3 722)	-	-	-	-	(3 463)	(3 722)
Other comprehensive income	-	-	-	-	5 155	-	5 155	-
<b>Total comprehensive income</b>	<b>(3 463)</b>	<b>(3 722)</b>	<b>-</b>	<b>-</b>	<b>5 155</b>	<b>-</b>	<b>1 692</b>	<b>(3 722)</b>
<b>Closing Balance at 30 June</b>	<b>3 839</b>	<b>7 302</b>	<b>1 123</b>	<b>1 123</b>	<b>5 528</b>	<b>373</b>	<b>10 490</b>	<b>8 798</b>

The above statement should be read in conjunction with the accompanying notes.

# Australian Pesticides and Veterinary Medicines Authority

## CASH FLOW STATEMENT

for the year ended 30 June 2015

	Notes	2015 \$'000	2014 \$'000
<b>OPERATING ACTIVITIES</b>			
<b>Cash received</b>			
Appropriation		743	29 974
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992 contribution</i>		34 390	-
Net GST received		980	867
Interest received		17	-
Other cash received		593	125
<b>Total cash received</b>		<b>36 723</b>	<b>30 966</b>
<b>Cash used</b>			
Employees		22 531	21 159
Suppliers		11 105	9 528
<b>Total cash used</b>		<b>33 636</b>	<b>30 687</b>
<b>Net cash flows from operating activities</b>	10	<b>3 087</b>	<b>279</b>
<b>INVESTING ACTIVITIES</b>			
<b>Cash received</b>			
Proceeds from sales of property, plant and equipment, and intangibles		3	2
<b>Total cash received</b>		<b>3</b>	<b>2</b>
<b>Cash used</b>			
Purchase of property, plant and equipment, and intangibles		2 010	2 138
<b>Total cash used</b>		<b>2 010</b>	<b>2 138</b>
<b>Net cash flows from or (used by) investing activities</b>		<b>(2 007)</b>	<b>(2 136)</b>
<b>FINANCING ACTIVITIES</b>			
<b>Cash used</b>			
Closing of the APVMA special account on 1 July 2014		13 424	-
<b>Total cash used</b>		<b>13 424</b>	<b>-</b>
<b>Net cash flows from or (used by) financing activities</b>		<b>(13 424)</b>	<b>-</b>
<b>Net increase or (decrease) in cash held</b>		<b>(12 344)</b>	<b>(1 857)</b>
Cash and cash equivalents at the beginning of the reporting period		13 633	15 490
<b>Cash and cash equivalents at the end of the reporting period</b>	6A	<b>1 289</b>	<b>13 633</b>

The above statement should be read in conjunction with the accompanying notes.



# Australian Pesticides and Veterinary Medicines Authority

## SCHEDULE OF COMMITMENTS

as at 30 June 2015

	2015	2014
	\$'000	\$'000
<b>BY TYPE</b>		
<b>Commitments receivable</b>		
GST recoverable on commitments	(827)	(935)
<b>Total commitments receivable</b>	<b>(827)</b>	<b>(935)</b>
<b>Commitments payable</b>		
<b>Other commitments</b>		
Operating leases <sup>1</sup>	8 192	9 560
Other commitments <sup>2</sup>	2 794	2 800
<b>Total other commitments</b>	<b>10 986</b>	<b>12 360</b>
<b>Net commitments by type</b>	<b>10 159</b>	<b>11 425</b>
<b>BY MATURITY</b>		
<b>Commitments receivable</b>		
One year or less	(210)	(182)
From one to five years	(568)	(554)
Over five years	(49)	(199)
<b>Total commitments receivable</b>	<b>(827)</b>	<b>(935)</b>
<b>Commitments payable</b>		
<b>Operating lease commitments</b>		
One year or less	1 420	1 369
From one to five years	6 233	6 008
Over five years	539	2 183
<b>Total operating lease commitments</b>	<b>8 192</b>	<b>9 560</b>
<b>Other Commitments</b>		
One year or less	2 780	2 712
From one to five years	14	88
<b>Total other commitments</b>	<b>2 794</b>	<b>2 800</b>
<b>Net commitments by maturity</b>	<b>10 159</b>	<b>11 425</b>

NB: Commitments are GST inclusive where relevant.

1. Operating leases included are effectively non-cancellable and comprise:

### Leases for office accommodation.

Lease payments for the rental of the APVMA's office at Amtech Estate, Symonston are subject to annual increase of 3.75%. During 11/12 the APVMA signed a new lease agreement, extending the lease term to October 2020, with a further two 5 year options available.

2. The nature of other commitments is for the purchase of scientific assessment services and general contractors/consultants goods and services.

The above schedule should be read in conjunction with the accompanying notes.

**Australian Pesticides and Veterinary Medicines Authority****NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS**

Note 1: Summary of Significant Accounting Policies

Note 2: Events After the Reporting Period

Note 3: Expenses

Note 4: Income

Note 5: Fair Value Measurements

Note 6: Financial Assets

Note 7: Non-Financial Assets

Note 8: Payables

Note 9: Provisions

Note 10: Cash Flow Reconciliation

Note 11: Contingent Assets and Liabilities

Note 12: Senior Management Personnel Remuneration

Note 13: Financial Instruments

Note 14: Financial Asset Reconciliation

Note 15: Appropriations

Note 16: Reporting of Outcomes

Note 17: Cost Recovery Summary

Note 18: Budgetary Reporting and Explanation of Major Variances

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 1: Summary of Significant Accounting Policies

##### 1.1 Objectives of the Australian Pesticides and Veterinary Medicines Authority

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an Australian Government controlled entity. The APVMA is responsible for the assessment and registration of pesticides and veterinary medicines and for their regulation up to and including the point of retail sale.

The APVMA administers the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) in partnership with the States and Territories and with the active involvement of other Australian government agencies.

Its role is to independently evaluate the safety and performance of chemical products intended for sale, making sure that the health and safety of people, animals and the environment are protected.

The APVMA (formerly National Registration Authority for Agricultural and Veterinary Chemicals) was established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. Following the introduction of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) on 1 July 2014, the APVMA was reclassified from an FMA Act entity to a corporate Commonwealth entity.

The APVMA is structured to meet a single outcome:

Outcome 1: Protection of the health and safety of people, animals, the environment, and agricultural and livestock industries through regulation of pesticides and veterinary medicines.

The continued existence of the APVMA in its present form and with its present programs is dependent on Government policy and on continuing appropriations by Parliament for the APVMA's administration and programs.

##### 1.2 Basis of Preparation of the Financial Report

The financial statements are general purpose financial statements and are required by section 42 of the PGPA Act.

The Financial Statements and notes have been prepared in accordance with:

- a) Financial Reporting Rule (FRR) for reporting periods ending on or after 1 July 2014; and
- b) Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board (AASB) that apply for the reporting period.

The financial statements have been prepared on an accrual basis and in accordance with the historical cost convention, except for certain assets at fair value. Except where stated, no allowance is made for the effect of changing prices on the results or the financial position.

The financial report is presented in Australian dollars and values are rounded to the nearest thousand dollars unless otherwise specified.

Unless an alternative treatment is specifically required by an accounting standard or the FRR, assets and liabilities are recognised in the statement of financial position when and only when it is probable that future economic benefits will flow to the entity or a future sacrifice of economic benefits will be required and the amounts of the assets or liabilities can be reliably measured.

However, assets and liabilities arising under executory contracts are not recognised unless required by an accounting standard.

Liabilities and assets that are unrecognised are reported in the schedule of commitments or the schedule of contingencies.

Unless alternative treatment is specifically required by an accounting standard, income and expenses are recognised in the Statement of Comprehensive Income when and only when the flow, consumption or loss of economic benefits has occurred and can be reliably measured.

##### 1.3 Significant Accounting Judgements and Estimates

In the process of applying the accounting policies listed in this note, the APVMA has made the following judgements that have the most significant impact on the amounts recorded in the financial statements: the fair value of leasehold improvements have been taken to be the market value of similar properties as determined by an individual valuer. In some instances, entity buildings are purpose-built and may in fact realise more or less in the market.

No accounting assumptions or estimates have been identified that have a significant risk of causing a material adjustment to carrying amounts of assets and liabilities within the next accounting period.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 1: Summary of Significant Accounting Policies

##### 1.4 New Australian Accounting Standards

###### Adoption of new Australian Accounting Standard Requirements

The following standard has been adopted earlier than the application date as stated in the standard.

Standard	Nature of change in accounting policy and adjustment to financial statements
AASB 13 Fair value measurement	The amendments change AASB 13 Fair Value Measurement and provide relief for not-for-profit public sector entities from making some previously-required disclosures about the fair value measurement of property, plant and equipment assets which are primarily held for internal or policy use, rather than to earn revenue. More specifically, the disclosure of quantitative information about the significant unobservable inputs used in fair value measurements and the sensitivity of certain fair value measurements to changes in unobservable inputs is no longer required.

The following new standard was issued prior to the signing of the statement by the accountable authority and chief financial officer, were applicable to the current reporting period and had a material effect on the entity's financial statements:

Standard	Nature of change in accounting policy and adjustment to financial statements
AASB 1055 Budgetary reporting	AASB 1055 sets out budgetary disclosure requirements for whole-of-government financial statements, each government's General Government Sector (GGS) financial statements and the financial statements for each not-for-profit entity with the GGS. AASB 1055 requires disclosure of the original budget as well as explanations for major variances between the original budget and the actual amount disclosed in the financial statements. The original budget is the first budget presented to Parliament for the reporting period. When budget information has not been presented on the same basis and classification as the financial statements, AASB 1055 requires budget information to be restated to be consistent with the financial statements. Major variance explanation disclosures are those relevant to the information needs of users when assessing performance and accountability. AASB 1055 does not require prior-year budget comparatives.

All other new or revised standards and interpretations that were issued prior to the sign-off date and are applicable to the current reporting period did not have a material effect, and are not expected to have a future material effect, on the entity's financial statements.

###### Future Australian Accounting Standard Requirements

The following amended standards were issued by the Australian Accounting Standards Board prior to the signing of the statement by the accountable authority and chief financial officer, which are expected to have a material impact on the entity's financial statements for future reporting period(s):

Standard	Application date for the APVMA	Nature of impending changes in accounting policy and likely impact on initial application
AASB 2015-6 Extending related party disclosures to Not For Profit public sector entities	1 July 2016	AASB 2015-6 removed the exception that allowed not-for-profit public sector entities to avoid applying certain paragraphs of AASB 124 Related Party Disclosures. The amended standard will require these entities to identify and disclose transactions with key management personnel that occur outside the person's capacity as an ordinary taxpayer, or that involving a benefit not available to the general public.

All other new standards, revised standards, interpretations or amending standards that were issued by the Australian Accounting Standards Board prior to the sign-off date and are applicable to future reporting period(s) are not expected to have a future material impact on the entity's financial statements.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 1: Summary of Significant Accounting Policies

##### 1.5 Revenue

Revenue from the sale of goods is recognised when:

- a) the risks and rewards of ownership have been transferred to the buyer;
- b) the APVMA retains no managerial involvement nor effective control over the goods;
- c) the revenue and transaction costs incurred can be reliably measured; and
- d) it is probable that the economic benefits associated with the transaction will flow to the APVMA.

Revenue from rendering of services is recognised by reference to the stage of completion of contracts at the reporting date. The revenue is recognised when:

- a) the amount of revenue, stage of completion and transaction costs incurred can be reliably measured; and
- b) the probable economic benefits with the transaction will flow to the entity.

The stage of completion of contracts at the reporting date is determined by reference to the proportion that costs incurred to date bear to the estimated total costs of the transaction.

Receivables for goods and services, which have 30 day terms, are recognised at the nominal amounts due less any impairment allowance account. Collectability of debts is reviewed at balance date. Allowances are made when collectability of the debt is no longer probable.

Interest revenue is recognised using the effective interest method as set out in AASB 139 *Financial Instruments: Recognition and Measurement*.

##### Resources Received Free of Charge

Resources received free of charge are recognised as revenue when, and only when, a fair value can be reliably determined and the services would have been purchased if they had not been donated. Use of those resources is recognised as an expense. Resources received free of charge are recorded as either revenue or gains depending on their nature.

Contributions of assets at no cost of acquisition or for nominal consideration are recognised as gains at their fair value when the asset qualifies for recognition, unless received from another non-corporate or corporate Commonwealth entity as a consequence of a restructuring of administrative arrangements (refer to Note 1.7).

##### Revenue from Government

Funding received or receivable from non-corporate Commonwealth entities (appropriated to the non-corporate Commonwealth entity as a corporate Commonwealth entity payment item for payment to the APVMA) is recognised as Revenue from Government unless they are in the nature of an equity injection or a loan.

Corporate Commonwealth entities can not recognise monies collected on behalf of the Commonwealth as administered revenue or an asset. As fees and charges paid by industry is administered in nature, amounts owed to the APVMA can not be recognise as revenue or a trade receivable.

##### 1.6 Gains

##### Resources Received Free of Charge

Resources received free of charge are recognised as gains when, and only when, a fair value can be reliably determined and the services would have been purchased if they had not been donated. Use of those resources is recognised as an expense.

Resources received free of charge are recorded as either revenue or gains depending on their nature.

Contributions of assets at no cost of acquisition or for nominal consideration are recognised as gains at their fair value when the asset qualifies for recognition, unless received from another Government entity as a consequence of a restructuring of administrative arrangement (refer to Note 1.7).

##### Sale of Assets

Gains from disposal of assets are recognised when control of the asset has passed to the buyer.

##### 1.7 Transactions with the Government as Owner

##### Equity Injections

Amounts appropriated which are designated as 'equity injections' for a year (less any formal reductions) and Departmental Capital Budgets (DCBs) are recognised directly in contributed equity in that year.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 1: Summary of Significant Accounting Policies

##### Restructuring of Administrative Arrangements

Net assets received from or relinquished to another Government entity under a restructuring of administrative arrangements are adjusted at their book value directly against contributed equity.

##### Other Distributions to Owners

The FRR require that distributions to owners be debited to contributed equity unless it is in the nature of a dividend.

#### 1.8 Employee Benefits

Liabilities for 'short-term employee benefits' (as defined in AASB 119 *Employee Benefits*) and termination benefits due within twelve months of balance date are measured at their nominal amounts.

The nominal amount is calculated with regard to the rates expected to be paid on settlement of the liability.

Other long-term employee benefits are measured as net total of the present value of the defined benefit obligation at the end of the reporting period minus the fair value at the end of the reporting period of plan assets (if any) out of which the obligations are to be settled directly.

##### Leave

The liability for employee benefits includes provision for annual leave and long service leave. No provision has been made for sick leave as all sick leave is non-vesting and the average sick leave taken in future years by employees of the APVMA is estimated to be less than the annual entitlement for sick leave.

The leave liabilities are calculated on the basis of employees' remuneration at the estimated salary rates that applied at the time the leave is taken, including the APVMA's employer superannuation contribution rates to the extent that the leave is likely to be taken during service rather than paid out on termination.

The liability for long service leave has been determined by reference to the 'short-hand method' as outlined in the *Resource Management Guide No. 125 - Commonwealth Entities Financial Statements Guide* as at 30 June 2015. The estimate of the present value of the liability takes into account attrition rates and pay increases through promotion and inflation and is discounted using the 10 year bond rate at 30 June 2015.

##### Separation and Redundancy

Provision is made for separation and redundancy benefit payments. The APVMA recognises a provision for termination when it has developed a detailed formal plan for the terminations and has informed those employees affected that it will carry out the terminations.

##### Superannuation

The majority of staff of the APVMA are members of the Commonwealth Superannuation Scheme (CSS), the Public Sector Superannuation Scheme (PSS) or the PSS accumulation plan (PSSap).

The CSS and PSS are defined benefit schemes for the Australian Government. The PSSap is a defined contribution scheme.

The liability for defined benefits is recognised in the financial statements of the Australian Government and is settled by the Australian Government in due course. This liability is reported by the Department of Finance and Deregulation's administered schedules and notes.

The APVMA makes employer contributions to the employee superannuation scheme at rates determined by an actuary to be sufficient to meet the current cost to the Government. The APVMA accounts for the contributions as if they were contributions to defined contribution plans.

The liability for superannuation recognised as at 30 June represents outstanding contributions for the financial year.

#### 1.9 Leases

A distinction is made between finance leases and operating leases. Finance leases effectively transfer from the lessor to the lessee substantially all the risks and rewards incidental to ownership of leased assets. An operating lease is a lease that is not a finance lease. In operating leases, the lessor effectively retains substantially all such risks and benefits. The APVMA has no finance leases.

The discount rate used is the interest rate implicit in the lease. Leased assets are amortised over the period of the lease. Lease payments are allocated between the principal component and the interest expense.

Operating lease payments are expensed on a straight line basis that is representative of the pattern of benefits derived from the leased assets.

#### 1.10 Fair Value Measurement

The entity deems transfers between levels of the fair value hierarchy to have occurred at the end of the reporting period.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 1: Summary of Significant Accounting Policies

##### 1.11 Cash

Cash is recognised at its nominal amount. Cash and cash equivalents includes:

- a) cash on hand; and
- b) demand deposits in bank accounts with an original maturity of 3 months or less that are readily convertible to known amounts of cash and subject to insignificant risk of changes in value.

##### 1.12 Financial assets

The APVMA classifies its financial assets in the following categories:

- a) financial assets as at fair value through profit or loss;
- b) held-to-maturity investments;
- c) available-for-sale financial assets; and
- d) loans and receivables.

The classification depends on the nature and purpose of the financial assets and is determined at the time of initial recognition. Financial assets are recognised and derecognised upon trade date.

##### Effective Interest Method

The effective interest method is a method of calculating the amortised cost of a financial asset and of allocating interest income over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset, or, where appropriate, a shorter period.

Income is recognised on an effective interest basis except for financial assets that are recognised at fair value through the profit and loss.

##### Financial Assets at Fair Value Through Profit or Loss

Financial assets are classified as financial assets at fair value through profit or loss (FVTPL) where the financial assets:

- a) have been acquired principally for the purpose of selling in the near future;
- b) are a derivative that is not designated and effective as a hedging instrument; or
- c) are a part of an identified portfolio of financial instruments that the APVMA manages together and has a recent actual pattern of short-term profit-taking.

Assets in this category are classified as current assets.

Financial assets at fair value through profit or loss are stated at fair value, with any resultant gain or loss recognised in profit or loss. The net gain or loss recognised in profit or loss incorporates any interest earned on the financial asset. Interest earned on any financial assets at FVTPL is included in line item 'Change in fair value through profit and loss' and is not to be included again in the line item 'Interest'. The APVMA has no financial assets at fair value through the profit or loss.

##### Available-for-Sale Financial Assets

Available-for-sale financial assets are non-derivatives that are either designated in this category or not classified in any of the other categories.

Available-for-sale financial assets are recorded at fair value. Gains and losses arising from changes in fair value are recognised directly in reserves (equity) with the exception of impairment losses. Interest is calculated using the effective interest method and foreign exchange gains and losses on monetary assets are recognised directly in profit or loss. Where the asset is disposed of or is determined to be impaired, part (or all) of the cumulative gain or loss previously recognised in the reserve is included in surplus and deficit for the period.

Where a reliable fair value cannot be established for unlisted investments in equity instruments, these instruments are valued at cost. The APVMA has no available-for-sale financial assets.

##### Held-to-Maturity Investments

Non-derivative financial assets with fixed or determinable payments and fixed maturity dates that the group has the positive intent and ability to hold to maturity are classified as held-to-maturity investments. Held-to-maturity investments are recorded at amortised cost using the effective interest method less impairment, with revenue recognised on an effective yield basis. The APVMA has no held-to-maturity investments.

##### Receivables

Trade receivables, and other receivables that have fixed or determinable payments that are not quoted in an active market are classified as 'receivables'. Receivables are measured at amortised cost using the effective interest method less impairment. Interest is recognised by applying the effective interest rate.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 1: Summary of Significant Accounting Policies

##### Impairment of Financial Assets

Financial assets are assessed for impairment at the end of each reporting period.

*Financial assets held at amortised cost* - if there is objective evidence that an impairment loss has been incurred for loans and receivables or held to maturity investments held at amortised cost, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the asset's original effective interest rate. The carrying amount is reduced by way of an allowance account. The loss is recognised in the Statement of Comprehensive Income.

*Available for sale financial assets* - if there is objective evidence that an impairment loss on an available-for-sale financial asset has been incurred, the amount of the difference between its cost, less principal repayments and amortisation, and its current fair value, less any impairment loss previously recognised in expenses, is transferred from equity to the Statement of Comprehensive income.

*Financial assets held at cost* - if there is objective evidence that an impairment loss has been incurred, the amount of the impairment loss is the difference between the carrying amount of the asset and the present value of the estimated future cash flows discounted at the current market rate for similar assets.

#### **1.13 Financial Liabilities**

Financial liabilities are classified as either financial liabilities 'at fair value through profit or loss' or other financial liabilities. 'trade date'.

##### Financial liabilities at Fair Value Through Profit or Loss

Financial liabilities at fair value through profit or loss are initially measured at fair value. Subsequent fair value adjustments are recognised in profit or loss. The net gain or loss recognised in profit or loss incorporates any interest paid on the financial liability.

##### Other Financial Liabilities

Other financial liabilities are initially measured at fair value, net of transaction costs.

Other financial liabilities are subsequently measured at amortised cost using the effective interest method, with interest expense recognised on an effective yield basis.

The effective interest method is a method of calculating the amortised cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or, where appropriate, a shorter period.

Supplier and other payables are recognised at amortised cost. Liabilities are recognised to the extent that the goods or services have been received (and irrespective of having been invoiced).

#### **1.14 Contingent Liabilities and Contingent Assets**

Contingent liabilities and contingent assets are not recognised in the statement of financial position but are reported in the notes. They may arise from uncertainty as to the existence of a liability or asset or represent an asset or liability in respect of which the amount cannot be reliably measured. Contingent assets are disclosed when settlement is probable but not virtually certain and contingent liabilities are disclosed when settlement is greater than remote.

#### **1.15 Acquisition of Assets**

Assets are recorded at cost on acquisition except as stated below. The cost of acquisition includes the fair value of assets transferred in exchange and liabilities undertaken. Financial assets are initially measured at their fair value plus transaction costs where appropriate.

Assets acquired at no cost, or for nominal consideration, are initially recognised as assets and revenues at their fair value at the date of acquisition, unless acquired as a consequence of restructuring of administrative arrangements. In the latter case, assets are initially recognised as contributions by owners at the amounts at which they were recognised in the transferor APVMA's accounts immediately prior to the restructuring.



## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 1: Summary of Significant Accounting Policies

##### 1.16 Property, Plant and Equipment

###### Asset Recognition Threshold

Purchases of property, plant and equipment are recognised initially at cost in the statement of financial position, except for purchases costing less than \$5 000 for leasehold improvements and \$2 000 for all other types, which are expensed in the year of acquisition (other than where they form part of a group of similar items which are significant in total).

The initial cost of an asset includes an estimate of the cost of dismantling and removing the item and restoring the site on which it is located. This is particularly relevant to 'makegood' provisions in property leases taken up by the APVMA where there exists an obligation to restore the property to its original condition. These costs are included in the value of the APVMA's leasehold improvements with a corresponding provision for the 'makegood' recognised.

###### Revaluations

Following initial recognition at cost, property, plant and equipment are carried at fair value. Valuations are conducted with sufficient frequency to ensure that the carrying amounts of assets do not differ materially from the assets' fair values as at the reporting date. The regularity of independent valuations depends upon the volatility of movements in market values for the relevant assets.

Revaluation adjustments are made on a class basis. Any revaluation increment is credited to equity under the heading of asset revaluation reserve except to the extent that it reverses a previous revaluation decrement of the same asset class that was previously recognised through operating result. Revaluation decrements for a class of assets are recognised directly through operating result except to the extent that they reverse a previous revaluation increment for that class.

Any accumulated depreciation as at the revaluation date is eliminated against the gross carrying amount of the asset and the asset restated to the revalued amount.

###### Depreciation

Depreciable property plant and equipment assets are written-off to their estimated residual values over their estimated useful lives to the APVMA using, in all cases, the straight-line method of depreciation.

Depreciation rates (useful lives), residual values and methods are reviewed at each reporting date and necessary adjustments are recognised in the current, or current and future reporting periods, as appropriate.

Depreciation rates applying to each class of depreciable asset are based on the following useful lives:

	2015	2014
Leasehold improvements	Shorter of lease term or useful life	Shorter of lease term or useful life
Property, Plant and Equipment	3 to 15 years	3 to 15 years

###### Impairment

All assets were assessed for impairment at 30 June 2015. Where indications of impairment exist, the asset's recoverable amount is estimated and an impairment adjustment made if the asset's recoverable amount is less than its carrying amount.

The recoverable amount of an asset is the higher of its fair value less costs to sell and its value in use. Value in use is the present value of the future cash flows expected to be derived from the asset. Where the future economic benefit of an asset is not primarily dependent on the asset's ability to generate future cash flows, and the asset would be replaced if the APVMA were deprived of the asset, its value in use is taken to be its depreciated replacement cost.

###### Derecognition

An item of property, plant and equipment is derecognised upon disposal or when no further future economic benefits are expected from its use or disposal.

##### 1.17 Intangibles

The APVMA's intangibles comprise internally developed and externally acquired software for internal use. These assets are carried at cost less accumulated amortisation and accumulated impairment losses.

Software is amortised on a straight-line basis over its anticipated useful life. The useful lives of the APVMA's software are 3 to 10 years (2014: 3 to 10 years).

All software assets were assessed for indications of impairment as at 30 June 2015.

##### 1.18 Taxation

The APVMA is exempt from all forms of taxation except Fringe Benefits Tax (FBT) and the Goods and Services Tax (GST).

Revenues, expenses and assets are recognised net of GST except:

- where the amount of GST incurred is not recoverable from the Australian Taxation Office; and
- for receivables and payables where applicable.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

*for the year ended 30 June 2015*

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#### Note 2: Events After the Reporting Period

There was no subsequent event that had the potential to significantly affect the ongoing structure and financial activities of the entity.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 3: Expenses

	2015 \$'000	2014 \$'000
<b>Note 3A: Employee benefits</b>		
Wages and salaries	16 687	16 055
Superannuation:		
Defined contribution plans	1 868	1 775
Defined benefit plans	1 138	1 147
Leave and other entitlements	1 938	1 909
Seperation and redundancies	77	-
Other employee benefits	405	555
<b>Total employee benefits</b>	<b>22 113</b>	<b>21 441</b>
<b>Note 3B: Suppliers</b>		
<b>Goods and services</b>		
Consultants	1 242	1 694
Contractors	7 052	6 369
Other	181	174
<b>Total goods and services</b>	<b>8 475</b>	<b>8 237</b>
Goods and services are made up of:		
Provision of goods – external parties	404	409
Rendering of services – related entities	3 659	3 661
Rendering of services – external parties	4 412	4 167
<b>Total goods and services</b>	<b>8 475</b>	<b>8 237</b>
<b>Other supplier expenses</b>		
Operating lease rentals - external parties		
Minimum lease payments	1 292	1 299
Workers compensation premiums	94	155
<b>Total other supplier expenses</b>	<b>1 386</b>	<b>1 454</b>
<b>Total supplier expenses</b>	<b>9 861</b>	<b>9 691</b>
<b>Note 3C: Depreciation and amortisation</b>		
Depreciation:		
Leasehold improvements	352	340
Property, plant and equipment	253	212
<b>Total depreciation</b>	<b>605</b>	<b>552</b>
Amortisation:		
Intangibles - Computer Software	598	289
<b>Total amortisation</b>	<b>598</b>	<b>289</b>
<b>Total depreciation and amortisation</b>	<b>1 203</b>	<b>841</b>

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 3: Expenses

	2015 \$'000	2014 \$'000
<b>Note 3D: Losses from asset sales</b>		
Infrastructure, plant and equipment		
Proceeds from sale	(3)	(2)
Carrying value of assets sold	13	10
<b>Total losses from assets sales</b>	<b>10</b>	<b>8</b>

### Note 4: Income

	2015 \$'000	2014 \$'000
<b>OWN-SOURCE REVENUE</b>		
<b>Note 4A: Other revenue</b>		
Resources received free of charge		
Remuneration of auditors	36	36
Other revenue	521	288
<b>Total other revenue</b>	<b>557</b>	<b>324</b>

### REVENUE FROM GOVERNMENT

#### Note 4B: Revenue from Government

Appropriations:		
Departmental appropriations	743	981
Departmental special appropriations	-	26 970
Department of Agriculture		
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i> contribution	28 441	-
<b>Total revenue from Government</b>	<b>29 184</b>	<b>27 951</b>

Department of Agriculture contribution is equal to the following fees and charges paid by industry:

Levies	16 263	17 059
Annual renewal fee	4 703	4 793
Product application fees	5 554	5 087
Good manufacturing practice (GMP) licence fees	1 021	1 252
Permits, actives and other fees	900	779
Industry funds returned to the budget	-	(2 000)
<b>Total industry contributions</b>	<b>28 441</b>	<b>26 970</b>

In 2014 industry fees and charges were returned to the APVMA via a departmental special appropriation.

**Australian Pesticides and Veterinary Medicines Authority**  
**NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS**  
*for the year ended 30 June 2015*

**Note 5: Fair Value Measurements**

The following table provides an analysis of assets and liabilities that are measured at fair value. The different levels of fair value hierarchy are defined below.

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities than the entity can access at measurement date.

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs for the asset or liability.

**Note 5A: Fair Value Measurements, Valuation Techniques and Input Used**

	Fair value measurements at the end of the reporting period			For Level 2 and 3 fair value measurements	
	2015 \$'000	2014 \$'000	Category (Level 1, 2 or 3) <sup>1</sup>	Valuation technique(s) <sup>1</sup>	Inputs used
<b>Non-financial assets<sup>2</sup></b>					
Leasehold improvements	1 731	2 055	Level 3	Depreciated Replacement Cost	Replacement Cost New (price per sq/m) Consumed economic benefit / Obsolescence of asset
Property, plant and equipment	548	590	Level 2	Market Approach	Adjusted market transactions
	212	255	Level 3	Depreciated Replacement Cost	Replacement Cost New Consumed economic benefit / Obsolescence of asset
<b>Total fair value measurement of assets in the statement of financial position</b>	<b>2 491</b>	<b>2 900</b>			

- No change in valuation technique occurred during the period.
- Fair value measurements - highest and best use differs from current use of non-financial assets (NFA's)**  
The highest and best use of all non-financial assets are the same as their current use.
- Recurring and non-recurring Level 3 fair value measurements - valuation processes**  
The APVMA procured valuation services from Australian Valuation Solutions (AVS) and relied on valuation models provided by AVS in 2014, no changes have occurred in 2015. The entity tests the procedures of the valuation model at least once every 12 months. The AVS has provided assurance that the model developed is in compliance with AASB 13.

**Australian Pesticides and Veterinary Medicines Authority**  
**NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS**  
*for the year ended 30 June 2015*

**Note 5: Fair Value Measurements**

**Note 5B: Level 1 and Level 2 Transfers for Recurring Fair Value Measurements**

There were no transfers between level 1 and level 2.

**Note 5C: Reconciliation For Recurring Level 3 Fair Value Measurements**

Recurring Level 3 fair value measurements - reconciliation for assets

	Non-financial assets			
	Leaschold improvements	Leaschold improvements	Property, plant and equipment	Total
	2015	2014	2015	2014
	\$'000	\$'000	\$'000	\$'000
Opening Balance <sup>1</sup>	2 055	2 274	255	2 310
Total gains/(losses) in accumulated depreciation <sup>2</sup>	(324)	(313)	(43)	(367)
Purchases	-	94	-	-
Transfer into Level 3 <sup>4</sup>	-	-	-	-
Transfer out of Level 3 <sup>4</sup>	-	-	-	-
<b>Closing balance</b>	<b>1 731</b>	<b>2 055</b>	<b>212</b>	<b>1 943</b>
			255	2 310

1. Open balance as determined in accordance with AASB 13

2. These losses are presented in the Statement of Comprehensive Income under Depreciation and Amortisation.

3. A minor adjustment was made to the 2014 comparative figures to amend the incorrect allocation of accumulated depreciation. This did not result in a change to the closing balance.

4. There have been no transfers between levels of the hierarchy during the year.

The entity's policy for determining when transfers between levels are deemed to have occurred can be found in Note 1.

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 6: Financial Assets

	2015 \$'000	2014 \$'000
<b><u>Note 6A: Cash and Cash Equivalents</u></b>		
Cash on hand or on deposit	1 289	209
Special Accounts	-	13 424
<b>Total cash and cash equivalents</b>	<b>1 289</b>	<b>13 633</b>
<b><u>Note 6B: Trade and Other Receivables</u></b>		
<b>Goods and services</b>		
Goods and services - related entities	123	134
Goods and services - external parties	40	609
<b>Total receivables for goods and services</b>	<b>163</b>	<b>743</b>
<b>Contribution receivable<sup>1</sup></b>		
Department of Agriculture	13 426	-
<b>Total contribution receivable</b>	<b>13 426</b>	<b>-</b>
<b>Other receivable</b>		
GST receivable from the Australian Taxation Office	94	125
<b>Total other receivables</b>	<b>94</b>	<b>125</b>
<b>Total trade and other receivables (gross)</b>	<b>13 683</b>	<b>868</b>
<b>Less impairment allowance account:</b>		
Goods and services	(17)	(305)
<b>Total impairment allowance account</b>	<b>(17)</b>	<b>(305)</b>
<b>Total trade and other receivables (net)</b>	<b>13 666</b>	<b>563</b>

1. An explanation of the contribution receivable can be found in Note 18B

#### Receivables are expected to be recovered in:

No more than 12 months	13 666	563
More than 12 months	-	-
<b>Total trade and other receivables (net)</b>	<b>13 666</b>	<b>563</b>

Receivables are aged as follows:

Not overdue	13 562	259
Overdue by:		
Less than 30 days	6	304
61 to 90 days	19	-
More than 90 days	96	305
<b>Total receivables (gross)</b>	<b>13 683</b>	<b>868</b>

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 6: Financial Assets

	2015 \$'000	2014 \$'000
The impairment allowance account is aged as follows:		
Not overdue	-	-
Overdue by:		
Less than 30 days	-	-
More than 90 days	(17)	(305)
<b>Total impairment allowance account</b>	<b>(17)</b>	<b>(305)</b>

#### Reconciliation of the impairment allowance account:

##### Movements in relation to 2015

	Goods and services \$'000	Total \$'000
<b>Opening balance</b>	<b>(305)</b>	<b>(305)</b>
Amounts reversed	288	288
Amounts written off	-	-
New impaired assets	-	-
<b>Closing balance</b>	<b>(17)</b>	<b>(17)</b>

##### Movements in relation to 2014

	Goods and services \$'000	Total \$'000
<b>Opening balance</b>	<b>(305)</b>	<b>(305)</b>
Amounts recovered and reversed	-	-
Amounts written off	-	-
New impaired assets	-	-
<b>Closing balance</b>	<b>(305)</b>	<b>(305)</b>

Credit terms for goods and services were within 30 days (2014: 30 days).



## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 7: Non-Financial Assets

	2015 \$'000	2014 \$'000
<b><u>Note 7A: Land and Buildings</u></b>		
Leasehold improvements		
Fair value	2 368	2 368
Accumulated depreciation	(638)	(313)
<b>Total leasehold improvements</b>	<b>1 730</b>	<b>2 055</b>
Makegood		
Fair value	269	269
Accumulated depreciation	(230)	(203)
<b>Total makegood</b>	<b>39</b>	<b>66</b>
<b>Total land and buildings (non-current)</b>	<b>1 769</b>	<b>2 121</b>

All leasehold improvement are subject to revaluation.

No indicators of impairment were found for land and buildings.

No leasehold improvements are expected to be sold or disposed of within the next 12 months.

#### **Note 7B: Property, Plant and Equipment**

Property, plant and equipment:		
Fair value	1 224	1 057
Accumulated depreciation	(463)	(212)
<b>Total property, plant and equipment (non-current)</b>	<b>761</b>	<b>845</b>

All infrastructure, plant and equipment is subject to revaluation. The carrying amount is included in the valuation figures above.

No indicators of impairment were found for property, plant and equipment.

No property, plant or equipment is expected to be sold or disposed of within the next 12 months.

#### **Revaluation of non-financial assets**

All revaluations were conducted in accordance with the revaluation policy stated at Note 1. No revaluation increments or decrements were recorded in 2015 or 2014. The latest revaluation was conducted on 30 June 2013 by an independent valuer.

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 7: Non-Financial Assets

#### Note 7C: Analysis of property, plant and equipment

**TABLE A – Reconciliation of the opening and closing balances of property, plant and equipment (2014-15)**

	Leasehold Improvements \$'000	Other P P & E \$'000	Total \$'000
<b>As at 1 July 2014</b>			
Gross book value	2 637	1 057	3 694
Accumulated depreciation and impairment	(516)	(212)	(728)
<b>Total as at 1 July 2014</b>	<b>2 121</b>	<b>845</b>	<b>2 966</b>
Additions:			
Purchase	-	170	170
Revaluation recognised in other comprehensive income	-	-	-
Impairments recognised in the operating result	-	-	-
Depreciation expense	(352)	(253)	(605)
Disposals:			
Disposal	-	(3)	(3)
Accumulated depreciation of disposed assets	-	2	2
<b>Total as at 30 June 2015</b>	<b>1 769</b>	<b>761</b>	<b>2 530</b>
<b>Total as of 30 June 2015 represented by:</b>			
Gross book value	2 637	1 224	3 861
Accumulated depreciation and impairment	(868)	(463)	(1331)
<b>Total as of 30 June 2015</b>	<b>1 769</b>	<b>761</b>	<b>2 530</b>

**TABLE B – Reconciliation of the opening and closing balances of property, plant and equipment (2013-14)**

	Leasehold Improvements \$'000	Other P P & E \$'000	Total \$'000
<b>As at 1 July 2013</b>			
Gross book value	2 543	653	3 196
Accumulated depreciation and impairment	(176)	-	(176)
<b>Total as at 1 July 2013</b>	<b>2 367</b>	<b>653</b>	<b>3 020</b>
Additions:			
Purchase	94	405	499
Revaluation recognised in other comprehensive income	-	-	-
Impairments recognised in the operating result	-	-	-
Depreciation expense	(340)	(212)	(552)
Disposals:			
Other disposals	-	(1)	(1)
Accumulated depreciation of disposed assets	-	-	-
<b>Total as at 30 June 2014</b>	<b>2 121</b>	<b>845</b>	<b>2 966</b>
<b>Total as at 30 June 2014 represented by:</b>			
Gross book value	2 637	1 057	3 694
Accumulated depreciation and impairment	(516)	(212)	(728)
<b>Total as at 30 June 2014</b>	<b>2 121</b>	<b>845</b>	<b>2 966</b>

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 7: Non-Financial Assets

	2015 \$'000	2014 \$'000
<b><u>Note 7D: Intangibles</u></b>		
Internally developed computer software at cost:		
Internally developed – in progress	2 214	1 540
Internally developed – in use	1 830	857
Accumulated amortisation	(873)	(573)
<b>Total internally developed computer software</b>	<b>3 171</b>	<b>1 824</b>
Purchased computer software at cost:		
Purchased computer software	2 317	2 332
Accumulated amortisation	(1 196)	(1 094)
<b>Total purchased computer software</b>	<b>1 121</b>	<b>1 238</b>
<b>Total intangibles (non-current)</b>	<b>4 292</b>	<b>3 062</b>

No indicators of impairment were found for any intangible assets.

No intangibles are expected to be sold or disposed of within the next 12 months.

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 7: Non-Financial Assets

#### Note 7E: Analysis of intangibles

#### Table A: Reconciliation of the opening and closing balances of intangibles (2014-15)

Item	Computer software internally developed \$'000	Computer software purchased \$'000	Total \$'000
<b>As at 1 July 2014</b>			
Gross book value	2 397	2 332	4 729
Accumulated amortisation and impairment	(573)	(1094)	(1 667)
<b>Total as at 1 July 2014</b>	<b>1 824</b>	<b>1 238</b>	<b>3 062</b>
Additions:			
Purchase or internally developed	1 655	185	1 840
Amortisation	(307)	(291)	(598)
Disposals:			
Disposal	(8)	(200)	(208)
Accumulated amortisation of disposed assets	7	189	196
<b>Total as at 30 June 2015</b>	<b>3 171</b>	<b>1 121</b>	<b>4 292</b>
<b>Total as of 30 June 2015 represented by:</b>			
Gross book value	4 044	2 317	6 361
Accumulated amortisation and impairment	(873)	(1 196)	(2 069)
<b>Total as of 30 June 2015</b>	<b>3 171</b>	<b>1 121</b>	<b>4 292</b>

#### Table B: Reconciliation of the opening and closing balances of intangibles (2013-14)

Item	Computer software internally developed \$'000	Computer software purchased \$'000	Total \$'000
<b>As at 1 July 2013</b>			
Gross book value	1 611	1 902	3 513
Accumulated amortisation and impairment	(851)	(941)	(1 792)
<b>Total as at 1 July 2013</b>	<b>760</b>	<b>961</b>	<b>1 721</b>
Additions:			
by purchase or internally developed	1 194	445	1 639
Amortisation	(121)	(168)	(289)
Disposals:			
Disposal	(408)	(15)	(423)
Accumulated amortisation of disposed assets	399	15	414
<b>Total as at 30 June 2014</b>	<b>1 824</b>	<b>1 238</b>	<b>3 062</b>
<b>Total as at 30 June 2014 represented by:</b>			
Gross book value	2 397	2 332	4 729
Accumulated amortisation and impairment	(573)	(1094)	(1 667)
<b>Total as at 30 June 2014</b>	<b>1 824</b>	<b>1 238</b>	<b>3 062</b>

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 7: Non-Financial Assets

	2015 \$'000	2014 \$'000
<b>Note 7F: Other Non-Financial Assets</b>		
Prepayments	283	306
<b>Total other non-financial assets</b>	<b>283</b>	<b>306</b>
Total other non-financial assets expected to be received in:		
No more than 12 months	262	306
More than 12 months	21	-
<b>Total other non-financial assets</b>	<b>283</b>	<b>306</b>

No indicators of impairment were found for other non-financial assets.

#### Note 8: Payables

	2015 \$'000	2014 \$'000
<b>Note 8A: Suppliers</b>		
Trade creditors and accruals	3 848	3 900
<b>Total supplier payables</b>	<b>3 848</b>	<b>3 900</b>

All supplier payables are expected to be settled within 12 months

Settlement is usually made within 30 days.

Suppliers in connection with		
Related parties	2 605	2 769
External parties	1 243	1 131
<b>Total other non-financial assets</b>	<b>3 848</b>	<b>3 900</b>

#### **Note 8B: Other Payables**

Salaries and wages	685	669
Superannuation	106	92
Unearned income	25	-
Lease incentive	213	253
Lease liability	660	628
<b>Total other payables</b>	<b>1 689</b>	<b>1 642</b>
Total other payables are expected to be settled in:		
No more than 12 months	856	801
More than 12 months	833	841
<b>Total other payables</b>	<b>1 689</b>	<b>1 642</b>

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 9: Provisions

	2015 \$'000	2014 \$'000
<b>Note 9A: Employee provisions</b>		
Long service leave	3 876	3 969
Annual leave	1 702	1 783
<b>Total employee provisions</b>	<b>5 578</b>	<b>5 752</b>
Employee provisions are expected to be settled in:		
No more than 12 months	2 022	1 565
More than 12 months	3 556	4 187
<b>Total employee provisions</b>	<b>5 578</b>	<b>5 752</b>
<b>Note 9B: Other provisions</b>		
Provision for restoration obligations	455	438
<b>Total other provisions</b>	<b>455</b>	<b>438</b>
All other provisions are expected to be settled in more than 12 months.		
<b>Carrying amount 1 July 2014</b>	<b>438</b>	<b>422</b>
Unwinding of discount or change in discount rate	17	16
<b>Closing balance 30 June 2015</b>	<b>455</b>	<b>438</b>

The APVMA currently has one agreement for the leasing of premises that have provisions requiring the APVMA to restore the premises to their original condition at the conclusion of the lease. The APVMA has made a provision to reflect the present value of this obligation.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 10: Cash Flow Reconciliation

	2015 \$'000	2014 \$'000
<b>Reconciliation of cash and cash equivalents as per statement of financial position to cash flow statement</b>		
<b>Report cash and cash equivalents as per:</b>		
Cash Flow Statement	1 289	13 633
Statement of Financial Position	1 289	13 633
<b>Difference</b>	<b>-</b>	<b>-</b>
 <b>Reconciliation of operating result to net cash from operating activities:</b>		
Net cost of services	(32 647)	(31 673)
Revenue from Government	29 184	27 951
Equity injection following restructure to a corporate Commonwealth entity	5 155	-
 <b>Adjustment for non-cash items</b>		
Depreciation / amortisation	1 203	841
Loss on disposal of assets	10	8
Closing of the APVMA special account on 1 July 2014	13 424	-
 <b>Changes in assets/liabilities</b>		
(Increase) / decrease in net receivables	(13 103)	1 840
(Increase) / decrease in prepayments	23	39
Increase / (decrease) in employee provisions	(174)	316
Increase / (decrease) in supplier payables	(52)	795
Increase / (decrease) in other payables	47	146
Increase / (decrease) in other provisions	17	16
<b>Net cash from operating activities</b>	<b>3 087</b>	<b>279</b>

#### Note 11: Contingent Assets and Liabilities

The APVMA had no quantifiable, unquantifiable or significant remote contingencies.



# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 12: Senior Management Personnel Remuneration

	2015 \$	2014 \$
<b>Short-term employee benefits:</b>		
Salary	1 442 528	1 633 386
Other allowances	-	15 350
<b>Total Short-term employee benefits</b>	<b>1 442 528</b>	<b>1 648 736</b>
<b>Post-employment benefits:</b>		
Superannuation	249 589	286 138
<b>Total post-employment benefits</b>	<b>249 589</b>	<b>286 138</b>
<b>Other long-term benefits:</b>		
Annual leave	113 942	127 562
Long service leave	49 667	55 849
<b>Total other long-term benefits</b>	<b>163 609</b>	<b>183 411</b>
<b>Seperations and terminations</b>	<b>76 730</b>	<b>-</b>
<b>Total employment benefits</b>	<b>1 932 456</b>	<b>2 118 285</b>

The total number of senior management positions in 2014 was eight. In October 2014, following an internal restructure, the total number of senior management positions dropped to six.

The 2014 comparative figures have been amended following the change in definition of senior management and the change in calculation of their remuneration.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 13: Financial Instruments

	2015 \$'000	2014 \$'000
<b><u>13A: Categories of financial instruments</u></b>		
<b>Financial Assets</b>		
Loans and receivables financial assets		
Cash and cash equivalents	1 289	13 633
Trade & other receivables	146	438
<b>Total loans and receivables</b>	<b>1 435</b>	<b>14 071</b>
<b>Total financial assets</b>	<b>1 435</b>	<b>14 071</b>
<b>Financial liabilities</b>		
<b>Financial liabilities measured at amortised cost</b>		
Other Liabilities		
Trade creditors and accruals	3 848	3 900
Other payables	1 476	1 389
<b>Total financial liabilities measured at amortised cost</b>	<b>5 324</b>	<b>5 289</b>
<b>Total financial liabilities</b>	<b>5 324</b>	<b>5 289</b>
<b><u>13B: Net gains or losses on financial assets</u></b>		
<b>Loans and receivables</b>		
Interest revenue	18	-
<b>Net gain/(loss) from financial assets</b>	<b>18</b>	<b>-</b>
<b><u>13C: Net gains and losses on financial liabilities</u></b>		
<b>Other Liabilities</b>		
Lease liability increase	(32)	(76)
<b>Net gain/(loss) from financial assets</b>	<b>(32)</b>	<b>(76)</b>

#### **13D: Fair value of financial instruments**

The net fair values of cash and cash equivalents, trade receivables and other receivables approximate their carrying amounts.

The net fair values for trade creditors and other liabilities are approximated by their carrying amounts.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 13: Financial Instruments

##### 13E: Credit risk

The APVMA is exposed to minimal credit risk as loans and receivables are cash, trade receivables and other receivables. The maximum exposure to credit risk is the risk that arises from potential default of a debtor. This amount is equal to the total of trade and other debtors (2015: \$163 000 and 2014: \$743 000).

To aid the APVMA to manage its credit risk, there are internal policies and procedures that guide employees on debt recovery techniques that are to be applied.

The APVMA holds no collateral to mitigate against credit risk.

##### Credit quality of financial instruments not past due or individually determined as impaired

	Not Past Due		Past due or impaired	
	Nor Impaired	Not Past Due Nor Impaired	Past due or impaired	Past due or impaired
	2015	2014	2015	2014
	\$'000	\$'000	\$'000	\$'000
<b>Loans and receivables</b>				
Cash and cash equivalents	1 289	13 633	-	-
Trade & other receivables	42	134	121	609
<b>Total</b>	<b>1 331</b>	<b>13 767</b>	<b>121</b>	<b>609</b>

##### Ageing of financial assets that are past due but not impaired for 2015

	0 to 30 days	31 to 60 days	61 to 90 days	90+ days	Total
	\$'000	\$'000	\$'000	\$'000	\$'000
<b>Loans and receivables</b>					
Trade & other receivables	6	-	19	96	121
<b>Total</b>	<b>6</b>	<b>-</b>	<b>19</b>	<b>96</b>	<b>121</b>

##### Ageing of financial assets that are past due but not impaired for 2014

	0 to 30 days	31 to 60 days	61 to 90 days	90+ days	Total
	\$'000	\$'000	\$'000	\$'000	\$'000
<b>Loans and receivables</b>					
Trade & other receivables	304	-	-	305	609
<b>Total</b>	<b>304</b>	<b>-</b>	<b>-</b>	<b>305</b>	<b>609</b>

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 13: Financial Instruments

##### 13F: Liquidity risk

The APVMA's financial liabilities are payables. The exposure to liquidity risk is based on the notion that the APVMA will encounter difficulty in meeting its obligations associated with financial liabilities.

This is highly unlikely due to the level of funds held in reserve as well as funding mechanisms available to the APVMA (Advance from the Finance Minister). The APVMA manages its budgeted funds to ensure it has adequate funds to meet payments as they fall due. In addition, the APVMA has policies in place to ensure timely payments are made when due and has no past experience of default.

##### Maturities for non-derivative financial liabilities 2015

	On demand 2015 \$'000	within 1 year 2015 \$'000	1 to 5 years 2015 \$'000	> 5 years 2015 \$'000	Total 2015 \$'000
<b>Other liabilities</b>					
Trade creditors and accruals	-	3 848	-	-	3 848
Other payables	-	832	567	77	1 476
<b>Total</b>	-	4 680	567	77	5 324

##### Maturities for non-derivative financial liabilities 2014

	On demand 2014 \$'000	within 1 year 2014 \$'000	1 to 5 years 2014 \$'000	> 5 years 2014 \$'000	Total 2014 \$'000
<b>Other liabilities</b>					
Trade creditors and accruals	-	3 900	-	-	3 900
Other payables	-	730	360	299	1 389
<b>Total</b>	-	4 630	360	299	5 289

##### 13G: Market risk

The APVMA holds basic financial instruments that do not expose the Agency to market risks. The APVMA is not exposed to 'Currency risk', 'Interest rate risk' or 'Other price risk'.

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 14: Financial Asset Reconciliation

	Notes	2015 \$'000	2014 \$'000
<b><u>Financial Assets</u></b>			
<b>Total financial assets as per statement of financial position</b>		<b>14 955</b>	14 196
Less: non-financial instrument components			
Contribution receivable	6B	13 426	-
Other receivables (GST receivable)	6B	<u>94</u>	<u>125</u>
Total other non-financial assets		<u>13 520</u>	<u>125</u>
<b>Total financial assets as per financial instruments note</b>		<b><u>1 435</u></b>	<u>14 071</u>

**Australian Pesticides and Veterinary Medicines Authority**  
**NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS**  
*for the year ended 30 June 2015*

**Note 15: Appropriations**

**Table A: Annual Appropriation ('Recoverable GST exclusive')**

	2015 Appropriation			Appropriation applied in 2015 (current and prior years)	Variance
	Appropriation Act		Total appropriation		
	Annual Appropriation	\$'000			
				\$'000	\$'000
DEPARTMENTAL					
Ordinary annual service	743		743	743	-
Other services	-		-	-	-
Equity	-		-	-	-
Total Departmental	743		743	743	-

	2014 Appropriation				Appropriation applied in 2014 (current and prior years)	Variance <sup>1</sup>	
	Appropriation Act	FMA Act		Total appropriation			
		Annual Appropriation	Section 30				Section 31
DEPARTMENTAL						\$'000	
Ordinary annual service	981		2	276	1 259	3 404	
Other services	-		-	-	-	-	
Equity	-		-	-	-	-	
Total Departmental	981		2	276	1 259	3 404	
						(2 145)	
						-	
						-	
						(2 145)	

Notes:

1. These variances are due to unspent Departmental Annual Appropriations in 2013.

**Note 15: Appropriations**

**Table B: Departmental Capital Budgets ('Recoverable GST exclusive')**

The APVMA did not receive any departmental capital budget funding during 2015 (2014: nil).

**Table C: Unspent Departmental Annual Appropriation ('Recoverable GST exclusive')**

There were no unspent departmental annual appropriations at 30 June 2015 (2014: nil).

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 16: Reporting of Outcomes

The APVMA has a single Outcome

#### Note 15A: Net Cost of Outcome Delivery

	Outcome 1	
	2015	2014
	\$'000	\$'000
<b>Departmental</b>		
Expenses	(33 204)	(31 997)
Own source income	557	324
<b>Net (cost)/contribution of outcome delivery</b>	<b>(32 647)</b>	<b>(31 673)</b>

Outcome 1 is described in Note 1.1.



# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 17: Cost Recovery Summary

	2015 \$'000	2014 \$'000
<b>Amounts applied</b>		
Payments from portfolio bodies	34 390	28 554
<b>Total amounts applied</b>	<b>34 390</b>	<b>28 554</b>
<b>Expenses</b>		
Departmental	31 904	30 692
<b>Total expenses</b>	<b>31 904</b>	<b>30 692</b>
<b>Revenue</b>		
Payments to portfolio departments	28 440	27 014
<b>Total revenue</b>	<b>28 440</b>	<b>27 014</b>
<b>Receivables</b>		
Overdue by		
Less than 30 days:	268	304
More than 90 days:	16	-
<b>Total receivables</b>	<b>284</b>	<b>304</b>
<b>Amounts written off:</b>		
Departmental	-	-
<b>Total expenses</b>	<b>-</b>	<b>-</b>

#### Cost recovered activities:

The agricultural and veterinary medicines chemical industry pay application fees to register new products and active constituents, amend a current registration, or apply for a permit. An annual fee is payable each year to renew the registration of a product. Product owners also pay an annual levy based on the sales of their registered products.

Documentation (Cost Recovery Impact Statement) for the above activities is available at [www.apvma.gov.au/node/4161](http://www.apvma.gov.au/node/4161).

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 18: Budgetary Reporting and Explanation of Major Variances

The following tables provide a comparison of the original budget as presented in the 2014-15 Portfolio Budget Statements (PBS) to the 2014-15 final outcome as presented in accordance with Australian Accounting Standards for the entity. The Budget is not audited.

Variances are considered to be 'major' based on the following criteria:

- the variance between budget and actual is greater than 10% and greater than \$250,000; and
- The variance between budget and actual is greater than 2% of the relevant category (Income, Expenses and Equity totals); or
- an item below this threshold but is considered important for the reader's understanding or is relevant to an assessment of the discharge of accountability and to an analysis of performance of an entity.

#### Note 18A: Departmental Budgetary Reports

##### Statement of Comprehensive Income

for the year ended 30 June 2015

	Actual 2015 \$'000	Budget <sup>1</sup> 2015 \$'000	Variance <sup>2</sup> 2015 \$'000
<b>NET COST OF SERVICE</b>			
<b>Expenses</b>			
Employee benefits	22 113	21 063	1 050
Suppliers	9 861	10 012	(151)
Depreciation and amortisation	1 203	1 107	96
Finance costs	17	-	17
Losses from asset sales	10	-	10
<b>Total Expenses</b>	<b>33 204</b>	<b>32 182</b>	<b>1 022</b>
<b>Own-Source Income</b>			
<b>Own-source revenue</b>			
Other revenue	557	339	218
<b>Total own-source revenue</b>	<b>557</b>	<b>339</b>	<b>218</b>
<b>Total Own-Source Income</b>	<b>557</b>	<b>339</b>	<b>218</b>
<b>Net Cost of Services</b>	<b>32 647</b>	<b>31 843</b>	<b>804</b>
Revenue from Government	29 184	30 239	(1 055)
<b>Surplus/(Deficit) Attributable to the Australian Government</b>	<b>(3 463)</b>	<b>(1 604)</b>	<b>(1 859)</b>
<b>OTHER COMPREHENSIVE INCOME</b>			
<b>Items not subject to subsequent reclassification to profit and loss</b>			
Equity injection following reclassification to a corporate Commonwealth entity	5 155	-	5 155
<b>Total other comprehensive income</b>	<b>5 155</b>	<b>-</b>	<b>5 155</b>
<b>Total Comprehensive Income/(Loss) Attributable to the Australian Government</b>	<b>1 692</b>	<b>(1 604)</b>	<b>3 296</b>

1. The APVMA's original budgeted financial statement that was first presented to parliament in respect of the reporting period (i.e. from the entity's 2014-15 Portfolio Budget Statements (PBS)).

2. Between the actual and original budgeted amounts for 2015. Explanations of major variances are provided at Note 18B.

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 18: Budgetary Reporting and Explanation of Major Variances

#### Note 18A: Departmental Budgetary Reports (continued)

##### Statement of Financial Position

for the year ended 30 June 2015

	Actual 2015 \$'000	Budget <sup>1</sup> 2015 \$'000	Variance <sup>2</sup> 2015 \$'000
<b>ASSETS</b>			
<b>Financial Assets</b>			
Cash and cash equivalents	1 289	12 942	(11 653)
Trade and other receivables	13 666	270	13 396
<b>Total financial assets</b>	<b>14 955</b>	<b>13 212</b>	<b>1 743</b>
<b>Non-Financial Assets</b>			
Land and buildings	1 769	2 015	(246)
Property, plant and equipment	761	819	(58)
Intangibles	4 292	2 382	1 910
Other non-financial assets	283	345	(62)
<b>Total non-financial assets</b>	<b>7 105</b>	<b>5 561</b>	<b>1 544</b>
<b>Total Assets</b>	<b>22 060</b>	<b>18 773</b>	<b>3 287</b>
<b>LIABILITIES</b>			
<b>Payables</b>			
Suppliers	3 848	3 263	585
Other payables	1 689	1 494 <sup>3</sup>	195
<b>Total payables</b>	<b>5 537</b>	<b>4 757</b>	<b>1 465</b>
<b>Provisions</b>			
Employee provisions	5 578	5 711 <sup>3</sup>	(133)
Other provisions	455	439	16
<b>Total provisions</b>	<b>6 033</b>	<b>6 150</b>	<b>(802)</b>
<b>Total Liabilities</b>	<b>11 570</b>	<b>10 907</b>	<b>663</b>
<b>Net Assets</b>	<b>10 490</b>	<b>7 866</b>	<b>2 624</b>
<b>EQUITY</b>			
Contributed equity	5 528	373	5 155
Reserves	1 123	1 123	-
Retained surplus	3 839	6 370	(2 531)
<b>Total Equity</b>	<b>10 490</b>	<b>7 866</b>	<b>2 624</b>

1. The APVMA's original budgeted financial statement that was first presented to parliament in respect of the reporting period (i.e. from the entity's 2014-15 Portfolio Budget Statements (PBS)).

2. Between the actual and original budgeted amounts for 2015. Explanations of major variances are provided at Note 18B.

3. \$685,000 has been reclassified from employee provisions to other payables for budget 2015. This is due to inconsistent classification of accrued salary and superannuation. In the PBS, these accruals are recorded as employee provisions while in the financial statements they are recorded as other payables.

**Note 18A: Departmental Budgetary Reports (continued)**

**Statement of Changes in Equity**  
*for the year ended 30 June 2015*

	Retained Earnings				Asset Revaluation Reserves				Contributed Equity/capital				Total Equity			
	Actual		Budget <sup>1</sup>		Actual		Budget <sup>1</sup>		Actual		Budget <sup>1</sup>		Actual		Budget <sup>1</sup>	
	2015	\$'000	2015	\$'000	2015	\$'000	2015	\$'000	2015	\$'000	2015	\$'000	2015	\$'000	2015	\$'000
Opening Balance																
Balance carried forward from previous period	7 302	7 974	(672)	(672)	1 123	1 123	-	-	373	373	-	-	8 798	9 470	(672)	(672)
Adjusted opening balance	7 302	7 974	(672)	(672)	1 123	1 123	-	-	373	373	-	-	8 798	9 470	(672)	(672)
Comprehensive income																
Surplus/(Loss) for the period	(3 463)	(1 604)	(1 859)	(1 859)	-	-	-	-	-	-	-	-	(3 463)	(1 604)	(1 859)	(1 859)
Other comprehensive income	-	-	-	-	-	-	-	-	5 155	5 155	-	-	5 155	-	5 155	5 155
Total comprehensive income	(3 463)	(1 604)	(1 859)	(1 859)	-	-	-	-	5 155	5 155	-	-	1 692	(1 604)	3 296	3 296
Closing Balance at 30 June	3 839	6 370	(2 531)	(2 531)	1 123	1 123	-	-	5 528	5 528	373	373	10 490	7 866	2 624	2 624

1. The APVMA's original budgeted financial statement that was first presented to parliament in respect of the reporting period (i.e. from the entity's 2014-15 Portfolio Budget Statements (PBS)).

2. Between the actual and original budgeted amounts for 2015. Explanations of major variances are provided at Note 18B.

# Australian Pesticides and Veterinary Medicines Authority

## NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

### Note 18: Budgetary Reporting and Explanation of Major Variances

#### Note 18A: Departmental Budgetary Reports (continued)

##### Cash Flow Statement

for the year ended 30 June 2015

	Actual 2015 \$'000	Budget <sup>1</sup> 2015 \$'000	Variance <sup>2</sup> 2015 \$'000
<b>Operating Activities</b>			
<b>Cash received</b>			
Appropriations	743	743	-
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i> contribution	34 390	29 496	4 894
Net GST received	980	1 074	(94)
Interest received	17	-	17
Other cash received	593	337	256
<b>Total cash received</b>	<b>36 723</b>	<b>31 650</b>	<b>5 073</b>
<b>Cash used</b>			
Employees	22 531	20 907	1 624
Suppliers	11 105	11 070	35
<b>Total cash used</b>	<b>33 636</b>	<b>31 977</b>	<b>1 659</b>
<b>Net cash flows from operating activities</b>	<b>3 087</b>	<b>(327)</b>	<b>3 414</b>
<b>Investing Activities</b>			
<b>Cash received</b>			
Proceeds from sales of property, plant and equipment	3	-	3
<b>Total cash received</b>	<b>3</b>	<b>-</b>	<b>3</b>
<b>Cash used</b>			
Purchase of property, plant and equipment	2 010	700	1 310
<b>Total cash used</b>	<b>2 010</b>	<b>700</b>	<b>1 310</b>
<b>Net cash flows from or (used by) investing activities</b>	<b>(2 007)</b>	<b>(700)</b>	<b>(1 307)</b>
<b>Financing Activities</b>			
<b>Cash used</b>			
Departmental balance of special account	13 424	-	13 424
<b>Total cash used</b>	<b>13 424</b>	<b>-</b>	<b>13 424</b>
<b>Net cash flows from financing activities</b>	<b>(13 424)</b>	<b>-</b>	<b>(13 424)</b>
<b>Net increase or (decrease) in cash held</b>	<b>(12 344)</b>	<b>(1 027)</b>	<b>(11 317)</b>
Cash and cash equivalents at the beginning of the reporting period	13 633	13 969	(336)
<b>Cash and cash equivalents at the end of the reporting period</b>	<b>1 289</b>	<b>12 942</b>	<b>(11 653)</b>

1. The APVMA's original budgeted financial statement that was first presented to parliament in respect of the reporting period (i.e. from the entity's 2014-15 Portfolio Budget Statements (PBS)).

2. Between the actual and original budgeted amounts for 2015. Explanations of major variances are provided at Note 18B.

## Australian Pesticides and Veterinary Medicines Authority

### NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS

for the year ended 30 June 2015

#### Note 18: Budgetary Reporting and Explanation of Major Variances

##### Note 18B: Departmental Major Budget Variances for 2015

Explanations of major variances	Affected line items (and statements)
<p>In April 2014, when the APVMA's budget for the 14-15 PBS was prepared, there was uncertainty as to whether the APVMA would become a non-corporate Commonwealth entity or a corporate Commonwealth entity when the PGPA Act commenced on 1 July 2014. Given that at the time the APVMA's current status was an FMA Act agency, the budget was prepared on the basis that the APVMA would become a non-corporate Commonwealth entity.</p> <p>However, as stated previously in Note 1, on 1 July 2014 the APVMA was re-classified as a corporate Commonwealth entity.</p> <p>The major change to the APVMA's financial statements following this re-classification was the closing of the APVMA's special account. The combined administered and departmental special account balance at 30 June 2014 of \$18.579 million was appropriated to a special appropriation. Monies held by the Department of Finance representing unspent cash from fees and charges paid by industry are now recorded as a receivable. Prior to 1 July 2014 these funds were held in a special account and recorded as cash.</p> <p>The administered portion of the \$18.579 million balance of the special account at 30 June 2014 was \$5.155 million. On 1 July 2014, this balance became an equity injection, based on the notion that the re-classification from an FMA Act agency to a corporate Commonwealth entity and the resulting dissolving of APVMA's administered function is a restructure of administrative arrangements.</p> <p>Actual total expenditure is approximately 3.2% above budget. This is largely due to increased staff levels required in the transitional years to complete the implementation of the Better Regulation reforms.</p> <p>Revenue from government is slightly under budget due to lower than anticipated fees and charges paid by industry. This decrease is also partially explained by the fact the APVMA can no longer recognise outstanding fees and charges as revenue or a trade receivable (refer Note 1.5 for further details).</p> <p>After the completion of the 14-15 PBS budget, it was decided that additional funds would be allocated to continue with the significant investment in internally developed software (intangibles) to support the on-going reforms to the APVMA's activities.</p> <p>Payables liability is higher than forecast largely due to the timing of supplier payments. The amount in the PBS was based on the situation where a significant proportion of creditors were paid just prior to year end.</p>	<ul style="list-style-type: none"> <li>• Cash and cash equivalents</li> <li>• Trade and other receivables (Statement of Financial Position)</li> <li>• Financing activities - Cash used (Statement of Financial Position)</li> <li>• Other Comprehensive Income (Statement of Financial Position)</li> <li>• Contributed equity (Statement of Change in Equity)</li> <li>• Employee benefits</li> <li>• Total expenditure (Statement of Comprehensive Income)</li> <li>• Cash received - Other cash received</li> <li>• Cash used - Total cash used (Statement of Comprehensive Income)</li> <li>• Revenue from Government (Statement of Financial Position)</li> <li>• Trade and other receivables (Statement of Financial Position)</li> <li>• Cash and cash equivalents</li> <li>• Non financial asset - Intangibles (Statement of Financial Position)</li> <li>• Cash received - Other cash received</li> <li>• Purchase of property, plant &amp; equipment (Cash Flow Statement)</li> <li>• Payables - Suppliers (Statement of Financial Position)</li> </ul>







# CHAPTER 5

## APPENDIXES





# APPENDIX A: ADVISORY BOARD AND COMMITTEES

## APVMA ADVISORY BOARD

The Chief Executive Officer (CEO) of the APVMA is supported by an Advisory Board selected and appointed by the Minister for Agriculture.

The Advisory Board does not have decision-making power. It advises the CEO and provides an expert consultative mechanism, either on its own initiative or at the request of the CEO, by providing advice and recommendations on issues relevant to the execution of the functions of the APVMA.

Arrangements for the Advisory Board's appointment, function and procedure, as well as its interaction with the CEO, are prescribed by legislation.

The Advisory Board consists of up to nine part-time members appointed by the minister for their expertise and experience in areas associated with the APVMA's stakeholder community. The individual members are appointed on the basis of their ability to contribute at the highest level to the national regulation of chemicals in Australia.

The experience of members reflects, as far as possible, each key stakeholder sector. These are the regulation of chemical products at state and territory level, the agricultural chemical and veterinary medicine industries, primary production, environmental toxicology, protection of consumer interests, public health, and work health and safety. In addition, the minister also has discretion to appoint a member who has experience in another field relevant to the APVMA's functions.

The Secretary of the Australian Government Department of Agriculture, or a person authorised by the secretary, may attend meetings. The CEO may also invite a person, other than an Advisory Board member or the secretary, to attend a meeting for the purpose of advising or informing it on any matter.

The Advisory Board currently comprises the following members, who were appointed for a three-year term commencing on 13 November 2012:

Lyn Fragar AO is a public health physician and an adjunct associate professor with the Australian Centre for Agricultural Health and Safety, University of Sydney. She currently chairs the Hunter New England Local Health District Board. Dr Fragar has been appointed as a board member for her expertise in public health, and work health and safety. She has also been appointed to the position of Chair of the Advisory Board.

Sandra Baxendell PSM is the Director of Goat Veterinary Consultancies. She has been a senior lecturer specialising in animal production at Curtin University, and has also worked in agricultural production and industry management roles. Dr Baxendell has extensive Queensland Government experience in a variety of roles, including Regional Director, General Manager (Chemical Use and Food Safety), Director Product Integrity, and Acting General Manager Plant Biosecurity and Product Integrity. Dr Baxendell has been appointed as a board member for her experience in the regulation of chemical products under state or territory law.

Bronwyn Capanna is the Executive Director of Accord Australasia, the industry association representing the hygiene, cosmetics and specialty products industry. She has more than 20 years experience in industry association management, and has held senior positions as a regulatory and technical executive in the not-for-profit and private sectors in Australia and the United Kingdom. She continues to be highly

engaged in regulatory reform at a national and international level. Ms Capanna has been appointed as a board member for her experience in a field relevant to the APVMA's functions under the optional provisions in the legislation.

John Hassell operates his own farming business, together with off-farm contracting in baling, spraying and clover harvesting. He is also a director of Co-operative Bulk Handling Ltd, Grain Pool Pty Ltd, Bulkwest Engineering Pty Ltd and other subsidiaries. Mr Hassell has previously worked as a farm and laboratory assistant with a range of companies. He is a member of the Western Australian Farmers Federation and the Pingelly Land Conservation District Committee. Mr Hassell has been appointed as a board member for his experience in primary production.

David Lawson is a financial counsellor, and runs his own consultancy and general counselling business. Mr Lawson was previously a sugar cane farmer, and ran a contracting and farm machinery hire business. He has held a number of senior representative roles in the sugar industry, and has experience representing consumer interests in the areas of financial counselling, telecommunications, energy and banking at a state and national level, including as a representative of the Consumers' Federation of Australia and as a member of the APVMA's community consultative committee. He chairs the management committee of a school for youth who are disengaged from the state school system. Mr Lawson has been appointed as a board member for his experience in protecting consumer interests.

Gordon Reidy is the Regional Manager Regulatory Affairs, Toxicology, Product Safety and Development Asia Pacific for the Sumitomo Chemical Company. Dr Reidy has held a range of toxicology-related roles in WorkSafe Australia, AGC Woodward-Clyde Pty Ltd, 3M Asia Pacific and Reckitt Benckiser. He served on the Drugs and Poisons Scheduling Committee, and the Basel Hazardous Waste Technical Committee. He has also been a board member of the Australian Consumer Products Industry Association. Dr Reidy has been appointed as a board member for his experience in environmental toxicology, including knowledge of the effects of chemicals in ecosystems.

Selwyn Snell is the Managing Director of Barawyn Pty Ltd. He has extensive experience in agribusiness, including in a number of senior roles spanning corporate management, financial and strategic planning, and farming research and development. He is the current Chair of Horticulture Innovation Australia Ltd, the Council of Rural and Research Development Corporations and the Queensland Government's Horticultural Development Committee. Mr Snell has been appointed as a board member for his experience in the agricultural chemical industry.

Roger Toffolon is the Director of Biosecurity Strategy, Legislation and Performance in the New South Wales Department of Primary Industries. Mr Toffolon has worked as an entomology researcher and has held a number of senior roles in the New South Wales Government, including Registrar of Pesticides, Program Leader for Agricultural and Veterinary Chemicals, and Manager of Biological and Chemical Risk Management. He has been appointed as a board member for his experience in the regulation of chemical products under state or territory law.

Lisa Wade is Director of Bellmount Consulting Pty Ltd, which provides consulting services to the agricultural and veterinary industries. Dr Wade was previously a veterinarian working in mixed practice in both Australia and the United Kingdom. She has experience in the research and development of a wide range of veterinary therapeutics, and experience with Australian and international regulatory systems. She has been a member of the Animal Health Alliance Issues Management Group and chaired the group's Antimicrobial Resistance Task Force. Dr Wade has been appointed as a board member for her experience in the veterinary chemical industry.

## Meetings and attendance

Advisory Board meetings were held on 25 August and 5 November 2014, and 11 February and 23 April 2015. All meetings were in Canberra. A summary of the key outcomes from each meeting is published on the APVMA website. Attendance at Advisory Board meetings is shown in Table A1.

**TABLE A1: ATTENDANCE AT ADVISORY BOARD MEETINGS, 2014–15**

Member	Meetings eligible to attend	Meetings attended
Lyn Fragar (Chair)	4	4
Sandra Baxendell	4	4
Bronwyn Capanna	4	4
John Hassell	4	3
David Lawson	4	4
Gordon Reidy	4	3
Selwyn Snell	4	4
Roger Toffolon	4	4
Lisa Wade	4	4
Australian Government Department of Agriculture representative	4	3

## Issues considered

In 2014–15, the board advised the CEO in relation to a range of strategic matters, including:

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

## Presentations

There were no external presentations to the board in 2014–15.

## Declarations of interest

Members of the board are required under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* to disclose, as soon as practicable, any direct or indirect financial interests that could conflict with the proper performance of the board's function. Any decision made in relation to a disclosure about a matter that is being considered, or about to be considered, at a meeting must be recorded in the minutes of the meeting.

Records of disclosures by board members are kept by the APVMA. No conflicts of interest that would conflict with the proper performance of the board's functions were declared at any meeting in 2014–15.

## APVMA AUDIT COMMITTEE

The APVMA Audit Committee is part of the APVMA governance and risk framework. Its terms of reference are to provide independent assurance and advice to the CEO in relation to the risk control and compliance framework, and the APVMA's financial and management responsibilities, and performance reporting and external accountability responsibilities.

The committee members include an external independent chair, a representative from an external organisation, and a member of APVMA executive management. Committee observers and advisers can include representatives from the Australian National Audit Office, the internal auditor, the APVMA CEO, the APVMA Chief Financial Officer, the APVMA Chief Information Officer and other management representatives.

## Meetings and attendance

The Audit Committee met four times in 2014–15: in September and November 2014, and February and May 2015. Attendance at Audit Committee meetings is shown in Table A2.

**TABLE A2: ATTENDANCE AT AUDIT COMMITTEE MEETINGS, 2014–15**

Representative	Member's organisation	Meetings eligible to attend	Meetings attended
Peter Hoefer	External independent chair	4	4
Tony de la Fosse	APVMA	4	4
Claude Gauchat	External organisation representative	4	4
Appointment pending	External organisation representative	4	0

## Issues considered

In 2014–15, the Audit Committee:

- reviewed the previous year's annual financial statements and Certificate of Compliance
- monitored the schedule for preparation of annual financial statements for 2014–15
- monitored the financial planning and performance of the APVMA
- monitored and advised on the implementation of the legislative reforms, the associated business reforms and IT enhancements from 1 July 2014

- monitored APVMA progress in implementing the *Public Governance, Performance and Accountability Act 2013* (PGPA Act)
- reviewed and monitored the Risk Management Plan and Risk Register
- reviewed the Fraud Control Plan 2014–16
- monitored key performance indicators of the committee
- monitored and advised on the internal audit program, including audits of science quality, corporate travel and credit cards, levies, enhanced security of confidential commercial information, procurement and implementation of the PGPA Act.

## Presentations

In 2014–15, the Audit Committee received an external presentation from the University of Melbourne, Centre of Excellence for Biosecurity Risk Analysis, on the development of a risk-based assessment framework for the APVMA.

## Declarations of interest

No conflicts of interest that would conflict with the proper performance of the Audit Committee's functions were declared at any meeting in 2014–15.

# MANUFACTURERS' LICENSING SCHEME INDUSTRY LIAISON COMMITTEE

The APVMA established the Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC) to provide a forum to discuss strategic and operational issues relating to the Manufacturers' Licensing Scheme and the Overseas Good Manufacturing Practice Scheme with industry representatives and auditors.

## Terms of reference

The terms of reference of the MLSILC are to:

- obtain the views of industry members and auditors on issues of an operational, technical or strategic nature
- advance the development and review of operating procedures, manufacturing standards and guidelines relevant to the Australian Manufacturers' Licensing Scheme and the Overseas Good Manufacturing Practice Scheme
- provide industry input into APVMA operational planning processes relating to manufacturing issues
- identify opportunities for regulatory reform within the existing framework
- consider the impact of proposed policy changes on APVMA operations, and implications for industry
- facilitate communication with industry and other stakeholders.

## Meetings and attendance

The committee met three times in 2014–15: in September and December 2014, and March 2015. Membership and attendance at MLSILC meetings are shown in Table A3.

**TABLE A3: MANUFACTURERS' LICENSING SCHEME INDUSTRY LIAISON COMMITTEE MEETINGS, 2014–15**

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Bruce Johnson (Chair, December 2014, March 2015)	APVMA	3	2
Kathryn Winterton (Chair, September 2014)		3	3
Suzanne Stokes (Secretary, September and December 2014)		2	2
Garry Hartridge (Secretary, March 2015)		1	1
Matthew Sherriff	Animal Medicines Australia Ltd	3	2
Ian Wheatley	Auditors' representative	3	3
John Aird	Feed Ingredients and Additives Association of Australia	3	2
Bill Blackhall	Veterinary Manufacturers and Distributors Association	3	3

## Issues considered

Issues considered in 2014–15 included:

- progress with auditing and licensing of veterinary medicine product manufacturers
- updates on APVMA regulatory reform activities
- progress with development of risk-based systems for scheduling audits and quantifying audit outcomes
- progress with release-for-supply arrangements with third-party toll manufacturers
- monitoring progress of the mutual recognition agreement between Australia and the European Community
- update on progress on conformity assessment and recognition by international regulatory bodies (eg FAMI QS—the Quality and Safety System for Specialty Feed Ingredients and their Mixtures)
- inspections of Australian veterinary manufacturers by the Therapeutic Goods Administration (TGA), conducted under a memorandum of understanding between the APVMA and the TGA.

## Declarations of interest

No matters were declared by any member of the MLSILC that would give rise to any personal material conflict of interest. Records of declarations are maintained by the APVMA.

# REGISTRATION LIAISON COMMITTEE

The Registration Liaison Committee is a consultative forum for the APVMA, representatives of the state and territory signatories to the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), and other relevant Australian Government agencies.

## Terms of reference

The terms of reference of the Registration Liaison Committee are to:

- align the outputs of the APVMA's registration processes and the chemical management objectives of the states and territories
- develop operational policies for the operation of the NRS, including those dealing with registration (including labelling), regulation, and appropriate use of agricultural and veterinary chemicals
- provide feedback on state and territory views on these issues, and particularly their impact on chemical users and the responsibilities of regulators
- address specific operating policy issues, as necessary
- provide input to operational planning priorities
- provide input to existing chemical review priorities.

## Meetings and attendance

As a result of operational requirements, the committee did not formally meet in 2014–15.

# APPENDIX B: FREEDOM OF INFORMATION

## REQUESTS FOR INFORMATION UNDER THE *FREEDOM OF INFORMATION ACT 1982*

The APVMA had 6 requests for information under the *Freedom of Information Act 1982* (FOI Act) in progress at the beginning of the 2014–15 financial year, and received an additional 24 requests during the year. During the year, 17 requests were finalised.

## INFORMATION PUBLICATION SCHEME

Agencies subject to the FOI Act are required to publish information for the public as part of the Information Publication Scheme (IPS). IPS information for the APVMA is available at [www.apvma.gov.au](http://www.apvma.gov.au).



# ACRONYMS AND ABBREVIATIONS

Administrative Act	<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>
AERP	Adverse Experience Reporting Program
agvet	agricultural and veterinary
Agvet Code	Agricultural and Veterinary Chemicals Code
Agvet Code Act	<i>Agricultural and Veterinary Chemicals Code Act 1994</i>
APS	Australian Public Service
APVMA	Australian Pesticides and Veterinary Medicines Authority
CEO	Chief Executive Officer
CSIRO	Commonwealth Scientific and Industrial Research Organisation
FAO	Food and Agriculture Organization of the United Nations
FMA Act	<i>Financial Management and Accountability Act 1997</i>
GJR	Global Joint Review
IT	information technology
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MRL	maximum residue limit
NATA	National Association of Testing Authorities
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
OECD	Organisation for Economic Co-operation and Development
PGPA Act	<i>Public Governance, Performance and Accountability Act 2013</i>
RSN	Regulatory Science Network
TGA	Therapeutic Goods Administration
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization
WHS	work, health and safety

# GLOSSARY

2014–15

1 July 2014 – 30 June 2015.

active constituent

The component of a pesticide or veterinary medicine product that is responsible for its physiological or pharmacological action.

adverse experience

Any undesirable experience arising from the use of a chemical; adverse experiences may affect human or animal health, the environment or other factors.

antibiotic

Substances produced by microorganisms that are antagonistic in high dilution to the growth and viability of other microorganisms.

applicant

A person or company who applies to the APVMA to register a pesticide or veterinary chemical for use in Australia.

approved label

The market product label that carries text approved and published by the APVMA.

compliance

Compliance with any applicable agvet law.  
*See also* noncompliance.

cost recovery

Fees and charges relating to the provision of government goods and services (including regulation) to the private and other nongovernment sectors of the economy.

extension of use

The agreed use of a pesticide or veterinary chemical for a purpose other than those specified on the original label. Registered products must be used only for purposes that are specified on the label, and the APVMA must grant permission for any extensions of use.

good manufacturing practice

Standards that ensure that products are consistently manufactured to the quality standards appropriate for their intended use and in accordance with their registration specifications.

licence

Authority to manufacture pesticides or veterinary medicines according to s. 123 of the Agvet Code.

maximum residue limit

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.

maximum residue limit standard

A list of agvet chemicals and the corresponding residue levels of these chemicals that are permitted in food and animal feed.

minor use

A use that would not produce sufficient economic return to an applicant to meet the cost of registering the product for that use.

nanotechnology

The design, characterisation and application of materials engineered at a molecular (nanometre-scale) level.

noncompliance	Noncompliance with any applicable agvet law. Noncompliance may include the sale and use of unregistered products, supply of restricted products to unauthorised users, unapproved labels, unfounded claims in advertising or other media, or active constituents that do not conform to APVMA standards.
nontarget	Crops, plants or animals that are not the target of the chemical, but may be affected by its use. <i>See also</i> spray drift.
pesticides	Substances or mixtures of substances intended for preventing, destroying, repelling or mitigating any pest. Also known as agricultural chemical products.
registrant	A person or company who registers a pesticide or veterinary medicine product for use in Australia.
registration	Official recognition that a pesticide or veterinary medicine is safe and will work when used according to the label. Before an agricultural or veterinary chemical product can be legally supplied, sold or used in Australia, it must be registered by the APVMA.
regulatory guidelines	A set of guidelines that provide details of how the relevant agvet legislation is enacted by the APVMA, and how agvet chemicals can be registered in Australia.
spray drift	The unintentional movement of pesticides from one area to another with the wind.
statutory time	The legislatively prescribed timeframe in which the APVMA must process applications for registration.
veterinary medicines	Substances or mixtures of substances intended for treating diseases or conditions in animals.

# LIST OF REQUIREMENTS

This annual report has been prepared in accordance with the APVMA's statutory obligations. These obligations are outlined in the *Requirements for Annual Reports for Departments, Executive Agencies and other Non-Corporate Commonwealth Entities* revised by the Department of the Prime Minister and Cabinet 25 June 2015. The reporting requirements have been identified under the legislation or requirements to which they relate, noting that a number of requirements are common to both.

REF*	DESCRIPTION	REQUIREMENT	PAGE
8(3) & A.4	Letter of transmittal	Mandatory	iii
A.5	Table of contents	Mandatory	iv–v
A.5	Index	Mandatory	155
A.5	Glossary	Mandatory	149–150
A.5	Contact officer(s)	Mandatory	ii
A.5	Internet home page address and Internet address for report	Mandatory	ii
9	<b>Review by Chief Executive, APVMA</b>		
9(1)	Review by Chief Executive, APVMA	Mandatory	vii
9(2)	Summary of significant issues and developments	Suggested	14–17
9(2)	Overview of agency's performance and financial results	Suggested	91–93
9(2)	Outlook for following year	Suggested	na
9(3)	Significant issues and developments—portfolio	Portfolio departments—suggested	na
10	<b>Agency overview</b>		
10(1)	Role and functions	Mandatory	2–3
10(1)	Organisational structure	Mandatory	5
10(1)	Outcome and programme structure	Mandatory	12–13
10(2)	Where outcome and programme structures differ from PB Statements/PAES or other portfolio statements accompanying any other additional appropriation bills (other portfolio statements), details of variation and reasons for change	Mandatory	18–83
10(3)	Portfolio structure	Portfolio departments—mandatory	na
11	<b>Report on performance</b>		
11(1)	Review of performance during the year in relation to programmes and contribution to outcomes	Mandatory	18–83
11(2)	Actual performance in relation to deliverables and KPIs set out in PB Statements/PAES or other portfolio statements	Mandatory	18–83

REF*	DESCRIPTION	REQUIREMENT	PAGE
11[2]	Where performance targets differ from the PBS/PAES, details of both former and new targets, and reasons for the change	Mandatory	18–83
11[2]	Narrative discussion and analysis of performance	Mandatory	18–83
11[2]	Trend information	Mandatory	18–83
11[3]	Significant changes in nature of principal functions/services	Suggested	na
11[3]	Performance of purchaser/provider arrangements	If applicable, suggested	na
11[3]	Factors, events or trends influencing agency performance	Suggested	na
11[3]	Contribution of risk management in achieving objectives	Suggested	86–87
11[4]	Performance against service charter customer service standards, complaints data, and the agency's response to complaints	If applicable, mandatory	87–88
11[5]	Discussion and analysis of the agency's financial performance	Mandatory	91–93
11[6]	Discussion of any significant changes in financial results from the prior year, from budget or anticipated to have a significant impact on future operations.	Mandatory	na
11[7]	Agency resource statement and summary resource tables by outcomes	Mandatory	92
12	<b>Management and accountability</b>		
	Corporate governance		
12[1]	Agency heads are required to certify that their agency complies with the 'Commonwealth Fraud Control Guidelines'.	Mandatory	87
12[2]	Statement of the main corporate governance practices in place	Mandatory	86
12[3]	Names of the senior executive and their responsibilities	Suggested	6–8
12[3]	Senior management committees and their roles	Suggested	73
12[3]	Corporate and operational plans and associated performance reporting and review	Suggested	6, 12, 66–69, 86
12[3]	Internal audit arrangements including approach adopted to identifying areas of significant financial or operational risk and arrangements to manage those risks	Suggested	86–87, 143–144
12[3]	Policy and practices on the establishment and maintenance of appropriate ethical standards	Suggested	na
12[3]	How nature and amount of remuneration for SES officers is determined	Suggested	na
	<b>External scrutiny</b>		
12[4]	Significant developments in external scrutiny	Mandatory	87–88
12[4]	Judicial decisions and decisions of administrative tribunals and by the Australian Information Commissioner	Mandatory	88

REF*	DESCRIPTION	REQUIREMENT	PAGE
12[4]	Reports by the Auditor-General, a parliamentary committee, the Commonwealth Ombudsman or an agency capability review	Mandatory	88
<b>Management of human resources</b>			
12[5]	Assessment of effectiveness in managing and developing human resources to achieve agency objectives	Mandatory	76–83
12[6]	Workforce planning, staff retention and turnover	Suggested	76, 78
12[6]	Impact and features of enterprise or collective agreements, individual flexibility arrangements (IFAs), determinations, common law contracts and Australian Workplace Agreements (AWAs)	Suggested	83
12[6]	Training and development undertaken and its impact	Suggested	81–82
12[6]	Work health and safety performance	Suggested	78–79
12[6]	Productivity gains	Suggested	na
12[7]	Statistics on staffing	Mandatory	76–78
12[8]	Enterprise or collective agreements, IFAs, determinations, common law contracts and AWAs	Mandatory	83
12[9] & B	Performance pay	Mandatory	77, 111–114
<b>Assets management</b>			
12[10]- [11]	Assessment of effectiveness of assets management	If applicable, mandatory	98–110
<b>Purchasing</b>			
12[12]	Assessment of purchasing against core policies and principles	Mandatory	88–89
<b>Consultants</b>			
12[13]- [22]	The annual report must include a summary statement detailing the number of new consultancy services contracts let during the year; the total actual expenditure on all new consultancy contracts let during the year (inclusive of GST); the number of ongoing consultancy contracts that were active in the reporting year; and the total actual expenditure in the reporting year on the ongoing consultancy contracts (inclusive of GST). The annual report must include a statement noting that information on contracts and consultancies is available through the AusTender website.	Mandatory	93
<b>Australian National Audit Office access clauses</b>			
12[23]	Absence of provisions in contracts allowing access by the Auditor-General	Mandatory	na
<b>Exempt contracts</b>			
12[24]	Contracts exempted from publication in AusTender	Mandatory	na
<b>Financial statements</b>			
13	Financial statements	Mandatory	91–137

REF*	DESCRIPTION	REQUIREMENT	PAGE
<b>Other mandatory information</b>			
14(1) & C.1	Work health and safety [Schedule 2, Part 4 of the <i>Work Health and Safety Act 2011</i> ]	Mandatory	78–79
14(1) & C.2	Advertising and market research [Section 311A of the <i>Commonwealth Electoral Act 1918</i> ] and statement on advertising campaigns	Mandatory	81, 93
14(1) & C.3	Ecologically sustainable development and environmental performance [Section 516A of the <i>Environment Protection and Biodiversity Conservation Act 1999</i> ]	Mandatory	88–89
14(1)	Compliance with the agency's obligations under the <i>Carer Recognition Act 2010</i>	If applicable, mandatory	na
14(2) & D.1	Grant programmes	Mandatory	na
14(3) & D.2	Disability reporting—explicit and transparent reference to agency level information available through other reporting mechanisms	Mandatory	79
14(4) & D.3	Information Publication Scheme statement	Mandatory	147
14(5)	Correction of material errors in previous annual report	If applicable, mandatory	na
E	Agency Resource Statements and resources for Outcomes	Mandatory	92–93, 131
F	List of Requirements	Mandatory	151–154

\* The reference is to the location of the item in the *Requirements for Annual Reports for Departments, Executive Agencies and other non-corporate commonwealth entities* (issued 25 June 2015) – for example, 'A.4' refers to the fourth item in Attachment A of the requirements.

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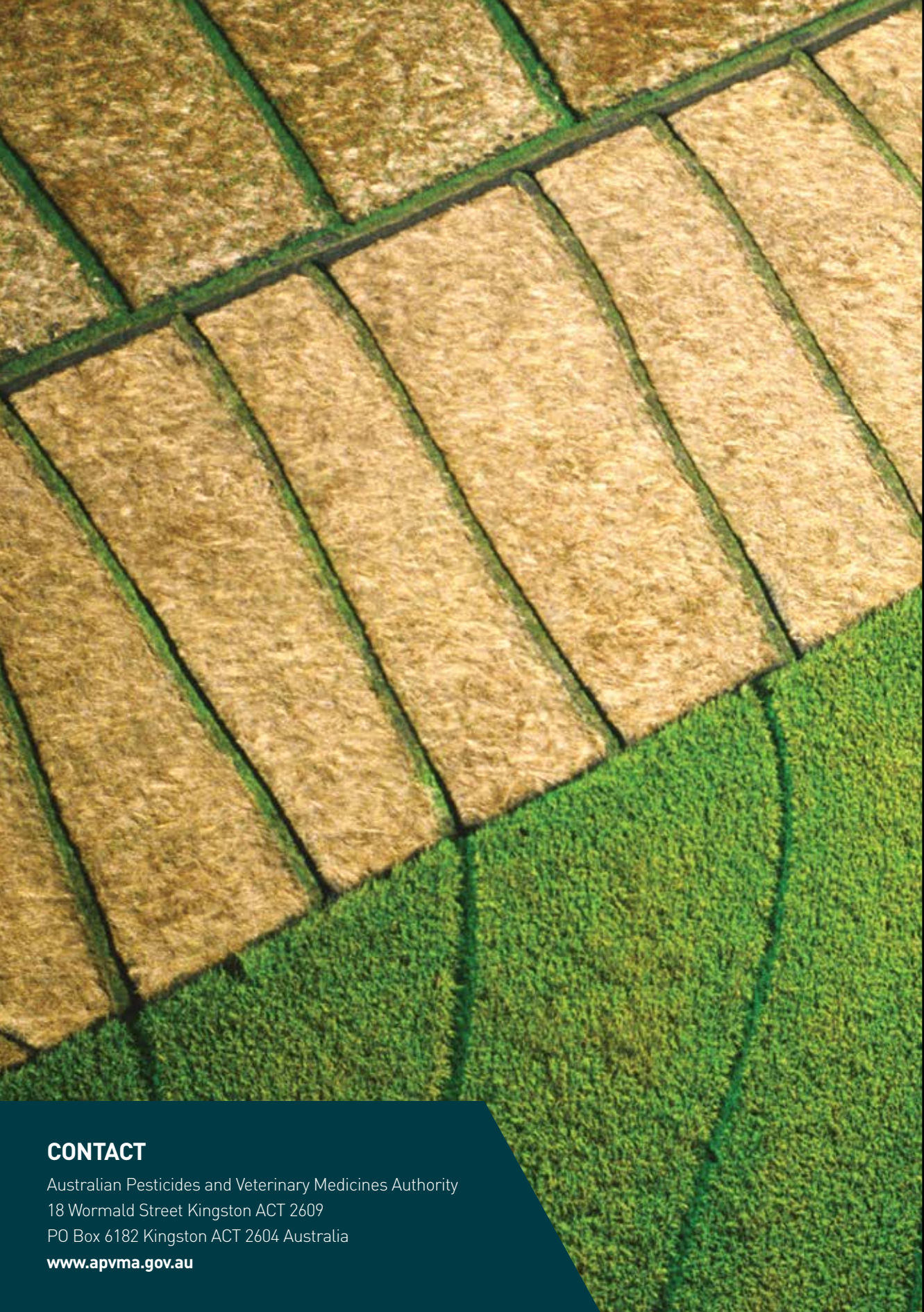
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