CHAPTER 1
Organisation overview
Corporate profile and purpose

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority responsible for the assessment and registration of agricultural chemicals and veterinary medicines (agvet chemicals) and for their regulation up to and including the point of retail sale. The APVMA evaluates the safety and performance of agvet chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected and that Australia’s international trade is not jeopardised through the use of the chemicals.

More than 11 500 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.

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 ensuring chemical products can be used safely. We license and audit veterinary manufacturers to ensure that they adhere to APVMA-prescribed manufacturing standards and regularly review chemicals, that are on the market, to ensure they are safe to use. We manage an Adverse Experience Reporting Program (AERP) to ensure early detection of unforeseen problems with registered chemicals, and also monitor the market for compliance, and review and take regulatory action on registered pesticides and veterinary medicines when concerns are raised.

The APVMA operates under an intergovernmental agreement between the Commonwealth Government and all states and territories. Under this agreement, the APVMA is responsible for regulating agvet chemicals up to and including the point of sale. The states and territories are responsible for regulating agvet chemicals after they are sold, a process which is known as ‘control of use’. The APVMA does not have responsibility for monitoring how chemicals are used.

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

Enabling legislation

The APVMA is established under the Agricultural and Veterinary Chemicals (Administration) Act 1992 (Administration Act).

Functions and powers are conferred on the APVMA by the Administration Act, the Agricultural and Veterinary Chemicals Code (Agvet Code) scheduled to the Agricultural and Veterinary Chemicals Code Act 1994, the Agricultural and Veterinary Chemicals Code Regulations 1995 (Agvet Regulations) and the Agvet Codes and Agvet Regulations of each state or participating territory.

The APVMA is a corporate Commonwealth entity under the Public Governance, Performance and Accountability Act 2013 (PGPA Act). A corporate Commonwealth entity is a body corporate that is legally separate from the Commonwealth.
Functions and powers
The key functions of the APVMA, which are set out in section 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
- ensure that approvals and registrations for active constituents for chemical products, chemical products and labels for containers for chemical products comply with the Agvet Code and the Agricultural and Veterinary Chemicals Code Regulations 1995 (Agvet Code Regulations)
- 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 the Australian Government and its agencies on matters relating to the management and control of chemical products
- collect and publish relevant information and statistics on approvals and registrations granted, and permits and licences issued under the Agvet Code
- facilitate a consistent approach to the assessment and control of agvet chemicals, in conjunction with the Australian Government and its agencies, and the states and participating territories
- exchange information relating to chemical products and their use, with overseas and international bodies that have similar functions to those of the APVMA
- report to or advise the minister on matters relating to the performance of the APVMA’s functions.

Ministerial directions and government policy orders
Under s. 10 of the Administration Act, the Australian Government minister responsible for administering pesticide and veterinary medicine legislation may direct the APVMA (in writing) concerning its functions or powers under Australian, state or territory laws. The APVMA must comply with any such direction. No ministerial directions or Government policy orders were issued to the APVMA during 2015–16.

Significant non-compliance issues with finance law
No issues were reported to the Minister for Agriculture and Water Resources under paragraph 19(1)(e) of the PGPA Act that related to non-compliance with the finance law in relation to the entity.
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 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 and Water Resources is currently conducting a first-principles review of the APVMA’s cost recovery arrangements.

The APVMA’s income for 2015–16 was $30.546 million, an increase of $0.805 million (2.71 per cent) from 2014–15 (see Chapter 4). The APVMA’s equity dropped to $7.312 million this year. This is $0.312 million above the APVMA’s nominal reserve of $7 million.

Significant activities and changes

During 2015–16 no significant changes affected the operations or structure of the APVMA.
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: APVMA organisation structure as at 30 June 2016

<table>
<thead>
<tr>
<th>Chief Executive Officer</th>
<th>Office of the Chief Executive Officer</th>
</tr>
</thead>
</table>
| **Scientific Assessment and Chemical Review** | Chemical Review  
Chemistry and Manufacture  
Residues and Trade  
Health Assessment Team  
Environmental Assessment Coordinator  
Efficacy Assessment Coordinator  
Scientific Standards and Data Guidelines  
Risk-Based Assessment Framework |
| **Registration Management and Evaluation** | Case Management and Administration Unit  
Veterinary Medicines  
Pesticides  
Minor Use  
Biologics  
Quality Oversight and Reporting |
| **Corporate Services** | Finance  
Human Resources and Development  
Information Management and Technology  
Procurement and Partnership Management  
Public Affairs and Communication |
| **Legal and Compliance** | Legal  
Compliance and Monitoring  
Manufacturing Quality and Licensing |
| **Office of the Chief Scientist** | Principal Scientist |

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 we meet our regulatory obligations. The executive and APVMA staff use their collective skills and experience 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 key stakeholders to set the organisation's vision, objectives and strategies to meet its legislative responsibilities. The CEO approves the APVMA's corporate 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.

Ms Cate Saunders
Executive Director, Corporate Services, and Chief Operating Officer
The Chief Operating Officer and Executive Director, Corporate Services manages finance and administration, human resources, public affairs and communication, information technology (including operations, security, information services and application development), procurement, business systems and organisational performance analysis. Key responsibilities include providing timely and accurate financial data and preparing financial plans, budgets and strategies that support the APVMA’s ability to deliver quality services with the funds available. The Executive Director 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 Elizabeth Carroll

A/g 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 staff on all aspects of the APVMA’s regulatory, administrative and corporate functions. Responsibilities include delivering the APVMA’s 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 these 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 office of the Chief Scientist.

We also recognise the following people who contributed to the APVMA executive team during 2015–16:

Mr Tony de la Fosse, Ms Geetha Nair and Dr Matthew O’Mullane.
Staff profile

Table 1 provides details of Australian Public Service (APS) employees employed at the APVMA under the Public Service Act 1999 in 2015–16.

We had 182 full-time and part-time ongoing staff at 30 June 2016. There were also 16 non-ongoing or casual staff, bringing the total number of staff to 198 (122 female, 76 male). No staff identify as being Indigenous. All staff are located in Canberra, except for one staff member who is in Perth.

In 2015–16, the separation rate for ongoing staff was 18.7 per cent, which is an increase from the 8.8 per cent separation rate of the previous year.

Table 1: APVMA staffing at 30 June 2016

<table>
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<tr>
<th>CLASSIFICATION</th>
<th>FULL-TIME (ONGOING)</th>
<th>PART-TIME (ONGOING)</th>
<th>NON-ONGOING AND CASUAL</th>
<th>TOTAL</th>
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<td>4</td>
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<tr>
<td>Trainee</td>
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<tr>
<td>Total</td>
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<td>198</td>
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</tbody>
</table>

APS = Australian Public Service; CEO = Chief Executive Officer; EL = executive level
Strategic framework and reporting

The APVMA corporate plan 2015–19 identifies four strategies (Figure 2):

- Strategy 1 – deliver regulatory decisions that are timely, science-based and proportionate to the risks managed
- Strategy 2 – reduce the burden on industry in complying with regulatory requirements
- Strategy 3 – build a client-focused approach to service delivery, committed to continuous improvement
- Strategy 4 – operate as a contemporary, high-performing and efficient organisation.

Figure 2: APVMA objectives and strategies

The APVMA operational plan 2015–16 identified a range of activities to achieve the corporate plan goals.