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.

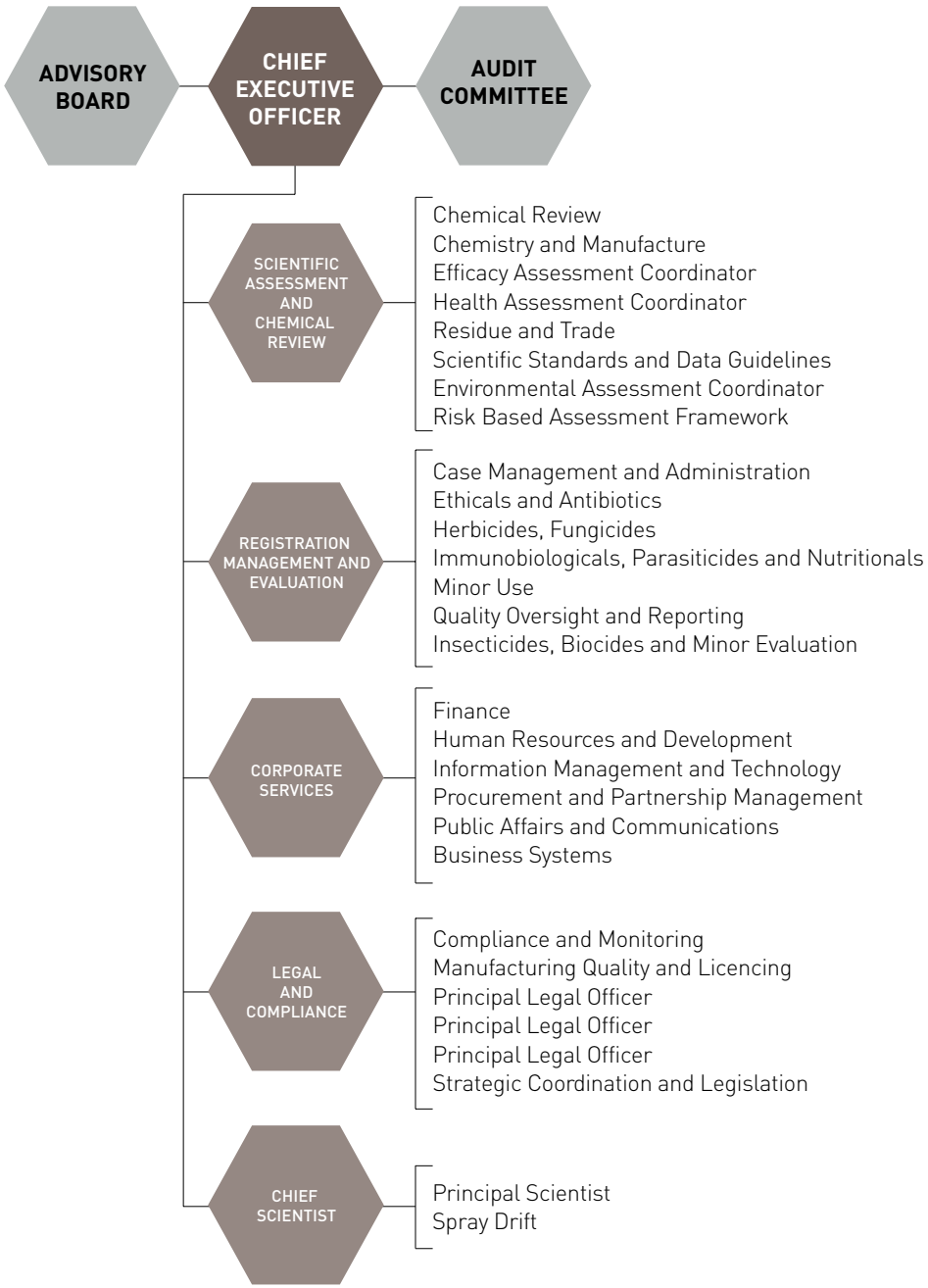
The Australian Government Department of Agriculture is currently conducting a first-principles review of the APVMA's cost-recovery arrangements.

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.