CHAPTER 4

Corporate governance and management

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 *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Our central planning document is the APVMA corporate plan, which defines the principal objectives of the APVMA and gives a broad outline of the strategies devised to achieve these objectives. The corporate plan aligns with the APVMA Regulator Performance Framework, which outlines our key performance measures.

In addition, each year we develop an operational plan that sets out the actions needed to achieve the objectives in the corporate plan. We measure our operational effectiveness annually through the performance indicators in the operational plan and the Portfolio Budget Statement (PBS).

Governance

Under the *Public Governance, Performance and Accountability Act 2013 (*PGPA Act), the APVMA is a Commonwealth corporate entity. The APVMA is a body corporate with a separate legal identity from the Commonwealth of Australia. The CEO of the APVMA is responsible for the governance and management of the APVMA, with the support of the executive team (see Chapter 2) and the Audit Committee (see below).

The APVMA governance structure aligns accountabilities to ensure decision making delivers best-practice scientific assessment and operational effectiveness. The APVMA CEO is the accountable authority for the purposes of the PGPA Act and is appointed as a statutory officer by the minister. The CEO, who is responsible for the management and governance of the authority together with the APVMA's executive team, is also responsible for delivering against the performance measures within the Regulator Performance Framework.

The APVMA governance committees (Table 6) adhere to the principles of public sector governance to provide accountability, transparency, integrity, stewardship, efficiency and leadership.

Table 6: APVMA governance committees

Group	Description
APVMA Relocation Advisory Committee	This committee provided strategic advice to the executive on major aspects of the relocation and the transition of operations from Canberra to Armidale, including the business model, digital strategy, strategic risk and mitigation, stakeholder issues and engagement. The committee was disestablished on 31 July 2019 following completion of the physical relocation to Armidale.
Executive Leadership Team	The Executive Leadership Team comprises the Senior Executive and is chaired by the CEO. The team provides strategic, whole-of-organisation advice and direction relevant to decision making, management and oversight of the APVMA's operations and performance.
Senior Leadership Team	The Senior Leadership Team provides a forum for the senior operational managers in the agency to identify opportunities for cross-agency collaboration, innovation and performance improvement, and to develop leadership.
Audit Committee	This subcommittee reports to the CEO. It assists the agency in discharging its responsibilities under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Public Governance, Performance and Accountability Act 2013* regarding financial reporting, performance reporting, risk oversight and management, internal control and compliance with relevant laws and policies. The committee is not responsible for the executive management of these functions.
Science Quality Committee	This subcommittee reports to the executive team. It advises and provides recommendations on matters of science and science quality relevant to the functions of the APVMA.
Enforcement Committee	This subcommittee reports to the executive team. It oversees the potential and actual use of coercive powers.
Change Management Committee	The board oversees the progress of projects that are significant to the operational direction of the agency, including project deliverables, resourcing requirements, timeframes and management of risks. It also ensures that cross-project opportunities and issues are identified and addressed. This committee took over the responsibilities of, and replaces, the former Major Projects Board, and the Relocation Program Board.
Business Systems and Technology Committee	The forum provides oversight of ICT work identified through the Business System Change Request process for new systems and system enhancements. The committee took over the responsibilities of, and replaces, the former Executive Leadership Team Prioritisation Forum.

The governance structure, senior management support and guidance material support operational effectiveness and help APVMA staff to adhere to the public sector values to be impartial, committed to service, respectful, accountable and ethical.

APVMA guidance material for employees includes policies relating to security, appropriate management of confidential information, financial and procurement practices, use of social media, conflicts of interest, travel, performance management and workplace safety. These policies operate in line with, and in addition to, requirements under the APS Code of Conduct and legislative framework governing the conduct of APS employees. The APVMA undertakes corporate risk management with regular review by executive staff.

The APVMA has a Work Health and Safety Committee and a Staff Consultative Committee to handle employee matters.

APVMA Audit Committee

Consistent with s. 45 of the PGPA Act, the CEO maintains an Audit Committee. The committee met four times in 2018–19. 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 concerning the risk control and compliance framework, 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 the APVMA executive team. Committee observers and advisers can include representatives from the Australian National Audit Office, the internal auditor, the APVMA CEO, Chief Financial Officer and other management representatives.

Manufacturers' Licensing Scheme Industry Liaison Committee

The Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC) is a forum for the APVMA to discuss with industry representatives and auditors strategic and operational issues relating to the Manufacturers' Licensing Scheme and the Overseas Good Manufacturing Practice Scheme.

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 effect of proposed policy changes on APVMA operations, and implications for industry
- facilitate communication with industry and other stakeholders.

Meetings and attendance

The committee met twice in 2018–19: in September 2018 and March 2019. Figures for membership and attendance at MLSILC meetings are shown in Table 7.

Table 7: Attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings, 2018–19

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Michelle Wooster (Chair)	APVMA	2	2
Garry Hartridge (Secretary)	APVMA	2	2
Maggie Hardy, Chief Regulatory Scientist	APVMA	1	1
Martin Snowball	Animal Medicines Australia Ltd	2	2
Noelene Davis	Feed Ingredients and Additives Association of Australia	2	1
Ian Wheatley	Auditors' representative	1	1
Tony Rowland	Auditors' representative	1	0
Jim Adams	Veterinary Manufacturers and Distributors Association	2	2

Issues considered

Issues considered in 2018–19 included:

- consultation for the proposed revision of the Australian Code of Good Manufacturing Practice
- update on the changes to audit scheduling based on risk rating
- successful recruitment of new auditors
- the possibility of adopting a first-party audit model for European Community—Australia Mutual Recognition Agreement certificates
- update on implementation of the memorandum of understanding (MOU) between the APVMA and the Therapeutic Goods Administration, and information on service-level agreements included in the MOU
- the APVMA's cost-recovery model for manufacturing licences
- use of 'Objective Connect' by auditors and its possible extension to industry as a replacement for secure email
- update on the Manufacturing Quality and Licensing team structure and staff transition
- accreditation of audits conducted to FAMI-QS (Feed Additive and Pre-Mixture System) standards and their recognition by the APVMA.

Declarations of conflicts of interest

There were no matters declared by any member of the MLSILC that would give rise to any personal material conflict of interest. The APVMA maintains records of declarations.

Science Quality Committee

The Science Quality Committee is a subcommittee reporting to the APVMA CEO and executive team. The committee provides advice and makes recommendations related to matters of science and science quality relevant to the functions of the APVMA.

The objectives of the committee are to:

- provide a forum for open debate of scientific issues relevant to the function of the APVMA
- foster and encourage regulatory scientific excellence in the APVMA
- approve and prioritise proposals for development and adoption of scientific methodologies
- test guidelines and guidance documents by the APVMA and partner advising agencies.

Related entity transactions

The APVMA contracted the Department of Environment to provide environmental scientific assessment advice during 2018–19. During 2018–19, there were 11 individual transactions totalling $114 000.

Consultation and collaboration

Our stakeholders are at the core of our business. Consulting and working with them, and with other regulatory agencies, to ensure we meet their needs is a priority. Stakeholders from industry, chemical users, government and the community provide input and are involved in our decision making and the development of guidelines and operational policy.

We work closely with the Australian Government Department of Agriculture to ensure policy and legislation development and change are effective and best placed to help our regulated entities.

In 2018–19, the APVMA conducted 36 public consultations on a range of topics including chemical product approvals, trade advice notices, public release summaries, chemical reviews, and revisions to the Australia New Zealand Food Standards Code. The annual industry information sessions did not proceed in 2018 because the APVMA was revising its approach to engagement and exploring new ways of engaging clients and stakeholders.

International engagement

The APVMA continued its program of international engagement in 2018–19, including participating in key international scientific and regulatory forums (Table 8) and welcoming international visitors to the APVMA (Table 9).

Table 8: APVMA participation in international forums

Meeting	Contribution	Date	Participants
American Chemical Society 256th National Meeting and Exposition	Jason Lutze presented on Australia's experiences in Joint Reviews, and attended a session on maximum residue limits harmonisation, spray drift and the use of monitoring data in regulatory assessments	August 2018	Jason Lutze
FAO/WHO Joint Meeting on Pesticide Residues	Chris Schyvens and Paul Humphrey attended this meeting as invited experts	September 2018	Paul Humphrey Chris Schyvens
VICH Anthelmintic Working Group	Teleconference with VICH Expert Working Group for Anthelmintic.	September 2018 (teleconference)	Michelle Wooster

Meeting	Contribution	Date	Participants
APEC food safety cooperation forum, maximum residue limits harmonisation workshop	Participant in the APEC food safety cooperation forum	October 2018	James Deller
Diethanolamine quad countries: toxicologists	Regular teleconference with regulatory scientists from other agencies to discuss issues of common concern	October 2018	Sheila Logan
Joint FAO/WHO Stakeholders Expert Consultation Meeting on the carryover of veterinary drug residues from feed to food	Resource person and rapporteur	January 2019	James Deller
OECD Expert Group on Electronic Exchange of Pesticide Data	Observer	January 2019	David Perry
VICH 6th Public Conference and 37th VICH Standing Committee	Observer	February 2019	Alan Norden
OECD Network on Illegal trade of Pesticides	Australian representative (committee member)	February 2019	Steven Harris
7th OECD Network on Illegal Trade of Pesticides	Australian representative (committee member, active participant)	March 2019	Steven Harris
Codex Committee on Pesticide Residues	Alternate Australian delegation lead at the meeting and participant in its electronic working groups establishing codex maximum residue limits and risk assessment policy	April 2019	Jason Lutze

Meeting	Contribution	Date	Participants
New Zealand Ministry for Primary Industries Agricultural Compounds and Veterinary Medicines (ACVM) Group	Sam Margerison presented to ACVM staff on regulation of agvet chemicals in Australia. Meetings were held with staff from ACVM and the Environmental Protection Authority, discussing the process for chemistry assessments in Australia and New Zealand, and the potential for harmonisation of assessment reports and sharing of assessments between the two agencies.	May 2019	Sam Margerison
OECD Expert Group on BioPesticides meeting and bioinformatics seminar	Observer	June 2019	Alan Norden
OECD 34th Working Group on Pesticides and Risk Reduction Seminar	The APVMA was Chair of two expert groups and participated in several others	June 2019	Alan Norden
OECD Residues Chemistry Expert Group	Jason Lutze is the Chair of the OECD Residues Chemistry Expert Group	Ongoing teleconferences	Jason Lutze
OECD Working Group on Residues Definition	Participant	Ongoing teleconferences	James Deller Jason Lutze
OECD Working Group on Technical Guideline 509 (crop field trials)	Participant	Ongoing teleconferences	James Deller

APEC = Asia-Pacific Economic Cooperation; FAO = Food and Agriculture Organization of the United Nations; OECD = Organisation for Economic Co-operation and Development; VICH = International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; WHO = World Health Organization

Table 9: APVMA engagement with visiting international delegations

Meeting	Date	Participants
South Korea Rural Development Authority	September 2018	Jason Lutze
Vietnam Ministry of Agriculture	November 2018	Jason Lutze James Deller
Canada Pest Management Regulatory Agency	November 2018	Alan Norden Maggie Hardy
Saudi Arabia Food and Drug Authority, CEO	November 2018	Jason Lutze
Japanese Ministry of Health, Labour and Welfare	March 2019	James Deller
New Zealand Ministry for Primary Industries	May 2019	Sam Margerison
Saudi Arabia Food and Drug Authority, technical specialists	June 2019	Gaye Weller James Deller

Accountability

Corporate risk management

The APVMA Risk Management Framework, which was updated in 2017–18, is a suite of documents that detail strategies for how the APVMA deals with risk. The Strategic and Enterprise Risk Profile specifies the most significant and material business risks being managed by the APVMA, and the APVMA Risk Management Framework articulates and describes the:

- APVMA's policy for the management of risk
- methodology used in the assessment of risk across the APVMA
- operation of APVMA's risk registers and the integration of risk management through the APVMA
- strategies to develop a risk-aware organisational culture where proactive risk management is at the forefront of the decision-making process.

The Operational Risk Register identifies and categorises key business risks which need structured management within the APVMA.

The APVMA has also developed a risk framework including a risk register and treatment strategy for the relocation project. The framework was reviewed by the APVMA Audit Committee and the Relocation Advisory Committee.

We now regularly report against the risks identified in our Strategic and Operational Risk Registers. We are currently reviewing the risk registers to ensure their currency, remove duplication and validate the effectiveness of the controls applied to date.

Fraud control

The APVMA has a fraud risk assessment and a fraud control plan that complies with the *Commonwealth fraud control guidelines*. The plan includes fraud prevention, detection, investigation, reporting and data collection procedures.

There were no cases of fraud reported or identified during 2018–19.

Reporting

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

The APVMA prepares reports of its performance in meeting regulatory obligations, and presents a range of statistics, including:

- registration of chemical products
- approval of active ingredients
- issuance of permits
- licensing and audit of veterinary medicines manufacturers
- preliminary assessment and pre-application assistance.

The reporting includes:

- the number of applications started and finalised
- the proportion of applications finalised within legislative timeframes
- work in progress at the end of the period.

Privacy

The APVMA adheres to the *Privacy Act 1988* and our privacy policy is on our website. Our operations were not subject to any report or determinations by the Privacy Commissioner in 2018–19.

Indemnities and insurance premiums

The APVMA's insurance with Comcover includes liability cover up to $150 million for professional indemnity, and directors' and officers' liability. The insurance premium paid to cover the 2018–19 financial year was $74 218 (excluding GST).

Judicial decisions and reviews by outside bodies

Parliamentary committees and other reviews

Parliamentary committees tabled two reports relevant to the APVMA's operations. The table below shows the dates of the inquiry reports, and the dates the Australian Government provided its response.

Table 10: Parliamentary committee reports tabled in 2018–19

Committee	Inquiry	Tabling date	Australian Government response date
Senate Rural and Regional Affairs and Transport References Committee	The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)	1 February 2019	11 April 2019
Senate Rural and Regional Affairs and Transport Legislation Committee	Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 [Provisions]	11 February 2019	9 April 2019

Auditor-General's reports

In 2018–19 the Auditor-General conducted one Australian National Audit Office (ANAO) report of relevance to the APVMA.

Administrative Appeals Tribunal

The Lord Howe Island First Peoples Association applied to the Administrative Appeals Tribunal (AAT) for review of the APVMA's decision to issue a permit to the Lord Howe Island Board.

On 14 April 2018, the AAT handed down its decision setting aside and substituting the decision under review (ie to issue permit PER85459 on certain conditions)—Lord Howe Island First Peoples Association and Australian Pesticides and Veterinary Medicines Authority [2019] AATA 748. The new permit retained substantially the same conditions as the old one, but with some additional precautions and detail added to existing directions.

Federal Court

Randlab P/L applied to the Federal Court for review of an Armidale Local Court magistrate's decision to issue a search warrant to the APVMA in relation to its premises. A hearing was conducted in the Federal Court on 5 and 6 June 2019.