



Outlook

Looking ahead to 2007–08, we will focus on building our capabilities to support the new governance framework and the performance expected of the APVMA. We will do this by optimising organisational structures and resource allocations and achieving outcomes in key priority reform areas covering our operation, regulation and stakeholder engagement. Our outlook and activities take into account important government initiatives such as the COAG Review of Hazardous Materials, the Productivity Commission's study of chemicals and plastics regulation, the Environment Protection and Heritage Council's national chemicals management initiative and a scheduled review of the APVMA's cost recovery arrangements. We will continue to actively engage in these policy reform agendas.

Our *Operational Plan 2007–08*, approved by the Hon Sussan Ley, Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry in June 2007, provides the framework for our activities. In working to achieve our objectives for 2007–08 we will focus on a number of priorities including:

- improving both the efficiency and effectiveness of our operations through optimising the administration of the legislation and implementing ANAO recommendations
- strengthening our interaction with stakeholders, particularly the rural sector, through implementing the review of existing stakeholder forums and through better relationship management
- raising the standard of service, engagement and transparency through initiatives to improve consultation and communication with stakeholders and enhancing staff issues management skills
- continuing to develop the APVMA website to enhance information architecture, assist more intuitive searching and provide more relevant content to stakeholders
- enhancing the quality of regulatory science through training by Science Fellows and the Science Fellows Forum
- consolidating current initiatives to improve the cost effective and timely availability of safe, effective chemicals for minor uses
- delivering tangible outcomes from work sharing and cooperation with regulators in other countries
- reducing the regulatory burden by expanding the functionality of the electronic application registration system and enhancing the framework for listed registration and reservation
- advancing labelling reform
- aligning processes with FSANZ to enter MRLs in the Food Standards Code in a timely manner
- supporting the export of Australian primary produce by further enhancing the communication of trade advice, contributing to the Japanese Positive List Project and advancing the development of the software for determining export intervals
- continuing legislative reform of the compliance toolkit and more effectively using existing powers
- reviewing the Ag QA Scheme
- recruiting, retaining and developing quality, valued people.



Business management framework and accountability



Corporate governance

Uhrig review implementation—changed governance arrangements for the APVMA

In 2002 the Australian Government commissioned a review of the corporate governance arrangements for statutory authorities and office holders, to identify reforms that might optimise their performance, particularly their accountability frameworks, without compromising their statutory duties. A key task of the review was to develop a template of governance principles that could be applied to all statutory authorities and office holders.

The *Review of the Corporate Governance of Statutory Authorities and Office Holders* (often referred to as the Uhrig Report) was completed in June 2003¹. It proposed two governance templates for statutory authorities depending on their kind of operation: the Board template, where a governing board is responsible for the governance and performance of an authority; and the Executive Management template, where an executive manager or management group (such as a commission) is responsible for the governance and performance of an authority.

The government largely accepted the recommendations of the review and further clarified its expectations in the *Governance Arrangements for Australian Government Bodies*², released in August 2005. Ministers assessed the governance arrangements of all Australian Government statutory authorities in their portfolios (such as the APVMA) against the Uhrig governance templates and principles. In June 2006 the Minister for Agriculture, Fisheries and Forestry, the Hon Peter McGauran MP, confirmed that the future governance arrangements for the APVMA would be based on the Executive Management template. The reform includes a transition to financial regulation under the *Financial Management and Accountability Act 1997* (the FMA Act) and a transition of staff to employment under the *Public Service Act 1999* (the PS Act).

Over the past 12 months, the APVMA has worked with DAFF to make the changes to the Administration Act to give effect to the governance reforms. The APVMA has also undertaken significant preparatory work to ensure it complies with the FMA Act, the PS Act and all subordinate legislation, and to ensure the appropriate structures and procedures are in place so that the APVMA's high standards of corporate governance can be maintained.

The APVMA is subject to the new arrangements from 1 July 2007. The APVMA is to remain a body corporate with a separate legal identity from the Australian Government and retains its independence. The APVMA's powers and functions remain unchanged. An executive manager, the Chief Executive Officer (the CEO), who has responsibility for the governance and management of the APVMA, replaces the governing Board of Directors. The CEO is to be supported by an Advisory Board, consisting of up to nine part-time members with a similar range of skills and experiences to those of the previous APVMA Board of Directors. The role of the Advisory Board is to provide advice and make recommendations to the CEO.

The reforms only affect the governance arrangements for the APVMA and do not affect the Authority's functions or the administration of the NRS for agricultural and veterinary chemicals.

1 Available from http://www.finance.gov.au/GovernanceStructures/docs/The_Uhrig_Report_July_2003.pdf

2 Available from <http://www.finance.gov.au/finframework/docs/FMR2.pdf>

Legislative framework

Section 3 of the Administration Act states that the statutory objective of the Act is to establish a national registration authority (the APVMA) to administer laws relating to agricultural and veterinary chemical products.

The functions of the APVMA include:

- assessing the suitability for sale and evaluation of active constituents of proposed or existing chemical products and labels for chemical products
- keeping a register of approvals and licences granted
- providing information to government and the public in relation to pesticides and veterinary medicines
- cooperating with the Australian Government and its agencies and the states and participating territories to facilitate a consistent national approach to the procedures for the assessment and control of pesticides and veterinary medicines, and to develop codes of practice, guidelines and standards in relation to the use of such products.

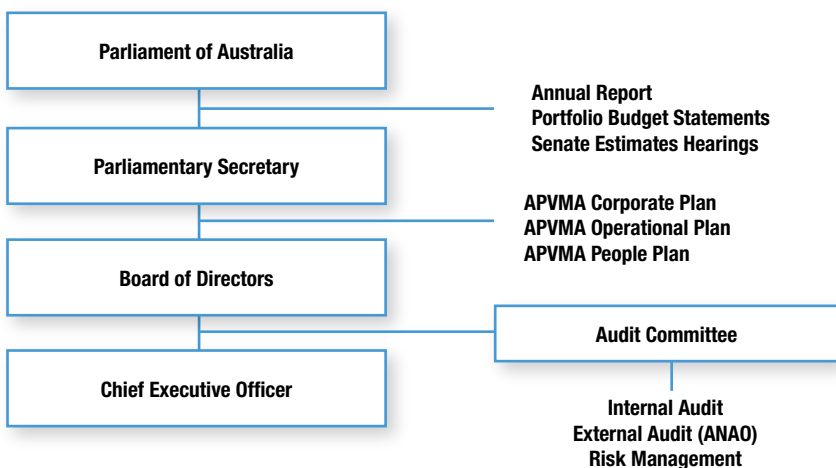
In performing its functions, the APVMA is obliged to have regard to the principle of ecologically sustainable development and the need to use, conserve and enhance community resources. The APVMA is a body corporate and consisted of a Chairperson and eight Directors up to 30 June 2007. The APVMA Board met on a regular basis to determine policy that complied with the statutory objective, monitor performance in achieving the objective and to implement the strategies set out in the APVMA's approved plans.

Corporate governance overview

As an Australian statutory authority the APVMA operated, until 30 June 2007, under the requirements of the CAC Act and was subject to the other legislative requirements governing CAC Act agencies.

The broad corporate governance framework of the APVMA to 30 June 2007 is shown in Figure 9. A new corporate governance framework will be in place from 1 July 2007 and will be shown in the APVMA's Annual Report for 2007–08.

Figure 9 APVMA corporate governance framework to 30 June 2007



The APVMA's corporate governance framework to 30 June 2007 was underpinned by the following internal and external accountability structures that will continue in 2007–08 as required by the new corporate governance arrangements:

Internal accountability structures

Internal accountability structures in the APVMA include the Corporate Plan, the Operational Plan, the Risk Management Plan, the People Plan, the Fraud Control Plan, internal delegations, the quality control system and regular review of performance. An active Internal Audit Program is overseen by the APVMA's Audit Committee. Until 30 June 2007 this committee comprised three Directors appointed by the Board of Directors. The Audit Committee reported to the Board. The Board approved the budget and monitored the financial performance of the organisation. These arrangements will be adapted from 1 July 2007 to meet the new governance arrangements.

The APVMA's Annual Operational Plan utilises the Balanced Scorecard (BSC) methodology and is developed after wide consultation with stakeholders. Comprehensive strategies including detailed performance indicators are included in the plan. The Parliamentary Secretary approves the APVMA's Operational Plan each year.

External accountability structures

The APVMA is subject to the same financial reporting requirements as Australian Government agencies. Full accrual-based financial statements are reproduced in the APVMA's Annual Report each financial year. The ANAO scrutinises the APVMA's accounts each year and the APVMA has, since inception, always received unqualified audit reports from the ANAO. The APVMA is subject to the review of its budget and activities through the Senate Estimates process.

During the reporting period, the APVMA worked to implement the outcomes of the 2006 Uhrig review of the APVMA's corporate governance arrangements, with the expectation of commencing operations in accordance with FMA Act requirements from 1 July 2007.

Board meetings

The APVMA Board of Directors held six meetings in 2006–07. In keeping with its policy of seeking direct feedback from stakeholders, three meetings were held outside Canberra:

- northern Victoria (August 2006) focusing on spray drift management and consultations with representatives of the hop growing and forestry industries in the Ovens Valley
- South Australia (October 2006) focusing on spray drift management, the 2,4-D and sheep ectoparasiticides reviews, chemical user training programs, controlled environment horticulture, management of chemicals in peri-urban areas and minor use reforms in the Clare Valley and Adelaide plains (Virginia) areas
- north Queensland (May 2007) focusing on the consultations with the sugarcane industry in the Gordonvale area south of Cairns and technical presentations concerning marine environment research and impacts of water quality on the Great Barrier Reef.

Topics and issues before the Board of Directors during 2006–07 included:

- strategic planning, priorities and initiatives for 2006–09 leading to the Board endorsing the APVMA *Operational Plan 2007–08* and *Annual Budget 2007–08*
- approving the 2005–06 Financial Statements and draft 2005–06 Annual Report for submission to the Parliamentary Secretary
- updates on external reviews affecting the APVMA including preparations to implement the outcomes of the Uhrig review and implementing the recommendations from the ANAO Performance Audit of the APVMA
- the annual appointment of Directors to the APVMA Audit Committee
- regular reports from the Audit Committee and on the activities of the APVMA's community, industry and registration consultative committees
- implementing Protective Security Manual requirements and planning for new government compliance reporting requirements for CAC Act and FMA Act agencies
- renegotiating the APVMA Collective Agreement aligned to the new governance arrangements
- overseeing the completion of the APVMA's move to new office accommodation in Symonston, ACT on schedule
- monitoring and improvement of evaluation timeframe performance while maintaining high levels of science quality in regulatory decisions
- implementing the Electronic Application Registration System and redesign of the APVMA website as part of enhanced corporate communication and stakeholder consultation mechanisms
- feedback on company visits and seminars conducted by the APVMA in various states to raise industry understanding of regulatory processes and requirements together with minor use, community and chemical user forums and the inaugural APVMA Science Fellows Symposium in May 2007
- accountability, efficiency and transparency of APVMA activities, combined with further strengthening of ties with the APVMA's counterpart regulators overseas including New Zealand, the People's Republic of China, Canada, the United Kingdom and Germany
- APVMA input to discussions on the proposed National Chemical Environmental Management Framework
- in-house comparisons of international approaches to environmental risk assessment and a survey of the operational effectiveness of the Restricted Chemical Product scheme in the states and territories
- briefings on the implementation of the Joint Expert Technical Committee on Antimicrobial Resistance (JETACAR) recommendations and on industry's *drumMuster* and ChemClear® programs
- reports on the progress of legislation amendments, matters relating to regulatory decisions before the AAT, development of a framework for security sensitive chemicals, regulation of 'low-regulatory risk' products, possible reforms to external efficacy assessment processes, harmonisation of MRL processes with FSANZ,

revision to product registration and labelling guidelines, strengthening of the APVMA quality assurance and compliance framework and the progress of minor use reforms.

The Board received regular updates on the status of reviews under the APVMA's Chemical Review Program including the implementation of review outcomes. The Board also reviewed the work of the Chemical Review Program, and in this it:

- released the Preliminary Review Findings of the review of azinphos-methyl active constituent approvals, product registrations and associated label approvals
- suspended the registrations and label approvals of 2,4-D high volatile esters until 29 April 2009
- confirmed a previous decision to initiate a review of oral, intramammary and injectable preparations of neomycin and associated labels
- made determinations relevant to the review of sodium fluoroacetate (1080) and released the associated Final Review Report and Regulatory Decision documents
- made determinations relevant to the review of carbaryl (Part 1: Home Garden, Home Veterinary, Poultry and Domestic Uses) and released the associated Final Review Report and Regulatory Decision documents
- initiated a review of carbendazim active constituent approvals, product registrations and associated label approvals and subsequently suspended carbendazim product label approvals for a period of two years
- initiated a review of thiophanate-methyl active constituent approvals, product registrations and associated label approvals
- suspended for a period of 18 months the label approvals of five diazinon products used for traditional jetting and dipping of sheep
- made determinations relevant to the review of dimetridazole and released the associated Final Review Report and Regulatory Decision documents
- made determinations relevant to the review of methyl bromide and released the associated Final Review Report and Regulatory Decision documents
- released the Preliminary Review Findings of the review of dichlorvos for public comment.

Corporate planning and reporting

As an independent Australian Government statutory authority, the APVMA is required to conduct rigorous corporate planning and reporting. The planning and reporting requirements of the APVMA are set out in Part 6 of the Administration Act.

In accordance with the enabling legislation, the APVMA's performance management framework embodies a number of plans and associated performance measuring and monitoring processes.

The APVMA's operational effectiveness is measured through the performance indicators set out in the Corporate and Annual Operational Plans.

Corporate and Annual Operational Plans

The APVMA's central planning document is the Corporate Plan. Each Corporate Plan has a life of three years. The current plan expires on 30 June 2009.

The CAC Act and Orders require the corporate plan to show outcomes, outputs, objectives and strategies aligned directly with the statutory objectives. The Board reviewed the statutory objectives, consulted with key stakeholders and established key performance indicators that are used to measure the APVMA's success in achieving its outcomes, allowing the APVMA's effectiveness to be assessed.

The Annual Operational Plan sets out the actions needed to achieve the outcomes in the Corporate Plan. The plan enabled the APVMA Board to assess the efficiency of the APVMA and its management. The Board determined the allocation of resources during the life of the Operational Plan.

The Operational Plan uses Kaplan and Norton's Balanced Scorecard (BSC) methodology. The use of the BSC methodology and, in particular, the use of strategy maps allows strategy to be 'visualised'. Performance is strengthened through a shared vision and common understanding of the activities required to achieve corporate goals.

The 2006–09 Corporate Plan was approved by the Parliamentary Secretary in June 2006. In late 2006, the APVMA began developing the 2007–08 Operational Plan which was approved by the Parliamentary Secretary in June 2007. Both the 2006–09 Corporate Plan and 2006–07 Operational Plan were prepared with input from stakeholders and detail the APVMA's outcomes and outputs, objectives and strategies to achieve its statutory objectives. The APVMA's CEO and new Advisory Board when appointed will continue to monitor these plans from 1 July 2007.

Performance review

The Board of Directors played a key role in the planning process by ensuring that the Corporate Plan and the Annual Operational Plan met the requirements of the Administration Act and the CAC Act, and produced outcomes that were in line with the statutory objectives.

The APVMA Board assessed organisational performance regularly against the Operational Plan. The CEO will continue to review the APVMA's performance from 1 July 2007.

Annual Report

The APVMA's performance is publicly reported in the Annual Report that is prepared according to the *Requirements for Annual Reports for Departments, Executive Agencies and FMA Act Bodies* issued by the Department of Prime Minister and Cabinet, the *Commonwealth Authorities and Companies (Report of Operations) Orders 2005* and the CAC Act.

The 2006–07 Annual Report details APVMA performance against each of the key outputs and performance indicators contained in the 2006–07 Portfolio Budget Statements.

Service charter

The APVMA aims to provide the highest quality of service to all its stakeholders and is committed to continuous improvement of its service. The APVMA Service Charter outlines the standards that the APVMA will meet in dealing with all external audiences.

The APVMA Service Charter was developed in consultation with stakeholders and is freely available to all interested parties on the APVMA's website or in hard copy.

Transparency in decision-making

The APVMA places a high priority on stakeholder interaction and consultation.

Involvement of industry, chemical users, government and community stakeholders in APVMA development and decision-making occurs in four ways:

- consultative committees
- public consultation
- publication of decisions
- access to management and staff.

Consultative committees

The APVMA meets regularly with four consultative committees representing the community, government, rural industries and the chemical industry to ensure it understands the concerns of those who have an interest in the regulation of agricultural and veterinary chemicals. The scope, membership and key issues dealt with by these committees in 2006–07 are described at Appendix B.

Additionally, summaries of the outcomes of APVMA Board meetings are published on the APVMA website.

Public consultation

The APVMA seeks input from interested stakeholders throughout the chemical registration and review processes as well as during the development of program reforms.

When the APVMA proposes to register a new chemical product with a new active ingredient, or to extend the use of an existing product from a non-food commodity to a human or animal food, public consultation occurs before a final decision is made. The APVMA prepares a Public Release Summary for new products containing new active constituents. These summaries are freely available for comment via the APVMA's website and include the outcome of the assessment and the conditions the APVMA proposes for the use of the product. The APVMA issues Trade Advice Notices where a proposed registration or change in registration conditions has the potential to affect Australia's trade. The advice notice is distributed to farm and commodity organisations seeking comment.

New data protection amendments have added greater transparency by requiring the APVMA to publish a summary ('Application Summary') once an application has been accepted for assessment. When registration applications have been granted, the APVMA is required to publish a summary ('Advice Summary') of the advice provided by government departments and agencies and other specialists the APVMA has consulted.

The Chemical Review Program consults widely with stakeholders throughout the review process. When a review is announced, the APVMA invites the public, chemical users and any interested parties to make submissions on any aspect of the chemical including performance, use practices and any adverse effects. There is also a public consultation period when the draft review report is released for comment. This takes place before the APVMA makes a final decision. There is consultation throughout the review process with various groups on more specific issues, for example the data required to maintain a particular use pattern. The release of all review reports is widely advertised through media releases, *APVMA Gazette* notices, the APVMA's website and by direct mail. These reports are available publicly on the APVMA's website.

Publication of decisions

The *APVMA Gazette* lists all APVMA notices and decisions including registrations, reviews and changes to registration status required by the Agvet Code. It is published monthly and is free of charge to registrants and can be downloaded from the APVMA's website: www.apvma.gov.au.

Access to management and staff

The APVMA's executive, managers and staff are accessible to industry and other stakeholders. Each operational area of the APVMA has designated contact officers whose contact details are published on the APVMA's website and are distributed via consultative committees and industry gatherings.

APVMA business systems

Information Services

Information Services manages the APVMA's files and archives according to standards required by the National Archives of Australia (NAA), AS ISO 15489.1-2 and other Australian Government requirements.

Two major projects had a significant impact on the records area. The efficient relocation of more than 22 000 files required a great deal of preparation and organisation with the move of premises from Barton to Symonston.

In addition, Information Services undertook the routine work of file creation (around 2100 administrative and 1000 product-related files), file location audits, parliamentary reporting, file sentencing, removal to off-site storage and scheduled destruction.

Information technology

Technical knowledge is a key asset for the APVMA. The organisation's advantage lies in the ability of its staff to quickly understand and integrate highly complex technical knowledge into a context that is understood and easily communicated to stakeholders. The APVMA relies heavily on data extraction and information processing.

During 2006–07 the APVMA continued to use information technology as a key driver to improve business processes and enhance stakeholder access to information. Key projects completed during the past 12 months include:

- as part of the move to the new building, the APVMA's servers were relocated to a new purpose-designed server room. The new facility includes dual air-conditioning, fire-resistant walls and an uninterrupted power supply
- the APVMA website was upgraded to include a new fresh contemporary look and better navigation facilities. The new website specifically acknowledges the diversity of APVMA stakeholder groups. New features include the 'Hot Topics' area on the front page, which allows the APVMA to actively engage in issues of the day
- as part of the move to the new building, a Voice over Internet Protocol (VoIP) telephone system was implemented. The system delivers new functionality to staff while ensuring it remains a cost-effective long-term telephony solution
- a new software application was developed to enable online reporting of Agricultural and Veterinary Medicine adverse experience reports. The new system allows for auto-population of internal databases once a data file has been validated

- the new Electronic Application and Registration System (EARS) allows registrants to submit category 8, 12 and 13 applications electronically to the APVMA over the Internet. The new system also allows registrants to monitor the progress of their applications (see box)
- an electronic IT helpdesk was implemented for APVMA staff. Staff are now able to help themselves by accessing solutions to commonly found problems and logging problems over the APVMA's Intranet
- the APVMA commissioned a connection to Fedlink (the Federal Government's secure email system that allows encrypted email communications between Australian Government agencies).

Electronic Application Registration System (EARS)

In May 2007 the APVMA released a world-leading electronic application system. The Electronic Application and Registration System (EARS) offers industry the opportunity to electronically submit and monitor applications for the registration of agricultural and veterinary chemicals. This system streamlines the application process creating efficiencies both for our clients and the APVMA.

While other regulators around the world are working toward the development of similar systems, the APVMA is the first agvet regulator to have launched such an application.

Developed by APVMA staff, the EARS software provides an easy-to-use, intelligent system to compile an application with validation to help ensure it is correct and complete. Submission is through a secure encrypted connection over the Internet, which will provide a fast and efficient method for lodging an application with the APVMA. Payments can also be made online and applicants can check the status of current application submissions lodged with the APVMA.

Ecologically sustainable development

In accordance with requirements of the EPBC Act and in line with the Agvet Code and the Australian Government's Greening of Government program, the APVMA has adopted an Environmental Management System (EMS).

The system, which uses ISO 14001: 1996 as its framework, is integrated into the APVMA quality management system with its auditing and continuous improvement requirements.

The EMS policy and procedures focus on environmentally aware purchasing, rates of consumption of non-renewable resources, life cycle costing, recycling and waste minimisation.

In late 2006, the APVMA relocated to new premises at Symonston ACT. The new building's design, features and finishes were strongly influenced by environmental practices.

The building has a number of water saving measures. These include water-efficient toilets (dual flush), flow-limiting tapware, AAA-rated fittings and large rainwater tanks. The rainwater tanks provide the sole method of watering the garden areas. Drought-tolerant plants have been selected as part of the landscaping plan.

In due course the new building will seek to achieve a 4–4.5 star energy efficiency rating.

As opportunities have arisen, the APVMA has joined environmental programs such as Greenfleet, a scheme to enrol fleet vehicles in a tree-planting, greenhouse gas emissions offset program.

A new home for the APVMA

In late October 2006, the APVMA moved to a new building in Amtech Park, North Symonston, ACT. Before the move, the APVMA occupied two separate buildings in Barton, ACT. The new building provides a purpose-built, designed office space that accommodates the entire organisation.

The rent is substantially lower than at Barton and the building is close to the agencies with which the APVMA regularly deals.



APVMA image

APVMA premises 18 Wormald St Symonston ACT

Internal and external scrutiny

APVMA Quality Management System

The APVMA continues to maintain strong controls over its key processes to ensure its legislative obligations are met. The APVMA quality management system emphasises responsiveness to customers and stakeholders, consistency of output, efficient resource management and continuous improvement. It is reviewed and monitored by a monthly managers' meeting and is subject to internal and external audit.

The APVMA was re-certified to AS/NZS ISO 9001: 2000 following a successful triennial audit in September 2005. A surveillance audit conducted in September 2006 revealed no major non-conformance and attracted favourable comments from the certifying organisation.

Fraud control

The APVMA has a Fraud Risk Assessment and a Fraud Control Plan in place that comply with the Australian Government's *Commonwealth Fraud Control Guidelines*. The Fraud Control Plan includes fraud prevention, detection, investigation, reporting and data collection procedures.

Auditor-General's reports

During the financial year the ANAO completed a performance audit of the APVMA. The recommendations of the audit report are discussed elsewhere in this report.

Ministerial directions/requests

The APVMA received one ministerial request during 2006–07. The request concerned the *Protective Security Manual 2005* (the PSM) and its adoption as a general policy of the Australian Government in accordance with section 28 of the CAC Act. While the APVMA was exempt from Ministerial notification under section 28 of the CAC Act, it has applied the PSM as a general government policy.

Courts and tribunals

One proceeding in the Administrative Appeals Tribunal (AAT) was carried over from 2005–06. The proceeding relates to the APVMA's regulatory decisions following the review of veterinary chemical products containing virginiamycin. This proceeding is still under way. Another AAT proceeding was commenced in 2006–07 that relates to the APVMA's decision to refuse to register a veterinary chemical product.

Ombudsman

The Ombudsman made no formal enquiries into the operations of the APVMA during 2006–07.

Parliamentary committees and other reviews

The APVMA appeared before the Agriculture Backbenchers' Committee in September 2006 to discuss the 2,4-D high volatile ester review, and in June 2007 to discuss the 1080 review.

Privacy

The APVMA adheres to the Information Privacy Principles as set out in the *Privacy Act 1998*. The APVMA's operations were not subject to any report or determination by the Privacy Commissioner. The APVMA has an entry in the current edition of the Privacy Commissioner's *Personal Information Digest*.

