Australian Pesticides & Veterinary Medicines Authority

Business management framework and accountability

BUSINESS MANAGEMENT FRAMEWORK AND ACCOUNTABILITY

CORPORATE GOVERNANCE

Legislative framework

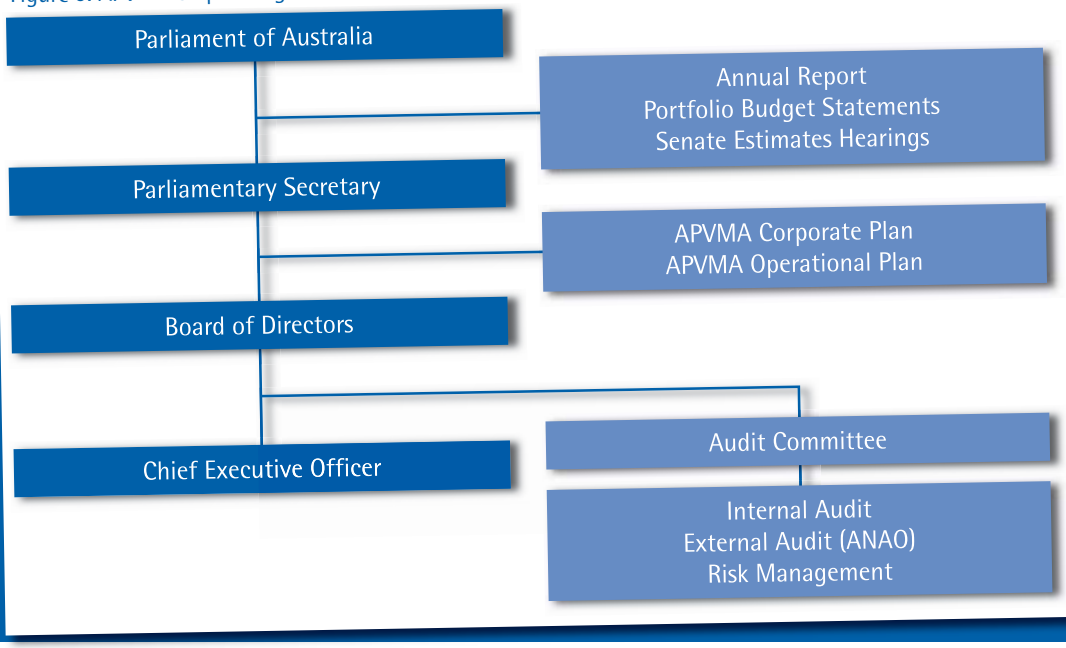
Section 3 of the Administration Act states that the statutory objective of the Act is to establish a National Registration Authority (the former NRA, now the APVMA) to administer laws relating to pesticides and veterinary medicines.

Section 7(1A) of the Act states that the functions of the APVMA include:

- assessment of the suitability for sale and evaluation of active constituents for 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 the performance of its functions the APVMA is obliged to have regard to the principle of ecologically sustainable development and the need to use, conserve and enhance the community's resources. Section 12 of the Act establishes the APVMA as a body corporate and Section 13 provides that it shall consist of a Chairperson

Figure 9. APVMA corporate governance framework



and eight Directors. The APVMA Board meets on a regular basis to determine policy that complies with the statutory objective, monitor performance in achieving the objective and implement the strategies set out in the APVMA's approved plans.

Corporate Governance overview

The APVMA is a statutory authority established by the Agricultural and Veterinary Chemicals (Administration) Act 1992. The APVMA operates under the requirements of the *Commonwealth Authorities and Companies (CAC) Act 1997* and is subject to the other legislative requirements governing CAC Act agencies.

The broad corporate governance framework is outlined in the diagram shown in Figure 9.

The APVMA's Corporate Governance framework is underpinned by the following internal and external accountability structures:

- **Internal accountability structures.** Internal accountability structures within the APVMA include the Corporate Plan, the Operational Plan, the Risk Management Plan, the Fraud Control Plan, internal delegations, the quality control systems and the regular review of performance. An active Internal Audit Program is overseen by the APVMA's Audit Committee which comprises three Directors appointed by the Board. The Audit Committee reports to the Board. The Board of the APVMA approves the budget and monitors the financial performance of the organisation. The APVMA's Annual Operational Plan utilises the Balanced Scorecard 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 Annual Operational Plan each year.
- **External accountability structures.** The APVMA is subject to the same financial reporting requirements as other Commonwealth agencies. Full accrual-based financial statements are reproduced in the Authority's Annual Report each year. The Authority's accounts are scrutinised each year by the Australian National Audit Office (ANAO) 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.

The APVMA's Corporate Governance arrangements will be reviewed against the Uhrig template in the second half of 2005.

Board meetings

The APVMA Board met six times in 2004–05. In keeping with its policy of seeking direct feedback from stakeholders, two meetings were held outside Canberra: in Toowoomba, Queensland (Oct 2004) and Launceston, Tasmania (February 2005). Stakeholder consultations in Toowoomba focused on minor use in horticulture and veterinary medicines. In northern Tasmania, the Board discussed regulatory issues with chemicals used in horticulture and forestry operations. In both locations, the Board also met informally with a range of representatives from the wider community, various agricultural industries, veterinarians, chemical suppliers and government. In conjunction with the June 2005 meeting in Canberra, the Board consulted wool growers and processors in Goulburn, NSW with a focus on the use of ectoparasiticides and was briefed on biotechnology research being undertaken at the CSIRO Plant Industry Laboratories in Canberra.

Matters and issues considered by the Board during 2004–05 included:

- approval of the APVMA's Annual Budget 2005–06, Operational Plan 2005–06 and IT Strategic Plan 2005–07
- strategic priorities and initiatives for 2005–06
- reform of the minor use system
- harmonisation of MRL procedures with FSANZ
- implementation of data protection as part of the Australia-United States Free Trade Agreement
- the new cost-recovery legislation and preparations to implement a new fee structure
- accountability, efficiency and transparency of APVMA activities
- proposal to recommend removal of the APVMA's current exemption under Section 28 of the CAC Act
- initiating a review of APVMA consultative committees

- office accommodation options following expiry of current leases
- proposals for refining the scope of APVMA regulatory activity
- the findings of research into community and industry awareness and attitudes to the regulatory system
- operational procedures for approving final printed labels
- appointment of Community Consultative Committee (CCC) members
- CCC recommendations for chemical review processes
- mechanisms for provision of independent human health technical advice
- new arrangements to ensure the enduring GMP compliance of overseas veterinary manufacturers
- amended procedures for approval of active constituents
- a review of residues assessment processes
- an operational resource needs assessment and timeframe improvement plan.

With respect to APVMA chemical review activities during the reporting period, the Board:

- initiated a review of procymidone
- endorsed final review findings and proposed outcomes of the review of arsenic timber treatments, virginiamycin, carbon disulfide and endosulfan
- approved the release for public comment of draft reports on the reviews of dimetridazole, carbon disulfide, atrazine, 1080, methiocarb and diuron
- noted progress reports and related regulatory activity concerning the reviews of virginiamycin, arsenic timber treatments, 1080, carbon disulfide and endosulfan.

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.

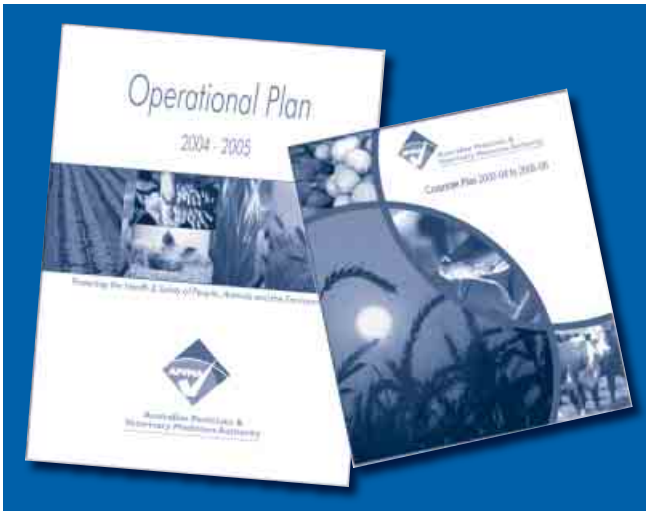
In accordance with the enabling legislation, the APVMA has a number of plans and associated performance measuring and monitoring processes in its performance management framework.

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

The APVMA has traditionally used the accrual accounting approach to budgeting and financial reporting and thus complied with the Commonwealth's Annual Information Management System.

Corporate and Annual Operational Plans

The APVMA's central planning document is the Corporate Plan. The Corporate Plan has a three-year focus, 2003–06, and outlines the APVMA's outcomes and outputs, objectives and strategies aligned with the statutory objective.



Section 50(4) of the Administration Act provides that the APVMA, in formulating its Corporate Plan, will define the goals of the APVMA, provide a broad outline of its strategies, set out its assessment of factors that may affect its performance and include such performance indicators as it thinks appropriate.

The *Commonwealth Authorities and Companies Act 1997* and Orders require the corporate plan to show outcomes, outputs, objectives and strategies aligned directly with the statutory objective. In determining the strategic direction for the APVMA the Board has reviewed the statutory objective, consulted with key stakeholders and established

key performance indicators which are used to measure the APVMA's success in achieving its desired outcomes, thus enabling an assessment of the APVMA's effectiveness.

The Annual Operational Plan outlines, at a strategic level, the actions necessary to achieve the desired outcomes stated in the Corporate Plan. The plan enables the Board to assess the efficiency of the APVMA and its management. The Board determines the allocation of resources during the life of the Annual Operational Plan.

The Annual Operational Plan is supported by individual sectional plans that identify responsible areas and individuals and allow progress to be monitored regularly.

Performance review

The Board plays a key role in the planning process by ensuring that the Corporate Plan and the Annual Operational Plan meet the requirements of the Administration Act and the CAC Act and produce outcomes that are in line with the statutory objective.

The APVMA Board assesses organisational performance quarterly against the deliverables nominated in the Annual Operational Plan.

Annual Report

APVMA 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 2004–05 Annual Report details APVMA performance against each of the key outputs and performance indicators contained in the 2004–05 Portfolio Budget Statements.

The Service Charter

The APVMA aims to provide the highest quality of service to all its stakeholders and is committed to the continuous improvement of its service delivery. 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 its stakeholders and is freely available to all interested parties.

Transparency in decision-making

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

Involvement by 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.

The APVMA meets regularly with a number of consultative committees to ensure two-way communication and partnerships that bring people together from the community, government, rural industries and the chemical industry to improve the way pesticides and veterinary medicines are regulated in Australia. The scope, membership and key issues dealt with by these committees are described at Appendix B.

Public consultation

The APVMA seeks input from interested stakeholders throughout the registration and chemical 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 final decisions are made. The APVMA prepares a Public Release Summary outlining new products with new active constituents. These are freely available as the basis for comment. The summaries 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 a change in registration conditions has the potential to impact on Australia's trade. The advice notice is distributed to farm and commodity organisations seeking comment.

The new data protection amendments have added greater transparency by requiring the APVMA to publish a 'summary of information' for each application once the application has passed through a preliminary assessment.

The Chemical Review Program consults widely with stakeholders throughout the review process. A significant amount of time is made available for public and industry consultation. Specific invitations to comment are issued at the beginning of a review and when the draft regulatory approach has been developed.

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. A public consultation period is also undertaken when the draft review report is released for comment. This takes place before the APVMA makes a final regulatory decision. The release of these draft reports is widely advertised, including through media releases, gazette notices, *APVMA News*, the APVMA's website and by direct mail. Final reports are also 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 via download from the APVMA website www.apvma.gov.au.

Access to management and staff

APVMA 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 website and are distributed via consultative committees and industry gatherings.

APVMA BUSINESS SYSTEMS

Records management

The records management area is a service unit which manages the APVMA files and archives according to standards required by the National Archives of Australia (NAA), AS4390: 1996 and other Parliamentary requirements. During 2004–05 around 2000 administrative and 1000 product-related files were created and 160 shelf metres of material (including 1500 data volumes) were transferred to long-term off-site storage.

A large sentencing program was completed with around 2400 files sentenced according to NAA authorities, with 200 proceeding to destruction.

Information technology

The APVMA is an organisation in which technical knowledge is a key asset. 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. There is a heavy reliance on data extraction and information processing. During the year 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 last 12-months include the following:

- **Completion of a new IT Strategic Plan.** During the reporting period the Authority completed a new IT Strategic Plan which critically reviewed the APVMA's existing IT architecture, systems and sub-systems and provided an action plan to guide IT development for the next two to three years.
- **Expansion of on-line services.** In early June 2005 the APVMA launched a new on-line e-payment module. The new module allows registrants to pay the annual fee over the Internet. The expansion of on-line payment options was suspended in 2003 pending the completion of the new cost-recovery arrangements. Now that a new fee structure is in place work will recommence to expand on-line services.
- **Commissioning of customer relationship management system.** During the year the Authority commissioned the Right Now customer relationship system. The new system delivers a seamless, multi-channel enquiry resolution platform and will allow stakeholders better access to information.
- **Data protection.** The introduction of new data protection legislation required that substantial changes be made to the APVMA's IT systems during the last 12 months.
- **New cost-recovery arrangements.** Substantial changes to the APVMA's IT systems were also required as a result of the new cost-recovery arrangements.

- **New anti-spam software.** Like many organisations, APVMA has seen a large increase over the last year in the volume and malicious nature of spam email. New anti-spam software introduced during the period has helped reduce the amount of spam email received by staff.

INTERNAL AND EXTERNAL SCRUTINY

APVMA Integrated Quality Management System

The APVMA continues to control its system of key processes strictly in accordance with its obligations as detailed in the legislation. Certified by SGS Systems and Services Certification P/L to AS/NZS ISO 9001: 2000, the standard is used as the framework of the APVMA quality system. It emphasises responsiveness to customers and stakeholders, consistency of output, efficient resource management and continuous improvement. The system is reviewed and monitored by a monthly executive meeting and is subject to internal audits and an annual external audit.

The APVMA Integrated Quality Management System is an integral part of maintaining systems excellence, promoting inter-program teamwork, individual ownership of processes and procedures, and continuous improvement.

AMENDMENTS TO LEGISLATION IN 2004–05

DATA PROTECTION

The *US Free Trade Implementation Act 2004* introduced data protection provisions into the agvet chemicals legislation.

Data protection is a well-established mechanism in the chemical regulatory regimes of most developed countries. Data protection provides protection to certain information provided by a person as part of an application to gain the required approvals and registrations to enable a product to enter the market. Protection is generally provided in the form of limitations on the use of certain information in particular circumstances, usually relating to the approval or registration of competing products.

The previous legislated APVMA data protection regime only applied to decisions relating to the approval of an active constituent or to reviews of existing chemicals.

The new data protection regime is designed to protect the investment of innovators against commercial use by competitors. The provisions introduced take the form of limits on the use by the APVMA of certain information provided in considering any subsequent application by a competitor for registration of a chemical product.

The reforms also introduce 'early disclosure' and other measures to increase the transparency of decision-making by the APVMA and stimulate access to protected information by competitors under reasonable market conditions. They also introduce measures to encourage registrants to apply for registration of additional 'minor uses'.

FEES REVIEW

APVMA activities are funded on a cost-recovery basis with operational revenue being collected mainly from registrants of pesticides and veterinary medicines. Fees are paid to apply for and maintain product registrations. Levies are also paid annually according to the level of disposal of registered products.

In 2005 the *Agricultural and Veterinary Chemicals Legislation Amendment (Levy and Fees) Act 2005* was passed by the Parliament, amending a number of Acts administered by the APVMA. The purpose of the legislation was to give better effect to the agreed policy between the Australian Government and all State and Territory governments that the APVMA should operate on a full cost-recovery basis and to give effect to the outcomes of several reviews of the APVMA's cost-recovery framework. It followed extensive public consultation, coordinated by the Australian Government Department of Agriculture, Fisheries and Forestry.

The legislation introduced a new fee structure for applications to the APVMA and modified the amount of the levy payable on annual sales of registered products. It also repealed a number of interim pieces of legislation introduced, when the APVMA was created, to facilitate imposition and collection of the levy in the first few years of operation of the APVMA.

In addition to legislative change, substantial amendments were made to the regulations supporting the legislation administered by the APVMA. The changes to the regulations complemented the amendments to the legislation and put in place a new, more cost-reflective, regime of application fees to apply to various applications for approval of active constituents and registration of chemical products.

Ecologically sustainable development

In accordance with requirements of the *Environment Protection and Biodiversity Conservation Act 1999* and in line with the Agvet Code and the Australian Government's Greening of Government program, the APVMA adopted an Environmental Management System (EMS) in March 2005.

The system, which uses ISO 14001: 1996 as its framework, has been integrated into the existing APVMA quality system and will therefore be subject to the same internal review, auditing and continuous improvement.

The APVMA's EMS policy and procedures focus on environmentally aware purchasing, rates of consumption of non-renewable resources, life-cycle costing, recycling and waste minimisation. The organisation's goal is to meet its self-imposed targets for reduction in consumption and waste. In May 2005 the ANAO audited the APVMA's EMS practices.

Fraud control

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

Auditor-General's reports

There were no reports by the Auditor-General on the operations of the APVMA during 2004–05.

Ministerial directions

The Minister for Finance issued the Finance Minister's (CAC Act Procurement) Directions on 1 December 2004, under subsection 47A(2) of the CAC Act 1997.

The APVMA did not receive any ministerial directions under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* during 2004-05.

Courts and tribunals

Two actions were commenced in the Commonwealth Administrative Appeals Tribunal (AAT) in 2004–05. One related to the APVMA's regulatory decisions following the review of veterinary chemical products containing virginiamycin. The other relates to a decision under the *Freedom of Information Act 1982* to release certain information. Both of those proceedings remain ongoing.

Four proceedings in the AAT were carried over from the previous reporting period. They all involved suppliers of silver-based pool and spa products. All of the proceedings are now finalised. In two of the proceedings the AAT confirmed that cartridges, comprising copper and silver that release copper and silver ions, are agricultural chemical products. In one proceeding the AAT varied the recall notice that had been issued by the APVMA such that the supplier only had to include a warning statement on the product label recommending users to use chlorine in conjunction with the product. The remaining proceeding was withdrawn by the applicant.

Ombudsman

No formal inquiries were made by the Ombudsman into the operations of the APVMA during 2004–05.

The APVMA did assist the Ombudsman with a number of general queries in relation to the National Registration Scheme.

Parliamentary committees and other reviews

During 2004–05, the APVMA was involved in two Parliamentary Inquiries.

The APVMA gave evidence to the House of Representatives Standing Committee Inquiry into the Impact of Pest Animals in Agriculture.

The APVMA made a written submission to the South Australian Parliamentary Inquiry into Multiple Chemical Sensitivity.

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.