



Australian Pesticides & Veterinary Medicines Authority

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 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 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 to implement the strategies set out in the APVMA's approved plans.

Governance and monitoring performance

The APVMA has a formal induction process in place for the benefit of all newly appointed Directors. The process provides information on all aspects of the organisation's structure, operations and formal responsibilities. As part of their induction process, Directors are informed of their ability to obtain independent professional advice, at the APVMA's expense, on all matters to do with the discharge of their responsibilities. The performance of Directors is subject to review by the portfolio as part of its routine processes of assessment of candidates for Board membership. The Board employs a program of closed sessions, independent of Executive Management, to discuss matters such as the effectiveness of Board operations and performance.

The APVMA Audit Committee, a sub-committee of the Board, is the central mechanism that the APVMA uses to identify likely areas of business risk and to develop appropriate responses. The Audit Committee oversees the development of a Risk Assessment and Risk Management Plan by

Amendments to the agvet chemicals legislation in 2003-04

Amendments to the Agvet Code

Substantial legislative amendments to the Agvet Code were made on 8 October 2003. The most significant of these amendments introduced a model for tiered approvals for certain chemicals and required changes to the label approval process.

'Tiered' registration

The amendments to the Agvet Code provide two new approaches to the regulation of agvet chemicals.

The first, known as 'listed registration', is available to certain agvet chemical products for which a tiered regulatory approach is appropriate. Before applications can be made for listed registration status, it is necessary for standards of composition, manufacture, labelling and other conditions to be pre-established for eligible chemical products. These standards have to be approved by the Minister. Applications for listed registration for eligible products can then be made, with the APVMA assessing whether the products meet the pre-established standards.

The second approach can classify a limited number of agvet chemical products as 'reserved chemical products' effectively excluding such products from regulatory control subject to certain conditions. This reservation from registration will only apply to products which present a known risk and which have well defined use patterns. Before regulations can be made for the reservation of any product, the APVMA must recommend reservation of the product to the Minister explaining why it is satisfied that the use of the product, in accordance with the proposed conditions, would not be a risk.

Label approval

Another significant change is that approval of a label (or variations to that approval) now requires applicants (or existing approval holders) to provide the APVMA with the marketed product label before a label can be approved. The previous practice of approving only the text of a label has ceased.

Amendments to the Administration Act

An amendment was made to Part 7A of the Administration Act on 12 March 2004. This amendment enables Australia to meet its obligations under the Stockholm Convention on Persistent Organic Pollutants (the Stockholm Convention) and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (the Rotterdam Convention). Both conventions establish certain provisions for the collection and use of information in relation to particular chemicals and oblige Australia to undertake certain controls in relation to the import, manufacture, use of, dealing with and export of particular chemicals.

A summary of the agvet chemicals legislation administered by the APVMA is available on the APVMA's web site.

management. The APVMA has a number of mechanisms in place to ensure the maintenance of a high level of ethical performance. The APVMA Board Charter outlines the responsibilities of Directors in the effective discharge of their duties.

The APVMA Service Charter outlines the standards that the APVMA will meet in dealing with all external audiences. There is a Code of Conduct for the performance of staff as well as a Code of Conduct for Directors. The staff Code of Conduct is underpinned by a number of formal management practices that provide clear guidelines for such things as internet and telephone use by staff.

Board meetings

The APVMA Board met six times in 2003–04. In keeping with its policy of seeking direct feedback from stakeholders, three meetings were held outside Canberra: in Rockhampton, Queensland (July 2003), Sydney (September 2003) and Moree, NSW (April 2004). Field visits associated with the Rockhampton meeting focused on beef production, horticulture and broad-acre crops. In Sydney, the Board visited horticultural market gardeners located in the south-west metropolitan area and met informally with representatives of the pesticides and veterinary medicines industry, community, professional and government stakeholders. The Moree field trip enabled the Board to interact with a range of stakeholders about chemicals issues in a rural community with a significant agricultural economy.

Issues considered or reported at Board meetings during 2003–04 included:

- development and implementation of strategies to build public awareness and confidence in the regulatory system and the APVMA's implementation of the AERP *Ag*
- new arrangements for the quality assurance of active constituents and agricultural chemical products
- proposals to improve procedures for prioritising chemical reviews and ways to strengthen communication of review outcomes to stakeholders
- approval of the APVMA's Annual Budget 2004–05, Corporate Plan 2003–04 to 2005–06 and Operational Plan 2003–04
- regulatory approaches for swimming pool and spa sanitising products
- a proposal to assess current and future operational needs
- approval of a revised Audit Committee Charter to include certain non-financial functions
- Risk Assessment/Risk Management and Major Incident Response plans
- finalisation of a new certified agreement for the APVMA for the period 2004–2007

- approval of revised delegations to reflect the current senior management structure and operational requirements
- negotiation of Service Level Agreements for technical services provided by OCS, NOHSC and the Department of the Environment and Heritage and with the States and Territories for efficacy evaluations
- ongoing development of a tiered regulatory scheme for low-risk chemical products
- approval of key principles and concepts for revision of the labelling codes for pesticides and veterinary medicines
- commencement of initiatives to reform the regulatory framework for minor use of chemicals in agriculture
- development of process improvements and guidelines to manage the risk of chemical residues in livestock and other food commodities
- harmonisation of MRL consultation procedures
- improved procedures for prioritising chemical reviews
- ongoing advice and assistance by the APVMA to develop legislative amendments to strengthen compliance powers in response to the Pan Pharmaceuticals incident, introduction of data protection as part of the Australia-United States Free Trade Agreement and proposed fee structure amendments.

With respect to APVMA chemical review activities, the Board:

- initiated chemical reviews of copper chrome arsenate, arsenic trioxide, benomyl and omethoate
- expanded the scope of the dimethoate review
- approved the release for public comment of draft reports on the reviews of endosulfan, fenitrothion, carbaryl, copper chrome arsenate and arsenic trioxide
- noted progress reports and related regulatory activity concerning current agvet chemical reviews including diazinon, ethylene oxide, carbon disulphide, virginiamycin and tributyltin.

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 2003–2006. It is updated annually and outlines the APVMA's outcome 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* (CAC Act) 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 the Prime Minister and Cabinet, the *Commonwealth Authorities and Companies Orders 2002* and the CAC Act.

The 2003–04 Annual Report details APVMA performance against each of the key outputs and performance indicators contained in the 2003–04 Portfolio Budget Statements.

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

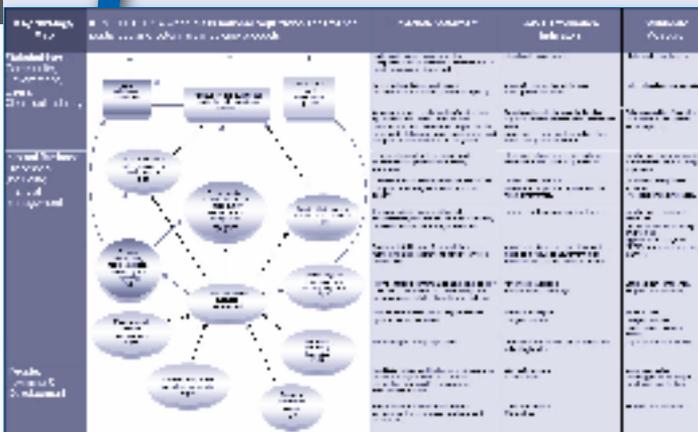
The APVMA seeks input from interested stakeholders throughout the registration and chemical review processes as well as during the development of program reforms.

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. During 2003–04 the APVMA published 19 Trade Advice Notices (16 from the Pesticides Program and three from the Veterinary Medicines Program).

Proposed data protection amendments will add greater transparency by requiring the APVMA to publish a Summary of Information

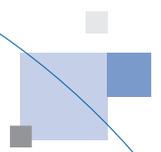
Operational planning— move to a Balanced Scorecard Methodology



During the reporting period substantial effort was devoted to the redevelopment of the APVMA's Operational Plan utilising the Balanced Scorecard Methodology. The methodology was developed in the early 1990s by Drs Robert Kaplan (Harvard Business School) and David Norton. It is now widely used as a method of strategy development and a communication tool.

The APVMA believes the adoption of the methodology across the organisation has improved the strategic planning process and enabled better understanding and communication of strategy, objectives and initiatives by stakeholders and staff.

Performance management will be enhanced as the methodology is applied across programs to create a common understanding of strategy. This will both improve alignment of key performance measures across all levels of the organisation and enhance performance monitoring by the APVMA Board and senior management.



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 web site and by direct mail. Final reports are also available publicly on the APVMA's web site.

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 web site www.apvma.gov.au.

Access to management and staff

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

Service charter

The APVMA aims to provide high quality service to all its stakeholders and is committed to the continuous improvement of its service delivery.

The APVMA Service Charter was developed in consultation with its stakeholders and is freely available to all interested parties.

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, AS4390:1996 and other Parliamentary requirements. During 2003–04 around 3000 files were created and 2500 scientific data packs were transferred to long-term off-site storage.

The existing system for capturing and archiving email was upgraded to provide more efficient storage and retrieval.

Information technology

During the year the APVMA continued to use information technology as a key driver to improve business processes and enhance stakeholder access to information. Information technology initiatives included:

- development of an online facility for the submission of agricultural adverse experience reports over the internet
- development of a secure online submission facility that allows registrants and manufacturers to report the volume of active constituents imported/exported and manufactured
- implementation of a virtual private network allowing secure remote access to key corporate data from any location utilising the internet
- enhancement of business intelligence across the organisation
- development of a software application to provide staff with key information on MRLs
- implementation of an email archiving system
- redesign of the external web site.

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. The ISO 9000 series of standards is used as the framework of the quality system, placing an emphasis on responsiveness to customers and stakeholders in addition to consistency of output, efficient resource management and continuous improvement.

The system is reviewed and monitored by a monthly executive meeting and audited both internally and through an annual external audit.

The 2003 legislative amendments necessitated significant process redesign, which has been incorporated into the quality system.

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.

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.

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 is developing an environmental management system that will comply with the requirements of International Standard AS/NZS ISO14001. The system will be part of an integrated management system comprising the quality management, occupational health and safety and environmental management systems. The environmental management system will promote environmentally friendly practices within the office environment. During the year an environmental audit was completed which required some issues such as waste paper disposal and energy and water consumption to be addressed or monitored.

Auditor-General's reports

There were no reports by the Auditor-General on the operations of the APVMA during 2003–04.

Ministerial directions

The APVMA did not receive any ministerial directions during 2003–04.

Courts and tribunals

Seven proceedings were commenced in the Commonwealth Administrative Appeals Tribunal in 2003–04 following regulatory decisions taken by the APVMA in respect of silver-based pool and spa products. Four of these proceedings involved regulatory decisions taken by the APVMA involving a particular supplier of pool and spa products. Only one of those proceedings remains ongoing.

Three proceedings followed recall action taken by the APVMA involving pool and spa ionisers. They remain ongoing.

No proceedings were carried over from the previous reporting period.

Ombudsman

No formal inquiries were made by the Ombudsman into the operations of the APVMA during 2003–04.

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

Parliamentary committees and other reviews

The APVMA did not participate in any parliamentary inquiries or reviews during 2003–04.

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.