Australian Pesticides & Veterinary Medicines Authority

Year In Review

YEAR IN REVIEW

CORPORATE PROFILE

Vision

To be recognised nationally and internationally as a best-practice regulator of pesticides and veterinary medicines that has the respect and confidence of governments, the community, the rural sector, chemical users and the chemicals industry.

Mission

To protect the health and safety of people and animals, the environment and trade and support Australian agriculture, through science-based, effective and efficient regulation of pesticides and veterinary medicines.

Who we are

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent Australian Government statutory authority responsible for the registration of pesticides and veterinary medicines prior to sale and their regulation up to and including the point of retail sale.

Responsible Minister

The APVMA is within the portfolio of the Minister for Agriculture, Fisheries and Forestry.

Senator the Hon. Richard Colbeck

Senator the Hon. Richard Colbeck, Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry, has direct portfolio responsibility for the APVMA. Senator Colbeck was appointed on 22 October 2004, replacing Senator Judith Troeth. The APVMA Chairperson reports regularly to Senator Colbeck on APVMA activities.

What we do

The work of the APVMA protects the health and safety of people, animals, the environment and trade.

The APVMA is responsible for administering and managing the National Registration Scheme (NRS). The Scheme sets out the regulatory framework for the management of pesticides and veterinary medicines in Australia. The APVMA does this in partnership with the State and Territory governments and with the active involvement of other Australian Government agencies. The APVMA administers and manages the Scheme's legislation and is responsible for registration, quality assurance and compliance of pesticides and veterinary medicines up to and including the point of retail sale. All registered products must be shown to work, be safe for people and the environment, and not unduly jeopardise Australia's trade with other nations. The APVMA also manages a number of programs that monitor the ongoing safety and performance of these registered products. The responsibility for the control of use of pesticides and veterinary medicines lies with the individual States and Territories.

Governing legislation

The APVMA operates in accordance with its governing legislation, the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act) and the Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The Administration Act sets out the APVMA's role as an independent statutory authority to undertake the Australian Government's responsibilities under the Scheme. The Agvet Code details operational provisions for approving active constituents, registering chemical products and approving labels.

Stakeholders

In undertaking its role, the APVMA consults with a range of stakeholders including:

- the general community
- the chemicals industry
- the Australian, State and Territory governments
- farmers and farm workers
- other users of agricultural and veterinary chemicals
- other national and international regulators.

Funding arrangements

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 annually maintain, product registrations. Levies are paid annually according to the level of disposals of registered products. In 2004–05 industry contributions were 96 per cent of total revenue (2003–04: 95 per cent).

As an agency operating on full cost-recovery, business efficiency, customer service transparency and accountability are key priorities for the APVMA.

Dr Kevin Sheridan AO, Chairperson

Dr Joe Smith, Chief Executive Officer

REPORT BY THE CHAIRPERSON AND CEO

The past year has seen significant change and reform across the APVMA. It has been a year of major legislative and operational change that has presented both challenges and opportunities to the Authority. Against this background, the year has also been one of significant achievements across the different programs.

In striving to deliver its corporate objectives, the APVMA has maintained the three key strategic themes introduced by the Board in the previous year. These are stakeholder confidence, operational excellence and informing policy, and they again provide a useful framework for reflecting on the year's progress and achievements.

Stakeholder confidence

Building and maintaining the confidence of our stakeholders is fundamental to the success of the APVMA—be they the broader community, government, the rural sector, the chemicals industry or Australia's trading partners. Confidence stems from both an awareness of what the APVMA does and a respect for the effectiveness and efficiency with which it does it. Our continued focus on operational excellence is therefore of critical importance. So, too, are our efforts to strengthen relationships and communication with our key stakeholder groups.

Our commitment to communication and transparency has been enhanced by an upgrade to the APVMA website, revision of PUBCRIS (our public agvet chemicals database) to make it more informative and flexible, introduction of a new electronic APVMA newsletter, the launch of a new electronic customer enquiry management system, commencing website publication of summaries of outcomes of Board meetings and targeted media engagement on specific issues. The recent launch of the APVMA's Account Manager Program, which sees senior staff being given responsibility for managing relationships with particular organisations, will also lead to further improvements in stakeholder relationships and mutual awareness of chemicals issues.

The APVMA has continued its endeavours to improve the effectiveness of its main consultative committees with an aim of achieving a more strategic focus for their activities. The APVMA has also consulted closely with industry, the rural sector, professional associations and community groups on a range of specific issues, including chemical reviews, data protection, the new fees structure, compliance initiatives, and maximum residue limits (MRLs) for veterinary medicines and minor use. Particular highlights have been industry input in the extensive rewrite of the Manual of Requirements and Guidelines (MORAG) and the associated seminars in major capital cities, cooperation in the revisions of the Code of Good Manufacturing Practice, and engagement of industry in implementing the new data protection legislation.

The APVMA is very conscious of the benefits that can be achieved through closer cooperation with its overseas regulatory counterparts. Through the exchange of information and collaboration on technical assessments, the APVMA and its counterparts can build mutual confidence and enhance efficiency and effectiveness of their respective activities. To this end, in May 2005 the APVMA signed a Memorandum of Understanding (MOU) with the Canadian Veterinary Drugs Directorate (VDD) to underpin cooperation on veterinary medicines regulation. This followed the signing of an MOU with the Canadian Pest Management Regulatory Agency (PMRA) in October 2004. An MOU has also been finalised between the APVMA and the New Zealand Food Safety Authority (NZFSA). The MOU formalises processes allowing reciprocal acceptance of manufacturing licences.

In addition to this bilateral cooperation, the APVMA has been actively engaged with the OECD Working Group on Pesticides, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and the Codex Alimentarius Commission. The APVMA has played a leading role in developing harmonised

regulatory requirements and frameworks to facilitate work sharing in evaluating agvet chemicals.

Operational excellence

Throughout the year the APVMA has maintained its strong focus on enhancing operational excellence, with major advances being made in different areas of our operations.

Substantial progress has been made in reforming our registration processes, both to accommodate new legislative requirements and to strengthen efficiency and quality.

One of our greatest challenges has been implementation of the new data protection legislation, and it is pleasing to see the positive engagement of industry in helping to ensure that it proceeded effectively. However, the additional requirements associated with data protection, together with the legislated label approval requirements from the previous year, have continued to challenge our registration timeframe performance. This remains a key priority for the APVMA, with initiatives to simplify processes and requirements and a restructure of our Registration Client Services and Registration Finalisation and Information Team into a unified Application Management and Enquiries (AME) team already in train. They build on the launch of our web-based Customer Relationship Management System, where stakeholders can obtain answers to frequently asked questions and lodge enquiries.

Fundamental to the continued effective operation of the APVMA is the provision of an appropriate funding base, and the passage of the new cost-recovery legislation ensures this will occur. The APVMA Board and management are very aware of the concerns which have been raised by some stakeholders in relation to the cost-recovery framework. We are maintaining a strong commitment to ensuring the APVMA fulfils its regulatory role as efficiently as possible, and to working with our stakeholders to achieve further reforms.

A major achievement associated with the introduction of the new fees structure has been the complete rewrite of the APVMA's Manual of Requirements and Guidelines. This was necessary to align requirements information with the new application categories and modules. However, the new web-based documentation provides greater clarity and will lead to efficiency and quality gains for both industry and APVMA evaluators.

Further to these internal reforms, the APVMA has given priority to improving the effectiveness of the critical relationships it has with Commonwealth and State agencies which provide expert evaluation services to it. This has been manifested through the negotiation of new Service Level Agreements (SLAs), clearly defining mutual expectations for service standards and costs.

Outside the registration areas, advances have been made on many fronts.

The past 12-months has seen the completion of several major chemical reviews. Among them were 1080, copper chrome arsenate, carbon disulfide, methiocarb, virginiamycin, dimetridazole, diuron and endosulfan. The new regulatory measures for endosulfan were complemented by the signing of an MOU between Cotton Australia, the Cattle Council of Australia, the Australian Lot Feeders Association and the Australian Cotton Ginners Association. This MOU, put in place to mitigate potential livestock residue risks associated with the use of endosulfan on cotton, provides a good example of the regulator working effectively with user groups.

Important initiatives in the Quality Assurance and Compliance Program are building excellence in the APVMA's 'post-registration' roles. A revised Code of Good Manufacturing Practice for veterinary medicines has been drafted and a new scheme for assuring ongoing compliance of overseas veterinary manufacturers launched. The new agricultural quality assurance scheme has been commenced, with preliminary audits conducted in preparation for full rollout of the program in the 2005–06 year. The new Agricultural Adverse Experience Reporting Program is also now fully operational.

The APVMA has always prided itself on the high quality of its people and its people management. In August 2004 the APVMA won the Australian Human Resource Institute (AHRI) National Award for Excellence in People Management. The award provides formal recognition of the APVMA's outstanding people and their management. Attracting, developing and retaining highly skilled scientific staff and fostering performance continue to be of great importance to the Authority.

Informing policy

The APVMA is not directly involved in policy development, but plays an important role in informing the policy development process as it relates to the regulation of pesticides and veterinary medicines. Policy development relating to the National Registration Scheme is the responsibility of the Australian, State and Territory governments as represented by the Primary Industries Ministerial Council (PIMC).

During the year, the APVMA contributed to the work of the Product Safety and Integrity Committee of PIMC. The APVMA's particular interests covered development of performance measures for the overall agvet chemical management scheme, training and accreditation of chemical users, minor use reform, and usage data collection. Building on its own internal efficiency improvements for minor use, and its hosting of a minor use forum in late 2003, the APVMA has worked closely with the Minor Use Taskforce to promote broader strategic reforms to enable better coordination and prioritisation of work to develop applications for minor use approvals.

In conjunction with the Australian Government, the Department of Agriculture, Fisheries and Forestry (DAFF), the Department of Health and Ageing, Food Standards Australia New Zealand (FSANZ), and the States, the APVMA has worked to develop a framework for more efficient integration of MRLs into the Australian Food Standards Code. Significant progress has now been made with this important initiative. The APVMA also played a key role in assisting DAFF with a number of legislative initiatives during the year, perhaps the most significant of which related to the new cost-recovery framework and data protection provisions.

The future

The APVMA is proud of its achievements in the last 12 months. It has been another year of major change with significant challenges along the way. In the year ahead, we can look to some consolidation, but with further focus on reform to build on the progress made so far.

Our new Operational Plan for 2005–06 flags a number of priority areas aimed at continuing to improve the efficiency and effectiveness of what we do. It encompasses reforms of registration process efficiency and quality, strengthening compliance and its visibility, building greater transparency and improving stakeholder communication. It will continue to drive reform in important areas such as minor use and MRL setting, and to complete key projects regarding spray drift and labelling. It seeks to make better use of low regulatory provisions while still ensuring key risk areas involving public health, environment and trade are effectively regulated. It looks to build international cooperation for the benefit of the Australian agvet chemicals management system.

In all, another ambitious set of challenging goals, which we will achieve through the commitment of our high quality, dedicated staff and the support of our stakeholders.

Dr Kevin Sheridan AO
Chairperson

Dr Joe Smith
Chief Executive Officer

PERFORMANCE FRAMEWORK 2004–05

Through the development of a world-class registration scheme for pesticides and veterinary medicines, the APVMA delivers the outcome of protecting the health and safety of people, animals and the environment and supporting Australian agricultural and livestock industries.

The APVMA has developed a performance framework that links its legislative objectives to an outcome/outputs model. This framework involves a detailed planning and reporting process incorporating the Portfolio Budget Statement, Corporate Plan, Annual Operational Plan and Annual Report.

The outcome, outputs and related performance indicators identified in the APVMA component of the Australian Government Department of Agriculture, Fisheries and Forestry Portfolio Budget Statements for 2004–05 reflect the APVMA's Corporate Plan 2003–04 to 2005–06. The Corporate Plan identifies the APVMA's corporate objectives. It presents a single outcome and a key output as outlined in the Portfolio Budget Statement that is supported by two principal goals. This information provides the basic framework for the presentation of the APVMA's performance for 2004–05.

The APVMA's outcome, key output, corporate objectives, strategies and performance indicators are illustrated in Figure 1.

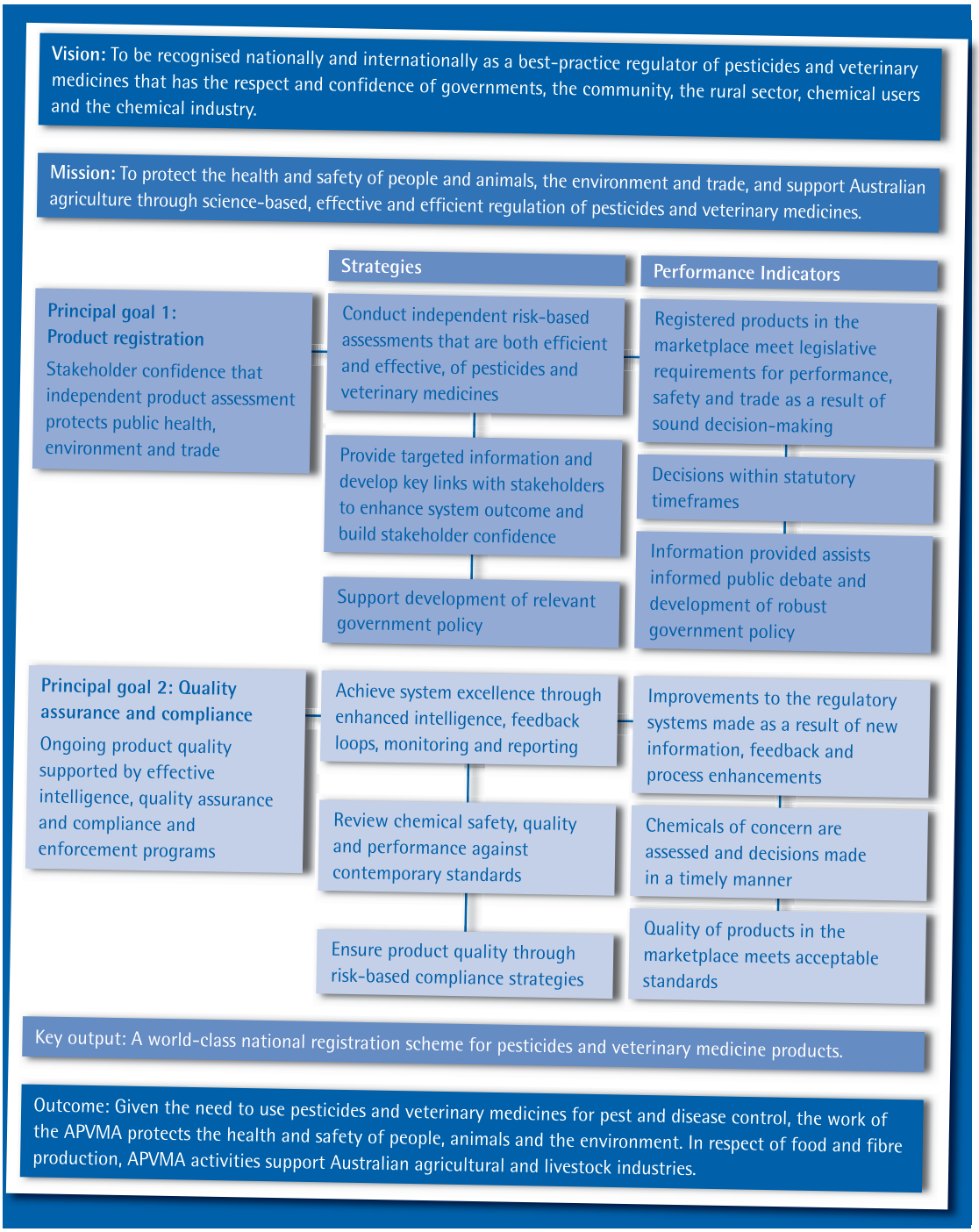
The APVMA achieves results consistent with the agreed outcome and key output through delivery of the principal goals that are supported by a number of strategies. Performance indicators have been identified for each principal goal.

The performance information contained in the next section of this report is presented in line with the outcome-output performance framework structure reflected in the APVMA's Corporate Plan 2003–04 to 2005–06. Progress in the realisation of the key output and principal goals is reported in terms of the nominated performance indicators as well as other major achievements.

Senator Troeth approved the Corporate Plan 2003–04 to 2005–06 in October 2003 and the Annual Operational Plan 2004–05 on 14 June 2004.

APVMA CORPORATE OBJECTIVES

Figure 1: APVMA corporate objectives, strategies and performance indicators



APVMA CORPORATE ACHIEVEMENTS 2004–05

Principal goal 1: Product registration

Stakeholder confidence that independent product assessment protects public health, environment and trade.

Strategy	Performance
Conduct independent risk based assessments that are both efficient and effective, of pesticides and veterinary medicines	■ Finalised 1429 applications for registration, variation to registration or label approval for pesticides (85 per cent within timeframe) ■ Finalised 871 applications for registration, variation to registration or label approval for veterinary medicines (98.5 per cent within timeframe) ■ Finalised 875 permit applications (82 per cent within timeframe) ■ Significant progress with a major reform agenda for minor use including continuing to manage the Minor Use Taskforce and supporting sub-committees and developing a strategic framework for future management of minor use issues ■ Led by APVMA Principal Scientists, strengthened regulatory science quality at the APVMA, increased domestic and international awareness of the APVMA ■ Implemented Service Level Agreements between the APVMA and Australian Government agencies and State and Territory reviewers who provide specialist advice to the APVMA. ■ Complete new Manual of Requirements and Guidelines (MORAG) to reflect legislative changes implemented on 1 July 2005 as part of the new cost recovery framework for the APVMA. ■ Implemented new data protection legislation linked to the US Free Trade Agreement Implementation Act (2004) ■ Launched an online service centre on the APVMA website that enable visitors to view information on a range of topics as well as submit specific enquiries to the relevant section of the APVMA. ■ Revised processes to improve the efficiency and effectiveness of APVMA risk assessments. ■ Completed a comprehensive review of APVMA residue evaluation process ■ Maintained ISO quality systems accreditation which covers all key APVMA processes ■ Developed several draft low regulatory registration scheme standards ■ Developed key labelling principles as part of the major review of the labelling of pesticides and veterinary medicines
Provide targeted information and develop key links with stakeholders to enhance system outcomes and build stakeholder confidence	■ Implemented a comprehensive communication plan ■ Website upgraded to incorporate the self-help service centre ■ Successfully launched the new electronic APVMA Newsletter ■ Hosted several issues-focussed meetings and seminars for APVMA stakeholders, including data protection and registration requirements ■ Conducted comprehensive stakeholder research ■ Finalised MOUs Canadian Pest Management Regulatory Agency and Veterinary Drugs Directorate, to underpin work and information sharing and cooperation ■ Participated in the key international forums including OECD, CODEX and VICH ■ Provided training for four veterinarians as part of the AusAid Iraq Rehabilitation Assistance facility ■ Built awareness of the Adverse Experience Reporting Program with target organisations ■ Gave presentations at targeted conferences and seminars on a range of topics related to the National Registration Scheme ■ Provided information materials to stakeholders including the new APVMA corporate CD and credentials document ■ Appropriately managed all media interest

Principal goal 1: Product registration (continued)

Strategy	Performance
Support development of relevant government policy	■ Provided input to the policy and legislative programs of the Australian Government Department of Agriculture, Fisheries and Forestry ■ Participated in the activities of the Product Safety and Integrity Committee of the Primary Industries Ministerial Council (PIMC) ■ Contributed to the activities of the Environment Protection and Heritage Council Working Group on Environmental Risk Management of Chemicals ■ Progressed reform of interaction with Food Standards Australia New Zealand (FSANZ) on incorporating maximum residue limits into the Food Standards Code ■ Pursued policy reforms to improve the availability of safe and effective chemicals for minor use

Principal goal 2: Quality assurance and compliance

Ongoing product quality supported by effective intelligence, quality assurance and compliance and enforcement programs

Strategy	Performance
Achieve system excellence through enhanced intelligence, feedback loops, monitoring and reporting	■ Completed a performance outcomes monitoring project for the overall National Registration Scheme ■ Implemented the Adverse Experience Reporting Program for agricultural chemicals (AERP*Ag*) and promoted the program to various stakeholders ■ Successfully managed the Adverse Experience Reporting Program for veterinary medicines (AERP*Vet*)
Review chemical safety, quality and performance against contemporary standards	■ Conducted reviews of 34 chemicals ■ Finalised four chemical reviews: arsenic timber treatments, benomyl, endosulfan and virginiamycin ■ Released six draft chemical reviews for public comment: 1080, atrazine, carbon disulfide, diuron, dimetridazole and methiocarb ■ Initiated the review of procymidone ■ Conducted a reconsideration of 1117 active constituents and 3461 products as part of the Quality Assurance Scheme for Agricultural Products to impose new conditions of registration to ensure product quality ■ Hosted a User Forum to identify ways to better understand implications of reviews for users and communicate review outcomes more effectively with stakeholder groups
Ensure product quality through risk-based compliance strategies	■ Addressed 324 reports of non-compliance through warnings, negotiated compliance and investigations ■ Managed 27 product recalls ■ Successfully managed the Manufacturers' Licensing Scheme (238 licensed manufacturers at 30 June 2005) ■ In conjunction with industry, completed revised draft of the Code of Good Manufacturing Practice (GMP) ■ Introduced a new scheme assuring continuing GMP compliance of overseas manufacturers ■ Issued 51 Export Certificates of compliance with the GMP Code for companies wishing to export veterinary medicines ■ Assessed 272 applications for consent to import unregistered or unapproved chemicals ■ Managed the National Hormonal Growth Promotant Monitoring and Control Program ■ Implemented the Quality Assurance Scheme for Agricultural Actives and Products

FINANCIAL PERFORMANCE

Revenue

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 registration of, and annually re-register, products. Levies are paid annually according to the level of disposals of registered products. In 2004–05 industry contributions were 96 per cent of total revenue (2003–04: 95%).

The APVMA's total revenue for 2004–05 was $19.31 million, an increase of $1.2 million (7%) from 2003–04. The increase in revenue is largely due to levy revenue which increased due to improved sales flowing from a partial respite to drought conditions in some areas. Levy revenue was particularly low in 2003–04 due to the effect of the drought on sales.

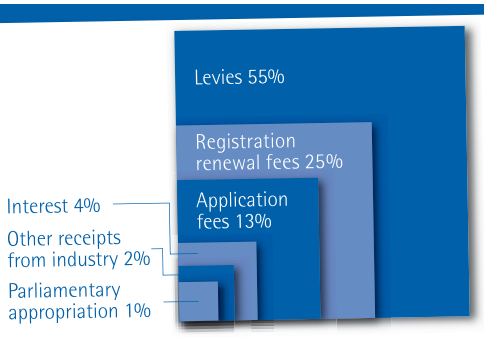


Figure 2: APVMA revenue 2004–05

Revenue	$
Receipts from Industry:	
Application fees	2,515,091
Levies	10,700,889
Registration renewal fees	4,840,701
Other receipts from industry	395,925
Interest	708,796
Parliamentary appropriation	123,000
Other revenue	22,114
Total income	19,306,516

Expenditure

Total operating expenses for the year ended 30 June 2005 were $20.57 million, a decrease of $1.06 million (5%). Key reasons for the decrease included less expenditure for agency scientific assessment services (where lower volumes of applications requiring agency assessments were received) and a series of short-term expenditure reductions implemented pending finalisation of the new cost-recovery arrangements.

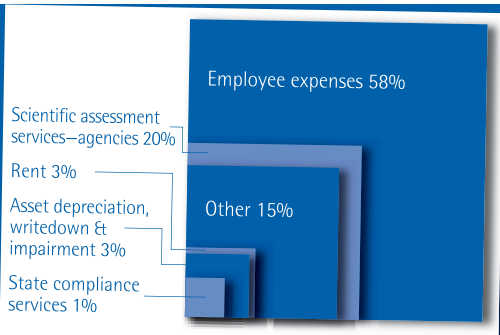


Figure 3: APVMA expenditure 2004–05

Expenditure	$
Employee expenses	11,970,556
Scientific assessment services—agencies	4,090,911
Asset depreciation, writedown and impairment	543,941
Rent	651,107
State compliance services	208,927
Other	3,108,059
Total expenditure	20,573,501

Cost-recovery

During the year the APVMA continued work in implementing the Government's revised cost-recovery framework for the APVMA. In March 2005 a final *Cost recovery Impact Statement* (CRIS) was released by the Department of Agriculture, Forestry and Fisheries. The necessary legislative amendments for the APVMA's revised fee structure passed through Parliament in March 2005. The majority of the provisions commenced on 1 July 2005.

In FY2004–05 the APVMA delivered a net operating loss of $1.27 million, resulting in a reduction in equity to $3.07 million (2003–04: $4.36 million). The new fee structure will allow equity to increase to levels considered appropriate by the APVMA Board.

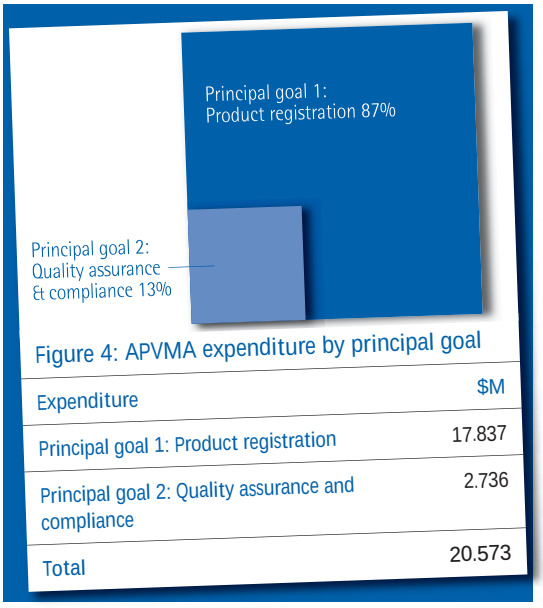


Figure 4: APVMA expenditure by principal goal

Expenditure	$M
Principal goal 1: Product registration	17.837
Principal goal 2: Quality assurance and compliance	2.736
Total	20.573

Figure 5: APVMA outcome-output expenditure (budget versus actual)