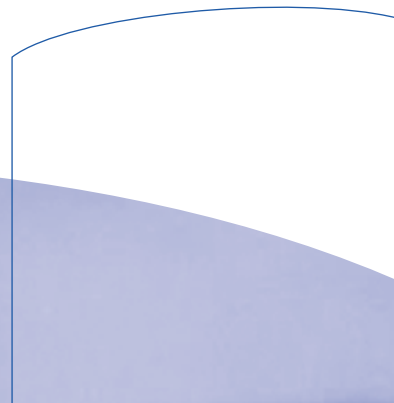




Australian Government



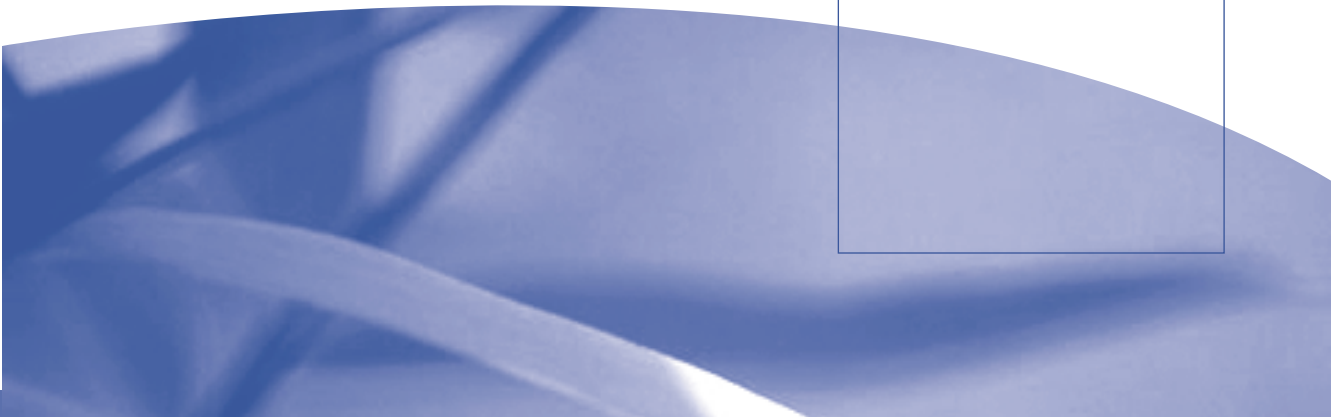
# AUSTRALIAN PESTICIDES & VETERINARY MEDICINES AUTHORITY

ANNUAL REPORT | 2002-03

A world-class national registration scheme for pesticides and veterinary medicine products.

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

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



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**Australian Pesticides &  
Veterinary Medicines Authority**

23 September 2003

Senator the Hon Judith Troeth  
Parliamentary Secretary  
To the Minister for Agriculture, Fisheries and Forestry  
Parliament House  
CANBERRA ACT 2600

Dear Senator

On behalf of the Australian Pesticides and Veterinary Medicines Authority I am pleased to provide the Annual Report for the year ending 30 June 2003 for your approval and tabling in Parliament.

The APVMA Board is responsible under Section 9 of the *Commonwealth Authorities and Companies Act 1997* for the preparation and content of a report of operations in accordance with the Finance Minister's Orders. I believe the Annual Report conforms to the provisions of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Commonwealth Authorities and Companies Act 1997 (CAC Act)*.

This Report is provided to you in accordance with a resolution of the APVMA Board of Directors. It highlights positively the work of an organisation that is clearly focused on meeting its responsibilities in a cost-effective, timely and responsible manner.

Yours sincerely

**Dr Kevin Sheridan AO**  
Chairperson



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# CHAIRPERSON'S REPORT

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It was an honour for me to be appointed chairman of the APVMA late last year. I knew the organisation reasonably well from my many dealings with it over the years and was confident that I was being asked to chair an effective and efficient organisation with a track record of success. I gladly and quickly accepted the opportunity. That decision has proven to be a good one.



It was an honour for me to be appointed chairman of the Australian Pesticides and Veterinary Medicines Authority (APVMA) late last year. I knew the organisation reasonably well from my many dealings with it over the years and was confident that I was being asked to chair an effective and efficient organisation with a track record of success. I gladly and quickly accepted the opportunity. That decision has proven to be a good one.

The APVMA has experienced a good deal of fundamental organisational change over the past twelve months. A management restructure, a new Board and Chairperson to settle in and added to that, a name change and a new corporate identity. On top of all this, the APVMA has remained focussed on its core functions and improved its performance on last year. For 2002-03 the APVMA finalised 2958 applications for registration, a 17 per cent increase on the previous year and importantly completed 97.2 per cent within statutory timeframes. This is a tribute to the professionalism of the staff and reflects a quality of performance that compares more than favourably with international standards.

In the early months of its term, the new APVMA Board set three strategic themes that it intends will underpin its leadership of the organisation. These themes are – Operational Excellence, Building Confidence and Informing Policy.

Pursuit of the strategic themes is now well under way within the APVMA and real progress is already being achieved.

## Operational excellence

The pursuit of operational excellence through continuous improvement is viewed by the Board as essential for the APVMA as it can be expected to have increasing demands placed upon it in coming years while pressure on resources also increases.

The performance of the organisation is already of a very high calibre as the figures I quoted above make clear. However there have been a number of initiatives completed and progressed during the year that will support the pursuit of heightened operational excellence.

Staff development is a priority for the APVMA and fundamental to its successful operation. The intensive training program for the Band 6, or middle management, staff was completed during the year and a flow-on program for operational staff (Band 4/5) commenced. A staff survey conducted early in 2003 showed improvements in the overall 'health' of the organisation based on a comparison with findings from a year 2000 survey. There were clear improvements in the key measures of attitudes to teamwork, organisation identity and training.

Over the year we continued to make advances in the quality and capacity of the business systems that we have in place. The existing electronic levy payment system was modified to allow product registrants to enter their product sales data online. The new system calculates the levy payable and provides an immediate electronic payment option for registrants. It benefits industry through the availability of a more efficient system and also enhances the APVMA's data gathering capacity.

The APVMA's key operating processes are controlled through a quality system accredited to the international standard ISO 9000. Over the year the system certification was updated to comply with the latest version of the ISO 9000 standard. The APVMA is now certified as complying with the requirements of ISO 9001:2000.

By the end of the calendar year, amendments to the Agvet Code will take effect to enable the introduction of a new system for the regulation of lower regulatory requirement products. The new system will reduce regulatory requirements for these types of products and will mean lower costs and reduced time for registration.

The new system will also add to the operational excellence of the APVMA by freeing some resources to be devoted to higher risk regulatory issues within the organisation.

The APVMA is also working to introduce a new scheme for the approval of active constituents for chemical products. They will be required to meet specified standards to gain approval and will no longer be based on site of manufacture as is currently the case. The new scheme is expected to result in an even more robust regulatory system for agricultural chemical products.

## Confidence building

The Board sees a high level of confidence in the regulatory system and the regulator itself by the community, users and the chemicals industry as fundamental to the continued successful operation of the APVMA. That confidence is developed through the actions the APVMA takes and awareness and understanding of the APVMA and its requirements. It also comes through ongoing consultation with stakeholders and transparency of the organisation's processes and decisions.

The APVMA's main vehicle for sustained two-way communication with interest groups in the Australian community is its Community Consultative Committee. In the first half of 2003 the relationship between the APVMA and the committee has been greatly strengthened to increase the committee's active involvement in consideration of issues. The role of the committee is set to be further enhanced in the future.

We are currently developing a broad based communications program designed to build awareness of the APVMA and the national regulatory system. In particular it will provide for effective two-way flow of information with stakeholders.

I see the name change to the Australian Pesticides and Veterinary Medicines Authority as a positive step in building understanding and confidence in the regulator. The new name clearly identifies our role as a government regulatory body with a national focus and responsibility for regulating pesticides and veterinary medicines. It is a better vehicle to effectively communicate what we

are about. A crucial ingredient in any effort to build confidence is simply ensuring that we are easily identified and our role is clear.

Ensuring compliance with the law is another vital part of our efforts to build the confidence of all stakeholders in us and the regulatory system. It is an area in which we are active and will become increasingly so. The coming year will see considerable strengthening and refocus of our compliance program.

In the past year the APVMA received 297 reports alleging non-compliance through the advertising or supply of unregistered and unapproved chemicals. A total of 247 reports were resolved and finalised in the year.

There was considerable recall activity in the year. The APVMA facilitated 18 voluntary product recalls and managed five compulsory recalls. The recall of a number of veterinary treatments that followed the suspension of the APVMA manufacturing licence for Pan Pharmaceuticals Ltd drew some public and media interest.

The Adverse Experience Reporting Program for Veterinary Products is a valuable quality assurance program that helps ensure that marketed products remain safe, effective and of acceptable quality. A major review of the program resulted in operational changes that have produced significant efficiency gains. Over the course of the year, 2500 adverse experience reports concerning the use of veterinary medicines were assessed and corrective action taken where necessary.

Providing the opportunity for the public to report problems or adverse experiences with products is particularly valuable from the compliance and quality assurance perspective. This facility is to be extended to the area of Agricultural Products. An Adverse Experience Reporting Program for Agricultural Products is to be introduced in the new year and planning is well progressed. The program will operate on similar principles to the veterinary program and is expected to significantly boost the quality assurance of agricultural chemical products. It is anticipated that the new program will attract much greater public interest and involvement and is likely to focus heavily on public health issues.



## Informing policy

The system for the management of agricultural and veterinary chemicals has functioned successfully for more than a decade. It has met its goals of protecting public health, the environment and the nation's trade while providing access to essential chemicals for those who use them. However, as time goes by, the system must change to meet changing needs. The APVMA Board firmly believes that the organisation has the skills, knowledge and experience necessary to make a positive contribution to the policy development process concerning various aspects of the Australian agricultural and veterinary chemicals management system.

Although the APVMA is not directly involved in policy development it does have the capacity to offer valuable information and advice. Opportunities for the APVMA to 'inform' policy development will be explored for the future.

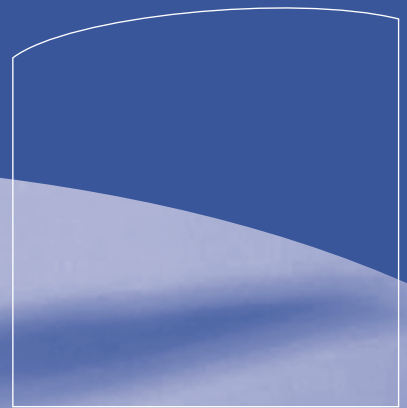
The APVMA conducted a workshop as part of this year's ABARE Outlook Conference to consider the many issues raised in some recent reviews and reports on the management of agricultural and veterinary chemicals in Australia. The workshop provided the opportunity for key stakeholders to expand on the issues raised in the reports.

The APVMA produced a report from that workshop that consolidates the key issues identified at the workshop and in the review reports. The APVMA report aims to assist consideration of the future of the Australian agricultural and veterinary chemical management system. It was prepared by the APVMA to contribute to policy development in keeping with the Board's wish to help inform the policy process.

The APVMA has achieved much in 2002-03. It has successfully delivered its core functions with increased efficiency and, through a number of other important initiatives, has laid the foundations to be an even more effective body in the coming year.

Dr Kevin Sheridan AO





## YEAR IN REVIEW

APVMA | ANNUAL REPORT



The APVMA embraced considerable change over the course of 2002-03 that will have a major impact over the coming years. In August 2002 a new organisational structure was implemented that involved the removal of one layer of management, the concentration of activity through six program areas and an increased focus on scientific excellence through the establishment of three principal scientist positions.



The APVMA embraced considerable change over the course of 2002-03 that will have a major impact over the coming years. In August 2002 a new organisational structure was implemented that involved the removal of one layer of management, the concentration of activity through six program areas and an increased focus on scientific excellence through the establishment of three principal scientist positions.

A new Board was appointed for a three-year term from October 2002 along with a new Chairperson, Dr Kevin Sheridan AO. In March 2003, Senator Troeth launched the new name, the Australian Pesticides and Veterinary Medicines Authority. The new name is seen as more clearly identifying the organisation's role and area of focus and will help enhance stakeholders' awareness and understanding.

Other specific highlights for the year from the APVMA's program areas are set out below.

## Registration

The APVMA finalised 2958 applications for registration over the year, a significant increase of 17 per cent on the previous year. Some 97.2 per cent of these were completed within the APVMA's statutory timeframes which compares favourably with the 96.2 per cent achieved in 2001-02.

A total of 948 applications for permits were finalised. This is around the same level as the previous year. Of the permits finalised, 123 were for emergency use. Included in these were permits for the control of silverleaf whitefly and red imported fire ants in Queensland. The APVMA worked with Crop Protection Approvals, Horticulture Australia and Queensland Fruit and Vegetable Growers to develop ways to increase the efficiency of the permit scheme for minor use crops.

A two-day information seminar was conducted in Canberra for current and potential registrants to increase awareness of the APVMA's requirements and processes. The seminar format was developed based on feedback from participants at previous seminars. The seminar was well received by the 100 participants. The level of interest in attending was high and exceeded the number of actual places available.

The program for the review and update of advisory documentation continued with new guidelines drafted for:

- promotional packaging
- registration of products used on sperm and ova
- registration of veterinary complementary medicines
- post-harvest treatments
- determining emergency uses and research purposes
- determining minor uses.

## Chemical review

During the year there was continued reform of processes for reviewing existing chemicals, with emphasis on more issues-focussed and responsive reviews.

During the year three chemical reviews were completed. Of these, one resulted in the cancellation of certain products while two resulted in voluntary cancellation of registrations. The draft reports of two reviews were released for public consultation. Eight chemical reviews were initiated over the year.

There were 29 chemical reviews ongoing as of 30 June 2003.

## Chemistry and residues evaluation

Chemistry evaluations were conducted for 150 active constituents and 255 agricultural and veterinary chemical product applications. As well, 71 residue evaluations for products were completed during the year. Some 95 per cent of all evaluations were finalised within required timeframes.

Development commenced on a scheme which aims to enhance the quality of agricultural chemical products available by basing the approval of active constituents on their meeting specified standards rather than depending on the source of the active constituent.

Guidelines for starter culture data for antimicrobial products were finalised. Consultations with stakeholders are proceeding on guidelines for milk maximum residue limits and withholding periods, poultry residue data requirements, residues at injection sites, stability data for veterinary chemicals and validation of analytical methods.

## Quality assurance and compliance

Over the course of the year there were 297 reports received alleging non-compliance through the advertising or supply of unregistered and unapproved chemicals. A total of 247 reports were finalised. Ten investigations were initiated with a view to prosecution. Of these, eight investigations were finalised and one prosecution was completed.

The APVMA facilitated 18 voluntary product recalls during the year and also managed five compulsory recalls. The most topical of these involved the recall of a number of veterinary treatments that followed the suspension of the APVMA manufacturing licence for Pan Pharmaceuticals Ltd.

Less than 1 per cent of manufacturers of veterinary chemical products now still hold conditional licences first issued when the Manufacturers' Licensing Scheme, a quality assurance program for the industry, was established.

Closer links were developed with the Australian Customs Service in an effort to limit the amount of unregistered and unapproved chemicals entering the country. In 2002-03, the APVMA issued 177 Consents to Import to allow the importation of unregistered or unapproved chemical products, mostly for use in research trials.

The Australian and state governments have a National Hormonal Growth Promotants Monitoring and Control System in place for the importation, supply and use of hormonal growth promotants (HGP). The APVMA continued to play a key role in the licensing and auditing of suppliers. By the end of 2002-03 there were 178 APVMA-authorised suppliers of HGPs in Australia.

A major review of the Adverse Experience Reporting Program for Veterinary Products resulted in a number of operational changes being made to the program. These have led to significant efficiency gains in the operation of the program. During the year 2500 (predominantly not serious) adverse experience reports concerning the use of veterinary medicines were assessed and corrective action taken where appropriate.

## Business systems

The APVMA's electronic levy payment system was enhanced to allow registrants to enter their product sales data online. A new facility that allows the public to submit adverse experience reports for veterinary products online was introduced. Electronic images of approved product labels can now also be viewed through the APVMA web site free of charge.

The APVMA's quality system certification was updated to comply with the latest version of the ISO 9000 series standard, ISO 9001:2000.

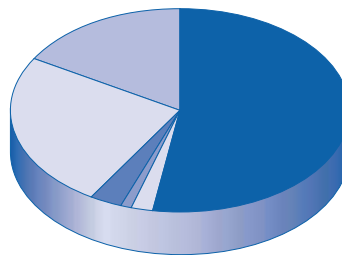
The popularity of the APVMA web site continued to grow with the site now attracting around 800 visitors each day.

## Funding arrangements

The APVMA's total revenue for 2002-03 was \$19.51 million. This revenue is collected mainly from the agvet chemicals industry. Fees are paid to apply for, and annually renew, product registrations. Levies are paid annually according to the level of disposals of registered agvet chemical products. In 2002-03 industry contributions were 95 per cent of total revenue (2001-02: 95 per cent).

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

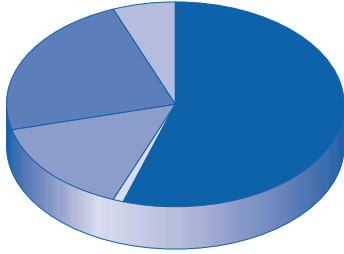
### APVMA expenditure for 2002-03



	\$	% of expenditure
■ <i>Employees</i>	10,783,059	53%
■ <i>Depreciation &amp; amortisation</i>	723,189	4%
■ <i>State compliance services</i>	196,897	1%
■ <i>Rent</i>	628,696	3%
■ <i>Scientific assessment services</i>	4,692,847	23%
■ <i>Other</i>	3,177,729	16%
	<b>20,202,417</b>	<b>100%</b>



APVMA revenue for 2002-03



	\$	% of revenue
■ <i>Levis</i>	<i>10,672,302</i>	<i>55%</i>
□ <i>Appropriation</i>	<i>116,000</i>	<i>1%</i>
■ <i>Application fees</i>	<i>2,863,270</i>	<i>15%</i>
■ <i>Renewal fees</i>	<i>4,508,401</i>	<i>23%</i>
■ <i>Other revenue</i>	<i>1,353,942</i>	<i>6%</i>
	<i>19,513,915</i>	<i>100%</i>

## Finance

Detailed financial statements are provided at page 53.

The APVMA recorded a deficit of \$688,502 for the year ended 30 June 2003.

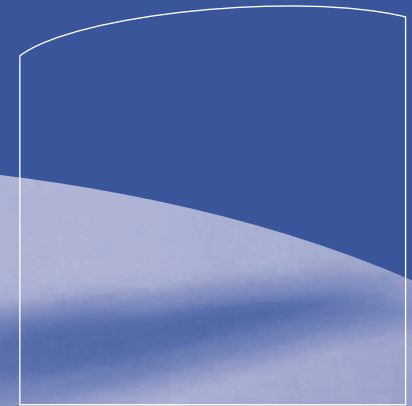
The APVMA's revenue for the year was \$19.51 million, a decrease of 1.3 per cent (\$250,000) from 2001-02. This was primarily due to an anticipated decrease in the Good

Manufacturing Practice licence fees of \$702,000, higher in 2001-02 due to a change in accounting treatment. The decrease was partially offset by an increase in levy revenue (\$314,000) and registration renewal fees (\$162,000).

Operating expenses totalled \$20.2 million, down 2 per cent (\$421,000) from 2001-02. This fall was primarily due to employee expenses, higher in 2001-02 due to redundancies and a change in the methodology used to calculate employee long-service leave provisions. The decrease in employee expenses was offset by an increase in Scientific Assessment Services of \$223,000, following the implementation of new service level agreements with the APVMA's Commonwealth advisory agencies. In addition, insurance increased by \$87,000 in line with premium increases market wide.

Asset additions for the year totalled \$532,630 and were primarily associated with the fit-out of the APVMA premises and implementation of a Storage Area Network.





## FUTURE OUTLOOK

APVMA | ANNUAL REPORT



There are a number of initiatives and policy developments that are likely to have significant influence on the nature of the APVMA's operations in 2003-04 and on its performance.

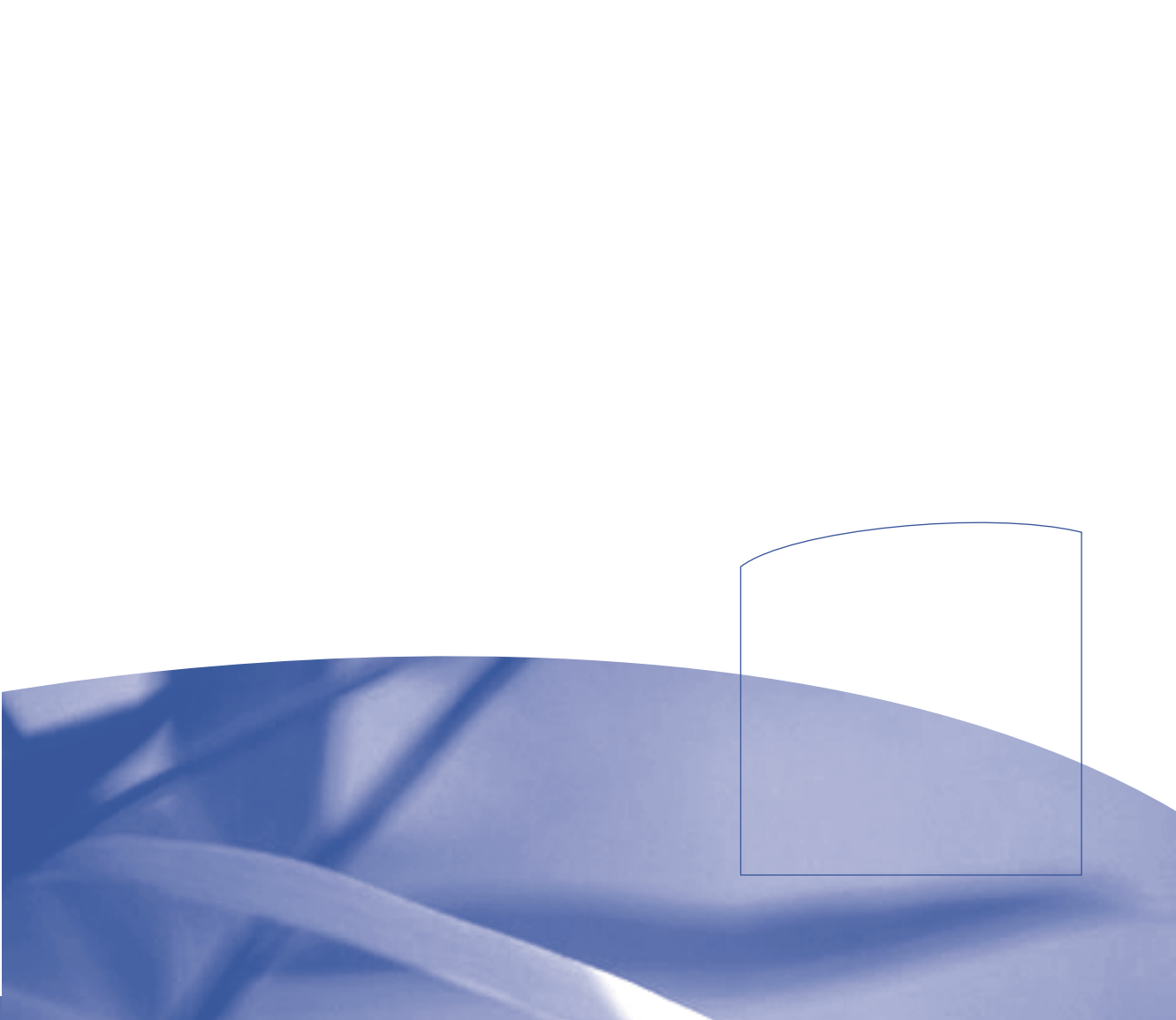


There are a number of initiatives and policy developments that are likely to have significant influence on the nature of the APVMA's operations in 2003-04 and on its performance.

These include:

- Amendments to the Agvet Code to take affect from late 2003 will introduce a range of changes, including a low regulatory framework, predominantly for low risk products. The benefits of the system will include lower costs of registration for these products, reduced time for registration and the reallocation of APVMA resources to focus on higher risk issues.
- An Adverse Experience Reporting Program for Agricultural Products is to be introduced in 2003-04. To operate on similar principles to the existing veterinary program, the new program will significantly boost the quality assurance of agricultural chemical products and address emerging issues associated with their use. It is anticipated that the new program will attract much greater public interest and involvement and is likely to focus heavily on public health issues.
- A decision by Government is expected on a new fees structure for APVMA activities. The new structure is expected to be implemented from 1 July 2004.
- A new scheme that bases the approval of active constituents on meeting specified standards and not on the source of the active constituent is being developed. This scheme will provide a unified system for approval of both agricultural and veterinary active constituents. It will focus on the quality of the active constituent rather than site of manufacture or source. It is anticipated that the scheme will strengthen the regulatory process for agricultural chemical products.
- The APVMA's compliance program will be considerably strengthened and refocused in 2003-04.
- Building awareness and confidence in the APVMA and the regulatory system with the community, users and the chemical industry will be a major strategic objective in 2003-04 and beyond. Initiatives will be undertaken to build awareness and understanding of the APVMA and its requirements, strengthen consultation with stakeholders and improve the transparency of key processes and decisions.





## REPORT OF OPERATIONS

APVMA | ANNUAL REPORT

A world-class national registration scheme for pesticides and veterinary medicine products.

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

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



## CORPORATE OVERVIEW

APVMA | ANNUAL REPORT



The State, Territory & Australian Governments agreed to establish the National Registration Scheme for Agricultural and Veterinary Chemicals in 1991. The Australian Pesticides and Veterinary Medicines Authority (APVMA) (known as the National Registration Authority for Agricultural and Veterinary Chemicals until March 2003) is responsible for administering and managing legislation established under the National Registration Scheme for Agricultural and Veterinary Chemicals on behalf of the State, Territory & Australian Governments.



## Role and background

The State, Territory & Australian Governments agreed to establish the National Registration Scheme for Agricultural and Veterinary Chemicals in 1991. The Australian Pesticides and Veterinary Medicines Authority (APVMA) (known as the National Registration Authority for Agricultural and Veterinary Chemicals until March 2003) is responsible for administering and managing legislation established under the National Registration Scheme for Agricultural and Veterinary Chemicals on behalf of the State, Territory & Australian Governments.

The legislation seeks to centralise aspects of the regulation of agricultural and veterinary (agvet) chemicals in Australia. In this role the APVMA assesses, registers and regulates agvet chemical products up to, and including, the point of retail sale. Responsibility for control of use of agvet chemicals, such as licensing of pest control operators and aerial spraying, continues to reside with individual states and territories.

Through the National Registration Scheme, the APVMA delivers registration, quality assurance and compliance. In particular, the APVMA:

- assesses the safety and performance of products;
- determines whether their use is likely to jeopardise trade; and
- regulates the supply of agvet chemicals to the Australian market by approving product labels and specifying conditions of use.

The work of the APVMA safeguards the health of people, animals and the environment, and international trade.

Appendix A provides an overview of the National Registration Scheme. It explains the registration process and the APVMA's role in the scheme.

## Ministerial responsibilities



The APVMA is an independent statutory authority within the portfolio of the Minister for Agriculture, Fisheries and Forestry, the Hon Warren Truss MP.

Senator the Hon Judith Troeth, Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry, has direct portfolio responsibility for the APVMA. The APVMA Chairperson reports regularly to Senator Troeth on APVMA activities. The Minister continues to have overall policy responsibility for agvet chemicals.

## Governing legislation

The APVMA operates under two key pieces of legislation:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992*, containing the Agricultural and Veterinary Chemicals Code (the Agvet Code). (The Act is referred to in this Annual Report as the Administration Act); and
- *Agricultural and Veterinary Chemicals Code Act 1994* (referred to in this Annual Report as the Code Act).

The Administration Act formally established the National Registration Scheme in 1993. It also sets out the APVMA's role as an independent statutory authority undertaking the Commonwealth's responsibilities under the scheme and provides the APVMA with its full range of powers.

The Agvet Code, scheduled to the Code Act, details the operational provisions for registering chemical products and approving active constituents.

Various other statutes and delegated legislation are also administered by the APVMA. These are described in detail at Appendix C.

## Stakeholders

The APVMA regulates people and companies who must:

- register products and obtain approval of product labels;
- obtain approval of active constituents;
- obtain permits to use chemicals in emergency, research and off-label situations; or
- obtain licences to manufacture veterinary chemical products.

The APVMA has a large number of stakeholders. They include the agvet chemicals industry, farmers, rural sector organisations, environmental, consumer and community groups, other Commonwealth and State/Territory government agencies that help operate the National Registration Scheme and international regulatory authorities.

## 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.

## Funding arrangements

The APVMA's total revenue for 2002-03 was \$19.51 million. This revenue is collected mainly from the agvet chemicals industry. Fees are paid to apply for, and annually renew, product registrations. Levies are paid annually according to the level of disposals of registered agvet chemical products. In 2002-03 industry contributions were 95 per cent of total revenue (2001-02: 95 per cent).

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

## Performance information

The outputs and related performance indicators identified in the APVMA component of the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) Portfolio Budget Statements for 2002-03 provide the basic framework for the presentation of the APVMA's performance information for this year.

Through the development of a world-class registration scheme for agvet chemical products, the APVMA is working toward the outcome of protecting the health and safety of people, animals and the environment and supporting Australian agricultural and livestock industries.

The specific outputs that the APVMA sought to achieve over the course of the year were:

- registration of agvet chemical products that are effective for their intended purpose and satisfy requirements for safety of people, animals, the environment and trade; and
- compliance with the law through product review, quality assurance and enforcement programs.

These outputs and the related performance indicators are central to the APVMA's key planning tools, its Corporate Plan and Operational Plan.

The Operational Plan and the Corporate Plan outlining the broad vision for the organisation for the period 2000-01 to 2002-03 were approved by Senator Troeth in June 2002.

## Organisational structure

The APVMA is divided into six programs, each of which reports through a Program Manager to the Chief Executive Officer (CEO) and the APVMA Board. Each program is divided into sections that have responsibility for specific operational or administrative functions.

Principal Scientists, responsible for the maintenance of scientific standards of excellence, are within the Pesticides, Veterinary Medicines, and Chemistry and Residues programs.



FIGURE 1: APVMA organisational and program structure at 30 June 2003



## APVMA Board of Directors

The APVMA's focus and strategic direction is determined by a Board of Directors, as provided for under the Administration Act. The Board comprises a Chairperson and eight other Directors. All Board appointments are non-executive positions and all are on a part-time basis. Directors are selected for their experience in areas including the regulation of chemical products at State or Territory level, the agricultural and veterinary chemicals industry, primary production, occupational health and safety, protection of consumer interests, the development or administration of Australian government policy or the operation or management of an Australian government statutory authority.

The current Board was appointed by Senator the Hon Judith Troeth, Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry on 16 October 2002 for a term expiring on 15 October 2005. The previous Board's term expired on 15 October 2002. The outgoing Board comprised Dr John Keniry (Chairperson), Mr Peter Bailey (Deputy Chairperson), Dr Lyn Fragar, Professor John McLean, Mr Mark Allison, Mr Ian Champion, Dr Peter Dingle, Mr Michael Nicholls and Mrs Merrilyn McPherson. Dr Fragar and Professor McLean were reappointed to the current Board.

It should be noted that Directors are not appointed to represent organisations or particular interest groups. The Board of Directors constitutes the APVMA and acts in its corporate interest by providing direction and overseeing its operations for the regulation of agricultural and veterinary chemicals up to and including at the point of retail sale. The Board ensures that the APVMA exercises its functions, powers and responsibilities consistent with the Administration Act, related Australian government legislation and Government policy direction. In so doing, the Board takes advice and recommendations from its key consultative committees, other stakeholders and APVMA staff. Responsibility for day-to-day operations rests with the CEO.

Details of Board meetings, attendance and declared interests are at Appendix B.



**Dr Kevin Sheridan AO**  
(Chairperson)  
B AgrSc, MS, PhD

Chairman Advisory Committee for the Centre for Rural and Remote Mental Health; Director General of NSW Agriculture (1988–2002); Chief Executive of the NSW Rural Assistance Authority (1996–2002); member of the Murray–Darling Basin Commission (1988–2002); Chairman of the Farrer Memorial Trust (1988–2002) and the Helen Newton Turner Trust (1993–2002). Has been involved in policy and use of agricultural and veterinary chemicals for the past 30 years.



**Dr Lyn Fragar AO**  
(Deputy Chairperson)  
MBBS, MPH, DipAgEc,  
DTM&H, FAFPHM,  
FRIPH, MAICD

Public health and occupational health physician. Director of the Australian Centre for Agricultural Health and Safety (University of Sydney); Secretary of Farmsafe Australia Inc; member of the Farm Health and Safety Industry Research and Development Advisory Committee of the Rural Industries Research and Development Corporation, and the International Association of Agricultural Medicine and Rural Health.



**Dr Gardner Murray**  
PSM, DVMS hc, BVMS,  
FAIM, MRCVS, MAICD

Qualifications in veterinary medicine and surgery and in administration. Has held a number of senior government positions including Executive Director, Australian Quarantine and Inspection Service and Bureau of Rural Sciences; currently Executive Director of Product Integrity, Animal and Plant Health (DAFF); Australia's Chief Veterinary Officer. Has extensive experience in animal health and food safety issues and has served on a wide range of national and international committees.



**Professor Jock McLean**  
BVSc, PhD, HDA  
(Hons)

Veterinary surgeon and Professor Emeritus, Swinburne University of Technology. Deputy Chairperson, Racing Analytical Services Ltd; member of the Commonwealth Advisory Committee on Pesticides and Health and the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (Veterinary Drugs); member of the APVMA Board since 2000. Experienced in the regulation of chemical products under the law of a State or Territory.



**Dr Catherine Hollywell**  
BSc (Hons), PhD

Manager Chemical Standards, Department of Primary Industries (Victoria). Represents Victoria's interests, as a signatory to the ministerial agreement which underpins the National Registration Scheme, on the National Signatories Working Group. Member of the Poisons Advisory Committee of the Department of Human Services, Victoria. Experienced in the regulation of chemical products under a law of a State or Territory.



**Hutch Ranck**  
BS Economics

Managing Director of DuPont Australia and New Zealand. Vice President of Avcare; Director of the Plastics and Chemicals Industry Association; the Business Council of Australia's appointee to the Prime Minister's Science, Engineering and Innovation Council. Has broad experience in several industries in sustainable development, product stewardship and quality systems.



**Tony Bates AM**  
BComm, FCPA, FCIS,  
FAICD

Broadly experienced business manager. Previously Managing Director of Cyanamid Australia and Cyanamid of New Zealand; former Chairman of Arthur Websters Pty Ltd; past President of Australian Business Ltd and Chair of the Federal Government's Biotechnology Consultative Committee. Chairman of Technico Pty Ltd and the Dairy Research and Development Corporation and a Director of CCI Holdings Ltd and Young Achievement Australia. Experienced in the development, registration and marketing of research based life science technologies through to full commercialisation into global markets, especially in Australia and Asia.



**Anne Story**  
B.App.Sc (Hort.  
Tech.)(Hons), MAIAST

Horticulturist, specialising in the handling, distribution and marketing of fresh produce. Commercial interests in vegetable production, processing and wholesaling businesses. Deputy Chancellor, University of Southern Queensland; Chair, Amenity Horticulture Industry Development Council (Queensland); member, Quarantine and Export Advisory Council (Canberra); Executive Officer of Australian United Fresh Transport Advisory Committee Ltd.



**Mara Bún**  
BA

Experienced in technology investment banking, management of non-profit organisations and consumer advocacy. A consultant with the Allen Consulting Group. Held senior management positions in the Australian Consumers' Association and Greenpeace Australia. Former Director of the National Office for the Information Economy, the Public Interest Advocacy Centre and the Australian Bush Heritage Fund. Has extensive experience in the protection of consumer interests.



## APVMA Management

The APVMA's senior management team comprises the CEO and six program managers. The principal scientists provide support for management on complex scientific issues and in the maintenance of scientific standards. The management team and their areas of responsibility, as at 30 June 2003, are described below.



**Chief Executive Officer**  
**Dr Alison Turner**  
BVSc, MSc, Dip Vet Cl Stud, FAICD

The CEO consults with the APVMA's Board and main stakeholders to set the organisation's vision, objectives and strategies to meet its legislative responsibilities. The CEO's principal responsibilities are to oversee the preparation of strategic, financial and operational plans and budgets for Board approval; monitor financial and operational performance; and oversee program performance to ensure the APVMA meets its objectives.

A large part of the CEO's time involves communicating with stakeholders, including State and Australian government agencies, community groups, farming organisations and the chemical industry.

The CEO takes a leadership role for the organisation, particularly in ensuring that a quality service is provided to clients and customers.



**Program Manager, Corporate Services**  
**Tony de la Fosse**  
BA, MBA, Grad Dip HRM, GAICD

The Program Manager, Corporate Services, provides strategic advice to the APVMA CEO and Board on finance and administration, human resources, information services, information technology, public relations and strategic projects.

Key responsibilities include provision of timely and accurate financial data, and preparation of financial plans, budgets and strategies that maximise the organisation's ability to deliver quality services within the constraints of its funding.

The position is also responsible for the library, records management, archive system, web site administration, e-commerce initiatives and effective communication with stakeholders.



**Program Manager, Pesticides**  
**Dr Joe Smith**  
BSc(Hons), PhD, FRACI, GAICD

The Program Manager, Pesticides, has overall responsibility for management of the APVMA's activities related to the evaluation, registration and review of agricultural chemical products.

Key responsibilities include provision of timely services and management of issues related to the assessment of applications to register or permit the use of agricultural chemical products. The Program Manager is responsible for the ongoing review of existing products to determine whether they continue to meet contemporary standards and for continuous improvement to enhance the efficiency and effectiveness of the registration and review processes.

The position has responsibility for providing leadership and strategic advice to the CEO and Board in relation to agricultural chemicals and broader organisational issues as part of the APVMA Executive team.



**Program Manager,  
Veterinary Medicines**  
**Martin Holmes**  
BSc, G Dip PSM

The Program Manager, Veterinary Medicines, has overall responsibility for the APVMA's activities related to the evaluation, registration and review of veterinary medicines.

Key responsibilities include provision of timely services and management of issues related to the assessment of applications to register or permit the use of veterinary chemical products. The Program Manager is responsible for the ongoing review of existing products to determine whether they continue to meet contemporary standards and for continuous improvement to enhance the efficiency and effectiveness of the registration and review processes.

The position has responsibility for providing leadership and strategic advice to the CEO and Board in relation to veterinary chemicals and broader organisational issues as part of the APVMA Executive team.



**Program Manager,  
Quality Assurance and  
Compliance**  
**Peter Raphael**  
BSc(Ind Chem), MSc  
(Elec Eng)

The Program Manager, Quality Assurance and Compliance, is responsible for ensuring manufacturers and suppliers of agricultural and veterinary chemical products comply with the Australian registration requirements set out in the Agvet Code, and for programs that assure the quality of veterinary chemical products. This responsibility extends up to and includes the point of retail sale, after which State laws apply.

The position is also responsible for negotiation and management of the scientific and compliance service provision arrangements with various federal and State government agencies.



**General Counsel and  
Program Manager  
Legal  
and Governance**  
**James Suter**  
BA (Hons). LLB

The General Counsel is responsible for ensuring that the APVMA fulfils its legislative objectives, operates as an accountable organisation and can respond effectively to legal challenge. The position oversees the development of the APVMA's governing legislation and acts as the Corporate Secretary to the APVMA Board. The General Counsel is responsible for ensuring that Board decisions are lawful and that the Board complies with the *Commonwealth Authorities and Companies Act 1997*.

As Program Manager Legal and Governance, the position is also responsible for corporate governance and the provision of Board secretariat services.



**Program Manager,  
Chemistry and  
Residues**  
**Dr Trevor Doust**  
BSc, MACVSc, GAICD

The Program Manager, Chemistry and Residues, has overall responsibility for the evaluation of chemistry and residue data and the assessment of the potential risk to trade for chemicals used on food animals and crops. The position oversees the setting of maximum residue limits and withholding periods related to the use of chemicals in food commodities and is responsible for the approval of agricultural and veterinary active constituents included in registered products.



Principal Scientist,  
Veterinary Medicines  
**Dr Timothy Dyke**  
BVSc, Dip Vet Clin  
Studies, MVSc, PhD,  
FACVSc, Diplomate  
American College of  
Veterinary Clinical  
Pharmacology

The Principal Scientist, Veterinary Medicines, is responsible for maintaining and improving the quality of science within the Veterinary Medicines Division and for leading the provision of scientific advice in relation to veterinary medicines and animal health.



Principal Scientist,  
Agricultural  
Chemicals  
**Dr David Loschke**  
BSc, PhD

The Principal Scientist, Agricultural Chemicals, is responsible for maintaining and improving the quality of science from the Pesticides Division and for leading the provision of scientific advice in relation to pesticides across the APVMA.



Principal Scientist,  
Chemistry and  
Residues  
**Dr Phil Reeves**  
BVSc, PhD, FACVSc

The Principal Scientist, Chemistry and Residues, is responsible for maintaining and improving the quality of science from the Chemistry and Residues Program and for leading the provision of scientific advice in relation to chemistry and residues across the APVMA.





# REPORT ON PERFORMANCE

APVMA | ANNUAL REPORT





## APVMA outcome-outputs framework

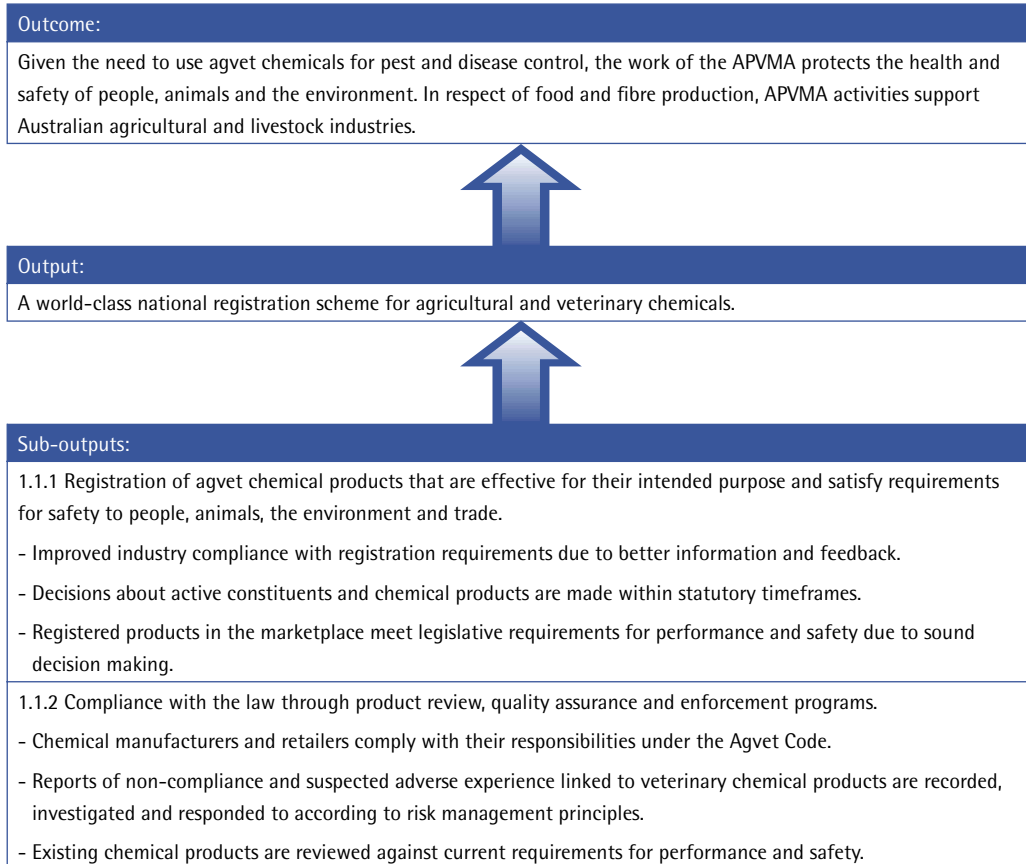
The APVMA has developed a performance framework that links its legislative objectives to an outcome-outputs model. This framework involves a detailed planning and reporting process incorporating the Portfolio Budget Statements, Corporate Plan, Operational Plan and Annual Report.

Central to the performance framework is the APVMA's outcome statement.

The APVMA achieves results consistent with the agreed outcome through delivery of the principal output which is supported by two sub-outputs. Each sub-output is supported by a number of individual performance measures.

The APVMA outcome-output structure for 2002-03 is set out in the diagram below.

The performance information contained in this report is presented in line with the output-performance measure structure. Progress in the realisation of each output is reported in terms of the nominated performance measures as well as other major achievements. The total funding employed in pursuit of the principal outcome was \$19.51 million. Staffing over the year (including contractors) averaged 128.



## Outcome performance report

The APVMA is conducting a research project to assemble data on the performance of the overall agricultural and veterinary chemicals regulatory system in working towards the agreed outcome. The performance is being assessed in terms of the regulatory system's impact on public health, worker exposure, environmental safety and trade. Research on environmental safety and trade has been completed while the data collection for public health and worker exposure is continuing.

### Public health

Relevant information that would be useful in providing feedback to the APVMA regarding the public health outcomes of the regulatory process has been identified and data has been collated and is now being critically examined. The aim was to collate five years of data.

Information relating to adverse health effects of pesticides exposure includes deaths, admissions to hospital and calls to Poisons Information Centres. In addition data relating to pesticides residues in food and in water supplies is being reviewed.

While the available data is generally lacking in the desired degree of specificity regarding particular products, preliminary examination suggests that the information will prove to be valuable to the APVMA in assessing the effectiveness of measures to protect the health and safety of the public.

### Worker exposure

Data relating to workers' compensation claims in all states is reported by the National Occupational Health and Safety Commission. Information relating to claims associated with exposure to plant treatments and animal treatments is being examined for a five-year period.

### Environmental safety

Data on environmental monitoring of pesticides conducted throughout Australia during 2000-2002 was collected from a variety of sources in an effort to obtain a national and regional picture. The data collected indicates that decades of pesticide use have resulted in detection of some pesticides in Australia's waters. Herbicides are the most commonly detected pesticides in surface water and shallow groundwater.

Importantly, pesticide monitoring found no evidence of the contamination of drinking water in Australia. Whilst there was some evidence of atrazine and molinate levels exceeding the respective drinking water health guideline value in some surface waters, these waters were not used as a drinking water source. Ten pesticides were reported which exceeded the ecosystem health guidelines, with atrazine exceeding the trigger values most frequently.

Overall, the results are encouraging in that the majority of the detections were below the Australian drinking water health guideline value. In addition, pesticide residue detections in Australian water resources were generally lower than those reported overseas.

### Trade

Australia conducts various programs to assess and mitigate trade risks and maintain access to markets for agricultural produce. The most significant of these in relation to residues of agricultural and veterinary chemicals is the National Residues Survey conducted by the Department of Agriculture, Fisheries and Forestry (DAFF).

The survey monitors around 30,000 randomly selected samples for residues in raw food commodities each year and the incidence of residues in excess of maximum residue limits reported in these surveys is extremely low. (See Table 1 below)

**Table 1: Percentage compliance with maximum residue limits for agricultural and veterinary chemicals in the National Residues Survey**

Commodity Group	1999-00	2000-01	2001-02
Meat products	99.98	99.98	99.87
Grain products	99.97	99.98	99.65
Horticultural products	99.98	99.96	98.83
Fisheries products	100.00	100.00	100.00

For chemical residues in food commodities, the rate of reported maximum residue limit violations is very low. This reflects the success of the measures put in place by government and industry to mitigate trade risks, a key element of which is the chemical product registration scheme operated by the APVMA.



## Output 1.1.1. Registration of agvet chemical products that are effective for their intended purpose and satisfy requirements for safety to people, animals, the environment and trade

*Improved industry compliance with registration requirements due to better information and feedback.*

### **Product registration requirements**

In addition to its ongoing evaluation and registration activities, the APVMA continued its program of reviewing and updating its advisory documentation. By providing this information, the APVMA aims to assist industry to satisfy legislative requirements for product registration and label approvals. This information is developed in consultation with industry, the states and the broader community, with all guidelines being published on the APVMA web site.

A number of new guidelines were drafted in the past year, including those for:

- promotional packaging;
- registration of products used on sperm and ova;
- registration of veterinary complementary medicines;
- administrative label amendment registration applications (category 38 & 39); and
- post-harvest treatments.

The APVMA is progressing a major review of the Agricultural and Veterinary Chemicals Labelling Codes, in conjunction with the states and other stakeholders. The aim of this review is to facilitate compliance with State control-of-use legislation and improve consistency and clarity of labels for users of chemical products.

### **Low regulatory system**

Under the existing Agvet Code, all agricultural and veterinary chemicals are subject to the same regulatory assessment process, irrespective of the hazards or risks they pose. Amendments to the Agvet Code to be proclaimed late in 2003 will introduce a low regulatory framework for lower risk products.

Under the low regulatory system the APVMA can reduce the regulatory burden on certain lower risk products by granting either:

- listed registration against a pre-determined standard; or
- reservation from registration, according to pre-determined conditions.

Products which may be suitable for listed registration include swimming pool chemicals, dairy detergents and sanitisers, aquarium products, medicated shampoos, and some pet foods which make therapeutic claims. Products that may be suitable for reservation from registration include lime when used as a fungicide, and citronella candles.

Benefits of the scheme will include lower costs of registration for these low risk products, reduced time for registration, and liberation of resources to enable the APVMA to focus more on higher risk matters.

Standards for listed registration and conditions for reservation from registration must be approved by the Minister and will be incorporated into Regulations to the Agvet Code. During the year industry and the APVMA have worked together to draft some initial standards and conditions, ready for introduction of the new system in late 2003.

### **International collaboration**

The APVMA adopted seven more International Committee for Harmonisation of Technical Requirements for Registration of Veterinary Medical Products (VICH) guidelines. Their adoption is consistent with the APVMA's commitment to international harmonisation of requirements for the registration of veterinary chemical products. Australian and New Zealand regulators have observer status on VICH and continued to contribute in relation to food safety, ecotoxicity, veterinary biologicals, antibiotic resistance, target animal safety and pharmacovigilance. All currently agreed VICH guidelines are available on the APVMA web site.

The APVMA also actively engaged in the work of the Organisation for Economic Cooperation and Development (OECD) Working Group on Pesticides and its related committees. The working group aims to facilitate common international approaches to pesticides regulation, through development of common evaluation and testing guidelines and promoting work-sharing

among member countries. During the year guidelines on microbial pesticides, endocrine disruptors, persistent bioaccumulative pesticides, and leaching of timber preservatives were progressed. In line with its own efforts in this area, the APVMA participated in OECD projects to harmonise requirements for electronic submission of registration applications. The APVMA also jointly evaluated a major new insecticide application with Canada and the USA.

### ***Minor uses and permits***

The APVMA continued to strengthen links with peak grower industry groups, with an emphasis on informing industries of data requirements and increasing understanding of processes and priorities to effectively address minor use needs through permits and/or registration.

In particular, the APVMA has worked with Crop Protection Approvals, Horticulture Australia, and Queensland Fruit and Vegetable Growers to explore ways to increase the efficiency of the permit scheme for minor use crops. One of the main aims is to reduce the fragmented approach to permit submission and consolidate the efforts of growers from the same industries by submitting a combined industry permit to cover a particular pest/disease instead of issuing permits to individual growers. In 2002–03 approximately 130 potential projects were screened by the APVMA and advice provided on data requirements. Efforts are also needed to coordinate advice and trial work proposals from the chemical companies for the minor use industries.

The APVMA regularly provided advice on requirements to the Jay 4 Grains Chemical Registration project, funded by the Grains Research and Development Corporation, with a view to assisting industry to understand requirements for data to support registration and/or Minor Use Permit applications.

The APVMA continued to implement outcomes of the Permits Review, including gazettal of Guidelines for Determining Emergency Uses and Research Purposes; and Guidelines for Determining Minor Uses.

### ***Chemistry and residues requirements***

The APVMA contributed to the Safemeat Drought Feeding Group that met fortnightly and managed

residues issues during the current drought. The APVMA assisted with technical risk assessments for unusual feeds, namely cotton trash, apple pomace, citrus pulp, grape pomace, vegetable wastes, cereals, legumes, peanuts and pineapples.

Consultation with stakeholders is now proceeding on the following guidelines that were developed by the Chemistry and Residues Program during 2002–03:

- Milk Maximum Residues Limits and Withholding Periods;
- Poultry Residue Data Requirements;
- Residues at Injection Sites;
- Stability Data for Veterinary Chemical; and
- Validation of Analytical Methods.

Guidelines for Starter Culture Data for Antimicrobial Products were finalised in 2002–03.

APVMA officers visited Asian vegetable, lettuce and cucumber growers and dairy and poultry producers during 2002–03. The visits gave the APVMA a better understanding of these industries and their needs, and the growers an understanding of what the APVMA does and how it can assist them. As a result of the visits and articles published, there was an increased ability of grower groups to utilise the APVMA's Minor Use Permit process and to understand residues-in-trade issues.

APVMA officers developed and coordinated the Australian delegation response to the Codex Committee on Pesticide Residues regarding the revision of the Codex Classification of Foods and Animal Feeds. Responses from State Departments of Agriculture, industry groups and consultants allowed Australia to provide a list of minor crops and other commodities which are currently not included in the Codex classification. Work on classification of minor crops, particularly Asian vegetables, is ongoing.

The requirement for Good Laboratory Practice (GLP) data requirements for residue trials commenced on 1 January 2003. The requirements for GLP are not mandatory for trials relating to permit approvals or for registration of minor crop uses. GLP training sessions for APVMA evaluators were provided by the National Association of Testing Authorities (NATA) followed by participation by APVMA evaluators in GLP audits conducted by NATA.



Consultation with the cattle industry continued on a range of issues, including labelling, community vendor declarations, national vendor declarations, old chemicals without grazing intervals and/or slaughter intervals on labels, prohibitions on labels, feeding of processed by-products and the setting and management of export slaughter intervals.

The APVMA also met with:

- the Australian Quarantine and Inspection Service to discuss hormonal growth promotant (HGP) use in cattle;
- the National Working Party on Grain Protection on chemicals for control of insects in stored grain;
- the Grains Research and Development Corporation to progress permits and registration for minor and major uses for cereal, oilseed and pulse crops; and
- State coordinators and the National Residue Survey to discuss residue, minor use, monitoring and surveillance issues in horticulture.

### ***Increasing stakeholder awareness***

APVMA staff gave presentations at conferences on many areas of the APVMA's responsibilities. These presentations are an important part of increasing awareness and understanding of the APVMA's roles and requirements for registration of agvet chemicals. In addition to the APVMA Industry Registration Seminars, presentations were given at SnackFruit 2002, MANIC 2002, the Low Chill Stonefruit Conference, the Biological Farmers Association National Conference, the RSPCA Scientific Forum on Animal Welfare in Relation to Vertebrate Pest Control, the Australian Postharvest Technical Conference, the Aerial Agriculture Association of Australia Conference, and international conferences such as the London Agchem

Forum and the Second Conference on International Harmonisation of Veterinary Medicinal Products held in Tokyo.

### ***Decisions about active constituents and chemical products are made within statutory timeframes.***

#### ***Finalisation of agricultural and veterinary chemical product registration applications 2002-03***

The APVMA began the year with 1212 applications in process for registration, variation of registration, or label approval of either agricultural or veterinary chemical products. An additional 3261 applications were received during the year, a substantial increase (601 or 22.6 per cent) over the previous year.

The APVMA finalised 2958 applications for registration, with 1516 applications in process at 30 June 2003. Of the applications finalised, 97.2 per cent were completed within statutory timeframes. This compared to 2529 finalisations, with 96.2 per cent finalised within timeframes, during the previous year.

The tables below include only those applications for which a statutory timeframe can be determined.

The APVMA's major review of all key business processes associated with screening, evaluation and finalisation of product and permit applications was completed, and revised processes which aim to improve effectiveness and efficiency are now being implemented.

#### ***Finalisation of permit applications 2002-03***

The APVMA commenced the year with 337 applications for permits in process. During the year a record number of applications (1054) were received. Of these, 797

**Table 2: Agricultural product registrations**

Class of application	Total no. registered or approved	No. finalised or approved vs statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		within timeframe	up to 20% above timeframe	>than 20% above timeframe		
15 month	4	2	2	0	15.1	23.5
8 month	97	72	17	8	7.4	15.1
6 month	2	1	0	1	8.8	11.7
5 month	69	52	8	9	4.2	8.5
3 month	1484	1481	1	2	0.4	2.2
<b>Total</b>	<b>1656</b>	<b>1608 (97.1%)</b>	<b>28</b>	<b>20</b>		

**Table 3: Veterinary product registrations**

Class of application	Total no. registered or approved	No. finalised or approved vs statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		within timeframe	up to 20% above timeframe	>than 20% above timeframe		
15 month	4	4	0	0	13.6	37.5
13 month	1	1	0	0	11.9	31.3
12 month	1	1	0	0	11.3	47.1
8 month	63	58	2	3	6.3	12.6
6 month	2	1	0	1	7.4	19.3
5 month	109	91	14	4	3.6	8.3
3 month	889	888	0	1	0.5	2.8
<b>Total</b>	<b>1069</b>	<b>1044 (97.7%)</b>	<b>16</b>	<b>9</b>		

(75.6 per cent) were for agricultural chemicals, 248 (23.5 per cent) were for veterinary chemicals and nine (<1 per cent) were for both agricultural and veterinary chemicals.

The APVMA finalised 948 applications of which 750 (79.1 per cent) resulted in the issue of a permit, 56 (5.9 per cent) did not require a permit, 134 (14.1 per cent) were withdrawn and eight (<1 per cent) were rejected because they did not satisfy the legislative criteria. The total number of applications in progress at the end of the year was 443.

A total of 123 emergency use applications were finalised, including permits for the control of silverleaf whitefly in several broad-acre and horticultural crops, and red imported fire ants in Queensland.

Approximately 87.2 per cent of applications (excluding emergencies) were finalised (permit issued or rejected) within the statutory timeframe. The average time taken to complete 90 day applications (which comprise 66.2 per cent of the total finalised) was 39 days and 240 day applications (27.3 per cent of the total finalised) 79 days.

An organisational restructure in August 2002 facilitated better alignment of permit and registration processes.

#### **Agricultural product permit applications**

Approximately 80 per cent of applications received were for Minor or Emergency Use permits and 20 per cent for research permits. The majority of applications received for Minor or Emergency Use permits were for vegetable (30 per cent) and fruit (24 per cent) crops. Other significant industry requests were for grains, oilseeds and

pulse crops (10 per cent), non-crop (13 per cent), nut crops (5 per cent) and forestry (4 per cent).

Permit applications for insecticides accounted for the highest proportion (50 per cent) followed by herbicides (30 per cent) and fungicides (20 per cent).

For a number of years the APVMA has encouraged the coordinated submission of Minor Use Permit applications via peak industry bodies. In 2002–03, approximately 45 per cent of applications for Minor and Emergency Use permits were received from peak industry bodies. Of these, Crop Protection Approvals Ltd and Queensland Fruit and Vegetable Growers accounted for approximately 25 per cent of total applications received, and a significant 46 per cent of all fruit and vegetable applications lodged with the APVMA. The work of these two organisations and other peak bodies in coordinating permit applications has increased significantly over the last few years, enhancing access to crop protection products for minor uses.

#### **Veterinary product permit applications**

Approximately 73 per cent of applications received were for minor or emergency uses and 27 per cent for research purposes, mostly in relation to autogenous vaccines. Of veterinary permits issued, approximately 26 per cent were for research purposes including three new active constituents being tested under practical field conditions; 20 per cent were to allow export of unregistered products; 51 per cent for uses including minor uses and extensions to shelf-life for batches of registered products and 3 per cent for emergency uses. The emergency use permits included control of clinical



avian encephalomyelitis in poultry, equine protozoal myoecephalitis, idiopathic vasculitis in dogs and paralysis ticks in cattle. Permits for vaccines/antibiotics accounted for the highest proportion (50 per cent) followed by parasiticides and nutrition (35 per cent) and veterinary ethicals (15 per cent).

### ***Chemistry and residues evaluation statistics***

The APVMA conducted chemistry evaluations of 150 active constituents and 255 agricultural and veterinary chemical products as well as 71 residues evaluations for agricultural and veterinary products during 2002–03. Of these, 95 per cent were finalised within statutory timeframes.

An agreed protocol was followed in the evaluation of the dietary risk associated with the use of an agvet chemical on food crops or food animals. This means that, before the APVMA registers a chemical product, all associated food safety issues must have been addressed to the satisfaction of Food Standards Australia New Zealand.

Applications for residue evaluations for agricultural and veterinary permits increased 90 per cent from the previous year (239 versus 126) and finalisation of residue evaluations increased by 79 per cent (222 versus 124).

### ***Gene Technology Regulator***

The APVMA worked closely with the Office of the Gene Technology Regulator (OGTR) in relation to regulation of agricultural and veterinary chemicals which contain or may be used on genetically modified materials. Where an agricultural or veterinary chemical product is based on gene technology or includes a product of gene technology, the APVMA is required to advise and consult with the OGTR. Conversely the OGTR seeks APVMA advice in relation to relevant applications made to it. The APVMA has worked with the OGTR to ensure process overlaps are managed effectively and efficiently, and has signed a memorandum of understanding to cover cooperation between the two regulators. Throughout the year, the APVMA liaised with the OGTR in relation to the regulation of genetically modified cotton, and herbicides to be used on genetically modified canola.

### ***Trade assessments***

The National Registration Scheme legislation requires that the APVMA be satisfied about a range of criteria relating to the use of registered agricultural or veterinary chemical products. The legislation also requires that use of products will not cause undue prejudice to Australia's trade. This criterion requires an evaluation of scientific, political and economic factors as they impact on trade. Accordingly, the APVMA has enhanced its formal evaluation procedure for trade considerations. A risk-assessment process and amended guidelines for the submission of data to satisfy the trade assessment were implemented following consultation with the chemical and user industries and state and territory Departments of Agriculture during 2002–03.

### ***Registered products in the marketplace meet legislative requirements for performance and safety due to sound decision making.***

#### ***Product registration and permit approval***

Each type of application processed during the year was evaluated in accordance with legislative requirements and published guidelines. APVMA evaluators conducted most of these evaluations and were responsible for overall registration decisions. Where necessary, external assistance was provided on issues of toxicology, public health, occupational health and safety, and the environment, by the following specialist government agencies:

- Department of Health and Ageing (Office of Chemical Safety in the Therapeutic Goods Administration);
- National Occupational Health and Safety Commission; and
- Department of the Environment and Heritage.

Where new chemicals or major new uses were being assessed advice was also obtained from the states in relation to efficacy, and crop and animal safety.

When the APVMA receives an application to register totally new chemical products based on new active constituents or major variations to the usage of currently registered products broad public consultation is undertaken through the publication of Public Release

Summaries and Trade Advice Notices. These documents are freely available to the public and interested organisations (including peak industry bodies in relation to possible impacts on trade) who are invited to comment on applications before the APVMA makes its final determination.

All internal processes, including the relationships with Commonwealth agencies and the states, are fully documented and subject to constant monitoring by external and internal auditors. These audits form the basis of continuing APVMA accreditation to AS/NZ ISO standards.

### ***Chemistry and residue evaluation***

The APVMA performs assessments on new and generic chemicals before their approval for sale. In particular, the manufacturing process, and the purity and content of chemicals are assessed to ensure compliance with the relevant standards. In this way, consistent profiles relating to efficacy, public health and environmental issues can be ensured for chemicals from different sources, and between batches from the one source.

Residue and trade assessments must demonstrate that products can be used safely and properly in the market place, including demonstrating the safety of potential residues in food, before registration is granted. Assessment of the latter involves toxicological evaluation (conducted by the Therapeutic Goods Administration), maximum residue limit evaluation, and a dietary exposure evaluation. Monitoring of residues in agricultural commodities occurs post-registration for compliance with maximum residue limits.

For 2002–03, the National Residue Survey reported that the rates of compliance with Australian maximum residue limits applying to agvet chemicals were 99.96 per cent for meat products, 99.92 per cent for grain products, 100 per cent for horticultural products, 100 per cent for fish products, 100 per cent for honey and 99.4 per cent for poultry.

### ***Trade***

A key objective of trade assessments is to ensure that Australian trade with other countries will not be prejudiced unduly as a result of product registration. During the year, the APVMA consulted with DAFF, SAFEMEAT and the states on a range of options for assessing risks related to residues in trade. Feedback

from this process resulted in amendments to Part 5B of the Requirements Document (Overseas Trade Aspects of Residues in Food Commodities) being implemented in 2003.

### ***International standards***

APVMA officers were active in the Codex Alimentarius Commission (Codex) and the Collaborative International Pesticides Analytical Council. APVMA officers chaired the Priorities Working Group meetings at the Codex Committee on Pesticide Residues and the Codex Committee on Veterinary Drug Residues in Foods, and completed technical evaluations for the Food and Agriculture Organization and World Health Organization's Joint Expert Committee on Food Additives and Contaminants.

The Collaborative International Pesticide's Analytical Council is the international body responsible for developing and publishing the standardised methods of analysis for pesticide products after extensive collaborative testing. Analytical methods described in the council's handbooks are used by the APVMA for determining compliance with pesticide specifications.

The APVMA also participated in a Food and Agriculture Organization/International Atomic Energy Agency meeting in October 2002 to plan training workshops for laboratory personnel from developing countries involved in the analysis and management of residues of veterinary drugs in food. The APVMA will participate as a trainer in the workshops to be held in 2003–04.

### ***Environment Protection and Biodiversity Conservation Act 1999***

In evaluating applications for registration of chemical products, one of the key areas the APVMA examines is the effect on the environment. The APVMA utilises the independent expertise of Department of the Environment and Heritage when undertaking environmental assessments, through an interagency service level agreement between the APVMA and the department. Use of registered products is appropriately controlled or restricted where there is a need to manage environmental risks.

The department's advice is not in derogation of any obligations on users under the *Environment Protection and Biodiversity Conservation Act 1999*. Under the Act, users must not take any action that may have a



significant impact on matters of national environmental significance such as nationally threatened species and ecological communities. Particular use of a chemical could therefore require separate assessment and approval under the *Environment Protection and Biodiversity Conservation Act 1999*.

## *Other major achievements*

### ***Organisational structure – integration and quality***

A new organisational structure was implemented this year. A key feature in relation to the registration programs was a greater integration of registration and permit functions, with the objective of achieving greater consistency between permit and registration processes. Similarly, the veterinary and pesticides review teams have been integrated with the registration program, to facilitate greater dialogue and awareness between the two areas.

The restructure also saw the creation of three new principal scientist roles in the Pesticides and Veterinary Medicines Divisions and Chemistry and Residues Program, for which a major priority has been the introduction of new quality review and improvement programs.

### ***Implementing international agreements***

The APVMA played a role in implementing international agreements. Advice was provided to government on the phase-out of the fumigant methyl bromide in accordance with the Montreal Protocol, and claims for critical use exemptions under the protocol were evaluated. Consistent with Australia's commitments to the International Maritime Organization, the APVMA worked with industry and other areas of government and product registrants to implement a voluntary phase out of all registrations of all marine uses of tributyltin based products.

### ***Trade Advice Notices***

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 notices are distributed to farm and commodity organisations, seeking comment. Sixteen Trade Advice Notices were released for public consideration in 2002–03.

### ***Public Release Summaries***

Public Release Summaries summarising evaluations and outlining all proposals to register new products with new active constituents are published by the APVMA. The summaries facilitate comment by the public on registration proposals. The summaries include the outcome of all assessments undertaken and any conditions the APVMA proposes to apply to the use of the product. During the year, six Public Release Summaries were published.

### ***Stockfeed guidelines***

The APVMA continued work on a four-year project to prepare a series of stockfeed guidelines. A further 18 guidelines (Animal Residue Data Sheets) were prepared in 2002–03 and 24 of these guidelines have now been posted to the APVMA web site. The guidelines determine acceptable feeding levels for animals consuming a commodity treated with chemicals, and this information will be available for farmers and stockfeed manufacturers to use when formulating animal diets. Appropriate use of the guidelines will facilitate risk management of diets containing chemical-treated commodities, and reduction in the risk of unacceptable residues in animal produce.

### ***Industry registration seminars***

Following the successful series of registration seminars in 2001–02, the APVMA agreed to conduct a formal program of registration seminars each year. A comprehensive two-day seminar for registrants and prospective registrants was held in Canberra in May 2003, and was designed to assist industry to understand APVMA data requirements and processes. One hundred participants attended this seminar, which was extremely well received.

### ***Scientific assessment services***

Service level agreements were re-negotiated with the Office of Chemical Safety (within the Therapeutic Goods Administration), National Occupational Health and Safety Commission and the Department of the Environment and Heritage who provide specialist advice to the APVMA. The service level agreements specify a defined level of performance and quality criteria, and have a fee-for-service basis. The APVMA finalised a memorandum of understanding with the Gene Technology Regulator to cover interactions between the agencies. The APVMA is currently negotiating a memorandum of understanding with the Expert Advisory Group on Antimicrobial Resistance.

### ***Agricultural chemical active constituents and products quality assurance***

During 2002–03 the APVMA progressed development of a scheme to enhance the quality of agricultural chemical products, to be introduced during 2003–04. Approval of active constituents is proposed to be based on their meeting a specified standard, and not depend on the source of the active constituent. The APVMA proposes to assess the quality of the active constituent in a product at the time of product registration. The APVMA intends to publish standards for active constituent approvals, and apply conditions of registration which require the product registrant to be responsible for maintaining the quality of the active constituent and the product.

This proposed scheme provides a unified system for approval of both agricultural and veterinary active constituents and will place the emphasis on the quality of the active constituent rather than the source of the active constituent. The scheme will increase the robustness of the regulatory process for agricultural chemical products.

### ***Data protection***

The Government has proposed the introduction of a new data protection scheme to enhance the current data protection provisions in relation to agvet chemical products. Currently, data submitted to the APVMA by primary registrants can, in some cases, be cross-referenced in the registration of image products (generic formulations) at no cost to the generic registrant. In these cases, the cost of generating the original data is borne solely by the primary registrant.

In anticipation of the introduction of a new data protection framework, and to be able to administer the new scheme once legislation is enacted, the APVMA has already undertaken a project to develop appropriate processes. These processes will be developed further when the precise nature of the proposed new framework is clear.





## Output 1.1.2 Compliance with the law through product review, quality assurance and enforcement programs.

*Chemical manufacturers and retailers comply with their responsibilities under the Agvet Code.*

### **Manufacturers' Licensing Scheme – promoting Good Manufacturing Practice**

The Manufacturers' Licensing Scheme is a quality assurance program that was established in 1996 in response to concerns over the quality of veterinary chemical products. Industry and government recognised that quality needs to be 'built into' rather than 'tested into' products. The primary objective of the scheme is to assure the quality of veterinary chemical products manufactured and supplied in Australia. To obtain and maintain a licence under the scheme, manufacturers must demonstrate compliance with the APVMA's Manufacturing Principles and the relevant Australian Code of Good Manufacturing Practice. Compliance is confirmed by regular audits by APVMA-authorized auditors or specified authorities recognised by the APVMA.

For veterinary chemical products manufactured overseas, the registrant must demonstrate that the product is manufactured to quality standards comparable to those applying to veterinary chemical products manufactured in Australia.

At 30 June 2003, the number of Australian-based manufacturers (including new applications) was 241. Table 4 shows manufacturers distributed according to category.

Table 4: Numbers of manufacturers licensed, or being assessed for a licence, under the Manufacturers' Licensing Scheme, by category, at 30 June 2003

Category of manufacturer	No. of manufacturers
1. Sterile and immunological products	43
2. Non-sterile (other than Categories 3 and 4)	93
3. Ectoparasiticides	14
4. Feed supplements and premixes	31
6. One-step manufacturers (labelling, packaging, analysis and testing etc.)	60
<b>Total</b>	<b>241</b>

As part of the registration process for veterinary medicines, overseas-based manufacturers are assessed for their compliance with Australian Good Manufacturing Practice (GMP) standards. During 2002-03, 129 such applications were assessed for compliance with Australian GMP standards.

The management of the Manufacturers' Licensing Scheme was closely integrated with the APVMA's recall, adverse experience and compliance programs and a firm approach is being taken with manufacturers who fail to comply with required standards. More stringent conditions have continued to be imposed on all new and existing licences to improve compliance and overcome excessive delays. As a consequence of these and other initiatives, only two manufacturers still hold conditional licences, issued at commencement of the scheme. At 30 June 2003, 11 per cent of licensed manufacturers were in the process of either applying for a new licence, changing site or changing ownership as a result of significant corporate activity within the veterinary chemical manufacturing industry.

The APVMA continued to provide assistance to industry, primarily through feedback to enquiries and follow-up to audits.

### ***Monitoring and control of hormonal growth promotant products***

The European Union requires continued assurance from Australia that beef and beef products imported into its member states have not been treated with hormonal growth promotant (HGP) products. To provide this assurance, the Commonwealth and state governments have put in place the National Hormonal Growth Promotant Monitoring and Control System.

The system enables Australian authorities to account for the importation, supply and use of HGPs. The APVMA plays a significant role in the operation and management of the system by authorising importers and resellers, and requiring that accurate records of supply be kept. At 30 June 2003, there were 178 APVMA-authorised suppliers.

The APVMA continued to operate a compliance audit program of authorised HGP suppliers. The frequency of audit is determined on a risk basis and includes verification or a follow-up audit to confirm implementation of major corrective actions identified during the first visit. During the year, the APVMA audited 69 HGP authorised suppliers (both retailers and wholesalers). A total of 96 per cent of the suppliers were found to be compliant (either on the first or follow-up visit) with 49 per cent being issued with a warning and being subject to an increased audit frequency.

### ***Monitoring and control of imported agricultural and veterinary chemicals***

Under the Administration Act it is an offence to import an unregistered chemical product or an unapproved active constituent into Australia. The APVMA therefore focuses its efforts on the import barrier in limiting the distribution of unregistered and unapproved chemicals in the Australian marketplace. This effort has recently been strengthened with closer links to the Australian Customs Service through exchange of information relating to enforcement of importation laws. Where a legitimate reason exists for a person or company to have possession of unregistered and unapproved chemical products in Australia, the APVMA issues a Consent to Import. The APVMA does not issue permits in contravention of schedule 9 of the Customs (Prohibited Imports) Regulations 1956 for organochlorine compounds.

In 2002–03, the APVMA assessed 229 applications, of which 177 were issued Consents to Import. The primary reason for importation was for use in research trials.

### ***Reports of non-compliance and suspected adverse experiences linked to veterinary chemical products are recorded, investigated and responded to according to risk management principles.***

#### ***Reports of non-compliance***

The APVMA encourages industry and the public to report the advertising and supply of unregistered and unapproved chemicals or any promotion of products that is inconsistent with their approved label. All reports received are acknowledged and assessed for action on the basis of the risk posed by the chemicals involved. Risk is based on the potential or actual harm to the environment, human or animal health or trade with other countries.

The reports assessed as representing a potential or actual high risk are dealt with by an inquiry that may escalate to an investigation, with a view to prosecution or product recall. Those assessed as representing a low to medium or continuing risk are dealt with mainly by warnings and negotiation to achieve compliance. During the year, 297 new reports were received. Of these 60 per cent were assessed as low risk, 32 per cent as medium or continuing risk, and 8 per cent as high risk.

A total of 247 reports were finalised during the year through warnings and negotiated compliance. Nine were referred for processing as a product recall and eight were considered for investigation.

#### ***Investigations and recalls***

During the year, the APVMA initiated ten investigations with a view to prosecution. Eight investigations were completed, with one being dealt with by a warning letter, and six by negotiated compliance or by being closed due to insufficient evidence to support any further action. One investigation was referred to the Director of Public Prosecutions.



One prosecution was completed with the following outcome. Acting on advice from a State government authority, the APVMA conducted an investigation into the supply of an unregistered pesticide containing pyrethrum. Pestech Australia Pty Ltd continued to supply the product known as Py-Bo after receiving a warning from the APVMA. The company pleaded guilty to three counts of supply of an unregistered product and one of communicating misleading information and was fined.

The APVMA provided assistance to industry and monitored conduct of 18 voluntary recalls that were completed during the year. The APVMA also managed five compulsory recalls as follows:

- The APVMA review outcome of September 2002 required that all products containing endosulfan bear an additional label setting out prohibited uses, new withholding periods for existing uses and precautions for dealing with treated stockfood. The APVMA issued recall notices to registrants and their distributors to ensure that all existing stock was correctly labelled and that purchasers of the stock during the preceding 12 months were provided with a copy of the amended instructions. APVMA staff conducted monitoring visits to distributors to ensure compliance with the recall notices.
- Specific batches of Trisoprim Antibacterial Tablet, Illium Pyraquantel Allwormer Tablets for Dogs, Troy Wormex Allwormer Tablets for Dogs and Double Strength Cosequin DS Double Strength Sprinkle Capsules for Dogs were recalled following the suspension of the APVMA manufacturing licence for Pan Pharmaceuticals Ltd. The APVMA could not be satisfied that batches of product manufactured by Pan after May 2002 would not have an unintended effect that could be harmful to animals treated with the products.
- Batches of Allfire Triasulfuron Herbicide were recalled following the detection of the contaminant quinoline. The APVMA could not be satisfied that the presence of quinoline in the formulation would not be an undue hazard to people exposed to it during its handling or people using anything containing its residues. The contaminated product has been returned to the country of origin.
- The review of diazinon products resulted in the voluntary recall of several diazinon products that did not contain an adequate stabiliser and the

compulsory recall of David Gray's Lawn and Insect Killer. In the case of these recalls the APVMA had determined that diazinon products based on hydrocarbon solvents formulated without an adequate concentration of stabiliser could degrade to toxic breakdown products over time, particularly if the contents of the container were mixed with a small amount of water. Such products were considered to be a risk to public health and animal safety.

### ***Quality assurance for agricultural products***

A significant proportion of investigations and recall actions in recent years have been associated with products which, while registered, were found in the marketplace not to comply with specifications established at time of registration. This experience reinforces the findings of a project reported in the 2001–02 Annual Report, which pointed to the need to strengthen quality assurance arrangements for active constituents and formulated agricultural products.

To progress this matter, the APVMA will shortly issue a new guideline giving registrants and contract formulators guidance on measures they can adopt to ensure marketed products continue to meet the specifications established at registration. At the same time, the APVMA is working to develop an approach to the approval of active constituents for agricultural products.

### ***Adverse Experience Reporting Program for Veterinary Chemicals***

The APVMA's Adverse Experience Reporting Program for Veterinary Chemicals (AERP Vet) is a quality assurance program established by the APVMA to facilitate responsible management of veterinary chemical products throughout their lifecycle. The aim of the AERP Vet is to ensure that products on the market remain safe and effective, are of acceptable quality and are used in the best possible way, and that instructions and warnings on labels are appropriate. Information received regarding suspected adverse reactions or 'adverse experiences' may identify a need for corrective action with respect to the product label (e.g. additional instructions, warning statements or precautions), manufacturing process, formulation, batch recall or review of registration, or education of the veterinary profession and the general public (via mechanisms such as articles in journals and publications) in better use or safety practices.

The scope of the AERP Vet is broad and covers adverse experience reports involving:

- human health issues;
- animal health issues, including domestic and native birds and animals;
- trade and residue issues;
- environmental damage; and
- lack of efficacy.

A major review of the AERP Vet was completed in 2002 and resulted in a number of significant changes to the operation of the program. These changes were aimed at ensuring that the APVMA meets international best practice for assessing and classifying adverse experience reports and determining what, if any, corrective action is required. The changes have resulted in improved efficiency of the program and more targeted outcomes. As a direct result of this improvement in efficiency, the APVMA has conducted a retrospective analysis of all adverse experience reports that were received since 1995 and published these in a combined report for 1995 to 2003, which is available on the APVMA web site at [http://www.apvma.gov.au/qa/aerp1995\\_2003.pdf](http://www.apvma.gov.au/qa/aerp1995_2003.pdf).

During 2002–03 over 2500 adverse experience reports involving use of veterinary medicines were assessed, classified and appropriate corrective action taken. This is a significant improvement in the efficiency of the program over previous years, due to streamlining of the procedures used for processing reports.

The outcomes of the AERP Vet for 2002–03 included:

- two nominations for chemical review,
- four label changes,
- one enforcement/public action (e.g. recall).

The AERP Vet continues to provide a valuable post-market surveillance role in monitoring the safety and efficacy of veterinary medicines provided to animal industries in Australia.

### ***Adverse Experience Reporting Program for Agricultural Products***

The APVMA will be introducing a program similar to the AERP Vet for agricultural products (to be known as the AERP Ag) in 2003–04. The objectives of the AERP Ag are essentially the same as the AERP Vet's objectives, i.e. to help ensure that when used correctly products on the market remain safe, effective, are of acceptable quality, are used appropriately and that instructions

and warnings on labels are appropriate. The APVMA acknowledges that it is important for the community to be able to report any problems that they experience with such products and to have them investigated and appropriate action taken.

Because there is a much wider public awareness of and potential exposure to the use of agricultural chemical products, it is expected that the AERP Ag will have a greater focus on public health issues and outcomes than has been the case with the AERP Vet.

An information package explaining in detail the purpose and objectives of the AERP Ag, and an outline of how the program will operate and what the outcomes will be, is available on the APVMA web site at <http://www.apvma.gov.au/qa/aerp.shtml>.

### ***Existing chemical products are reviewed against current requirements for performance and safety.***

At 30 June 2003, the Chemical Review Program had 29 ongoing reviews in hand. Fifteen of these are comprehensive reviews, covering all aspects of the respective active constituent, products and labels. Fourteen reviews focus on more specific aspects of products and/or their labels, some covering groups of products based on different active constituents. During the year three reviews were completed, of which one resulted in the cancellation of certain products while two resulted in voluntary cancellations of registrations. Draft reports for two further reviews were released for public consultation (see Table 5).

**Table 5: Chemical reviews completed or released for public comment in 2002–03**

Chemical review	Stage
Bioresmethrin	Voluntary cancellation
Diazinon	Draft for public release (active constituents, products and labels)
Diazinon	Complete Part 1: product cancellations
Mevinphos	Complete
Triforine	Voluntary cancellation and product recall
Virginiamycin	Draft for public release



Nine chemicals were selected for review during 2002–03. Eight reviews commenced (see Table 6) and the remaining review is scheduled to commence in October 2003. A comprehensive Review Scope Document was prepared and published for each of the reviews that has commenced and is available from the APVMA web site. The scope document details the background to a review including the reasons for review and the aspects of active constituent approval, product registration and/or labels that are to be examined.

**Table 6: Chemical reviews initiated in 2002–03**

Chemical review	Stage
Arsenic timber treatments*	Data call-in
Carbon disulfide*	Data call-in
Diuron*	Assessment
Fenamiphos*	Data call-in
Maldison (Malathion)*	Data call-in
Molinate*	Data call-in
Triforine	Voluntary cancellation and product recall
2, 4 D*	Data call-in

\* Review Scope Document available on APVMA web site.

### ***Diazinon review – Part 1: product cancellations***

The review of the insecticide diazinon, one of the most widely used insecticides in Australia, was announced in December 1996 as part of the APVMA's second cycle of Existing Chemical Review Program reviews. The review has reconsidered all the active constituent approvals of diazinon, the registration of all products containing diazinon and the approval of the associated product labels.

Draft reports of the APVMA's findings from its review of existing data for diazinon were released in August 2000 and September 2002. The draft reports detailed a range of concerns with the ongoing use of diazinon, most notably with the continued registration of a limited range of products.

In April 2003 the APVMA completed the review of certain diazinon products that are hydrocarbon-based formulations without adequate stabiliser. Diazinon products based on hydrocarbon solvents formulated

without added stabiliser can degrade to toxic breakdown products over time, particularly if the contents of the container are mixed with a small amount of water. It was concluded that such products are a risk to public health and animal safety. Therefore the APVMA suspended and/or cancelled registration and label approvals of affected products, and initiated appropriate recall action.

In addition, the APVMA determined that certain diazinon products, while containing adequate stabiliser, nonetheless pose a risk to the environment, as the use of diazinon products as dog and kennel liquid flea treatments may have an unintended effect that is harmful to the aquatic environment, particularly if the concentrate or wastewater containing used product is allowed to enter waterways. In this case the APVMA cancelled the registration of affected products and determined to phase them out by April 2004.

The assessment of other diazinon approvals and registrations by the APVMA is continuing.

### ***Mevinphos review***

In 1997 the APVMA made interim review decisions regarding mevinphos, a broad-spectrum organophosphorus insecticide. The APVMA reviewed the data and information available at that time. The review found that mevinphos poses significant unacceptable risks to the health of users who mix, load and apply the chemical, and due to high toxicity, mevinphos could have a significant adverse impact on aquatic organisms. Consequently, mevinphos use was limited to brassica crops, with a maximum of three applications per crop per season, and at least two weeks between applications. Other label changes were required regarding protection of the environment. At that time the APVMA required that new data and information be provided.

The APVMA's supplementary review of this data confirmed that the limits imposed in 1998 needed to be continued for use of mevinphos on broccoli, cabbage and cauliflower. However, for Brussels sprouts further modifications were made to the label instructions, better reflecting agricultural practices with this crop.

Based on the assessment of worker exposure studies, the APVMA was satisfied that mevinphos is unlikely to pose an undue hazard to users provided that label instructions are observed, exposure mitigation methods specified are instituted, the product is used in accordance with

Good Agricultural Practices, and safe work practices are followed. Given the hazardous nature of mevinphos, special equipment, knowledge, skills and qualifications are required for its safe use. Products containing mevinphos were therefore declared to be restricted chemical products (as a related action), thereby only being available to persons who have been suitably authorised by relevant state authorities.

### ***Virginiamycin review***

The review of products containing the antibiotic virginiamycin was announced in August 2000 and was based on concern about the potential hazard of animal derived antibiotic-resistant bacteria to human health (report of the Joint Expert Advisory Committee on Antibiotic Resistance, September 1999). The review focused on whether continued use of products containing virginiamycin would be likely to have an effect that is harmful to human beings. The review also examined whether the products are effective for the purposes claimed and whether labels contained adequate instructions.

In conducting the review the APVMA sought expert scientific advice on the public health issues related to the continuing use of virginiamycin in food-producing animals from the Expert Advisory Group on Antimicrobial Resistance of the National Health and Medical Research Council within the Department of Health and Ageing.

A draft report outlining the review's findings was released for public comment in April 2003. The draft report finds that current label instructions are not adequate and allow for unlimited duration of use. It concludes that the use of products in this way may increase the likelihood of harmful effects to humans through human exposure to resistant bacteria of animal origin. However the report further concludes that the use of virginiamycin under professional veterinary management for short, defined periods is unlikely to have an effect that is harmful to human beings. The efficacy assessment concluded that the products are effective for certain defined therapeutic uses but there was insufficient information to define the use of the products for general claims of growth promotion.

Based on the review's draft report the APVMA proposes to vary the conditions of label approval for products containing virginiamycin and affirm the registration of those products used for the prevention of lactic acidosis

in sheep and cattle and the prevention of necrotic enteritis in chickens.

The deadline for public comment on the draft report was 31 July 2003.

### ***Endosulfan review***

The APVMA's review of endosulfan is continuing. However, the APVMA took a number of interim actions during the year.

During the endosulfan review, analysis of new residue information indicated that use of endosulfan on certain 'leafy vegetables' and salad greens might result in plants that had endosulfan residues exceeding the Acute Reference Dose, i.e. the level at which a person can safely consume pesticide residues in a single meal. Within days of the finding, the APVMA suspended the registrations of all endosulfan products, issued new instructions for safe use of the products on other crops and required the relabelling of all products from the warehouse to the farm. The APVMA has taken follow-up action to monitor compliance with these measures, talking with suppliers and auditing their records. The review continues, looking into other residue, health and occupational health and safety issues, with the draft report anticipated by the end of 2003.

### ***Other major achievements***

#### ***Export facilitation – Good Manufacturing Practice (GMP)***

Australian-based manufacturers exporting agricultural or veterinary chemicals must comply with requirements imposed by the country into which the goods are being imported. The extent to which importing countries recognise the National Registration Scheme and the Manufacturers' Licensing Scheme varies considerably.

To facilitate the export of Australian manufactured veterinary products, the APVMA issued 110 certificates during 2002–03, significantly more than during 2001–02. Certificates of Export and Manufacture (Approved GMP) and Certificates of Manufacture (Approved GMP) confirm that the manufacturer of the exported veterinary product is licensed by the APVMA and is inspected regularly for compliance with the relevant Australian Code of GMP. The certificates are recognised by a number of South-East Asian, Middle Eastern and South American countries



including Taiwan, Korea, Singapore, Malaysia, the Philippines, Indonesia, Kuwait, Saudi Arabia, United Arab Emirates, Columbia, Costa Rica, Venezuela and Argentina.

The APVMA is recognised as a Competent Authority under the Mutual Recognition Agreement on Conformity Assessment Between Australia and the European Community and as such is able to issue Certificates of GMP Compliance of a Manufacturer for eligible manufacturers exporting to the European Community. The terms of the Mutual Recognition Agreement were negotiated at a time when the Manufacturers' Licensing Scheme was in its infancy. As a consequence, the Mutual Recognition Agreement requires that audits be conducted by the Therapeutic Goods Administration against its Code of GMP for Human Medicinal Products or the relevant GMP code of the importing country (where the former does not cover the particular product).

The APVMA supports international harmonisation and hosted visits in 2002–03 by officers from the Malaysian Ministry of Health, the New Zealand Food Safety Authority and the United Kingdom Veterinary Medicines Directorate. An APVMA officer attended the 28th Ad Hoc Meeting of GMP Inspection Services at the European Agency for the Evaluation of Medicinal Products, London. The APVMA also contributed to the further development of the maintenance program as part of the Mutual Recognition Agreement. The maintenance program sets out the intentions of the parties for the continued maintenance and development of confidence in each other's regulatory systems for the manufacture of veterinary chemical products and human therapeutic goods.

### ***Education and awareness***

A significant factor in achieving compliance by the community is an understanding of the requirements of legislative provisions impacting on chemical product manufacturers, importers, suppliers and users. The APVMA substantially increased its efforts during the year to provide further sources of information to chemical industry stakeholders.

The APVMA continued to implement its education and awareness program with a further upgrade of the APVMA web site to include a page devoted to product recalls and compulsory testing.

APVMA officers took part in GMP training seminars arranged by the Veterinary Manufacturers and Distributors Association in association with Avcare. APVMA officers described the audit process and outlined manufacturers' obligations and responsibilities under the Manufacturers' Licensing Scheme. The seminars were held in Sydney, Melbourne and Brisbane and attended by 164 participants.

### ***Advertising and promotion***

A high proportion of complaints to the APVMA relate to promotion of unregistered products and advertising containing claims that are inconsistent with the claims on approved labels. The majority of this advertising impacts on commercial competitiveness. The APVMA considers that it would not serve the public interest in many cases to pursue these minor contraventions through the courts. The APVMA has embarked on a campaign to raise industry awareness and APVMA compliance officers attended Equitana 2002 – The National Equine Show and the Sydney Pet Expo to provide advice on compliant promotion of equine and companion animal products.



**BUSINESS MANAGEMENT FRAMEWORK & ACCOUNTABILITY**

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## 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 agricultural and veterinary products.

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 chemical products; and
- cooperating with governments and authorities of the Commonwealth, states and the participating territories to facilitate a consistent national approach to the procedures for the assessment and control of chemicals and to develop codes of practice, guidelines and standards in relation to the use of chemical 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.

### *Planning and reporting*

The planning and reporting requirements of the APVMA are set out in Part 6 of the Act. Section 50(4) provides that the APVMA, in formulating its Corporate Plan, shall 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 APVMA's programs are described in detail in the Annual Operational Plan which shows how the APVMA will maximise outputs from available resources to meet its outcomes. 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 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 Board regularly reviews management progress in achieving plan objectives through both formal and informal contact with management and key stakeholders. Quantitative and qualitative key performance indicators are used in the review process.

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

### *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 Business Risk Plan by management.

The APVMA has a number of mechanisms in place to manage the maintenance of a high level of ethical performance. A Board Charter outlines the responsibilities of Directors in the effective discharge of their duties. The APVMA Service Charter clearly 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 2002–03. In keeping with its policy of meeting the APVMA's stakeholders in the field for direct feedback on regulatory issues, two of those meetings were held outside Canberra – in Perth (August 2002) and Hobart (April 2003).

The meeting in Perth was preceded by a field visit to the Albany area where the Board inspected forestry plantations and was briefed on pest control issues in forestry, other agriculture and native wildlife conservation. In Tasmania, the Board visited aquaculture research and production facilities in the Huon Valley. Meetings with local stakeholders were conducted on both occasions.

A wide range of matters came before the Board including:

Chemical registration, quality assurance and compliance

- the APVMA's regulatory response to the Pan Pharmaceuticals incident;
- development of the Adverse Experience Reporting Program for Agricultural Chemicals (AERP Ag);

- active constituent and agricultural chemical product quality assurance;
- revision of procedures for evaluating residues in trade;
- the APVMA's compliance enforcement position and creation of an in-house Regulatory Compliance Committee;
- the revision of registration requirements for spray drift and chemical containers;
- intra-agency procedures for adopting maximum residue limits;
- preparations for the introduction of data protection;
- development of a user accreditation scheme;
- briefings on the regulation of genetically modified products and methodologies concerning acute dietary intake assessments;
- progress toward implementation of recommendations by the Joint Expert Technical Advisory Committee on Antibiotic Resistance.

Chemical review

- initiation of chemical reviews involving fipronil, molinate, diuron, triforine, carbon disulfide and arsenic-based timber and termite treatments;
- release for public comment of the draft virginiamycin review report;
- regulatory action pursuant to the chemical reviews of diazinon, mevinphos, endosulfan and triforine;
- voluntary cancellation of the bioresmethrin review and expansion of the scope of the carbaryl review.

Corporate management

- the annual budget and financial statements;
- strategic influences on the regulatory scheme, corporate and operational planning;
- program resourcing, performance monitoring and improvement;
- corporate governance arrangements including transition to the new Board of Directors and risk management;
- preparations for implementing legislative amendments including low regulatory product registration requirements;
- the APVMA fee structure review;



- preparations to implement National Competition Policy Review recommendations;
- launch of the APVMA as the Authority's new name and development of an overall communication strategy;
- a greater emphasis on community consultation;
- feedback from participation in international forums such as OECD, Codex and VICH;
- implementation of corporate restructure and employee development programs;
- ongoing development of APVMA information technology systems including e-commerce.

Further information about the APVMA Board is provided at Appendix B.

## *Corporate planning and reporting documents*

As an independent statutory authority the APVMA is required to conduct rigorous corporate planning and reporting.

### *Annual Report*

The Annual Report 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 Orders 2002* and the *Commonwealth Authorities and Companies Act 1997*.

The 2002–03 Annual Report details APVMA performance against each of the key outputs and performance indicators contained in the 2002–03 Portfolio Budget Statements.

### *Corporate and Annual Operational plans*

The APVMA's operational effectiveness is measured through the performance indicators set out in the Corporate and Annual Operational plans. 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 central planning document is the APVMA Corporate Plan. The Corporate Plan has a three-year focus 2000–2003 which is updated annually and outlines the APVMA's outcomes and outputs, objectives and strategies aligned with the statutory objective.

The Annual Operational Plan outlines, at a strategic level, the actions necessary to achieve the desired outcomes stated in the Corporate 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 APVMA Board assesses organisational performance quarterly against the deliverables nominated in the Annual Operational Plan. APVMA performance is also publicly reported in the Annual Report.

## *Transparency in decision making*

### *Consultation in APVMA processes and decision making*

Communication and consultation with stakeholders is a high priority for the APVMA. Involvement by industry, government and community stakeholders in APVMA development and decision making occurs in four ways:

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

The consultative committees are important conduits used by the APVMA to exchange information on issues relating to agvet chemicals. The scope, membership and key issues dealt with by these committees are described at Appendix D.

### *Public consultation*

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 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 Code Act. It is published monthly and is free of charge to registrants and via download from the APVMA web site [www.apvma.gov.au](http://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.

## **Communication with stakeholders**

A range of communication initiatives were implemented over the year to keep stakeholders informed of major issues and developments, raise awareness of the APVMA role and support the work of the program areas. These included:

- the ongoing development and refinement of a range of information materials and information sheets on key issues and the operations of the APVMA. These were distributed widely to industry users, registration applicants and the general community;
- the issue of seven media releases announcing major developments. For the most part these related to decisions resulting from chemical reviews;
- employing a 'list server' email subscription service to inform interested stakeholder subscribers of new developments and disseminate key information;
- publication of the *APVMA News* containing information on key developments and issues of interest to stakeholders;
- monthly publication of the *APVMA Gazette* containing details of product registration and approval matters;
- the targeted distribution of information to key stakeholders concerning the name change from the NRA to the APVMA; and
- responding in a timely way to a steady stream of enquiries from stakeholders and the general community on chemical issues. Numerous enquiries from media dealing with issues of varying complexity were also handled. The majority of these concerned chemical review outcomes and actions.

### ***Rural awareness***

A continuing priority for communication in 2002–03 was raising awareness in rural areas of the role of the APVMA and promoting the importance of only using registered products and always following label directions through the tagline 'Use the right chemical ...use the chemical right'.

Participation in rural field days remained an important communication tool. The APVMA participated in field days at Warragul and Wandin-Silvan in Victoria, Henty and Gunnedah in New South Wales, Launceston in Tasmania and attended the Equitana event held in Brisbane.



Advertisements were placed in industry publications available in all states informing chemical users of the organisation's name change to the APVMA.

## APVMA business systems

*APVMA web site –*  
*<http://www.apvma.gov.au>*

The APVMA web site remains an invaluable tool for the dissemination of agvet chemical information. During the period, the site was rebadged following the organisational name and logo change.

New features added during 2002–03 include substantial improvements to the online payments options, a re-written Quality Assurance and Compliance Program area including a product recall information area and an online reporting facility for adverse experiences with veterinary chemical products. A facility was added to the web site that allows a user to view an electronic image of the approved product label. A link is provided from the core product database (PUBCRIS) to the image of the approved label. A facility was also added that allows chemical producers to securely lodge active constituents volume data with the APVMA online.

The site attracts around 800 visitors per day of whom about one-third are repeat visitors. The most popular features are the database of registered products (PUBCRIS) and the database of permits for minor and off-label uses.

### *Records management*

Records management is an ongoing activity within the APVMA. The year saw two major developments.

Following a two-year process of research, planning and stakeholder consultation, the APVMA completed stage three of the National Archives of Australia's DIRKS methodology (Designing and Implementing a Record Keeping System) and thus received endorsement of its records retention and disposal policies. This project completed the evaluation of record keeping practices against AS 4390-1996. APVMA's record keeping has undergone substantial external scrutiny over the past few years, including an Australian National Audit Office audit

in 2001–02. Related policies and procedures are certified to ISO 9001-2000 and are therefore also regularly audited internally.

In 2003 the APVMA implemented an email capturing and storage system. This reflects the importance of the growing amount of official correspondence exchanged using email and provides a legal assurance that copies of all emails can be readily produced when required.

### *Information technology*

Further substantial progress was made in the redevelopment of the APVMA's information technology systems.

Major developments included:

- Electronic commerce – As forecast in last year's Annual Report the existing electronic levy payment system has been enhanced to allow registrants to enter their product sales data online. The new system then automatically calculates the correct levy and provides immediate e-payment options. The extension of the system from simple levy payment to auto-calculation and e-payment offers industry users a greatly improved facility.
- Submission of sales data online – Each year the APVMA receives information from agvet chemical producers on the annual volume of chemicals sold. The data has traditionally been provided in paper-based formats. During 2002–03 an online submission facility was created. The new facility allows industry to securely submit their sales volume data to the APVMA online and is a significant improvement on the old system.
- Labels on the web – As forecast in last year's Annual Report, the APVMA's web site was enhanced to allow users to view an electronic image of the approved product labels (free of charge) online.
- Online submission facility for adverse experience reports for veterinary products – A new facility that allows members of the public to submit adverse experience reports for veterinary products online has been introduced. The new facility provides members of the public with the ability to quickly and simply submit these reports to the APVMA. The new system is significantly more efficient than the old paper-based reporting system.

## *Fees review implementation*

Substantial progress was made towards developing a new fee structure for the APVMA. The proposed new fee structure reflects recommendations arising from the National Competition Policy and other reviews of APVMA cost recovery arrangements. It has been referred to government for consideration.

## Internal and external scrutiny

### *APVMA Quality Management System*

The APVMA continues to control its system of key processes strictly in accordance with its obligations as detailed in the legislation. All processes are controlled within the framework of the international ISO 9000 series.

In November 2002 the APVMA updated its system certification to comply with the latest version of the ISO 9000 series standard. The APVMA is now certified as compliant with the requirements of ISO 9001: 2000. During the external audit that preceded certification update, the APVMA occupational health and safety program, which is aligned with AS 8401, was incorporated in the external, international ISO certification and audit process.

During 2002–03 the APVMA's continuous improvement program progressed with a complete review of core registration processes to ensure alignment with the current Agvet Code and optimise the effectiveness and efficiency of the procedures involved.

The documented system is available to all staff via the APVMA intranet, ensuring that staff always have the latest version of all documents and processes. APVMA management maintains system oversight through the Performance Review and Performance Improvement committees, both of which meet monthly.

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

## *Fraud control*

In accordance with the Commonwealth Fraud Control Guidelines the APVMA has in place a Fraud Control Plan. The plan includes fraud prevention, detection, investigation, reporting and data collection procedures. The plan is based on a comprehensive fraud risk assessment conducted across all APVMA core areas.

## *Ecologically sustainable development*

In accordance with requirements of the *Environment Protection and Biodiversity Conservation Act 1999* and in line with the Commonwealth Government's Greening of Government program the APVMA has embarked on the development of 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.

Energy efficiency, recycling and green awareness will be the primary aims of the system, which is expected to be in place by the end of 2003.

## *Auditor-General's reports*

There were no reports by the Auditor-General on the operations of the APVMA during 2002–03.

## *Ministerial directions*

The APVMA did not receive any ministerial directions during 2002–03.

## *Courts and tribunals*

No new proceedings were commenced against the APVMA in 2002–03 and none were carried over from the previous reporting period.

## *Ombudsman*

No formal inquiries were made by the Ombudsman into the operations of the APVMA during 2002–03.

The APVMA did assist the Ombudsman in some inquiries in relation to the regulatory arrangements for licensing of veterinary chemical manufacturers



### Parliamentary committees and other reviews

The APVMA did not participate in any parliamentary inquiries or reviews during 2002-03.

### 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.

## Human resource management

The APVMA had a total of 128 staff at 30 June 2003. The total staffing of the APVMA according to full- and part-time status and temporary status is shown in Table 7.

Staff movements, including appointments, resignations, retirements, retrenchments, redundancies and dismissals are shown in Table 8.

### Workplace diversity

The APVMA is committed to maintaining the excellence and diversity of its staff. To ensure this occurs the APVMA has developed a Workplace Diversity Plan that incorporates:

- employee awareness of workplace diversity;
- training for supervisors;
- Workplace Diversity Contact Officer training; and
- collection and recording of statistical data.

Workplace diversity maintains the basic principles of equal employment opportunity (EEO), ensuring that the employment-related disadvantages of women, Aboriginal and Torres Strait Islander people, people of non-English speaking background and people with disabilities are considered.

Workplace diversity, however, goes beyond rectifying disadvantage and correcting past actions. Managing diversity builds upon the foundation of EEO but goes a step further to ensure each organisation develops human resource management strategies to value and accommodate differences in the background, perspectives and family responsibilities of employees. Workplace diversity acknowledges the positive contribution a diverse workforce can make to an organisation. By embracing workplace diversity the APVMA will maximise the skills of its staff and their diverse backgrounds.

A breakdown of staffing by gender appears in Table 9, and a profile of staff according to representation of EEO groups appears at Table 10.

### Occupational health and safety (OHS)

The APVMA continued to demonstrate a strong commitment to OHS.

Achievements included:

- conducting emergency evacuation drills;
- increasing internal communication and awareness regarding procedures and emergency contacts;
- implementing a Building Emergency Management Plan for Salvation Army House;
- arranging professional workplace assessments for new employees and other employees as requested;
- replacing non-height-adjustable desks;
- purchasing ergonomic equipment in accordance with individual employee needs;
- running a Health Week program with activities including health assessments, fitness assessments, yoga, pilates and tai chi, sporting activities, stress management activities and lectures, and health lectures, e.g. work/life balance, coping with stress, healthy diet and office injury prevention;

Table 11: Reportable accidents and dangerous occurrences in APVMA in 2002-03

Accidents resulting in death	Nil
Accidents causing serious personal injury	Nil
Accidents causing incapacity of five days or more	Nil
Dangerous occurrences not resulting in death, serious personal injury or incapacity	1

Table 7: APVMA staffing at 30 June 2003

Classification	Full-time (permanent)	Part-time (permanent)	Temporary	Total
Executive	7	0	0	7
Principal scientists	3	0	0	3
Band 6	22	0	2	24
Band 5	25	1	0	26
Band 4	29	0	1	30
Band 3	19	2	6	27
Band 2	6	1	4	11
Band 1	0	0	0	0
<b>Total</b>	<b>111</b>	<b>4</b>	<b>13</b>	<b>128</b>

Table 8: Staff movements at APVMA during 2002-03

Classification	Separated	Recruited
Executive	3	1
Principal scientists	0	0
Band 6	0	1
Band 5	4	1
Band 4	5	4
Band 3	2	5
Band 2	1	11
Band 1	0	0
<b>Total</b>	<b>15</b>	<b>23</b>

Note: Of the 23 staff recruited, 12 were temporary.

Table 9: APVMA staffing at 30 June 2003 by gender

Classification	Male	Female	Total staff
Executive	6	1	7
Principal scientists	3	0	3
Band 6	17	7	24
Band 5	17	9	26
Band 4	18	12	30
Band 3	3	24	27
Band 2	1	10	11
Band 1	0	0	0
<b>Total</b>	<b>65</b>	<b>63</b>	<b>128</b>

Table 10: EEO profile of APVMA staff as at 30 June 2003\*

Classification	People of non-English speaking background	People with a disability
Executive	0	0
Principal scientists	0	0
Band 6	3	1
Band 5	5	1
Band 4	1	1
Band 3	4	3
Band 2	0	0
Band 1	0	0
<b>Total</b>	<b>13</b>	<b>6</b>

Note: \* Based on voluntary disclosure of EEO information by staff.



- running an active OHS Committee, including the Fitness and Recreation Subcommittee; and
- arranging eyesight tests and other minor medical assistance.

## *Commonwealth Disability Strategy*

The APVMA incorporates the principles of the Commonwealth Disability Strategy in its Workplace Diversity Plan and other management practices.

Applicants for vacancies are invited to advise the selection committee of any disability when making application to ensure this is appropriately considered.

The provision of information is an area where significant enhancements were achieved. The APVMA's web site has been designed as an accessible information service for clients and the general public.

The APVMA raised the awareness of disabilities by having briefings for staff to better understand the issues for people with disabilities and how to assist employees who have difficulty, e.g. people with hearing impairment.

Approximately 4.6 per cent of APVMA employees have identified as having a disability and further work is planned to provide more assistance and support for these employees.

## *Certified agreement*

The APVMA's current three-year certified agreement took effect in April 2001. During 2002–03 implementation of the agreement continued and all initiatives have now been successfully implemented.

Negotiations for the next certified agreement commenced in July 2003.

## *Management practices*

The APVMA has a number of management practices in place which define the key corporate processes. To ensure that these management practices are contemporary and consistent with the current certified agreement, the practices were reviewed and, where appropriate, new practices have been developed.

New management practices have been developed for email capture, storage and access, management of classified information and revision of personal leave guidelines.

## *Performance, training and selection*

Under the certified agreement, a new Performance Management Scheme was introduced. The aim of the scheme is to provide a framework for managing individual performance with a clear link between individual performance and organisational priorities. Two full cycles of the new Performance Management Scheme have now been completed and the results indicate that the system has been successful.

Learning and development opportunities increased throughout 2002–03. The APVMA continued its strong commitment to training including the Study Encouragement Scheme. The scheme has been successful in assisting staff to gain relevant tertiary qualifications and to ensure they remain at the peak of their respective professions. Nine employees, approximately 8 per cent of the workforce, were sponsored to undertake further tertiary study.

A development program for Band 4 and 5 officers (APS 6 and Executive Level 1 equivalent) was put in place. The aims of the program are to:

- build the strategic capability of the Band 4/5 group;
- enhance the current and future ability of participants to contribute to the leadership and management of the APVMA;
- prepare participants for opportunities to perform at Executive Level 1 (either within or outside the APVMA); and
- contribute to the overall succession planning strategy of the APVMA.

The program will continue in 2003–04 with further modules being offered in a range of relevant skills.

## *Staff survey*

The APVMA conducted a staff survey to gauge the level of employee satisfaction and to benchmark the results against the staff survey conducted in 2000. The response to the survey was positive with 86 per cent of employees completing and submitting the survey in comparison to 81 per cent in 2000.

The results provided management with a good indication of the areas of high staff satisfaction plus information on where improvements are necessary. Management has been working with the Staff Consultative Committee

to address these issues. Individual program and division managers are also working with their staff to address their particular identified needs.

Overall, the results were very positive with significant improvement and/or positive trends in results from the 2003 survey compared with the 2000 findings in the following areas:

- induction and training;
- careers aspirations and retention;
- occupational health and safety;
- organisational identity;
- teamwork; and
- attitudes towards performance appraisal.

### *Employee self-service human resource management system – KIOSK*

A new human resource management self-service system for employees was introduced in 2002–03. Termed KIOSK, the system reduces paperwork and processing. The system provides immediate access to personal records for employees, fast and efficient electronic processing of leave applications, full history of pay and conditions entitlements and an electronic record of personal details.







**FINANCIAL STATEMENTS**

APVMA | ANNUAL REPORT





## INDEPENDENT AUDIT REPORT

To the Minister for Agriculture, Fisheries and Forestry

### Scope

I have audited the financial statements of the Australian Pesticides and Veterinary Medicines Authority for the year ended 30 June 2003. The financial statements comprise:

- Statement by Directors;
- Statements of Financial Performance, Financial Position and Cash Flows;
- Schedules of Commitments and Contingencies; and
- Notes to and forming part of the Financial Statements.

The directors of the Authority are responsible for the preparation and presentation of the financial statements and the information they contain. I have conducted an independent audit of the financial statements in order to express an opinion on them to you.

The audit has been conducted in accordance with the Australian National Audit Office Auditing Standards, which incorporate the Australian Auditing Standards, to provide reasonable assurance as to whether the financial statements are free of material misstatement. Audit procedures included examination, on a test basis, of evidence supporting the amounts and other disclosures in the financial statements and the evaluation of accounting policies and significant accounting estimates. These procedures have been undertaken to form an opinion as to whether, in all material respects, the financial statements are presented fairly in accordance with Accounting Standards and other mandatory professional reporting requirements in Australia and statutory requirements so as to present a view which is consistent with my understanding of the Authority's financial position, its financial performance and its cash flows.

The audit opinion expressed in this report has been formed on the above basis.

**Audit Opinion**

In my opinion the financial statements:

- (i) have been prepared in accordance with the Finance Minister's Orders made under the *Commonwealth Authorities and Companies Act 1997*; and
- (ii) give a true and fair view, in accordance with applicable Accounting Standards and other mandatory professional reporting requirements in Australia and the Finance Minister's Orders, of the financial position of the Australian Pesticides and Veterinary Medicines Authority as at 30 June 2003, and its financial performance and cash flows for the year then ended.

Australian National Audit Office



Puspá Dash  
Senior Director

Delegate of the Auditor-General

Canberra  
15 September 2003

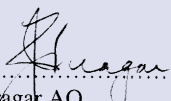


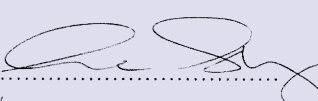
**Australian Pesticides and  
Veterinary Medicines Authority**

**Statement by Directors**

In our opinion, the attached financial statements give a true and fair view of the matters required by the Finance Minister's Orders made under the *Commonwealth Authorities and Companies Act 1997* for the year ended 30 June 2003.

In our opinion, at the date of this statement, there are reasonable grounds to believe that the Authority will be able to pay its debts as and when they become due and payable.

Signed   
Dr Lyn Fragar AO  
Acting Chairperson

Signed   
Anne Story  
Director

12 September 2003

12 September 2003

**Statement of Financial Performance**  
for the year ended 30 June 2003

	Notes	2003 \$	2002 \$
<b>Revenues from Ordinary Activities</b>			
Revenue from Government	3(a)	116,000	114,000
Sales of Goods and Services	3(b)	27,363	50,448
Interest Received	3(c)	756,523	746,988
Revenue from Sale of Assets	3(d)	39,382	-
Industry Contributions	3(e)	18,534,156	18,720,787
Other Revenue		40,491	131,828
<b>Total Revenues from Ordinary Activities</b>		<b><u>19,513,915</u></b>	<b><u>19,764,051</u></b>
<b>Expenses from Ordinary Activities</b>			
Employees	4(a)	10,783,059	11,346,686
Suppliers	4(b)	8,679,079	8,542,912
Depreciation and Amortisation	4(c)	723,189	724,912
Write-down of Assets		-	9,356
Value of Assets Sold	3(d)	17,090	-
<b>Total Expenses from Ordinary Activities</b>		<b><u>20,202,417</u></b>	<b><u>20,623,866</u></b>
<b>Net (Deficit)/Surplus</b>		<b>(688,502)</b>	<b>(859,815)</b>
Net credit to Asset Revaluation Reserve	9	56,882	-
Decrease in Accumulated Results on application of transitional provisions in accounting standard AASB 1041 Revaluation of Non-Current Assets	9	(122,661)	-
<b>Total changes in equity other than those resulting from transactions with owners as owners</b>		<b><u>(754,281)</u></b>	<b><u>(859,815)</u></b>

The above statement should be read in conjunction with the accompanying notes.



**Australian Pesticides and  
Veterinary Medicines Authority**

**Statement of Financial Position**

as at 30 June 2003

	Notes	2003 \$	2002 \$
<b>ASSETS</b>			
<b>Financial Assets</b>			
Cash	5(a)	4,396,182	5,414,553
Investments	5(a)	9,500,000	10,000,000
Receivables	5(b)	1,185,889	1,243,255
<b>Total Financial Assets</b>		<b>15,082,071</b>	<b>16,657,808</b>
<b>Non-financial Assets</b>			
Infrastructure, Plant and Equipment	6(a)	1,238,571	1,423,332
Intangibles	6(b)	576,076	664,743
Other	6(d)	305,097	666,907
<b>Total Non-financial Assets</b>		<b>2,119,744</b>	<b>2,754,982</b>
<b>Total Assets</b>		<b>17,201,815</b>	<b>19,412,790</b>
<b>LIABILITIES</b>			
<b>Interest Bearing Liabilities</b>			
Lease	7(a)	8,217	24,360
<b>Total Interest Bearing Liabilities</b>		<b>8,217</b>	<b>24,360</b>
<b>Payables</b>			
Suppliers	7(b)	1,752,334	2,636,019
Unearned Income		4,485,716	4,623,851
Other	7(c)	184,060	244,504
<b>Total Payables</b>		<b>6,422,110</b>	<b>7,504,374</b>
<b>Provisions</b>			
Employees	8	2,877,745	3,236,032
<b>Total Provisions</b>		<b>2,877,745</b>	<b>3,236,032</b>
<b>Total Liabilities</b>		<b>9,308,072</b>	<b>10,764,766</b>
<b>NET ASSETS</b>		<b>7,893,743</b>	<b>8,648,024</b>
<b>EQUITY</b>			
Reserves	9	5,672,882	5,616,000
Accumulated Surplus	9	2,220,861	3,032,024
<b>Total Equity</b>		<b>7,893,743</b>	<b>8,648,024</b>
<b>Current Liabilities</b>		<b>8,908,966</b>	<b>10,148,877</b>
<b>Non-current Liabilities</b>		<b>399,106</b>	<b>615,889</b>
<b>Current Assets</b>		<b>14,717,678</b>	<b>16,659,428</b>
<b>Non-current Assets</b>		<b>2,484,137</b>	<b>2,753,362</b>

The above statement should be read in conjunction with the accompanying notes.

Australian Pesticides and  
Veterinary Medicines Authority

**Statement of Cash Flows**  
for the year ended 30 June 2003

	Notes	2003 \$	2002 \$
<b>OPERATING ACTIVITIES</b>			
<b>Cash Received</b>			
Appropriations		116,000	222,000
Sales of Goods and Services		30,060	47,268
Interest Received		765,922	716,674
Industry Contributions		18,387,371	18,116,726
GST Received from ATO		1,011,363	961,919
Other		106,544	92,119
<b>Total Cash Received</b>		<u>20,417,260</u>	<u>20,156,706</u>
<b>Cash Used</b>			
Employees		(11,245,005)	(10,313,562)
Suppliers		(10,197,378)	(10,205,859)
<b>Total Cash Used</b>		<u>(21,442,383)</u>	<u>(20,519,421)</u>
<b>Net Cash used by Operating Activities</b>	10	<u>(1,025,123)</u>	<u>(362,715)</u>
<b>INVESTING ACTIVITIES</b>			
<b>Cash Received</b>			
Proceeds from Sales of Infrastructure, Plant and Equipment		39,382	-
Proceeds from Floating Rate Note		500,000	447,868
<b>Total Cash Received</b>		<u>539,382</u>	<u>447,868</u>
<b>Cash Used</b>			
Payments for Infrastructure, Plant and Equipment		(532,630)	(758,883)
<b>Total Cash Used</b>		<u>(532,630)</u>	<u>(758,883)</u>
<b>Net Cash from/(used by) Investing Activities</b>		<u>6,752</u>	<u>(311,015)</u>
<b>Net Decrease in Cash Held</b>		<u>(1,018,371)</u>	<u>(673,730)</u>
Cash at the Beginning of the Reporting Period		5,414,553	6,088,283
<b>Cash at the End of the Reporting Period</b>		<u>4,396,182</u>	<u>5,414,553</u>

The above statement should be read in conjunction with the accompanying notes.



**Australian Pesticides and  
Veterinary Medicines Authority**

**Schedule of Commitments**

as at 30 June 2003

	2003	2002 \$
<b>BY TYPE</b>		
Capital Commitments		
Plant and Equipment	-	-
<b>Total Capital Commitments</b>	<u>-</u>	<u>-</u>
Other commitments		
Operating leases	2,425,484	2,934,069
Other commitments	418,401	441,703
<b>Total Other Commitments</b>	<u>2,843,885</u>	<u>3,375,772</u>
Commitments receivable	(258,535)	(306,888)
<b>Net Commitments</b>	<u>2,585,350</u>	<u>3,068,884</u>
<b>BY MATURITY</b>		
One year or less	1,237,827	1,252,455
From one to five years	1,347,523	1,816,428
Over five years	-	-
<b>Net Commitments</b>	<u>2,585,350</u>	<u>3,068,884</u>
<b>Operating Lease Commitments</b>		
One year or less	943,208	935,998
From one to five years	1,482,276	1,998,071
Over five years	-	-
<b>Net Operating Commitments</b>	<u>2,425,484</u>	<u>2,934,069</u>

Leases are effectively non-cancellable and comprise:

- leases for office accommodation
- lease for a motor vehicle used for general business activities
- leases in relation to computer equipment

NB: Commitments are GST inclusive where relevant.

### Schedule of Commitments (continued)

as at 30 June 2003

Nature of the Lease	General description of the leasing arrangement
<b>Leases for office accommodation</b>	<p>Lease 1: Salvation Army House, Brisbane Avenue, Barton</p> <ul style="list-style-type: none"><li>Lease payments are subject to an annual increase in accordance with upwards movements in the CPI. However a market review will be performed at the end of the third year (1 April 2004) if the option to renew is exercised. The option to renew for a period of 2 years and 13 days is included in Commitments.</li></ul> <p>Lease 2: John Curtin House, Brisbane Avenue, Barton</p> <ul style="list-style-type: none"><li>In September 2004 &amp; 2005 there will be an increase of 4% each year. If the option to renew is exercised the rent is to be calculated at \$317 per square metre.</li></ul>
<b>Lease in relation to computer equipment</b>	<ul style="list-style-type: none"><li>The lessor provides all computer equipment as designated in the supply contract for 3 years. The Authority may vary the originally designated requirement subject to incurring a penalty.</li></ul>
<b>Motor Vehicle</b>	<ul style="list-style-type: none"><li>The lease period is 24 months or 40,000 kms.</li><li>Subject to 30 days prior written notice, the Authority may return the leased vehicles to the lessor at any time during the term of the lease, however an early return fee will apply.</li><li>The Authority may request an extension of the lease term for a period of up to 3 months from its originally specified expiry date.</li></ul>

The above schedule should be read in conjunction with the accompanying notes.

**Australian Pesticides and  
Veterinary Medicines Authority****Schedule of Contingencies**

as at 30 June 2003

	Notes	2003 \$	2002 \$
<b>CONTINGENT LOSSES</b>		<u><b>NIL</b></u>	<u><b>NIL</b></u>
<b>CONTINGENT GAINS</b>		<u><b>NIL</b></u>	<u><b>NIL</b></u>

The above schedule should be read in conjunction with the accompanying notes.

**Notes to and forming part of the  
Financial Statements**  
for the year ended 30 June 2003

**1. Summary of Significant Accounting Policies**

**1.1 Basis of Accounting**

The financial statements are required by clause 1(b) of Schedule 1 to the *Commonwealth Authorities and Companies Act 1997* and are a general purpose financial report.

The statements have been prepared in accordance with:

- Finance Minister's Orders (being the *Commonwealth Authorities and Companies (Financial Statements for the reporting periods ending on or after 30 June 2003) Orders*);
- Australian Accounting Standards and Accounting Interpretations issued by the Australian Accounting Standards Board; and
- Consensus Views of the Urgent Issues Group.

The financial statements have been prepared on an accrual basis and are in accordance with the historical cost convention, except for certain assets, which, as noted, are at valuation. Except where stated, no allowance is made for the effect of changing prices on the results or the financial position of the Authority.

Assets and liabilities are recognised in the Authority's Statement of Financial Position when and only when it is probable that future economic benefits will flow and the amounts of the assets or liabilities can be reliably measured. Assets and liabilities arising under agreements equally proportionately unperformed are however not recognised unless required by an Accounting Standard. Liabilities and assets that are unrecognised are reported in the Schedule of Commitments and the Schedule of Contingencies.

Revenues and expenses are recognised in the Authority's Statement of Financial Performance when and only when the flow or consumption or loss of economic benefits has occurred and can be reliably measured.

**1.2 Changes in Accounting Policy**

The accounting policies used in the preparation of these financial statements are consistent with those used in 2001-02, except in respect of:

- the initial revaluation of infrastructure, plant & equipment on a fair value basis (refer to Note 1.11); and
- the imposition of an impairment test for non-current assets carried at cost (refer to Note 1.11 and 1.12).

**1.3 Reporting by Outcomes**

The Net Cost of Outcome is presented in Note 2. The net costs shown include any intra-government costs that would be eliminated in calculating the actual Budget outcome.

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<sup>1</sup> Formerly the National Registration Authority for Agricultural and Veterinary Chemicals. Refer *Year in Review* in the Annual Report.



**Australian Pesticides and  
Veterinary Medicines Authority**

**Notes to and forming part of the  
Financial Statements**  
for the year ended 30 June 2003

**1.4 Appropriations**

*Revenue Appropriations*

Revenues from government are revenues to assist with strategies to address "minor uses" – the situation where the cost of registering a chemical for a particular crop is greater than the expected commercial return to the manufacturer.

Appropriations for outputs are recognised as revenue to the extent that they have been received into the Authority's Bank account or are entitled to be received by the Authority at year end.

Industry contributions are appropriated to the Authority by the Parliament in accordance with s58 (1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

*Non-Revenue Appropriations*

The Authority did not receive any capital appropriations or equity injections during the year.

**1.5 Revenue**

All material revenues described in this note are revenues relating to the core operating activities of the Authority. Details of revenue amounts are given in Note 3, *Operating Revenue*.

Revenue from the fees and charges contributed by industry is recognised during the period to which the fee or charge relates.

Revenue from the sale of goods and services is recognised upon receipt of money and/or delivery of goods to customers, whichever is the most appropriate.

Interest revenue is recognised on a proportional basis taking into account the interest rates applicable to the financial assets.

Revenue from the disposal of non-current assets is recognised when control of the asset has passed to the buyer.

**1.6 Employee Benefits**

*Benefits*

Liabilities for services rendered by employees are recognised at the reporting date to the extent that they have not been settled.

Liabilities for wages and salaries (including non-monetary benefits), annual leave, sick leave are measured at their nominal amounts. Other employee benefits expected to be settled within 12 months of their reporting date are also to be measured at their nominal amounts.

The nominal amount is calculated with regard to the rates expected to be paid on settlement of the liability.

All other employee benefit liabilities are measured as the present value of the estimated future outflows to be made in respect of services provided by employees up to the reporting date.

**Notes to and forming part of the  
Financial Statements**  
for the year ended 30 June 2003

*Leave*

The liability for employee benefits includes provision for annual leave and long service leave. No provision has been made for sick leave as all sick leave is non-vesting and the average sick leave taken in future years by employees of the Authority is estimated to be less than the annual entitlement for sick leave.

The leave liabilities are calculated on the basis of employees' remuneration, including the Authority's employer superannuation contribution rates to the extent that the leave is likely to be taken during service rather than paid out on termination.

The liability for long service leave is determined by reference to the short hand method.

In 2002-03 a downward adjustment was made to the long service leave provision to reflect the value at which the entitlement is expected to be settled.

*Separation and Redundancy*

Provision is also made for separation and redundancy payments in cases where positions have been formally identified as excess to requirements, and a reliable estimate of the amount payable can be determined.

*Superannuation*

Employees of the Authority are members of the Commonwealth Superannuation Scheme (CSS) and the Public Sector Superannuation Scheme (PSS). Temporary employees of the Authority contribute to the Australian Government Employees Superannuation Trust (AGEST). The liability for their superannuation benefits is recognised in the financial statements of the Commonwealth and is settled by the Commonwealth in due course.

The Authority makes employer contributions to the Commonwealth at rates determined by the actuary to be sufficient to meet the cost to the Commonwealth of the superannuation entitlements of the Authority's employees.

The liability for superannuation as at 30 June represents outstanding contributions for the final fortnight of the year.

**1.7 Leases**

A distinction is made between finance leases which effectively transfer from the lessor to the lessee substantially all the risks and benefits incidental to ownership of leased non-current assets and operating leases under which the lessor effectively retains substantially all such risks and benefits.

Where a non-current asset is acquired by means of a finance lease the asset is capitalised at the present value of minimum lease payments at the inception of the lease and a liability recognised for the same amount. Leased assets are amortised over the period of the lease. Lease payments are allocated between the principal component and the interest expense.

Operating lease payments are expensed on a basis which is representative of the pattern of benefits derived from the leased assets.

Lease incentives taking the form of 'free' leasehold improvements and rent holidays are recognised as liabilities. These liabilities are reduced by allocating lease payments between rental expense and reduction of the liability.



**Australian Pesticides and  
Veterinary Medicines Authority**

**Notes to and forming part of the  
Financial Statements  
for the year ended 30 June 2003**

**1.8 Cash**

Cash means notes and coins held and any deposits held at call with a bank or financial institution.

**1.9 Financial Instruments**

Accounting policies in relation to Financial Instruments are stated at Note 14, *Financial Instruments*.

**1.10 Acquisition of Assets**

Assets are recorded at cost on acquisition except as stated below. The cost of acquisition includes the fair value of assets transferred in exchange and liabilities undertaken.

**1.11 Infrastructure, Plant and Equipment**

*Asset Recognition Threshold*

Purchases of infrastructure, plant and equipment are recognised at cost in the Statement of Financial Position, except for purchases costing less than \$2,000, which are initially expensed in the year of acquisition (other than when they form part of a group of similar items which are significant in total).

*Revaluations*

Infrastructure, plant and equipment are carried at valuation. Revaluations undertaken up to 30 June 2002 were done on a deprival basis; revaluations since that date are at fair value. This change in accounting policy is required by Australian Accounting Standard AASB 1041 *Revaluation of Non-Current Assets*.

Fair and deprival values for each class of assets are determined as shown below.

<b>Asset Class</b>	<b>Fair Value Measured at:</b>	<b>Deprival Value Measured at:</b>
Infrastructure - Leasehold Improvements	Depreciated Replacement Cost	Depreciated Replacement Cost
Plant & Equipment	Market Selling Price	Depreciated Replacement Cost

Under both the deprival and fair value, assets which are surplus to requirement are measured at their net realisable value. At 30 June 2003 the Authority held no surplus assets.

The financial effect for 2002-03 of this change in policy relates to those assets to be recognised at fair value at 30 June 2003. The financial effect of the change is given by the difference between the carrying amount at 30 June 2002 of these assets and their fair values as at 1 July 2002. The financial effect by asset class is as follows:

<b>Asset Class</b>	<b>Adjustment</b>	<b>Contra Account</b>
Infrastructure - Leasehold Improvements	\$56,882	Asset Revaluation Reserve
Plant & Equipment	(\$122,661)	Accumulated Results

**Notes to and forming part of the  
Financial Statements**  
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Accounting Standard AAS 6 Accounting Policies requires, where practicable, presentation of the information that would have been disclosed in the 2001-02 Statements had the new accounting policy always been applied. It is impracticable to present this information.

*Frequency*

In 2002-03, infrastructure, plant and equipment were revalued.

*Conduct*

All valuations are conducted by an independent qualified valuer.

*Recoverable Amount Test*

From 1 July 2002, Schedule 1 no longer requires the application of the recoverable amount test in AAS 10 *Recoverable Amount of Non-Current Assets* to the assets when the primary purpose of the asset is not the generation of net cash inflows.

No infrastructure, plant and equipment have been written to recoverable amount per AAS 10. Accordingly the change in policy has had no financial effect.

*Depreciation and Amortisation*

Depreciable infrastructure, plant and equipment assets are written-off to their estimated residual values over their useful lives to the Authority using, in all cases, the straight-line method of depreciation. Leasehold improvements are amortised on a straight-line basis over the lesser of the estimated useful life of the improvements or the unexpired period of the lease.

Depreciation/amortisation rates (useful lives) and methods are reviewed at each balance date and necessary adjustments are recognised in the current, or current and future reporting periods, as appropriate. Residual values are re-estimated for a change in prices only when assets are revalued.

The Authority's depreciation/amortisation rates applying to each class of depreciable asset are as follows:

	2002-2003	2001-2002
Infrastructure	26% - 30%	13% - 26%
Plant and Equipment	5% - 50%	5% - 33%



**Australian Pesticides and  
Veterinary Medicines Authority**

**Notes to and forming part of the  
Financial Statements  
for the year ended 30 June 2003**

**1.12 Intangibles**

The Authority's intangibles comprise internally developed and externally acquired computer software. The assets are carried at cost.

From 1 July 2002, Schedule 1 no longer requires the application of the recoverable amount test in Australian Accounting Standard AAS 10 *Recoverable Amount of Non-Current Assets* to the assets of authorities when the primary purpose of the asset is not generation of net cash inflows.

However, Schedule 1 now requires such assets, if carried on the cost basis, to be assessed for indications of impairment. The carrying amount of impaired assets must be written down to the higher of its net market selling price or depreciated replacement costs.

All software assets were assessed for impairment as at 30 June 2003 and none were found to be impaired.

Software is amortised on a straight-line basis over their anticipated useful lives.

The Authority's amortisation rate for intangible assets is as follows:

	2002-2003	2001-2002
Intangibles	33%	33%

**1.13 Taxation**

The Authority is exempt from all forms of taxation except fringe benefits tax and the goods and services tax (GST).

Revenue, expenses and assets are recognised as net of GST:

- except where the amount of GST incurred is not recoverable from the Australian Taxation Office; and
- except for payables and receivables.

**1.14 Insurance**

The Authority has insured for risks through the Governments insurable risk managed fund, called 'Comcover'. Workers compensation is insured through Comcare Australia.

**1.15 Comparative Figures**

Comparative figures have been adjusted to conform to changes in presentation in these financial statements where required.

**1.16 Rounding**

Amounts are presented in whole dollars except in Note 14, *Financial Instruments*, where amounts are rounded to the nearest \$1,000.

**Notes to and forming part of the  
Financial Statements**  
for the year ended 30 June 2003

**2. Reporting by Segments and Outcomes**

*Reporting by Segments*

The Authority operates primarily in a single industry and geographical segment being the regulation of agricultural and veterinary chemicals in Australia.

The Authority is structured to meet a single outcome and output. In addition the Authority has no Administered revenues, expenses, assets and liabilities.

Given the need to use agricultural and veterinary chemicals for pest and disease control, the work of the Authority protects the health and safety of people, animals and the environment. In respect to food and fibre production, the Authority's activities support Australian agricultural and livestock industries.

*Reporting by Outcomes for 2002-2003*

	<b>2003</b>	2002
	<b>\$</b>	\$
Total Expenses	<b>20,202,417</b>	20,623,866
Costs Recovered from Provision of Goods & Services to the Non-Government Sector	<b>24,318</b>	45,269
Other External Revenues		
Sales of Goods and Services	<b>3,045</b>	5,179
Interest	<b>756,523</b>	746,988
Industry Contributions	<b>18,534,156</b>	18,720,787
Revenue for Sales of Assets	<b>39,382</b>	-
Other Revenue	<b>40,491</b>	131,828
Total	<b>19,373,597</b>	<u>19,604,782</u>
Net Cost/(contribution) of outcome	<b>804,503</b>	973,815



**Australian Pesticides and  
Veterinary Medicines Authority**

**Notes to and forming part of the  
Financial Statements**

for the year ended 30 June 2003

	2003 \$	2002 \$
<b>3. Operating Revenues</b>		
(a) - Revenue from Government Appropriation	<u>116,000</u>	<u>114,000</u>
(b) - Sales of Goods and Services		
Goods	3,181	5,454
Services	24,182	44,994
Total	<u>27,363</u>	<u>50,448</u>
Goods and Services were sold to:		
Related	3,045	5,179
External	24,318	45,269
	<u>27,363</u>	<u>50,448</u>
(c) - Interest		
Bank Deposits & Floating Rate Note	<u>756,523</u>	<u>746,988</u>
(d) - Net Gain from Sale of Assets		
Infrastructure, plant & equipment:		
Proceeds from disposal	39,382	-
Net book value of assets disposed	<u>(17,090)</u>	<u>-</u>
Total	<u>22,292</u>	<u>-</u>
(e) - Industry Contributions		
Levies	10,672,302	10,358,281
Registration Renewals	4,508,401	4,346,400
Application Fees	2,863,270	2,877,992
Good Manufacturing Practice	207,900	909,902
Permits and Other Fees	282,283	228,212
Total	<u>18,534,156</u>	<u>18,720,787</u>

**Notes to and forming part of the  
Financial Statements**  
for the year ended 30 June 2003

	2003 \$	2002 \$
<b>4. Operating Expenses</b>		
(a) - Employee Expenses		
Wages and Salaries	8,940,635	8,295,446
Superannuation	1,165,227	1,158,090
Separation & Redundancies	-	194,168
Other Employee Expenses	<u>642,373</u>	<u>1,652,872</u>
Total Employee Benefits Expenses	10,748,235	11,300,577
Workers Compensation premiums	<u>34,824</u>	<u>46,085</u>
Total Employee Expenses	<u><u>10,783,059</u></u>	<u><u>11,346,662</u></u>
(b) - Suppliers Expenses		
Goods from Related Entities	4,818	6,678
Goods from External Entities	604,183	626,465
Services from Related Entities	5,085,292	4,697,436
Services from External Parties	2,158,173	2,461,118
Operating Lease Rentals	<u>826,613</u>	<u>751,215</u>
Total	<u><u>8,679,079</u></u>	<u><u>8,542,912</u></u>
Operating lease payments comprise minimum lease payments only.		
Included in supplier expenses are finance charges in respect of finance leases totalling \$965.		
(c) - Depreciation and Amortisation		
Depreciation of Infrastructure, Plant & Equipment	435,600	449,756
Amortisation of Intangibles	<u>287,589</u>	<u>275,156</u>
Total	<u><u>723,189</u></u>	<u><u>724,912</u></u>



**Australian Pesticides and  
Veterinary Medicines Authority**

**Notes to and forming part of the  
Financial Statements  
for the year ended 30 June 2003**

	2003 \$	2002 \$
<b>5. Financial Assets</b>		
<b>(a) - Cash</b>		
Cash at bank and on hand	4,168,267	5,325,900
Deposits at call	227,915	88,653
Investments	<u>9,500,000</u>	<u>10,000,000</u>
	<u><u>13,896,182</u></u>	<u><u>15,414,553</u></u>
Balance of cash as at 30 June shown in the Statement of Cash Flows	<u><u>4,396,182</u></u>	<u><u>5,414,553</u></u>
<b>(b) - Receivables</b>		
Goods & Services	881,170	813,021
Less: Provision for Doubtful Debts	<u>(1,512)</u>	<u>-</u>
	<u>879,658</u>	<u>813,021</u>
GST Receivable	255,154	306,591
Interest Receivable	41,638	51,038
Other Debtors	<u>9,439</u>	<u>72,605</u>
Total Receivables (net)	<u><u>1,185,889</u></u>	<u><u>1,243,255</u></u>
Receivables (gross) which are overdue are aged as follows:		
Not Overdue	1,096,545	1,210,976
Overdue by:		
- less than 30 days	-	-
- 30 to 60 days	62,289	-
- 60 to 90 days	-	-
- more than 90 days	<u>28,566</u>	<u>32,279</u>
	<u><u>1,187,401</u></u>	<u><u>1,243,255</u></u>
The provision for doubtful debts is aged as follows:		
Not Overdue	-	-
Overdue by:		
- less than 30 days	-	-
- 30 to 60 days	-	-
- 60 to 90 days	-	-
- more than 90 days	<u>1,512</u>	<u>-</u>
	<u><u>1,512</u></u>	<u><u>-</u></u>

**Notes to and forming part of the  
Financial Statements**  
for the year ended 30 June 2003

	2003 \$	2002 \$
<b>6. Non-financial Assets</b>		
<b>(a) - Infrastructure, Plant &amp; Equipment</b>		
At Cost	-	2,969,188
Accumulated Depreciation	<u>-</u>	<u>(1,545,856)</u>
	-	1,423,332
At 2002-03 Valuation (Fair Value)	1,673,197	-
Accumulated Depreciation	<u>(434,626)</u>	<u>-</u>
Total	<u><u>1,238,571</u></u>	<u><u>1,423,332</u></u>

Plant and equipment under finance lease is subject to revaluation. The carrying amount is included in the valuation figures above and is separately disclosed in Table A in Note 6(c) below.

All revaluations are independent and are conducted in accordance with the revaluation policy stated at Note 1.

A valuation of infrastructure, plant and equipment was carried out as at 1 July 2002 by Simon B O'Leary, AAPI MSAA and Bryan Hurrell, FAPI of the Australian Valuation Office.

<i>Movement in Asset Revaluation Reserve</i>		
Increment for Infrastructure	<u>56,882</u>	<u>-</u>
Total	<u><u>56,882</u></u>	<u><u>-</u></u>
<b>(b) - Intangible Assets</b>		
Externally Acquired Computer Software - at cost	916,239	764,957
Accumulated amortisation	(665,370)	(490,653)
Impairment write-down	<u>-</u>	<u>-</u>
Total	<u><u>250,869</u></u>	<u><u>274,304</u></u>
Internally Developed Software - at cost	504,445	456,805
Accumulated amortisation	(179,238)	(66,366)
Impairment write-down	<u>-</u>	<u>-</u>
Total	<u><u>325,207</u></u>	<u><u>390,439</u></u>
Total	<u><u>576,076</u></u>	<u><u>664,743</u></u>



Australian Pesticides and  
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**Notes to and forming part of the  
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(c) - Analysis of Infrastructure, Plant, Equipment and Intangibles

**TABLE A: Movement summary 2002-03 for all assets**

Item	Infrastructure, Plant and Equipment	Intangibles	TOTAL
<b>As at 1 July 2002</b>			
Gross book value	2,969,188	1,221,762	4,190,950
Accumulated depreciation/amortisation	(1,545,856)	(557,019)	(2,102,875)
<b>Net book value</b>	<b>1,423,332</b>	<b>664,743</b>	<b>2,088,075</b>
<b>Additions</b>			
By purchase	333,708	198,922	532,630
From acquisition of operations	-	-	-
Net revaluation increment/decrement	(65,779)	-	(65,779)
Depreciation/amortisation expense	(435,600)	(287,589)	(723,189)
Recoverable Amount write-downs	-	-	-
<b>Disposals</b>			
From disposal of operations	(17,090)	-	(17,090)
Other Disposals	-	-	-
<b>As at 30 June 2003</b>			
Gross book value	1,673,197	1,420,684	3,093,881
Accumulated depreciation/amortisation	(434,626)	(844,608)	(1,279,234)
<b>Net book value</b>	<b>1,238,571</b>	<b>576,076</b>	<b>1,814,647</b>

**TABLE B: Assets at Valuation**

Item	Infrastructure, Plant and Equipment	Intangibles	TOTAL
<b>As at 30 June 2003</b>			
Gross book value	1,673,197	-	1,673,197
Accumulated depreciation	(434,626)	-	(434,626)
<b>Net Book Value</b>	<b>1,238,571</b>	<b>-</b>	<b>1,238,571</b>

	2003 \$	2002 \$
(d) - Other Non-financial Assets		
Prepayments	<u>305,097</u>	<u>666,907</u>

**Notes to and forming part of the  
Financial Statements**  
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	2003 \$	2002 \$
<b>7. Liabilities</b>		
<b>Interest Bearing Liabilities</b>		
(a) - Lease		
Finance Lease Commitments		
Payable:		
Within one year	8,425	18,336
In one to five years	-	8,425
In more than five years	-	-
Minimum lease payments	<u>8,425</u>	<u>26,761</u>
Deduct: Future finance charges	<u>(208)</u>	<u>(2,401)</u>
Lease Liability	<u><u>8,217</u></u>	<u><u>24,360</u></u>
Lease liability is categorised as follows:		
Current	8,217	16,143
Non-current	-	8,217
Total Interest Bearing Liabilities	<u><u>8,217</u></u>	<u><u>24,360</u></u>
<b>Payables</b>		
(b) - Suppliers		
Trade Creditors	226,344	1,136,175
Accrued Expenses	1,507,897	1,480,767
Accrued Fringe Benefits Tax	18,093	19,077
Total Supplier Payables	<u><u>1,752,334</u></u>	<u><u>2,636,019</u></u>
All supplier payments are current.		
(c) - Other		
Lease Incentive Liability	<u>184,060</u>	<u>244,504</u>
Total Other Payables	<u><u>184,060</u></u>	<u><u>244,504</u></u>



Australian Pesticides and  
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Notes to and forming part of the  
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	2003 \$	2002 \$
<b>8. Provisions</b>		
Salaries and Wages	503,084	376,432
Leave	2,174,306	2,532,669
Superannuation	200,355	154,464
Separation and Redundancy	-	172,467
Aggregate Employee Benefit Liability	<u>2,877,745</u>	<u>3,236,032</u>
Current	2,596,759	2,806,925
Non Current	<u>280,986</u>	<u>429,107</u>
	<u>2,877,745</u>	<u>3,236,032</u>

**9. Equity**

Item	Accumulated Results	General Reserve	Asset Revaluation Reserve	TOTAL EQUITY
Balance 1 July 2002	3,032,024	5,616,000	-	8,648,024
Net Surplus/(Deficit)	(688,502)	-	-	(688,502)
Net revaluation increment/decrement	-	-	56,882	56,882
Decrease in Accumulated Results on application of transitional provisions in accounting standard AASB 1041	-	-	-	-
Revaluation of Non-Current Assets	(122,661)	-	-	(122,661)
Balance 30 June 2003	<u>2,220,861</u>	<u>5,616,000</u>	<u>56,882</u>	<u>7,893,743</u>

**10. Cash Flow Reconciliation**

Reconciliation of operating deficit to net cash used by operating activities:

Operating (Deficit)/Surplus	(688,502)	(859,815)
Depreciation and Amortisation of Plant and Equipment	435,600	449,756
Amortisation of Intangibles	287,589	275,156
Loss on Disposal of Assets	(22,292)	-
Write-down of Assets	-	9,356
Changes in Assets and Liabilities		
(Increase)/decrease in Receivables	57,364	(737,302)
(Increase)/decrease in Prepayments	361,809	(612,750)
Increase/(decrease) in Unearned Income	(138,135)	165,406
Increase/(decrease) in Payables	(960,270)	(7,007)
Increase/(decrease) in Provisions	(358,286)	954,485
<b>Net cash used by operating activities</b>	<u>(1,025,123)</u>	<u>(362,715)</u>

**Notes to and forming part of the  
Financial Statements**  
for the year ended 30 June 2003

**11. Remuneration of Directors**

Directors of the Authority during the year were:

Dr Kevin Sheridan	Chairperson	Appointed 16 October 2002
Dr Lynette Fragar	Deputy Chairperson*	Re-Appointed 16 October 2002
Mr Anthony Bates		Appointed 16 October 2002
Ms Mara Bún		Appointed 16 October 2002
Dr Catherine Hollywell		Appointed 16 October 2002
Professor John McLean		Re-Appointed 16 October 2002
Dr Gardner Murray		Appointed 16 October 2002
Dr Chris Parker		Appointed 16 October 2002 Resigned 31 October 2002
Mr Hutch Ranck		Appointed 16 October 2002
Ms Anne Story		Appointed 15 November 2002
Dr John S Keniry		Term Expired 15 October 2002
Mr Peter Bailey		Term Expired 15 October 2002
Mr Mark Allison		Term Expired 15 October 2002
Mr Ian Champion		Term Expired 15 October 2002
Dr Peter Dingle		Term Expired 15 October 2002
Ms Merrilyn McPherson		Term Expired 15 October 2002
Mr Michael Nicholls		Term Expired 15 October 2002

\*Appointed Deputy Chairperson 18 December 2002.

	2003 \$	2002 \$
Aggregate amount of superannuation payments in connection with the retirement of directors	2,702	Nil
Other remuneration received or due and receivable by directors of the Authority	156,329	152,974
Total remuneration received or due and receivable by directors of the Authority	159,031	152,974

The number of directors of the Authority included in these figures are shown below in the relevant remuneration bands.

Remuneration Range	Number	
	2003	2002
Nil	5	2
\$1 - \$9,999	4	0
\$10,000 - \$19,999	5	6
\$20,000 - \$29,999	3	0
\$30,000 - \$39,999	0	1
<b>Total</b>	<b>17</b>	<b>9</b>

**Other Transactions with Directors or Director Related Entities**

During the year, directors and their director-related entities transacted with the Authority under the same terms and conditions available to other suppliers and agricultural and veterinary chemical companies.



**Australian Pesticides and  
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**Notes to and forming part of the  
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**12. Remuneration of Officers**

The number of officers who received or were due to receive total remuneration of \$100,000 or more:

Remuneration Range	Number	
	2003	2002
\$100,000 - \$109,999	-	-
\$110,000 - \$119,999	-	1
\$120,000 - \$129,999	-	-
\$130,000 - \$139,999	-	1
\$140,000 - \$149,999	-	2
\$150,000 - \$159,999	2	2
\$160,000 - \$169,999	1	1
\$170,000 - \$179,999	-	1
\$180,000 - \$189,999	-	-
\$190,000 - \$199,999	-	-
\$200,000 - \$209,999	1	-
\$210,000 - \$219,999	1	1
\$220,000 - \$229,999	-	-
\$230,000 - \$239,999	-	-
\$240,000 - \$249,999	-	-
\$250,000 - \$259,999	-	-
\$260,000 - \$269,999	1	-
<b>Total</b>	<b>6</b>	<b>9</b>

	2003 \$	2002 \$
The aggregate amount of total remuneration of officers shown above.	<b>1,148,150</b>	1,411,947

The officer remuneration includes all officers concerned with or taking part in the management of the Authority during 2002-03 except the Board Chairperson. Details in relation to the Chairperson have been incorporated into Note 11, *Remuneration of Directors*.

The variation in band categorisation from 2001-02 is the result of disclosure of full year remuneration in 2002-03 for officers appointed part way through 2001-02, changes to Senior Executive Officers remuneration and movements in annual leave and long service leave balances.

**13. Auditors Remuneration**

The audit of the Authority is carried out by the Australian National Audit Office (ANAO). The amount payable for audit services in auditing the financial statements for the reporting period was \$21,000 (2001-02: \$21,000). No other services have been provided by the ANAO during the reporting period.

**Notes to and forming part of the  
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**14. FINANCIAL INSTRUMENTS**

(a) Terms, conditions and accounting policies

Financial Instrument	Notes	Accounting Policies and Methods (including recognition criteria and measurement basis)	Nature of underlying instrument (including significant terms and conditions affecting the amount, timing and certainty of cash flows)
<i>Financial Assets</i>		Financial assets are recognised when control over future economic benefits is established and the amount of the benefit can be reliably measured.	
Deposits at Call	5(a)	Deposits at call are recognised at cost. Interest is accrued as it is earned.	The deposit at call is with the Commonwealth Bank of Australia, and at 30 June 2003 earned an effective rate of interest of 4.65% (2002: 4.55%).
Investments	5(a)	The floating rate note is recognised at cost. Interest is accrued as it is earned.	The floating rate note is with the Commonwealth Bank of Australia, and at 30 June 2003 earned an effective rate of interest of 5.09% (2002: 5.38%)
Receivables for Goods and Services	5(b)	These receivables are recognised at the nominal amounts due less any provision for bad and doubtful debts. Provisions are made when collection of the debt is judged to be less rather than more likely.	Terms are: <ul style="list-style-type: none"> <li>• GMP Licence Receivable – Maximum fee payable of \$6,000, payable by equal annual instalments in accordance with regulation 72A of the AgVet Codes.</li> <li>• Other Goods and Services - Net 30 days.</li> </ul>
<i>Financial Liabilities</i>		Financial liabilities are recognised when a present obligation to another party is entered into and the amount of the liability can be reliably measured.	
Finance Lease	7(a)	Liabilities are recognised at the present value of the minimum lease payments at the beginning of the lease.	At reporting date, the authority had a finance lease with an unexpired term of 7 months. The interest rate implicit in the lease is averaged at 14.58% (2002: 14.58%). The lease liability is settled by then lease assets.
Trade Creditors	7(b)	Creditors, accruals and unearned income are recognised at their nominal amounts, being the amounts at which the liabilities will be settled. Liabilities are recognised to the extent that the goods or services have been received (and irrespective of having been invoiced).	Settlement is usually made net 30 days.



Australian Pesticides and  
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**Notes to and forming part of the  
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for the year ended 30 June 2003

**14. FINANCIAL INSTRUMENTS (continued)**

**(b) Interest Rate Risk**

Financial Instrument	Notes	Floating Interest Rate	Fixed Interest Rate						Non-Interest Bearing	Total	Weighted Average Effective Interest Rate			
			1 year or less		1 to 2 years		2 to 5 years				> 5 years		02-03	01-02
			02-03	01-02	02-03	01-02	02-03	01-02			02-03	01-02	%	%
\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	%	%		
Financial Assets (Recognised)														
Cash at Bank	5(a)	4,166	5,324	-	-	-	-	-	4,166	5,324	4.50	4.31		
Cash on Hand	5(a)	-	-	-	-	-	-	2	2	2	N/A	N/A		
Deposits at Call	5(a)	228	89	-	-	-	-	228	89	4,627	4,157			
Investments	5(a)	9,500	10,000	-	-	-	-	-	0	10,000	5.185	4.687		
Receivables for Goods & Services	5(b)	-	-	-	-	-	-	1,186	1,243	1,186	1,243	N/A	N/A	
Total Financial Assets (Recognised)		13,894	15,413	-	-	-	-	1,188	1,245	15,082	16,658			
Total Assets		-	-	-	-	-	-	-	-	17,202	19,413			
Financial Liabilities (Recognised)														
Finance lease	7(a)	-	-	8	-	-	-	-	-	8	24	14.58	14.58	
Payables	7(b)&(c)	-	-	-	-	-	-	6,238	7,260	6,238	7,260	N/A	N/A	
Total Financial Liabilities (Recognised)		-	-	-	-	-	-	6,238	7,260	6,246	7,284			
Total Liabilities		-	-	-	-	-	-	-	-	9,308	10,765			

**Notes to and forming part of the  
Financial Statements**  
for the year ended 30 June 2003

14. FINANCIAL INSTRUMENTS (continued)

(c) Net Fair Value of Financial Assets and Liabilities

Note	2003		2002		
	Total Carrying Amount	Aggregate net fair value	Total Carrying Amount	Aggregate net fair value	
	\$'000	\$'000	\$'000	\$'000	
<b>Financial Assets (Recognised)</b>					
Cash at Bank	5(a)	4,166	4,166	5,324	5,324
Cash on Hand	5(a)	2	2	2	2
Commercial Bill	5(a)	-	-	-	-
Deposits at call	5(a)	228	228	89	89
Investments	5(a)	9,500	9,500	10,000	10,000
Receivables for Goods and Services	5(b)	1,186	1,186	1,243	1,243
<b>Total Financial Assets (Recognised)</b>		<b>15,082</b>	<b>15,082</b>	16,658	16,658
<b>Financial Liabilities (Recognised)</b>					
Finance lease liabilities	7(a)	8	8	24	24
Payables	7(b)&(c)	6,238	6,238	7,260	7,260
<b>Total Financial Liabilities (Recognised)</b>		<b>6,246</b>	<b>6,246</b>	7,284	7,284

*Financial Assets*

The net fair values of cash, investments and non-interest-bearing monetary financial assets approximate their carrying amounts.

The net fair values of receivables for goods and services and other assets, all of which are short term in nature, are approximated by their carrying amounts.

*Financial Liabilities*

The net fair value for trade creditors, all of which are short term in nature, are approximated by their carrying amounts.



**Australian Pesticides and  
Veterinary Medicines Authority**

**Notes to and forming part of the  
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**14. FINANCIAL INSTRUMENTS (continued)**

**(d) Credit Risk Exposure**

The Authority's maximum exposure to credit risk at reporting date in relation to each class of recognised financial assets is the carrying amount of those assets as indicated in the Statement of Financial Position.

The Authority has no significant exposure to any concentrations of credit risk.

**15. AVERAGE STAFFING LEVELS**

	<b>2003</b>	<b>2002</b>
The average staffing levels of the Authority during the year were:	115	117

**16. ESTABLISHMENT**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) and is controlled by the Commonwealth. The principal responsibilities of the APVMA are described in the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) and the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act).



## APPENDICES

APVMA | ANNUAL REPORT





## Appendix A: Overview of the National Registration Scheme

The APVMA administers legislation established under the National Registration Scheme on behalf of the Commonwealth, States and Territories and is responsible for the assessment, registration and regulation of agricultural and veterinary (agvet) chemical products up to, and including, the point of retail sale.

Before an agricultural or veterinary chemical product can be sold in Australia, it must be assessed and registered by the APVMA.

Chemical companies are required to provide extensive data to demonstrate that a product will be effective for the uses described on the label, will be safe for humans and non-target species, and will not pose unacceptable risks to the environment or trade with other nations.

When products are evaluated, the APVMA takes full account of the nature of the product, the amount and completeness of data for consideration, and the extent of consultation required between the APVMA, manufacturers, advisory agencies, and the states or territories.

Residues studies on crops and animals are evaluated to establish a maximum residue limit and withholding period. Recommendations for using the product are checked to see that they are consistent with the data provided, and labelling is examined to ensure it is accurate and meets Commonwealth and state legislative requirements.

### *Specialist advice from agencies*

For specialist advice during the assessment process, the APVMA receives input from a number of Commonwealth agencies:

- The Therapeutic Goods Administration's Office of Chemical Safety within the Department of Health and Aging evaluates toxicology data submitted by applicants to determine if any health risk may be posed to the community.
- Environment Australia evaluates the environmental implications of products submitted for registration and recommends measures to avoid or minimise adverse environmental effects.

- The National Occupational Health and Safety Commission conducts occupational health and safety assessments to ensure that any risks arising out of workers' exposure to agricultural and veterinary (agvet) chemical products are minimised.
- Food Standards Australia and New Zealand assesses the dietary intake implications of residues in food and in cooperation with the APVMA sets maximum residue limits.
- The Office of the Gene Technology Regulator provides advice in relation to products of gene technology.
- The Expert Advisory Group on Antimicrobial Resistance addresses the implications of the use of antibiotics in agriculture.
- The Australian Quarantine and Inspection Service advises on quarantine safety matters associated with imported biological products.

At some stages of the evaluation process, consultation may occur with the states and territories, other Australian government agencies, and a range of expert panels or committees that provide advice to the APVMA. This process ensures that appropriate knowledge and experience is incorporated into the assessment process. Figure A1 shows the registration process.

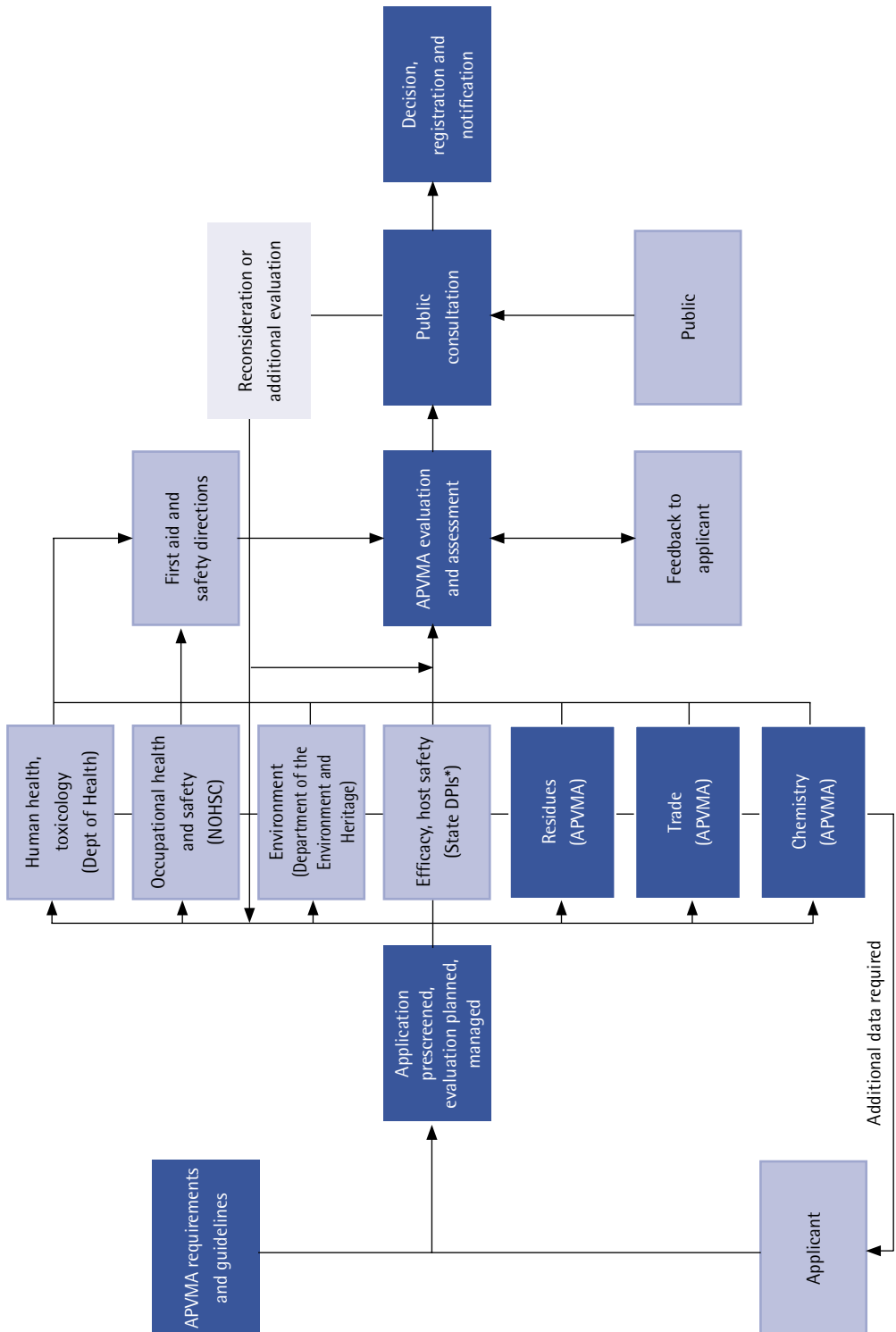
Applicants are consulted during the evaluation process, particularly on technical issues or areas of concern.

Before registering a product containing a new active constituent, or amending a registration to allow a major change of use, the APVMA publishes a summary of an evaluation as a basis for public comment.

These public release summaries are advertised in the *APVMA Gazette* to notify the community that the product is under assessment, to offer further information and to invite comment, which is taken into account before final decisions are made. The APVMA also sends a copy to interested stakeholders who have requested copies.

When an assessment is complete, the product is either registered or the application is rejected. In many cases, the APVMA proposes amendments to the draft label as a requirement of approval.

FIGURE A1: Registration process for agricultural and veterinary chemicals





## *Regulation and monitoring*

Agricultural and veterinary chemical products are not registered forever.

The APVMA operates four programs that monitor agvet chemicals after registration. These programs have the capacity to bring about regulatory action if registration standards are not maintained or if new information dictates the need to reconsider the conditions of registration.

## *Chemical review*

The Chemical Review Program reconsiders the registration of agricultural and veterinary chemicals in the marketplace where potential risks to safety and performance have been identified. A review may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical or product.

Under the program, reviews may be based on one or more areas of registration, such as environmental safety, or may be comprehensive, covering all aspects of the chemical's registration.

## *Compliance*

The standards set at registration are enforced in the marketplace using a range of compliance strategies applied at the relevant point in the supply chain, which extends from the import barrier to retail premises.

Compliance involves the assessment of risk and application of appropriate enforcement responses to alleged breaches of the Code Act reported by a range of stakeholders, including industry, other government agencies and the general public or identified via the APVMA's intelligence function. The reports investigated can relate to unregistered products, supply of restricted products to unauthorised users, unapproved labels, claims in advertising, or formulations and active constituents.

The APVMA liaises regularly with state and territory government departments to ensure effective communication and coordination of effort.

## *Reporting of adverse experiences*

The Adverse Experience Reporting Program for Veterinary Chemicals (AERP Vet), introduced in January 1995, requires registrants of veterinary chemical products to report any adverse effects resulting from use of a product. Members of the public are also invited to report adverse experiences that may be linked to the use of a veterinary chemical product. Reports are investigated and, where required, regulatory action can be taken.

## *Manufacturers' Licensing Scheme*

The APVMA's Manufacturers' Licensing Scheme, introduced in March 1996, requires all Australian based manufacturers of veterinary chemical products to be licensed and to meet standards described in a Code of Good Manufacturing Practice. The scheme includes audits of manufacturing premises. It aims to ensure the quality of veterinary chemical products manufactured and supplied in Australia.

## *Consultation*

The APVMA places a high priority on communication with the various stakeholders involved in the National Registration Scheme. It operates or participates in a number of consultative forums on issues relating to agvet chemicals and products. These consultative mechanisms have been instrumental in developing key programs and priorities. Further information on consultation undertaken in 2002–03 through the APVMA's committees is provided at Appendix D.

## *Improving the systems*

The APVMA is committed to the continuous improvement of the systems and processes it uses to register and regulate agvet chemicals.

## Appendix B: APVMA Board of Directors

The current Board was appointed on 16 October 2002 and will serve until 15 October 2005. The Board met six times in 2002–03; attendance by current and previous Directors is detailed in Table B1. Four meetings were held in Canberra and one each in Perth and Hobart to promote interaction with stakeholders in the field.

Contact: Mr Alan Hill, Executive Officer, APVMA Board, telephone (02) 6272 5238.

### *Declared interests*

Directors are required to declare material personal interests in relation to any matters before the Board for deliberation. Declarations by Directors are detailed in Table B2.

### *Indemnities and insurance*

The APVMA has provided indemnity to each Director and several APVMA staff. The APVMA maintains directors'

and officers' liability insurance as set out in Table B3. The nature of the liabilities covered and the amount of premium payable under the contract of insurance are confidential under the terms of the policy.

### *Audit Committee*

The primary objective of the Audit Committee is to assist with the Board's responsibilities relating to the APVMA's financial accounting and reporting practices. The current committee was appointed on 29 November 2002 and comprises Dr Lyn Fragar (Chairperson), Ms Anne Story and Mr Hutch Ranck. The Audit Committee met in July and August 2002 and in March and June 2003. Meetings coincided with key financial year milestones for provision of advice and reports to the Board. Attendance is detailed in Table B4.

**Table B1: Attendance at APVMA Board meetings in 2002–03**

Name	Meetings attended	Meetings eligible
Dr John Keniry (Chairperson until 15 Oct. 2002)	2	2
Mr Peter Bailey (Deputy Chairperson until 15 Oct. 2002)	1	2
Mr Ian Champion (Director until 15 Oct. 2002)	2	2
Mr Peter Dingle (Director until 15 Oct. 2002)	2	2
Mr Michael Nicholls (Director until 15 Oct. 2002)	2	2
Prof John McLean (Director reappointed 16 Oct. 2002)	6	6
Mrs Marilyn McPherson (Director until 15 Oct. 2002)	2	2
Dr Lyn Fragar (Director reappointed 16 Oct. 2002, appointed Deputy Chairperson 18 Dec. 2002)	6	6
Mr Mark Allison (Director until 15 Oct. 2002)	2	2
Dr Kevin Sheridan (Chairperson appointed 16 Oct. 2002)	4	4
Dr Chris Parker (Director appointed 16 Oct. 2002, resigned 31 Oct. 2002)	0	0
Ms Anne Story (Director appointed 15 Nov. 2002)	3	4
Dr Catherine Hollywell (Director appointed 16 Oct. 2002)	4	4
Mr Anthony Bates (Director appointed 16 Oct. 2002)	4	4
Mr Hutch Ranck (Director appointed 16 Oct. 2002)	4	4
Ms Mara Bún (Director appointed 16 Oct. 2002)	3	4
Dr Gardner Murray (Director appointed 16 Oct. 2002)	3	4



Table B2: Declared interests

Board meeting	Declaration
<p><b>NRA64</b></p> <p>Feb. 2003</p>	<p><b>Performance outcomes for registration of agvet products</b></p> <p>Dr Fragar disclosed that she had a potential conflict of interest in respect to a proposed initiative to measure the performance outcomes for registration of agvet products. Dr Fragar advised that the APVMA is currently negotiating with the Australian Centre for Agricultural Health and Safety (ACAHS) for provision of reports relevant to this initiative. Her interest relates to her position as Director of the ACAHS. The Board considered that Dr Fragar's interest should not disqualify her from taking part in discussions about the matter in the context of initial planning for 2003-04.</p>
<p><b>NRA61</b></p> <p>Aug. 2002</p>	<p><b>Chemical review diazinon – supplementary information</b></p> <p>Dr Fragar disclosed that she had a potential conflict of interest in this matter. Dr Fragar's interest relates to her position as Director of the ACAHS. ACAHS is providing technical advice to the National Farmers' Federation and Australian Wool Innovation on methodology for a generic study of ectoparasiticide exposure of workers in relation to the NRA's review of diazinon. On advice from the General Counsel, the Board considered that Dr Fragar's interest should not disqualify her from taking part in deliberations or voting on the matter.</p> <p><b>Chemical review nomination – diuron</b></p> <p>Mr Allison disclosed that he had a potential conflict of interest in this matter. Mr Allison's interest relates to his position as Managing Director of Wesfarmers Landmark Ltd, a company that has a controlling interest in Artfern Pty Ltd, which is an approval holder of the active constituent diuron and the registrant of products containing diuron. Pursuant to 27J of the CAC Act, the remaining Board members were not satisfied that Mr Allison's interest should allow him to be present to consider and vote on the matter.</p>

Table B4: Audit Committee – meetings attended in 2002-03

Name	Meetings eligible	Meetings attended
Mr Peter Bailey (Chairperson until 15 Oct. 2002)	2	2
Mr Ian Champion (Director until 15 Oct. 2002)	2	2
Mr Michael Nicholls (Director until 15 Oct. 2002)	2	2
Dr Lyn Fragar (Chairperson appointed 29 Nov. 2002)	2	2
Ms Anne Story (appointed 29 Nov. 2002)	2	2
Mr Hutch Ranck (appointed 29 Nov. 2002)	2	2

Table B3: Indemnities and insurance for APVMA directors and officers 2002–03

Officers	Class	Indemnity agreement	Director & officer liability insurance
Dr John Keniry	Director (Chairperson until 15 Oct. 2002)	✓	✓
Mr Peter Bailey	Director (Deputy Chairperson until 15 Oct. 2002)	✓	✓
Mr Ian Champion	Director (until 15 Oct. 2002)	✓	✓
Dr Peter Dingle	Director (until 15 Oct. 2002)	✓	✓
Mr Michael Nicholls	Director (until 15 Oct. 2002)	✓	✓
Prof John McLean	Director (reappointed 16 Oct. 2002)	✓	✓
Mrs Marilyn McPherson	Director (until 15 Oct. 2002)	✓	✓
Dr Lyn Fragar	Director (reappointed 16 Oct. 2002)	✓	✓
Mr Mark Allison	Director (until 15 Oct. 2002)	✓	✓
Dr Kevin Sheridan	Director (appointed Chairperson 16 Oct. 2002)	✓	✓
Dr Chris Parker	Director (appointed 16 Oct. 2002, resigned 31 Oct. 2002)	✓	✓
Ms Anne Story	Director (appointed 15 Nov. 2002)	✓	✓
Dr Catherine Hollywell	Director (appointed 16 Oct. 2002)	✓	✓
Mr Anthony Bates	Director (appointed 16 Oct. 2002)	✓	✓
Mr Hutch Ranck	Director (appointed 16 Oct. 2002)	✓	✓
Ms Mara Bún	Director (appointed 16 Oct. 2002)	✓	✓
Dr Gardner Murray	Director (appointed 16 Oct. 2002)	✓	✓
Dr Alison Turner	CEO	✓	✓
Mr Peter Raphael	Program Manager, Quality Assurance & Compliance	✓	✓
Dr Martin Holmes	Program Manager, Veterinary Medicines	✗	✓
Mr Tony de la Fosse	Program Manager, Corporate Services	✓	✓
Dr Joe Smith	Program Manager, Pesticides	✗	✓
Mr James Suter	General Counsel	✓	✓
Dr Eva Bennet-Jenkins	Manager, Veterinary Review, Registration & Client Services	✗	✓
Dr Trevor Doust	Program Manager, Chemistry & Residues	✗	✓
Mr Ron Hogg	A/g Manager, Veterinary Chemicals Evaluation	✗	✓



## Appendix C: Legislation

### *Background to the legislation establishing the national registration scheme and the APVMA*

Prior to March 1995, the Commonwealth held responsibility for the evaluation and assessment of selected agvet chemical products and their clearance for registration. The states and territories were responsible for the registration and control of use of all agvet chemical products.

Initially the Commonwealth's involvement in the clearance process was informal. However from 1 July 1989 the arrangements were put on a legislative basis with the enactment of the *Agricultural and Veterinary Chemicals Act 1988* which established the then Australian Agricultural and Veterinary Chemicals Council to undertake clearance activities.

In July 1991, the Commonwealth, states and territories agreed to establish the National Registration Scheme for Agricultural and Veterinary Chemicals. The National Registration Scheme is a partnership between the Commonwealth and the states/territories. The aim of the scheme was to place under one national umbrella the assessment and registration of all agvet chemical products previously undertaken independently by the Commonwealth and each of the states and territories.

The first major step in establishing the National Registration Scheme was the establishment on 15 June 1993 of the then National Registration Authority for Agricultural and Veterinary Chemicals (NRA) as an independent statutory authority of the Commonwealth under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. The *Agricultural and Veterinary Chemicals Act 1988*, which provided the legislative basis for the former arrangements, was initially amended at the same time to transfer the powers and functions of the outgoing Australian Agricultural and Veterinary Chemicals Council to the NRA.

However, on 15 March 1995, following the commencement of a suite of Commonwealth and State/Territory legislation, the National Registration Scheme came into full operation. The 1995 package of legislation repealed the 1988 Act and established a new legislative regime for the NRA's operations. The 1995 legislation

gave the then NRA its full range of responsibilities for the regulation and control of agricultural and veterinary chemicals up to the point of retail sale. The states and territories continued to retain responsibility for control-of-use activities, such as licensing of pest control operators and aerial spraying.

The centrepiece of the 1995 legislation is the Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, which contains the detailed operational provisions for registering chemical products and provides the NRA with its full range of regulatory powers.

The Agvet Code is a law of the Commonwealth that only applies in the Australian Capital Territory. To enable the Agvet Code to have national coverage, each of the states and the Northern Territory enacted complementary legislation that has the effect that the Agvet Code of the Australian Capital Territory is applied as a law of each State and the Northern Territory. Taken together they are referred to as the Agvet Codes.

Other Acts in the legislative package contain the cost recovery mechanisms – in particular, the imposition, assessment and collection of a levy on sales of chemical products – which establish the NRA as an independent, self-funding, regulatory body.

On 5 March 2003 Senator the Hon Judith Troeth, Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry, announced that the NRA would now be known as the Australian Pesticides and Veterinary Medicines Authority (APVMA) pending changes to legislation to formally change the name of the authority.

### *Legislation administered by the APVMA*

A summary of the laws administered by the APVMA appears below.

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

This Act, which came into effect on 15 June 1993, establishes the then NRA as an independent statutory authority of the Commonwealth responsible for the regulation and control of agvet chemicals in Australia up to the point of retail sale.

This Act contains all the internal details of the establishment of and the functions and powers of the APVMA, how it is constituted, how it is to hold its meetings, the Corporate and Annual Operating Plans it must prepare, and details relevant to the management of its finances.

This Act also contains other matters relating to the regulation of agvet chemicals that are clearly within the constitutional authority of the Commonwealth such as the regulation of the importation, manufacture and exportation of agvet chemicals.

It also contains provisions modifying the Agvet Codes for the purposes of giving effect to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in relation to the giving of exclusivity for data associated with the approval of new active constituents.

The original Act was No. 262, 1992 as amended by the following amendment Acts: – No. 94, 1993; No. 37, 1994; No.76, 1994; No.94, 1994; No. 85, 1995; No. 59, 1996; No.152, 1997; No. 102, 1998; No.4, 1999; No. 146, 1999; No. 156, 1999; No. 137, 2000; No. 170, 2000; and No. 115, 2001.

### ***Agricultural and Veterinary Chemicals (Administration) Regulations***

These regulations, made under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, commenced on 15 March 1995. They prescribe the fees for export certificates and the form of search warrant to be used when there is a suspected offence in relation to the importation, manufacture or exportation of agricultural or veterinary chemicals. They also specify the quantity of active constituents below which an annual return of the importation, manufacture and exportation of these active constituents is not required.

The original Regulations were Statutory Rules 1995, No 28 as amended by SR 1997, No. 320.

### ***Agricultural and Veterinary Chemicals Act 1994***

This Act, which also commenced on 15 March 1995, contains the constitutional and other legal provisions that enable the Agvet Code to have effect. The essence of the legislative arrangements which give effect to the National Registration Scheme is, by means of complementary adoptive legislation, for the Commonwealth Parliament to pass a law establishing the Agvet Code in the Australian Capital Territory. This Act

so applies the Agvet Code, as it is in force for the time being. The Agvet Code then is applied by the legislatures of the states and the Northern Territory as a law of those jurisdictions by State/Territory complementary Acts: the *Agricultural and Veterinary Chemicals [state/Northern Territory] Acts 1994*.

This federal Act also contains the Commonwealth provisions which partly 'federalised' the Agvet Codes even though the codes apply in the states and the Northern Territory as the law of those jurisdictions. That is, for most practical purposes the Agvet Codes have the general characteristics of Commonwealth rather than State laws. In particular, this 'federalisation' allows the Commonwealth's *Acts Interpretation Act 1901* to apply for the purposes of interpreting the Agvet Codes so there is a uniform interpretative regime. Also, the Commonwealth's administrative law package applies, that allows exclusive rights of review of APVMA decisions taken under the Agvet Codes as though the decisions were made under Commonwealth laws. Additionally, the Commonwealth Director of Public Prosecutions is empowered to prosecute for any offences against the legislation even though such offences are offences against the laws of the states or territories concerned.

The original Act was No. 36, 1992 as amended by the following amendment Acts: – No. 152, 1995; No. 57, 2000; No. 81, 2001; and No. 83, 2001.

### ***Agricultural and Veterinary Chemicals Regulations 1999***

These Regulations, made under the *Agricultural and Veterinary Chemicals Act 1994*, commenced on 22 December 1999. The Regulations prescribe functions in relation to the Director of Public Prosecutions of the Commonwealth which enable the Director to bring prosecutions and proceedings for offences against the Agvet Codes or the Agvet Regulations.

The Regulations were Statutory Rules 1999, No 326. No amendments have been made to these Regulations.

### ***Agricultural and Veterinary Chemicals Code Act 1994***

This Act, which also commenced on 15 March 1995, contains as a schedule to the Act the Agvet Code, which has the detailed provisions allowing the APVMA to evaluate, approve or register, and review active constituents and agricultural and veterinary chemical products (and their associated labels); to issue permits;



and to licence the manufacture of chemical products. The Agvet Code also contains detailed offence provisions allowing the APVMA to regulate the control of agvet chemicals and has other provisions for ensuring compliance with, and enforcement of, the Agvet Code. As well, the code contains provisions for data protection compensation for review data.

The original Act was No. 47, 1994 as amended by the following amendment Acts: – No. 129, 1994; No. 88, 1995; No.59, 1996; No.22, 1997; No. 170, 2000; No.55, 2001; and No. 115, 2001.

#### ***Agricultural and Veterinary Chemicals Code Regulations 1995***

These Regulations were made under the *Agricultural and Veterinary Chemicals Code Act 1994* and came into effect on 15 March 1995. The Regulations prescribe detailed provisions of the Agvet Code including the approval and registration process, control of chemical products, notification numbers and records to be kept of hormonal growth promotants, exemptions in relation to licences for the manufacture of chemical products, and timeframes and fees for assessment of applications. They also include schedules of the categories of applications for registration and approval that can be made and of restricted chemical products.

The original Regulations were Statutory Rules 1995, No 27 as amended by the following amendment regulations: – SR 1995, No. 54; SR 1995, No. 137; SR 1995, No. 187; SR 1996, No. 83; SR 1996, No. 111; SR 1996, No. 162; SR 1996, No. 216; SR 1997, No. 264; SR 1999, No. 215; SR 1999, No. 247; SR 2002, No. 60; SR 2002, No. 207; and SR 2003, No. 8.

#### ***Agricultural and Veterinary Chemicals Code Order 1999***

This Order, made under the *Agricultural and Veterinary Chemicals Code Act 1994*, came into effect on 31 October 1999. The Order specifies standard labels for swimming pool and spa hypochlorites that come within application Category 23A.

The Order was Statutory Rules 1999, No 242. No amendments have been made to this Order.

#### ***Veterinary Chemical Products (Excluded Stockfood Non-active Constituents) Order***

This Order, made under the *Agricultural and Veterinary Chemicals Code Act 1994*, commenced on 15 March 1995. The Order excludes certain stockfood constituents

as listed in the Order from the definition of a veterinary chemical product.

The Order was Statutory Rules 1995, No 59. No amendments have been made to this Order.

#### ***Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994***

#### ***Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994***

#### ***Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994***

These three Acts, which all commenced on 15 March 1994, support the system of levies provided for in the Collection of Levy Act.

The Acts actually impose levy on, respectively, chemical products imported into Australia and sold wholesale; on Australian manufactured chemical products; and on imported chemical products sold directly as retail.

The original Acts were No. 39, 1994; No. 38, 1994; and No. 40, 1994. No amendments have been made to these Acts.

#### ***Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994***

This Act, which also commenced on 15 March 1995, contains measures that allow for the assessment and collection of levies in regard to agricultural and veterinary products registered for use in Australia. Together with the three levy imposition Acts, this Act provides for the collection of levy imposed by those levy imposition Acts. The Act also makes provision for certain powers of entry, inspection and seizure of documents and other material to determine the amount of levy, if any, that is payable. It also contains provisions for an appeal and review process where a person is dissatisfied with an assessment made under the Act.

The original Act was No. 41, 1994 as amended by the following amendment Acts: – No. 72, 1994; No. 94, 1994; No.36, 1995; No. 137, 2000; and No. 115, 2001.

#### ***Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995***

These Regulations, which commenced on 6 June 1995, prescribe the State laws under which an agricultural or veterinary chemical product is registered under the *Agricultural and Veterinary Chemical Products*

(*Collection of Levy*) Act 1994 and specify the rate of levy for 1995–96 and subsequent years.

The maximum levy that can be payable in respect of a particular chemical product for 1995–96 and subsequent years is increased to \$25 000. The form of search warrant to be used when there is a suspected offence under the Collection of Levy Act is also prescribed.

The original Regulations were Statutory Rules 1995, No. 120 as amended by SR 2000. No. 91.

### *Amendments to the Agvet Chemicals Legislation in 2002–03*

There were three amendments to the Agvet chemicals legislation administered by the APVMA in 2002–03. These are as follows.

1. An amendment was made to the Agricultural and Veterinary Chemicals Code Regulations 1995 by the Agricultural and Veterinary Chemicals Code Amendment Regulations 2002 (No.1) [SR 2002, No. 207]. This amendment, which commenced on 12 September 2002, declares concentrated pindone products to be restricted chemical products by inclusion of a new item 9 in Schedule 4 of the Agvet Code Regulations.

A notice of these amendments was published in the *NRA Gazette* No. 1 of 7 January 2003.

2. An amendment was made to the Agricultural and Veterinary Chemicals Code Regulations 1995 by the Agricultural and Veterinary Chemicals Code Amendment Regulations 2003 (No.1) [SR 2003, No. 8]. This amendment, which commenced on 27 February 2003, declares mevinphos products to be restricted chemical products by inclusion of a new item 10 in Schedule 4 of the Agvet Code Regulations.

A notice of these amendments was published in the *APVMA Gazette* No. 5 of 6 May 2003.

3. Amendments were made to the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; the *Agricultural and Veterinary Chemicals Code Act 1994* and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2003* [No. 13, 2003] on 8 April 2003. However, these amendments will not commence until 8 October 2003.

The amendments provide for additional systems of authorisation of chemical products – to be known as registered listed chemical products and reserved chemical products.

Other important reforms included in the amendments are changes to the steps of approving a label to make it clear that the actual printed label to appear on the container of a product is being approved, rather than just the text instructions; new provisions that, in circumstances where an approval or registration ceases, allow existing stocks to pass through the supply chain and be used, where this can be done with safety; new provisions allowing the APVMA to conduct preliminary assessments of applications and, where they are totally unsatisfactory (that is, the APVMA considers the deficiencies can not be reasonably rectified), to reject them as never having been properly made

A notice of the details of these amendments will be gazetted in early October 2003 prior to their commencement.

### **Further information**

A complete description of these laws, including details of each of the amendments, is available on request from the Legal and Governance Program of the APVMA on (02) 6272 3756.



## Appendix D: Committees

### *Community Consultative Committee*

The Community Consultative Committee is a vital forum for two-way communication between the APVMA and the broader Australian community. Committee members are drawn from organisations representing community interests in regulation of agricultural and veterinary chemicals. They provide advice and community views to the APVMA and recommend ways to address areas of concern.

The committee informs the community of matters relating to agricultural and veterinary chemicals and reports to the APVMA on issues of interest to the community about the use of agricultural or veterinary chemicals. The committee is asked for input on important issues the APVMA is dealing with and makes recommendations on any further work that might be undertaken to resolve issues of community concern.

The committee met in July, October and December 2002 and in May 2003.

**TABLE D1: Membership of and attendance at Community Consultative Committee meetings in 2002–03**

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Professor Cameron Hazlehurst (Chair until March 2003)	Independent	3	3
Ms Dorothy Bowes (until March 2003)	Allergy, Sensitivity & Environmental Health Association	3	3
Mr Scott Kinear (until March 2003)	Organic Federation of Australia	3	2
Mr Ben Cole	Total Environment Centre	4	4
Mr Andrew Duncan	WA Farmers Federation	4	3
Ms Jane Fuller	Women's Rural Network	4	3
Mr Sam Beechey	Australian Workers' Union	4	2
Ms Alison Brinson	Chemcert Australia	4	4
Ms Jenni Mack – Chair (appointed March 2003)	Australian Consumers Association	1	1
Ms Liz Hanna (appointed March 2003)	Public Health Association of Australia; Royal College of Nursing Australia	1	1
Ms Anne Stanton (appointed March 2003)	National Toxics Network	1	1
Mr Sid Cowling (appointed March 2003)	Organic Federation of Australia; Australian Independent Organic Inspectors Association	1	1

Contact: Kathleen Allan, telephone (02) 6272 3794.

Issues considered during 2002–03 included:

- the development of an adverse experience reporting program for agricultural products;
- spray drift management;
- urban chemical use education;
- data protection for agvet product registrants;
- agvet chemical use outcome monitoring and data collection;
- the review of arsenic based timber treatment products;
- antibiotic use in livestock; and
- strategic review of the management of agvet chemicals in Australia.

## *Industry Liaison Committee*

The Industry Liaison Committee is the main consultative forum between the APVMA and peak chemical industry organisations representing registrants.

### *Purpose*

The purpose of the committee is to:

- provide a forum for formal consultation and discussion with peak chemical industry organisations on APVMA operating policies and programs; and
- enhance cooperation in the management of the registration process and post-registration programs.

### *Objectives*

The objectives of the committee are to:

- progress the development of agreed standards and procedures for the assessment of agvet chemicals;
- obtain the views of industry members on issues of an operational, technical or strategic nature;
- provide industry input to APVMA operational planning processes;
- identify opportunities for reform within the existing regulatory framework; and
- provide a forum for reporting by the APVMA to industry on its performance.

## *Meetings*

The committee meets three times a year, each time with a specific purpose:

- April – to consider a detailed work plan on matters to be pursued through the committee in the next financial year;
- August – the APVMA's main opportunity to report to industry on its performance; and
- November – industry's main opportunity to contribute to APVMA planning.

Matters considered by the committee in 2002–03 included:

- international recognition and harmonisation;
- compliance costs of sheep products;
- globally harmonised system for labels;
- the review of APVMA fees;
- conventions on prior informed consent and persistent organic pollutants;
- reviewing the quality of efficacy reports and of fees to reviewers;
- industry registration seminars;
- electronic levy payments;
- electronic submission of applications;
- redevelopment of the APVMA database of registered products;
- developing service level agreements with service providers;
- revising first aid instructions and safety directions;
- quality assurance of agricultural active constituents and products;
- developing standards for low regulatory requirement products;
- annual returns of active ingredients;
- strategic review of agvet chemicals in Australia;
- liaising with Food Standards Australia New Zealand over the setting of maximum residue limits;
- proposed new legislation to provide for data protection; and
- reporting of adverse incidents involving agricultural chemical products.



TABLE D2: Membership of and attendance at Industry Liaison Committee meetings in 2002–03

Member	Organisation	Meetings eligible to attend	Meetings attended
Dr Alison Turner, Chairperson	APVMA	3	3
Dr Peter Holdsworth	Avcare Ltd	3	3
Ms Heather Neil	Avcare Ltd	2	2
Dr Faye Stenhouse	Avcare Ltd	2	2
Mr Geoff MacAlpine	Australian Consumer Et Specialty Products Association	3	2
Mr Neil McMahon	Pet Industry Joint Advisory Council of Australia Ltd	3	0
Mr Andrew Simons	Swimming Pool Et Spa Association of Australia	3	0
Mr Bruce McAllen	Plastics Et Chemicals Industries Association	3	2
Mr Ashley Vankrieken	Plastics Et Chemicals Industries Association	1	1
Mr Lindsay Showyin	Aerosol Association of Australia Inc	3	3
Mr Philip Fleming	Aerosol Association of Australia Inc	3	3
Mr Robert Schufft	Veterinary Manufacturers Et Distributors Association	3	3
Mr Neil Sammons	Veterinary Manufacturers Et Distributors Association	2	2
Mr Mike Craft	Veterinary Manufacturers Et Distributors Association	3	2
Mr Jim Adams	Veterinary Manufacturers Et Distributors Association	3	3
Mr Richard de Vos	Nursery and Garden Industry Association	1	1

Secretary: David Hutchison, telephone (02) 6271 6384.

### *Industry Technical Committee*

The Industry Technical Committee supports the Industry Liaison Committee by addressing technical issues affecting regulatory policy, programs and performance. Membership of the Industry Technical Committee is drawn mainly from the same industry groups represented on the Industry Liaison Committee.

During 2002–03, the Industry Technical Committee met twice in Canberra, in August 2002 and April 2003.

Matters before the committee in 2002–03 included:

- Low Regulatory Requirement Products scheme: developing standards for vitamins, mineral/amino acid, and complementary veterinary products;
- proposed amendments to the Ag Requirements Series – Guidelines for Registering Agricultural Chemicals concerning resistance;
- development of draft APVMA guidelines for adjuvants;
- development of draft APVMA guidelines for minor formulation changes to agricultural products;
- revisions to Ag Et Vet Manuals and Labelling Codes;
- project to improve processing times for applications;
- efficacy and safety reviews;
- quality assurance scheme for agricultural products;
- requirements of containers of registered products;
- globally harmonised system for labels of chemical products;
- minimum residue data requirements for veterinary 'image' products;
- applications for a trial protocol (category 50); and
- increased shelf-life of new registered products.

Table D3: Membership of and attendance at Industry Technical Committee meetings in 2002–03

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Mr Peter Raphael (Chairperson)	APVMA	2	2
Dr Joe Smith	APVMA	2	2
Ms Laura Lollback	Aerosol Association of Australia Inc	2	1
Ms Kathy Nolan	Australian Consumer Et Specialty Products Association	2	2
Mr Geoff MacAlpine	Australian Consumer Et Specialty Products Association	2	2
Mr Craig Suann	Australian Racing Board	2	1
Dr Norm Blackman	Australian Veterinary Association	2	2
Dr Peter Holdsworth	Avcare	2	2
Dr Fay Stenhouse	Avcare	2	2
Ms Ruth Davis	Australian Veterinarians in Industry	2	2
Mr Tom Grimes	Australian Veterinary Poultry Association	2	0
Mr Bruce McAllen	Plastics Et Chemicals Industries Association	1	0
Ms Stephanie Leach	Plastics Et Chemicals Industries Association	1	0
Mr Shane Walsh	Pet Food Industry Association of Australia	2	1
Mr Neil McMahon	Pet Industry Joint Advisory Council of Australia Ltd	2	0
Mr Greg O'Connell	Swimming Pool Et Spa Association of Australia	2	0
Mr Andrew Simons	Swimming Pool Et Spa Association of Australia	2	0
Dr Les Davies	Therapeutic Goods Administration	2	2
Mr Mike Craft	Veterinary Manufacturers Et Distributors Association	1	1
Mr Robert Schufft	Veterinary Manufacturers Et Distributors Association	2	1
Mr Neil Sammons	Veterinary Manufacturers Et Distributors Association	1	1
Mr Jim Adams	Veterinary Manufacturers Et Distributors Association	2	1
Mr Philip Fleming	Aerosol Association of Australia Inc	1	1

Contact: Thea Reiman, telephone (02) 6272 3744.



## *Registration Liaison Committee*

The Registration Liaison Committee is the main consultative forum between the APVMA, the states, territories and Commonwealth agencies relating to operational management of the National Registration Scheme. The committee meets twice each year in Canberra. During 2002–03, meetings were held in September 2002 and May 2003. The Commonwealth agencies represented on the committee are the Department of Agriculture, Fisheries and Forestry, Environment Australia, the National Occupational Health and Safety Commission and the Therapeutic Goods Administration's Office of Chemical Safety.

### *Purpose*

The committee works to ensure an efficient and coordinated approach to the Commonwealth's responsibilities for the supply of agricultural and veterinary chemicals up to and including the point of retail sale. The states and territories are responsible for control of use.

### *Terms of reference*

The committee's terms of reference are to:

- provide a forum for the ongoing development and operational management of the National Registration Scheme by an exchange of information between the states/territories and the APVMA pursuant to jurisdictional responsibilities under the National Registration Scheme;
- secure State/Territory and Commonwealth agency input to APVMA activities, particularly where they impinge on State/Territory responsibilities;
- identify, and provide opportunity for detailed examination of, key issues requiring management by both APVMA and the states; and
- secure expert advice as necessary.

Reports to the committee in 2002–03 included performance reports and continuous improvement activities relating to the APVMA's registration, permit, quality assurance/compliance and chemical review programs. Regulatory activity reports were provided by the states, territories, Commonwealth agencies and New Zealand. The committee received briefings on policy developments concerning the National Registration Scheme, legislative changes, data protection and

Australian participation in international forums, treaties and conventions. Other matters before the committee included:

- implementation of chemical review outcomes including user-training requirements;
- the Globally Harmonised System for Classification and Labelling of Chemicals;
- harmonisation of State and Territory control-of-use legislation;
- progress of the Agvet Labelling Code review;
- uniform regulation of high-risk (Schedule 7) agvet chemicals;
- standards for chemical residue assessment and acute dietary intake management;
- registration requirements relating to spray drift, seed colourants, animal welfare, vitamin and mineral products and products used in aquaculture;
- draft guidelines for the disposal of dipping solutions;
- arrangements for conducting efficacy reviews;
- ongoing enhancement of the National Registration Scheme database, internet access and development of e-commerce facilities; and
- active constituents and agricultural chemical products quality assurance.

The State and Territory Control of Use Working Group met in conjunction with meetings of the Registration Liaison Committee. The APVMA attended as an observer and to provide briefings to the working group as required.

## *Manufacturers' Licensing Scheme Industry Liaison Committee*

The Manufacturers' Licensing Scheme Industry Liaison Committee provides an opportunity for the APVMA to discuss strategic and operational issues related to the Manufacturers' Licensing Scheme with industry representatives. The committee met three times in 2002–03. Issues considered by the committee included:

- progress with auditing and licensing of veterinary chemical manufacturers, in particular conditional licence holders;

TABLE D4: Membership of and attendance at Registration Liaison Committee meetings in 2002–03

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Mr Peter Raphael (Chairperson September 2002 meeting)	APVMA	2	2
Dr Joe Smith (Chairperson May 2003 meeting)	APVMA	2	2
Mr David Power	ACT Department of Urban Services	2	0
Mr Lee Cook	NSW Agriculture	2	2
Mr Niall Johnston	NSW Environment Protection Authority	1	1
Ms Maryanne McCarthy	NSW Environment Protection Authority	1	1
Ms Kate Herring	NSW Environment Protection Authority	2	2
Mr Vlad Kawaljenko	NT Department of Business, Industry & Resource Development	2	2
Mr Wayne Thompson	Qld Department of Primary Industries	2	2
Mr John Kassebaum	SA Department of Primary Industries & Resources	2	2
Mr Mike Norman	Tas. Department of Primary Industries, Water & Environment	2	2
Ms Karen Armitage	Vic. Department of Natural Resources & Environment	1	1
Mr Kevin Hiser	Vic. Department of Primary Industries	1	1
Ms Sue Duncan	Vic. Department of Primary Industries	1	1
Mr Chris Sharpe	WA Department of Agriculture	2	2
Mr Andre Mayne	DAFF	2	1
Mr Ian Mortimer	DAFF	1	1
Mr Chris Lee-Steere	Department of Environment and Heritage	2	2
Dr Geoff Lovell	National Occupational Health & Safety Commission	2	2
Dr Les Davies	Therapeutic Goods Administration's Office of Chemical Safety, Department of Health & Ageing	2	1
Dr Andrew Bartholomaeus	Therapeutic Goods Administration's Office of Chemical Safety, Department of Health & Ageing	1	1
Mr Bill Roberts	Plant Health Committee	1	0
Dr Graeme Hamilton	Plant Health Committee	1	0
Mr Brian Pidford	NZ Ministry of Agriculture & Forestry	2	2
Dr Kevin Dunn	Animal Health Committee	1	0
Dr Brian Radunz	Animal Health Committee	1	0
Ms Joan Leary	Standing Committee on Fisheries & Aquaculture	1	0
Ms Melanie Buckley	Standing Committee on Fisheries & Aquaculture	1	1
Observer: Dr Matthew O'Mullane	Secretary, Advisory Committee on Pesticides & Health	2	1

Contact: Mr Alan Hill, telephone (02) 6272 5238.



- the proposed revision of the Australian Code of Good Manufacturing Practice (GMP) for Veterinary Chemicals with a view to harmonisation with international codes of GMP;
- availability of auditors and potential for conflict of interest ;
- organisation of the GMP training seminars for industry;
- improving communications with industry through the use of various tools including the internet; and
- operation and management of the various existing mutual recognition agreements and potential new ones.

### *Residues Advisory Committee*

The committee provides expert technical advice to the APVMA on issues and policy associated with chemical residues in food. The committee did not meet in 2002–03 but advice and comment on residue issues was sought out-of-session during the year.

### *Meat Consultative Committee*

At a SAFEMEAT meeting in July 2002 it was agreed that the Meat Consultative Committee be replaced by the SAFEMEAT Committee as a forum for consultation for the red meat industry and the APVMA on agvet chemical issues.

### *National Chemical Registration Information System External Users Group*

No meetings of the group were held during 2002–03.

**TABLE D5: Membership of and attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings in 2002–03**

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Mrs Fatima Beattie	APVMA	1	1 (Chairperson for 1 meeting)
Dr Bruce Johnson	APVMA	3	3 (Chairperson for 2 meetings)
Mr Graham Savage	APVMA	1	1 **
Mr Michael Nagajek	APVMA	2	2 **
Mrs Kathy Winterton	APVMA	3	1
Dr Peter Holdsworth	Avcare	3	3
Mr Ian Wheatley	Avcare	3	3
Mr Bill Blackhall*	Veterinary Manufacturers & Distributors Association	3	2 *
Mr Bruce Graham	Auditors' representative	3	2

\* Mr Iain Murray attended one meeting as a substitute for Mr Blackhall.

\*\* Mr Michael Nagajek replaced Mr Graham Savage (retired) as a representative of the APVMA.

**TABLE D6: Membership of Residues Advisory Committee in 2002–03**

Representative	Member organisation
Dr Trevor Doust (Chairperson)	APVMA
Mr Dennis Hamilton	Queensland Department of Primary Industries
Dr Tom McEwan	Consultant
Mr Robert Belcher	Consultant

Secretary: Dr Trevor Doust, telephone (02) 6272 3208.

## Appendix E: Freedom of information

Section 8 of the *Freedom of Information Act 1982* (the FOI Act) requires each Australian government agency subject to the Act to publish detailed information on its organisation, functions and powers, and on arrangements for public involvement in the formulation of agency policy or administration of any enactment or scheme. This statement, together with the information contained in this report, is intended to meet the requirements of the FOI Act.

### *Organisation and structure*

The APVMA operates nationally under the direction of a Board of Directors. Further details about the APVMA Board are in the Corporate Overview and at Appendix B. There is also an organisation chart in the Corporate Overview.

#### *The APVMA's offices are situated in Canberra at:*

Ground Floor, John Curtin House  
22 Brisbane Avenue  
Barton ACT 2600

#### *Postal address*

PO Box E240  
Kingston ACT 2604

### *APVMA's functions and powers*

The APVMA is responsible for assessing and registering agricultural and veterinary chemical products proposed for supply and use in Australia, and controls them up to the point of retail sale.

The APVMA has functions and powers that are conferred upon it by the Administration Act, by the Agvet Codes and the Agvet Regulations, and by certain State and Territory laws.

#### *Functions*

The APVMA's functions are:

- to assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products;
- to provide information to the governments and authorities of the Commonwealth, the states and participating territories about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for such products, and to cooperate with those governments and authorities on matters relating to the management and control of chemical products;
- to keep records and statistics of approvals and registrations it has granted, and permits and licences it has issued, under the Agvet Codes;
- to evaluate the effects of the use of chemical products in the states and participating territories;
- to cooperate with governments and authorities of the Commonwealth, states and participating territories, to facilitate a consistent approach to the assessment and control of chemicals;
- in cooperation with governments and authorities of the Commonwealth, states and participating territories, to develop codes of practice, standards and guidelines for, and to recommend precautions to be taken in connection with, the manufacture, export, import, sale, handling, possession, storage, disposal and use of chemical products in the states and participating territories;
- to collect, interpret, disseminate and publish information relating to chemical products and their use;
- to encourage and facilitate the application and use of results of evaluation and testing of chemical products;
- to exchange information relating to chemical products and their use with overseas and international bodies having functions similar to those of the APVMA;
- when requested by the Minister, or on its own initiative, to report to or advise the Minister on any matter relating to chemical products or arising in the course of the performance of its functions;
- to encourage and facilitate the introduction of uniform national procedures for control of the use of chemical products; and
- to fund, and cooperate in, a program designed to ensure that active constituents for proposed or existing chemical products, registered chemical products, and labels for containers for chemical products, comply with the Agvet Codes and the Agvet Regulations.



## Powers

The APVMA has powers to do all that is necessary or convenient to be done in connection with the performance of its functions, which may include:

- entering into contracts;
- acquiring, holding and disposing of real and personal property;
- occupying, using and controlling any land or building owned or held under lease by the Commonwealth, a State or a Territory and made available for the purposes of the APVMA;
- making available to the public, either without charge or upon payment of a fee to the APVMA, manuals, reports, lists of requirements and other documents; and
- doing anything incidental to any of its powers.

## Ministerial powers

In accordance with section 10 of the enabling legislation, the Administration Act, the Australian government Minister responsible for administering agvet chemicals legislation may direct the APVMA in writing in relation to the functions or powers that have been conferred on it under applicable Commonwealth or State laws. The APVMA must comply with any such direction. During 2002–03, the Minister gave no such direction.

In August 2002 the Minister for Agriculture, Fisheries and Forestry requested the APVMA to adopt the Commonwealth Fraud Control Policy. The APVMA has fully complied with that request.

## Access to information

The public may apply for the following information under the FOI Act:

- data packages provided by registration applicants for evaluation of agricultural and veterinary chemical products;
- APVMA files on specific chemical evaluations and on a range of topics relating to APVMA operations and functions; and
- meeting papers, briefs, minutes, and resolutions of decisions of the APVMA Board and consultative committees.

## Web site

Information on the APVMA's structure, functions, powers and publications may be obtained via the APVMA's home page at <http://www.apvma.gov.au>.

## Public registers

The APVMA maintains databases to store, manipulate and record product applications, to track submissions, and for product registration details, financial records, mailing lists and other information. Some other information, such as staff details, and industry and stakeholder contact details, is stored on databases.

Access to the following public registers is possible by arrangement, by visiting the APVMA offices, or through the APVMA's web site:

- the Register of Agricultural and Veterinary Chemical Products which is known as the Public Chemicals Registration Information System (PUBCRIS) (for information on numbers and approved uses of registered agvet products);
- the Record of Permits; and
- the Record of Approved Active Constituents for Chemical Products.

## Files and records

The APVMA maintains files on specific chemicals and on a range of topics relating to APVMA operations and functions. Agreements, protocols, criteria and guidelines on the registration process and the development of technical data are also maintained. The APVMA also retains technical information in the form of individual product applications.

## APVMA publications

The APVMA produces a range of publications on the National Registration Scheme and related matters. These publications are in the areas of:

- general information
- *APVMA News* (quarterly newsletter)
- *Agricultural and Veterinary Chemicals Gazette* (monthly Australian Government gazette)
- APVMA fact sheets
- APVMA community briefs

- APVMA Corporate Plan and Operational Plan
- APVMA Annual Report
- APVMA Service Charter
- media releases
- agricultural registration requirements series
- veterinary registration requirements series
- labelling code of practice
- guidelines on agricultural chemicals
- guidelines on veterinary chemicals
- guidelines on chemistry and manufacture
- specific guidelines
- efficacy and safety guidelines
- setting maximum residue limits
- guidelines for recall of agricultural and veterinary chemicals
- review of chemicals
- Good Manufacturing Practice
- reporting adverse experiences with chemicals
- agricultural and veterinary public release summaries.

Copies of publications may be obtained by contacting:

Public Relations Section

Ph: (02) 6272 3794

Fax: (02) 6272 5811

Email: [apvma.contact@apvma.gov.au](mailto:apvma.contact@apvma.gov.au)

### *Confidential information*

Some APVMA documents, particularly individual chemical product applications, contain confidential commercial information and may not be divulged except in accordance with the provisions of section 162 of the Agvet Codes.

### *Public consultation*

Special consideration is given to the APVMA's consultative mechanisms with the agvet chemicals industry and other relevant specialised industry sectors and community groups.

The APVMA has a general policy of making itself accessible to industry associations and community organisations, regularly inviting interested parties to meet with the Board or its other committees. It consults on a regular basis with a wide range of groups and organisations with relevant interests and maintains close contact with rural and service industries, researchers and other government agencies with an interest in agricultural and veterinary chemicals. For more detail on the APVMA's consultative framework, see Appendix D.

### *Requests for information under the FOI Act in 2002–03*

Seven requests for information under the FOI Act were received during 2002–03.

Requests for access to documents under the FOI Act can be made by writing (with the associated application fee) to:

FOI Coordinator  
National Registration Authority  
PO Box E240  
Kingston ACT 2604

The power to grant or refuse access to APVMA documents is held by each of the program managers. The CEO has internal review powers. Initial enquiries may be made by telephoning (02) 6272 3896.





## Appendix F: Consultancies

In 2002-03, the APVMA spent a total of \$294,603 on consultants, with 27 new consultancy contracts let during that period. The following table lists only those consultancies let to the value of \$10,000 or more.

The reason for engaging the consultancy services was a requirement for specialist expertise not available within the APVMA.

Consultant	Activity	Amount
ACIL Tasman	Facilitate APVMA Board Planning Day	\$13,558
Citec	E-commerce	\$48,253
David Wilson Consulting	Strategic Review	\$10,000
Deloitte Touche Tohmatsu	Strategic Risk Assessment	\$26,391
DAFF	Identification of the Impacts on Water Systems and Supplies of the Use of Ag & Veterinary Chemicals	\$49,500
Workplace Research Associates	Staff Attitude Survey	\$23,040
IBM Consulting (formerly Price Waterhouse Coopers Consulting)	Update of Activity Based Costing Model for Fees Review and Associated Financial Models	\$22,775
MPB Chartered Accountants	GST Review and Tax Compliance Advice	\$29,458
Taverner Minds	User Accreditation Project	\$11,000



## Glossary

ABARE	Australian Bureau of Agricultural and Resource Economics
ACAHS	Australian Centre for Agricultural Health and Safety
actives	active constituents
Administration Act	<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>
AERP Ag	proposed Adverse Experience Reporting Program for Agricultural Products
AERP Vet	Adverse Experience Reporting Program for Veterinary Chemicals
agvet chemicals	agricultural and veterinary chemicals
Agvet Code	Agricultural and Veterinary Chemicals Code
APVMA	Australian Pesticides and Veterinary Medicines Authority (formerly National Registration Authority for Agricultural and Veterinary Chemicals)
CAC Act	<i>Commonwealth Authorities and Companies Act 1997</i>
CEO	Chief Executive Officer
Code Act	<i>Agricultural and Veterinary Chemicals Code Act 1994</i>
Codex	Codex Alimentarius Commission
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
DIRKS	Designing and Implementing a Record Keeping System
DPIs	[State/Territory] Departments of Primary Industries
EEO	equal employment opportunity
FOI	freedom of information
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GTR	Gene Technology Regulator
HGP	hormonal growth promotant
ISO	International Organisation for Standardization
NOHSC	National Occupational Health & Safety Commission
NRA	National Registration Authority for Agricultural and Veterinary Chemicals (now Australian Pesticides and Veterinary Medicines Authority)
OECD	Organisation for Economic Cooperation and Development
Off-label	A term used to describe the different use patterns allowed under a permit
OGTR	Office of the Gene Technology Regulator
OHS	occupational health and safety
permit	Allows the legal use of a chemical in ways different to those specified on the product label or the limited use of an unregistered chemical
PUBCRIS	Public Chemicals Registration Information System
registration	Process of assessment and evaluation to determine a chemical's safety and efficacy
RSPCA	Royal Society for Prevention of Cruelty to Animals
TRIPS agreement	Trade-Related Aspects of Intellectual Property Rights agreement
VICH	International Committee for Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products



## Compliance Index

This annual report has been prepared in accordance with the *Commonwealth Authorities and Companies (Report of Operations) Orders 2002* and the Requirements for Annual Reports issued by the Department of the Prime Minister and Cabinet in June 2003.

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