



APPENDICES

APPENDIX A: THE APVMA'S ADVISORY BOARD

An Advisory Board supports the APVMA's CEO. The Advisory Board provides advice and makes recommendations to the CEO. The CEO is responsible for the governance and management of the authority, including the performance of its functions and the exercise of its powers.

While the Advisory Board does not have decision-making power, it advises the CEO and provides an expert consultative mechanism.

The Advisory Board consists of up to nine part-time members appointed by the Minister for their experience in areas including the regulation of chemical products at state and territory level, the agricultural chemical industry, the veterinary medicine industry, primary production, environmental toxicology, protection of consumer interests, public health and occupational health and safety. The Minister also has the discretion to appoint an additional Board member who has experience in a field relevant to the APVMA's functions.

The experience of Advisory Board members complements the role and responsibilities of the APVMA and includes representation from each key stakeholder sector.

Table A.1 Advisory Board attendance at meetings 2007–08

	MEETINGS ATTENDED	MEETINGS ELIGIBLE TO ATTEND
Mr Mark Allison (appointed 20 July 2007)	4	4
Mr Claude Gauchat (appointed 20 July 2007)	4	4
Ms Jenni Mack (appointed 20 July 2007)	4	4
Mr Wayne Cornish (appointed 20 July 2007)	2	4
Dr Richard Russell (appointed 11 October 2007)	3	4
Professor Michael Moore (appointed 20 July 2007)	4	4
Mr Simon Robinson (appointed 20 July 2007)	4	4
Mr Roger Toffolon (appointed 20 July 2007)	4	4
Mr Bill Magee (DAFF representative)	1	1
Mr Tom Aldred (DAFF representative)	2	3

Alan Hill telephone 02 6210 4786.

Declarations of Interest

There were no matters members of the Advisory Board declared that would give rise to any personal, material conflict of interest. Records of matters so declared are maintained by the APVMA.

Highlights

The Advisory Board provided advice to the Chief Executive Officer in the following areas:

- procedures for identifying appropriate current topics, emerging trends and issues on which to contribute strategic advice to the CEO within the Advisory Board's Terms of Reference
- reforming the APVMA efficacy assessment framework
- a proposed review of the registration and approvals for acephate
- budget revenue and expenditure assumptions and the review of APVMA cost recovery framework
- enhancing relationships and two-way communications with community, industry and government stakeholders
- the APVMA's submissions to the PC's Study on Chemicals and Plastics Regulation
- managing the likely impacts from the PC's study recommendations and COAG Task force 'early harvest' reforms
- the draft Preliminary Regulatory Impact Statement on Spray Drift
- corporate planning, risk management and development of the 2008–09 Annual Operational Plan
- improvements to project planning and management of chemical reviews
- registration and permit application timeframe performance
- Community Consultative Committee recruitment
- compliance strategy and investigations
- development of an APVMA position on independent testing of generic products

- recommendations relating to the review of the registration and approvals of fenitrothion
- release of the findings and regulatory actions relating to the review of atrazine
- the potential for developing a chemical use database and progressing harmonised control of use for agvet chemicals
- preparations for the regulation of nanotechnology materials
- the effectiveness of the Adverse Experience Reporting Program
- enhancing interaction between the Advisory Board and APVMA Audit Committee.

Audit committee

The APVMA Audit Committee plays a key role in the agency’s corporate governance and risk framework. It provides independent assurance to the Chief Executive to ensure the effective and efficient use of resources by reviewing the performance and operation of internal controls and performance management systems.

An independent member external to the agency chairs the APVMA Audit Committee and membership includes a member appointed by the APVMA Advisory Board, two Program Managers including Corporate Services Program Manager and an APVMA Executive Level 2 officer.

The committee approves the APVMA’s Internal Audit Program and advises the Chief Executive on risk, fraud and performance. The committee provides assurance to the Chief Executive that the APVMA is compliant with the Department of Finance and Deregulation Certificate of Compliance requirements and provides advice on preparation and review of financial statements.

Audit Committee meetings in 2007–08 were held in August and November 2007 and in February and May 2008 to coincide with key financial year milestones for provision of advice and reports to the CEO. Attendance at Audit Committee meetings is shown in Table A.2.

Table A.2 Attendance at APVMA Audit Committee meetings 2007–08

	MEETINGS ATTENDED	MEETINGS ELIGIBLE TO ATTEND
Mr Len Early	4	4
Mr Claude Gauchat	4	4
Dr Timothy Dyke	1	1
Mr Martin Holmes	3	3
Mr Jonathan Taylor	4	4
Mr Tony de la Fosse	1	1
Mr Daniel Webb	1	1
Ms Joanne Mitchell	2	2

APPENDIX B: COMMITTEES

Community Consultative Committee

Purpose

The APVMA's Community Consultative Committee (CCC) provides a direct link between the national agvet chemical regulator and the Australian community. It provides a forum for two-way communication between the APVMA and representative community organisations that have an interest in the way pesticides and veterinary medicines are regulated. The committee addresses issues that the community and the APVMA raise with it. The committee met four times in 2007–08 in September, December, March and June.

Terms of reference

The CCC's terms of reference require it to:

- communicate community views to the APVMA on a range of issues about pesticides and veterinary medicines
- encourage informed community debate by conveying information from the APVMA to community networks and explaining the operations and processes of the APVMA to the community
- convey community concerns to the APVMA about pesticides and veterinary medicines
- recommend to the APVMA further work that might be undertaken to resolve issues of community concern relating to the registration of pesticides and veterinary medicines
- advise on matters referred to it by the APVMA.

Issues considered

At each meeting, members report to the APVMA about committee-related activities as well as details of any important issues of concern. The APVMA provided reports to each meeting detailing registration and review activities for pesticides and veterinary medicines as well as quality assurance and compliance matters.

Highlights

Significant achievements for the committee in 2007–08 were:

- continued progress on the development of a harshness indicators guide, targeted at users of home garden products.
- presentation on the research the WHO Collaborating Centre for Research on Children's Health is undertaking on major environmental factors that impact on the health and well-being of children from conception to adolescence from Professor Sly
- providing advice on a community engagement charter as part of the APVMA's wider stakeholder engagement strategy
- continued work on advancing the emerging issues project in agvet chemical regulation
- Dr Heather Yeatman started as the new Chair of the CCC in March 2008 after Ms Jenni Mack completed her term as Chair.

Attendance at CCC meetings for 2007–08 is shown in Table B.1.

Table B.1 Membership and attendance at Community Consultative Committee meetings 2007–08

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Ms Jenni Mack (Chair, December 2007)	Australian Consumers Association	2	2
Dr Heather Yeatman (Chair, January 2008)	Public Health Association of Australia	2	2
Mr Sam Beechey	Australian Workers' Union	3	2
Ms Jo Immig	National Environmental Consultative Forum	3	2
Mr Peter Cone	National Farmers' Federation	4	3
Dr Elizabeth Hanna	Public Health Association of Australia	1	1
Mr Neville Prowse-Brown	Australian Landscape Trust, East Gippsland Landcare Network, Victorian Farmers Federation East Gippsland District Council	4	4
Ms Julie Northridge	National Audit and Registration Agency	4	3
Mr John Temperley	Farmsafe Australia Inc	4	4
Mr Joe Elbustani	Greenhouse Vegetables Association, NSW Farmers Association	4	3

Secretariat: K Blakers telephone 02 6210 4932

In 2007–08 Dr Timothy Dyke was the APVMA's executive advisor to the committee for the August meeting. Dr Simon Cubit was the APVMA's advisor for the December, March and June meetings.

Industry Liaison Committee

Purpose

The Industry Liaison Committee (ILC) was established in 1995 and is the main consultative forum for the APVMA and peak chemical industry organisations representing registrants.

In 2007–08 the ILC met in Canberra in August, November and April.

The purpose of the ILC is to:

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

Terms of reference

The committee's terms of reference 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 regulatory reform within the existing framework
- enable reporting by the APVMA to industry of its performance
- address specific operating policy issues through working groups
- consider the impact of proposed macro-policy changes on APVMA operations and implications for industry.
- projects to reduce elapsed time
- future direction on MORAG
- comment on the proposed industry model of stakeholder engagement framework
- the APVMA's cost recovery review
- registration process for low regulatory risk chemicals
- compliance reforms
- project planning of new applications
- PC chemicals and plastics study

Issues considered

- labelling reform

Attendance at ILC meetings for 2007–08 is shown in Table B.2.

Table B.2 Membership of and attendance at Industry Liaison Committee meetings 2007–08

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Dr Eva Bennet-Jenkins (Chair)	Australian Pesticides and Veterinary Medicines Authority	3	3
Mr Geoff MacAlpine	ACCORD Australasia	3	2
Ms Kathy Nolan	ACCORD Australasia	3	2
Ms Dusanka Sabic	ACCORD Australasia	1	1
Mr Lindsay Showyin	Aerosol Association of Australia Inc.	3	3
Dr Philip Fleming	Aerosol Association of Australia Inc.	3	3
Dr Peter Holdsworth	Animal Health Alliance (Australia) Ltd	3	2
Ms Paula Matthewson	CropLife Australia	3	1
Dr Adrian Harris	CropLife Australia	3	3
Mr John Firth	Generic Agricultural Chemical Association	3	0
Mr Kevin Bodnaruk	Nursery and Garden Industry Australia	3	2
Mr Bernard Lee	Plastics and Chemicals Industries Association	0	0
Ms Stephanie Leach	Plastics and Chemicals Industries Association	3	3
Mr Paul Simons	Swimming Pool and Spa Association of Australia	2	0
Mr Robert Schufft	The Veterinary Manufacturers and Distributors Association Ltd/Pet Industry Association of Australia	3	3
Mr Ian Saunders	Association Ltd/Pet Industry Association of Australia	3	3
Mr Neil Sammons	Association Ltd/Pet Industry Association of Australia	1	1

Industry Technical Committee

Purpose

The Industry Technical Committee (ITC) supports the Industry Liaison Committee (ILC) by addressing technical issues affecting regulatory policy, programs and performance. Membership of the ITC is drawn from industry groups represented on the ILC and from other specialist scientific and technical groups. In 2007–08, the ITC met in Canberra in September, February and June.

The objectives of the ITC are to:

- provide input to the development of operating procedures and publications
- review and consider the technical work of the APVMA
- address specific technical issues through working groups.

Terms of reference

The ITC was created by the ILC to:

- improve the functioning of the ILC for industry and the APVMA by dealing with specific technical issues
- provide a forum for peak industry and technical/professional bodies to progress technical, administrative and other relevant issues.

Issues considered

Issues before the ITC in 2007–08 included:

- reports of working group/consultation
- the APVMA's Adverse Experience Reporting Program
- data protection
- progressing on the development of an agricultural practices handbook
- World Association for the Advancement of Veterinary Parasitology guidelines
- gazettal of product name changes
- new guidelines and operational policies
- inter-row crop spraying
- nursery plant definitions/classifications
- herbicide mode of action groupings
- progress on duplication of requirements by statutory organisations
- submersible cage dippers for diazinon products
- progress of preparation of guidelines for therapeutic horse feeds (stock feeds) that require registration as veterinary medicines
- compliance strategic reform and review of Ag QA Scheme
- efficiency issues and projects to reduce elapsed time for applications
- draft permit for consumer trials
- pre-draft operational policy on repack products

Attendance at ITC meetings for 2007–08 is shown in Table B.3.

Table B.3 Membership of and attendance at Industry Technical Committee meetings 2007–08

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Mr Martin Holmes (Chair)	Australian Pesticides and Veterinary Medicines Authority	3	3
Ms Kathy Nolan	ACCORD Australia	3	2
Mr Geoff McAlpine	ACCORD Australia	3	2
Dr Philip Fleming	Aerosol Association of Australia	3	1
Mr Lindsay Showyin	Aerosol Association of Australia	3	2
Ms Michelle Wilson	SC Johnson	3	0
Mr Michael HR Hambrook	Australian Paint Manufacturers' Federation	3	1
Vacant	Australian Racing Board	3	0
Dr Keren Cox-Witton	Australian Veterinarians in Industry	3	3
Dr Bruce Twentyman	Australian Veterinary Association	3	1
Dr Peter Holdsworth	Animal Health Alliance (Australia) Ltd	3	2
Dr Adrian Harris	CropLife	3	3
Mr Kevin Bodnaruk	Horticulture Australia Limited	3	1
Dr Roger Bektash	Pet Food Industry Association of Australia	3	3
Ms Stephanie Leach	Plastics and Chemicals Industries Association	3	3
Mr Ian Saunders	The Veterinary Manufacturers and Distributors	3	3
Mr Neil Sammons	Association/Pet Industry Association of Australia	1	1
Mr Robert Schufft		3	2

Secretariat: K Blakers telephone 02 6210 4932

Manufacturers' Licensing Scheme Industry Liaison Committee

Purpose

The Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC) was established to provide a forum for the APVMA to discuss strategic and operational issues related to the Manufacturers' Licensing Scheme (MLS) with industry representatives and auditors. The committee met four times in July and October 2007 and in January and April 2008.

Terms of reference

The committee was created to promote active engagement of key stakeholders by:

- obtaining the views of industry members and auditors on issues of an operational, technical or strategic nature
- advancing the development and review of operating procedures, manufacturing standards and guidelines relevant to the MLS
- providing industry input into APVMA operational planning processes related to manufacturing issues

- identifying opportunities for regulatory reform within the existing framework
- considering the impact of proposed policy changes on APVMA operations and implications for industry
- facilitating communication with industry and other stakeholders.
- feedback from manufacturers on the audit process
- role of MLS ILC with Security Sensitive Chemicals
- various GMP issues, including computer validation, risk analysis, time frames, audit closure and scheduling of audits

Highlights

Issues considered during 2007–08 included:

- implementation of the new Manufacturing Principles and the associated Australian Code of Good Manufacturing Practice for Veterinary medicines
- implementation of the new audit report forms and processes
- initiatives to minimise duplication between the APVMA and the Australian Quarantine and Inspection Service (AQIS)
- progress with auditing and licensing of veterinary medicine product manufacturers
- auditor recruitment
- industry seminars to be held in 2008–09
- progress with the Overseas GMP Scheme
- review of the Overseas GMP Scheme
- various Overseas GMP issues including requirement to maintain evidence of GMP compliance and the auditing of overseas sites
- operation and management of mutual recognition agreements.

Attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings is shown in Table B.4.

Table B.4 Membership and attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings 2006–07

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Dr Bruce Johnson (Chair)	Australian Pesticides and Veterinary Medicines Authority	4	4
Mrs Kathryn Winterton	Australian Pesticides and Veterinary Medicines Authority	4	4
Mr Drew Ward (Secretariat July to December)	Australian Pesticides and Veterinary Medicines Authority	2	2
Miss Rheannon McNeil (Secretariat January to June)	Australian Pesticides and Veterinary Medicines Authority	2	2
Mr Andrew Duncum	Animal Health Alliance (Australia) Ltd	4	2
Dr Peter Holdsworth	Animal Health Alliance (Australia) Ltd	4	4
Mr Ian Wheatley	Auditors' representative	4	3
Mr Bill Blackhall	The Veterinary Manufacturers and Distributors Association	4	4

Registration Liaison Committee

The Registration Liaison Committee (RLC) is the main consultative forum for the APVMA, representatives of the state and territory signatories to the National Registration Scheme (NRS) and other relevant Australian government agencies.

Purpose

The main purpose of the RLC is to provide a forum for the development and operational coordination of the NRS and for consultation on the development of operational policies, guidelines and protocols in both the APVMA and the signatory organisations, to allow effective alignment of the agvet chemical control objectives of the APVMA and states and territories.

Terms of reference

The terms of reference of the RLC are to:

- align the outputs of the APVMA's registration processes and the chemical management objectives of the states and territories
- develop operational policies for the operation of the NRS including those dealing with registration (including labelling), regulation and appropriate use of agricultural and veterinary medicines
- provide feedback on state and territory views on these issues and particularly their impact on chemical users and the responsibilities of regulators
- address specific operating policy issues as necessary
- provide input to operational planning priorities
- provide input to existing chemical review priorities.

Formal meetings of the RLC were held in Canberra in September 2007 and March 2008, and by teleconference in November 2007.

Issues considered

The RLC agendas provide updates on participating agencies' operational activities, consultation and consideration of topical issues and progression of matters contained in the RLC/APVMA Work Plan. The APVMA's reports in 2007–08 included pesticides and veterinary medicines registration activities, permits and minor use, quality assurance and compliance and chemical review progress and priorities. The states, territories, other Australian government departments and New Zealand reported on legislative and policy developments, control of use and regulatory activity within their jurisdictions.

Highlights

Matters before RLC during the 2007–08 reporting period included:

- implementation of the Chemical Review Priority Scoring System, key amendments to Chemical Review procedures aimed at better targeting chemical reviews and improving productivity together with a range of website enhancements to help stakeholders to access information
- the APVMA's implementation of the Uhrig review of corporate governance arrangements and recommendations from the 2006 ANAO performance audit
- procedures for managing residues detections in 'follow' or rotational crops
- consultation on revisions to APVMA bio-equivalence guidelines
- APVMA permit and minor use reforms and activities including:
 - commencing the development of a small scale consumer trial permit
 - further transfer of existing minor use permits to registered product labels
 - proposed development of agreed permit procedures for European wasp baits

- development of an agreed definition of ‘nursery stock’ in consultation with industry
- developing data requirements and guidelines for chemicals used in shielded spraying equipment
- release for public comment of proposed changes to the APVMA *The Guidelines for Determining Minor Use*
- streamlining procedures for identifying ‘prime’ or key states and territories for specialist advice on minor use applications
- consultations with the states and territories on efficacy review procedures
- progress updates and consultation on the chemical reviews of diazinon, atrazine, 2,4-D, copper chrome arsenate, virginiamycin, fenitrothion and 1080.
- consultation on finalising Part 1 of the fenthion review, in particular the proposed Restricted Chemical Product declaration for fenthion bird control products.
- data protection in relation to product trials
- re-establishment of the dip disposal working group
- updates on the ‘state-based approvals’ project, preparations to review the AERP Ag program, work to align APVMA and FSANZ procedures for setting MRLs and policy consideration of displaying export intervals on product labels
- reporting on APVMA engagement in OECD, VICH and other international forums and working groups
- consultation with the state and territories on efficacy review procedures
- progress reports on the Productivity Commission study of chemicals and plastics regulation
- finalising the development of the APVMA spray drift guidelines
- communication of changes and updates to permits
- regulatory responses to the equine influenza outbreak
- control and use of pentobarbitone euthanasia products
- feedback on state and territory control of use and label stewardship presentations to the Industry Liaison Committee
- reports on Industry Waste Reduction Scheme programs (*drumMUSTER* and ChemClear)
- operational impacts of the APVMA restructure of operational programs and responsibilities
- implementing the final report on Effectiveness of the Restricted Chemical Product Framework
- a request for comment on the final draft of Appendix J/Restricted Chemical Product report.

Attendance at RLC meetings is shown in Table B.5.

Table B.5 Membership and attendance at Registration Liaison Committee meetings and teleconferences 2007–08

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Mr Martin Holmes (Chairperson) Dr John Owusu A/g Chairperson (November 2007)	Australian Pesticides and Veterinary Medicines Authority	3	2 1
Mr David Power Ms Stella Williams (November 2007)	Environment Protection, ACT Chief Minister's Department	3	1 1
Mr Lee Cook	Department of Primary Industries, NSW	3	3
Mr Andrew Hawkins	Department of Environment and Climate Change, NSW	3	2
Ms Sue Duncan	Department of Primary Industries, Vic.	3	3
Mr John Kassebaum Ms Petra Lennon	Primary Industries and Resources, SA	3	2 1
Mr Ian Parr	Department of Primary Industries and Water, Tas.	3	1
Mr Vlad Kawaljenko	Department of Primary Industry, Fisheries and Mines, NT	3	2
Mr Wayne Thompson Ms Cassie Wright (March 2008)	Department of Primary Industries and Fisheries, Qld	3	2 1
Mr Chris Sharpe	Department of Agriculture and Food, WA	3	2
Dr Martin Matisons	Department of Health, WA	3	2
Ms Maree Zinzley Ms Trish Whitaker	Agricultural Chemicals and Veterinary Medicines Group, New Zealand Food Safety Authority	3	3 3
Dr Geoff Thompson	Office of Chemical Safety, Australian Department of Health and Ageing	3	2
Mr Greg Plummer Dr Ian Pitt (September 2007)	Chemical Assessment Section, Australian Department of the Environment, Water, Heritage and the Arts	3	2 1

Secretariat: Alan Hill telephone 02 6210 4786

APPENDIX C: 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 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.

Requests for information under the Freedom of Information (FOI) Act in 2007–08

The APVMA received 13 requests for information under the FOI Act during 2007–08.

To request access to documents under the FOI Act write (with the associated application fee) to:

FOI Coordinator
Australian Pesticides and Veterinary
Medicines Authority
PO Box 6182
Kingston ACT 2604

The CEO, each of the program managers and the section managers hold the power to grant or refuse access to APVMA documents. The CEO and program managers have internal review powers. Initial FOI enquiries may be made by telephoning 02 6210 4785.

Organisation and structure

During the reporting period, the APVMA operated under the direction of the CEO. Further details about the CEO and organisational structure are in Chapter 5, 'The Organisation', and at Appendix A.

The APVMA's premises are situated in Canberra at:

18 Wormald Street
Symonston ACT 2609

Postal address:

PO Box 6182
Kingston ACT 2604

The APVMA's functions and powers

The APVMA is responsible for assessing and registering pesticides and veterinary medicines 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, the Agvet Code 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
- provide information to the Australian Government and its agencies and 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 Australian government agencies on matters relating to the management and control of chemical products
- keep records and statistics of approvals and registrations it has granted, and permits and licences it has issued under the Agvet Code

- evaluate the effects of the use of chemical products in the states and participating territories
- cooperate with the Australian Government and its agencies and the states and participating territories to facilitate a consistent approach to the assessment and control of chemicals
- in cooperation with the Australian Government and its agencies and the states and participating territories, 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
- collect, interpret, disseminate and publish information relating to chemical products and their use
- encourage and facilitate the application and use of results of evaluation and testing of chemical products
- 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, report to or advise the Minister on any matter relating to chemical products or arising in the course of the performance of its functions
- encourage and facilitate the introduction of uniform national procedures for controlling the use of pesticides and veterinary medicines
- 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 Code 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 of Australia, 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
- doing anything incidental to any of its powers.

Ministerial powers

In accordance with section 10 of the Administration Act, the Australian Government Minister responsible for administering agricultural and veterinary medicines legislation may direct the APVMA in writing in relation to the functions or powers that have been conferred on it under applicable Commonwealth of Australia, state and territory laws. The APVMA must comply with any such direction. The Minister gave no such direction in 2007–08.

Access to information

Website

Information on the APVMA's structure, functions, powers and publications may be obtained via the APVMA's website 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. Staff details and industry and stakeholder contact details are stored on databases. Access to the following public registers is possible by arrangement, by visiting the APVMA office during business hours, or through the APVMA's website:

Register of chemical products, known as the Public Chemicals Registration Information System (PUBCRIS), for information on numbers and approved uses of registered pesticides and veterinary medicines

Record of Permits

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 its 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 publications on the NRS and related matters. These publications include:

- *Agricultural and Veterinary Chemicals Gazette* (monthly Australian Government gazette)
- information sheets
- community briefs
- Corporate Plan and Annual Operational Plan
- Annual Report
- Service Charter
- People Plan
- media releases
- *Manual of Requirements and Guidelines* (MORAG Ag and Vet)
- labelling code of practice
- guidelines for pesticides
- guidelines for veterinary medicines
- guidelines on chemistry and manufacturing aspects
- specific guidelines
- efficacy and safety guidelines
- setting maximum residue limits
- guidelines for recall of agricultural and veterinary medicines
- review of chemicals
- code of Good Manufacturing Practice
- reporting adverse experiences with pesticides or veterinary medicines
- agricultural and veterinary public release summaries.

Copies of publications may be obtained by contacting:

Public Affairs Section
 Tel: 02 6210 4871
 Fax: 02 6210 4874
 Email: contact@apvma.gov.au
 Website: <http://www.apvma.gov.au>

Confidential information

Some APVMA documents, particularly individual chemical product applications, contain confidential commercial information and may not be divulged by the APVMA except in accordance with the provisions of section 162 of the Agvet Code or released under the FOI Act.

Public consultation

Special consideration is given to the APVMA's consultative mechanisms with the agricultural and veterinary medicines 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. 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 medicines. For more detail on the APVMA's consultative framework, see Appendix B.

APPENDIX D: CONSULTANCIES

In 2007–08, the APVMA spent \$676 772 (GST inclusive) on consultants, awarding 36 consultancy contracts during that period. The following table lists only those consultancies engaged to the value of \$10 000 or more (including GST) and details the amounts actually paid by the APVMA in the financial year.

Selection processes are described in terms drawn from the *Commonwealth Procurement Guidelines*. ‘Direct sourcing’ refers to a selection process where neither a tender nor a panel was used. In these situations, multiple quotes were obtained, the number of quotes depending on the value of the procurement. APVMA Finance Procedure 4 ‘Purchasing’ outlines the number of quotes required:

Purchase of goods/services	to \$2000	One verbal or written quote
Purchase of goods/services	\$2001 to \$10 000	Two written quotes
Purchase of goods/services	\$10 001 to \$30 000	Three written quotes
Purchase of goods/services	Over \$30 000	Tender

For purchases under \$80 000, exemptions to these requirements may be approved in some circumstances.

Table D.1 Consultancies over \$10 000

NAME	AMOUNT	ACTIVITY	SELECTION PROCESS	JUSTIFICATION
Broadleaf Capital International	\$31 460	Development of a scientific risk management framework	Direct sourcing	Specialist skills
Clayton Utz Lawyers	\$264 284	Legal advice	Legal panel	Specialist skills
Haddo Pty Limited	\$27 640	Website management	Direct sourcing	Specialist skills
Hall Regulatory Consulting	\$30 494	Review of Chemical Review section	Direct sourcing	Specialist skills
Hall Regulatory Consulting	\$12 441	MORAG Ag part 8 revision	Direct sourcing	Specialist skills
National Measurement Institute	\$11 000	Fixed asset revaluation	Direct sourcing	Specialist skills
Pesticides Regulation Consultancy	\$66 550	Specialist audit consultancy services	Legal panel	Specialist skills
PricewaterhouseCoopers	\$27 500	Activity Based Costing study	Direct sourcing	Specialist skills
Reading Room	\$16 500	Website redesign	Direct sourcing	Specialist skills
Smithworks Consulting	\$16 555	Management of annual report	Direct sourcing	Additional Resources
Trentora Pty Limited	\$50 029	IT support projects	Direct sourcing	Specialist skills
Vose Consulting	\$24 234	Expert witness services	Direct sourcing	Specialist skills
Total	\$578 687			

APPENDIX E: ADVERTISING AND MARKET RESEARCH

The following table sets out particulars of amounts over \$10 000 (including GST) that the APVMA paid during 2007–08 to advertising agencies or general advertising. The APVMA did not undertake any market research, polling or direct mail activities that cost over \$10 000.

Table E.1 Amounts over \$10 000 paid for advertising

NAME	AMOUNT	ACTIVITY
Fairfax Media	\$16 550	Open letters in response to a series of <i>Sydney Morning Herald</i> articles
<i>Farm Guide</i>	\$12 925	AERP advertising and general APVMA promotion
Total	\$29 475	

APPENDIX F: CORRECTION OF PREVIOUS REPORT

2006-07 Advertising and Market Research

No amounts over \$10 000 were paid to any advertising agencies or for general advertising. The APVMA did not undertake any market research, polling or direct mail activities that cost over \$10 000.

ACRONYMS

ACRONYM/ WORD	TITLE OR MEANING
AAT	Administrative Appeals Tribunal
ABC	Activity-based Costing Project
ACCORD	ACCORD Australasia Limited, the national advocate for the consumer, cosmetic, hygiene and specialty products sector
ACT	Australian Capital Territory
AERP	Adverse Experience Reporting Program (AERP <i>Ag</i> for pesticides and AERP <i>Vet</i> for veterinary medicines)
AGM	annual general meeting
Agvet Code	Agricultural and Veterinary Chemicals Code scheduled to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
Agvet/agvet	agricultural and veterinary
ANAO	Australian National Audit Office
ANU	Australian National University
APS	Australian Public Service
APVMA	The Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
AVA	Australian Veterinary Association
AWA(s)	Australian Workplace Agreement(s)
BRS	Bureau of Rural Sciences (Australia)
BSC	Balanced Scorecard [methodology]: means of visualising strategy in the APVMA's Corporate and Annual Operational Plans (after Kaplan and Norton)
BVDs	By-product Vendor Declarations
CAC Act	<i>Commonwealth Authorities and Companies Act 1997</i>
CA	Collective Agreement
CBF	competency-based framework
CCC	Community Consultative Committee (of the APVMA)
CCPR	United Nations FAO/WHO Codex Committee on Pesticides Residues
CCRVDF	United Nations FAO/WHO Codex Committee on Residues of Veterinary Drugs in Foods
CDDP	Commonwealth Director of Public Prosecutions
CEO	Chief Executive Officer (of the APVMA)
CHRIS HR	Third-party software used to generate employee salary payments
CLA(s)	Common Law Agreement(s)
COAG	Council of Australian Governments
CRIS	Cost Recovery Impact Statement

CRP	Chemicals Review Program
CVDs	Commodity Vendor Declarations
DAFF	Department of Agriculture, Fisheries and Forestry (Australia)
DAFWA	Department of Agriculture and Food, Western Australia
DECC	Department of Environment and Climate Change, New South Wales
DEW	former Department of Environment and Water Resources (Australia)
DEWHA	Department of the Environment, Water, Heritage and the Arts (Australia)
DoHA	Department of Health and Ageing (Australia)
DPI	Department of Primary Industries (NSW)
DPP	Director of Public Prosecutions (Australian states and territories)
EARS	Electronic Application and Registration System
EEO	Equal Employment Opportunity
EFTA	European Free Trade Association
EGMU	Expert Group on Minor Uses
EMS	Environmental management system
EPBC Act	<i>Environment Protection and Biodiversity Conservation Act 1999</i>
ESI(s)	Export Slaughter Interval(s)
EU	European Union
FAO	Food and Agriculture Organization (of the United Nations)
FMA Act	<i>Financial Management and Accountability Act 1997</i>
FOI	Freedom of Information
FOI Act	<i>Freedom of Information Act 1982</i>
FSANZ	Food Standards Australia New Zealand
FSC	Food Standards Code
GHS	Globally Harmonised System for Classification and Labelling of Chemicals
GMP	[Code of] Good Manufacturing Practice
HAL	Horticulture Australia Limited
HAWC	Health and Wellbeing Committee (of the APVMA)
HGP(s)	hormonal growth promotants
HR	human resources
HVE(s)	high volatile ester(s)
ILC	Industry Liaison Committee (of the APVMA)
ILS	Integrated Leadership Scheme
ISO	International Organization for Standardization
IT	Information technology
ITC	Industry Technical Committee (of the APVMA)

JECFA	Joint Expert Committee on Food Additives (of FAO/WHO)
JMPR	Joint FAO/WHO Meetings on Pesticide Residues
MHLW	Ministry of Health, Labour and Welfare (Japan)
MLS	Manufacturers' Licensing Scheme (Australia)
MLSILC	Manufacturers Licensing Scheme Industry Liaison Committee (of the APVMA)
MORAG	<i>Manual of Requirements and Guidelines</i> (of the APVMA)
MOU(S)	Memorandum of Understanding
MRA(s)	Mutual Recognition Agreement(s)
MRL	Maximum Residue Limit
MULO	Minor Use Liaison Office (joint venture of DAFF and the APVMA, Australia)
NAA	National Archives of Australia
Nchem	National Framework for Chemicals Environmental Management (Australia)
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRS	National Registration Scheme (Australia)
NSW	New South Wales (Australian state)
NT	Northern Territory (Australian territory)
NVRQS	National Veterinary Research and Quarantine Service (Korea)
OCS	Office of Chemical Safety (in the DoHA)
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator (Australia)
PBS	Portfolio Budget Statements (of DAFF)
PC	Productivity Commission (Australia)
PCRL	Priority Candidate Review List
PIRSA	Department of Primary Industries and Resources, South Australia
PMRA	Pest Management Regulatory Agency (Canada)
PPE	personal protective equipment
PRF	Preliminary Review Findings
PS Act	<i>Public Service Act 1999</i>
PSIC	Product Safety and Integrity Committee (of the Primary Industries Ministerial Council)
PUBCRIS	Public Chemicals Registration Information System
Qld	Queensland (Australian state)
QMAC	Quarantine and Market Access Conference (of the Quarantine and Exports Advisory Council, Australia)
RCEG	Residue Chemistry Expert Group
RECFIND	information management software
RF	Review Findings

RIRDC	Rural Industries Research and Development Corporation (Australia)
RLC	Registration Liaison Committee (of the APVMA)
RRSG	[Pesticide] Risk Reduction Steering Group (of the OECD)
RSG	[Pesticide] Registration Steering Group (of the OECD)
SA	South Australia (Australian state)
SLA(s)	Service Level Agreement(s)
SES	Senior Executive Service
SQL	database computer language designed for the retrieval and management of data in relational database management systems
SRP	Special Review Program
Tas.	Tasmania (Australian state)
VFF	Victorian Farmers Federation
VMDA	Veterinary Manufacturers and Distributors Association (Australia)
Vic.	Victoria (Australian state)
VICH	International Committee for Harmonisation of Veterinary Drug Registration Requirements
WA	Western Australia (Australian state)
WAAVP	World Association for the Advancement of Veterinary Parasitology
WHO	World Health Organization (of the United Nations)

ABBREVIATIONS AND GLOSSARY

ACRONYM/ WORD	TITLE OR MEANING
active ingredient	the component of the pesticide or veterinary medicine product responsible for its physiological or pharmacological action
adjuvant	whatever aids in removing or preventing a disease, especially a substance added to a prescription to aid the operation of the main ingredient
Administration Act	<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>
Ag QA Scheme	Quality Assurance Scheme for Agricultural Chemicals
Agvet Code	Agricultural and Veterinary Chemicals Code scheduled to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
Agvet/agvet	agricultural and veterinary
antiprotozoal agent	a class of pharmaceuticals used to treatment a protozoan infection
anthelmintic	destroying or expelling intestinal worms
ChemCert	National Farm Chemical User Training Program
ChemClear	chemical waste disposal program for the safe management of unwanted agvet chemicals
Codex	Codex Alimentarius Commission (United Nations)
Comcover	Australian Government's insurance fund
Commvault Server	a computer application used to back up computer network systems
cost recovery	fees and charges related to the provision of government goods and services (including regulation) to the private and other non-government sectors of the economy
CropLife Australia	represents the developers, registrants, manufacturers and formulators of plant science solutions for use in agriculture and the management of pests in other settings
<i>drumMuster</i>	the Australian national program for the collection and recycling of empty, cleaned, non-returnable crop production and on-farm animal health chemical containers
elapsed time	the overall time take for the APVMA to determine the outcome for an application for registration. It includes statutory time and applicant time in addressing deficiencies with applications
finfish	term used to distinguish true fish, having fins and gills, from shellfish, crayfish, or jellyfish
Gradlink	Graduate Careers Expo coordinated by Rimfire Resources Employment Agency
grandfathered products	all products that were registered under the transitional arrangements between the Commonwealth of Australia and the states and territory governments that existed at the time of the creation of the APVMA (then the NRA) in March 1995
Growcom	advocate for the Queensland horticulture industry
label	directions for a product's safe and effective use attached to a container
licence	authority to manufacture veterinary medicines according to s.123 of the Agvet Code
lousicide	product used for delousing animals
minor use	a use that would not produce sufficient economic return to an applicant to meet the cost of registering the product for that use

nanotechnology	refers to the design, characterisation and application of materials engineered at a molecular (nanometer) level to take advantage of their small size and/or novel properties. Although there is no agreed national or international definition of a nanomaterial, the general consensus in the scientific community is that a nanomaterial is engineered to measure approximately 1 to 100 nm in at least one dimension. One nanometer is one-billionth of a metre, or 100 000 times less than the width of a human hair.
pesticides	also known as agricultural chemical products
post-emergence	growth stages after seeds emerge from the soil surface.
registrant	a person who, or a company that, registers a pesticide or veterinary medicine product for use in Australia
salmonids	of, belonging to, or characteristic of the family Salmonidae, which includes the salmon, trout, and whitefish
spinosad	a new chemical class of insecticides whose active ingredient is derived from a naturally occurring soil dwelling bacterium and is used to control a variety of insects
statutory time	the legislatively prescribed timeframe in which the APVMA must process applications for registration
timeshift	a system of phased submission that allows applicants to submit an application for which not all the data are complete
Uhrig (review)	<i>Review of the Corporate Governance of Statutory Authorities and Office Holders, 2003</i>

COMPLIANCE INDEX

This Annual Report has been prepared in accordance with the *Requirements for Annual Reports for Departments, Executive Agencies and FMA Act Bodies* revised by the Department of the Prime Minister and Cabinet in June 2008. The report also adheres to the *Compliance Checklist for DAFF Portfolio Statutory Authority 2007–08 Annual Reports*.

Requirement

Advisory Board, 3, 5, 28, 33, 52, 53, 55, 61, 65

- particulars, 65, 121
- meetings held, 122, 123
- meeting attendance, 122, 123

Annual Operational Plan, 6, 53, 54, 66, 122, 135

Audit committee, 53, 54, 55, 123,

Australian National Audit Office Access Clauses, nil to report

Certification (of Financial Statements), 74–76

Chief Executive Officer's report, 3–5

Commonwealth Disability Strategy, 72

Contact officers, ii, 122, 125, 126, 128, 129, 132, 133, 135

Corporate Plan, 6, 53–55, 61, 122, 135

Corporate governance, 51, 53–54, 86, 123, 130

Description of organisation, 61–64

Developments since end of financial year, affecting

- operations in future financial years, nil to report
- results of those operations in future financial years, nil to report
- state of affairs in future financial years, nil to report

Directors, see Advisory Board

Effects of Ministerial directions, 134

Enabling legislation, 2, 52

Exempt contracts, nil to report

External scrutiny, 58

- judicial decisions, 58
- decisions of administrative tribunals, 58
- Auditor-General's reports, 58
- parliamentary committee reports, 59
- Commonwealth Ombudsman's reports, 58

Financial statements, 73–119

Glossary, 140, 144

General policies of the government, (FMA Act), iii, 3, (see also Financial Statements)

Indemnities and insurance premiums for officers, N/A

Index, 149

Internet homepage address and Internet address for report, ii, 135

Judicial decisions and reviews by outside bodies, 58–59

Legislative functions, 2, 86, 133

Legislative objectives, 2, 52

Letter of transmittal, iii

Location of major activities and facilities, 133

Management of human resources, 3–5, 66–71

- productivity gains, 3–5
- statistics on staffing, 66–71
- certified agreements and AWAs, 68
- performance pay, 70

Name of responsible Minister, 2

Operations and financial results, 1–48

principal outputs, 6–48

major investing and financing activities, 2 (see also Financial Statements)

key financial and non-financial performance indicators, 6, 13–16, 54, 55

Organisational structure, 64

Outlook, 5, 49–50

Performance assessment, 3–5, 6–59

efficiency and effectiveness in producing outputs, 3–5

clear links between outcomes, strategies and principal outputs, 6–50

developments since end of financial year that have affected or may significantly affect operations or financial results in the future, nil to report

Review of operations, 1–50

- performance review, 1–50, 55
 - statutory objectives and functions, 2, 52, 86, 133
 - Corporate Plan, 6, 54, 55, 61
 - principal outputs and contribution to outcomes, 6–50
 - Service Charter, 53
 - summary resource tables by outcomes, 10–13
- influences on performance, 3–5 (see also below)
 - factors, events or trends, 3–5, 49–50
 - risks and opportunities, 9, 13, 26, 40, 44, 49, 50, 53, 54, 58, 61, 70, 87

Service Charter, 55

Significant changes in state of affairs and/or principal activities, 3–5, 86

Significant events, 3–5

Stakeholders, 3, 49, 55, 56, 57, 58, 61, 62, 122, 128, 136

Subsidiaries, N/A

Table of contents, v–viii

Enabling legislation requirements

Borrowings, N/A

Human resources development program, 69–70

Ministerial directions, 134

Performance against performance indicators, 10–13

- Corporate Plan, 6–13
- Annual Operational Plan, 6–13

Significant purchases and disposals of real property (see Financial Statements)

Variations to the Corporate Plan and Annual Operational Plan, (see page 6, N/A)

Other reporting requirements

Funding of consultation costs for industry representative organisations N/A

Other legislative requirements

- Advertising and market research, 138, 139
- Assets management (see Financial Statements)
- Consultants, 137
- Discretionary grants, N/A
- Ecologically sustainable development and environmental performance, 57
- Freedom of Information, 133–136
- Fraud control, 53, 54, 58
- Occupational health and safety, 28, 65, 71–72
- Purchasing, 16, 137

Corrections of errors in previous annual report, 139



INDEX

- AAT, *see* Administrative Appeals Tribunal
- abbreviations, 144
- Acceptable Daily Intake, 23
- access, 56, 133–136
to information, 133–136
to management and staff, 56
- accidents, staff, 72
- accommodation, 81
- accountability, 51, 54
external, 54
internal, 54
- achievements, 5, 6, 10, 124
- acronyms, 140
- active approval applications, 10
- active constituents, 10, 18, 21, 23, 24, 35, 39, 41, 52, 55, 58, 133, 134, 135
approved, 24
- Activity Based Costing Project, 29
- Acute Reference Dose, 23
- Administration Act, 2, 43, 52, 54, 117, 133, 134, 144
- Administrative Appeals Tribunal, 58, 140
- Adverse Experience Reporting Program, 32, 37, 38, 45, 62, 123, 127, 135, 140
- Adverse Experience Reporting System, 57
- adverse experience reports, 9, 12, 38, 39
online reporting, 12
- advice, Audit Committee, 123
- Advisory Board, 3, 5, 28, 33, 52, 53, 55, 61, 65–66, 121–123
attendance at meetings, 122, 123
Audit committee, 123
declarations of interest, 122
highlights, 122
meetings, 122
- AERP *Ag*, 38, 46, 139, 140, 148
- AERP *Vet*, 39, 46, 47, 140, 148
- Ag QA Scheme, 39, 47, 48, 51, 58, 135, 152
- Agricultural and Veterinary Chemicals (Administration) Act 1992*, 2, 117, 144
- Agricultural and Veterinary Chemicals (Administration) Amendment Act 2007*, 86
- Agricultural and Veterinary Chemicals Code, 2, 10, 30, 148, 152
- Agricultural and Veterinary Chemicals Code Act 1994*, 2, 140
- Agricultural and Veterinary Chemicals Code Regulations 1995, 22
- Agricultural and Veterinary Chemicals Gazette*, 135
- agvet chemical sales, 22, 57
- Agvet Code, 10, 26, 51, 64, 65, 70, 141, 142, 144, 148, 152
- ANAO, 20, 47, 55, 57, 61, 62, 66, 138, 148, *see also* Australian National Audit Office
- animal safety, 47