



APPENDICES

APPENDIX A: THE APVMA'S ADVISORY BOARD

Purpose

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 Advisory 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 2008–09

	MEETINGS ATTENDED	MEETINGS ELIGIBLE TO ATTEND
Mr Mark Allison (appointed 20 July 2007)	5	5
Mr Claude Gauchat (appointed 20 July 2007)	5	5
Ms Jenni Mack (appointed 20 July 2007)	5	5
Mr Wayne Cornish (appointed 20 July 2007)	4	5
Dr Richard Russell (appointed 11 October 2007)	3	5
Professor Michael Moore (appointed 20 July 2007)	4	5
Mr Simon Robinson (appointed 20 July 2007)	3	5
Mr Roger Toffolon (appointed 20 July 2007)	4	5
Mr Tom Aldred (DAFF representative)	3	5

Declarations of Interest

Members of the Advisory Board did not declare any matters 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:

- progressing the cost recovery project and development of the *Cost Recovery Impact Statement (2009)*, including management of issues arising
- ensuring quality assurance of agricultural chemicals and verification of imports
- reviewing of the registrant component of the AERP Ag
- developing and implementing a new reporting framework for executive management meetings
- managing and reporting of resources and workloads
- progressing APVMA activities associated with COAG chemicals and plastics regulatory reform agenda
- enhancing the management of compliance litigation matters, including giving consideration to developing an APVMA enforcement policy
- preparing for review of the Ag QA Scheme
- formulating objectives, strategies and priorities for the development of the *Corporate Plan 2009–2012* and the *Operational Plan 2009–2010*
- informing and obtaining Advisory Board input at the ‘scoping stage’ of chemical reviews
- identifying refinements to procedures for aligning and strengthening information exchange between the Advisory Board, CEO, executive management and other APVMA committees

- managing the APVMA's reputation and maintaining working relationships with stakeholders
- reviewing outcomes of the mid-year 2008–09 Budget and *Operational Plan 2008–2009* and developing the assumptions used in framing the 2009–10 Budget
- improving the effectiveness of the APVMA corporate governance and financial accountability frameworks
- developing measures to improve the early identification, engagement, capture and tracking of strategic advice including, where necessary, referral of specific issues out of session to Advisory Board members with particular expertise
- preparing a proposal to review of APVMA data requirements for metabolism studies
- developing an APVMA position on international harmonisation and work share arrangements
- developing the APVMA's position on proposals for implementing the Globally Harmonised System of Classification and Labelling of Chemicals in Australia
- identifying strategic discussion topics for consideration at future Advisory Board meetings.

Audit committee

Purpose

The APVMA's Audit Committee provides independent assurance and advice to the CEO on the APVMA's risk control and compliance framework and its external accountability responsibilities. The Chair of the Committee meets with the CEO following each meeting and minutes of the meeting are loaded onto the intranet for all staff to access.

Committee members include an independent chair, and representatives from the APVMA Advisory Board, APVMA executive, and non-executive APVMA staff member. Committee observers include representatives from the Australian National Audit Office, an internal auditor and the APVMA Finance Manager.

The Audit Committee met four times in 2008–09 (August and November 2008 and February and May 2009). Attendance at the committee meeting is shown in Table A.2.

Table A.2 Attendance at APVMA Audit Committee meetings 2008–09

MEMBER	MEETINGS ATTENDED	MEETINGS ELIGIBLE TO ATTEND
Len Early	4	4
Claude Gauchat	4	4
Martin Holmes	2	2
Kathleen Barden	3	3
Neville Matthew	1	2
Joanne Mitchell	4	4



Highlights

Significant achievements for the Audit Committee in 2008–09 were:

- reviewed the 2008–09 Annual Financial Statements
- monitored the schedule for the preparation of the 2008–09 Annual Financial Statements
- reviewed audit reports: *Workforce Planning (recruitment and retention strategy)*, the *Fraud Control Plan* and *Fraud Risk Assessment*
- established an APVMA intranet page that lists the minutes of meetings and internal audit reports
- undertook a review of the Audit Committee performance and identified areas for improvement (for example, development of key performance indicators).

APPENDIX B: PRODUCT APPLICATION CATEGORIES AND TIMEFRAMES

The target for the APVMA is to complete all applications in the statutory timeframe. The initiatives within the elapsed timeframe project are also intended to address the shortfall in statutory timeframe.

The 25 application categories are aggregated into statutory timeframe periods that are prescribed in Schedule 6 of the Agvet Code Regulations.

Registration statistics can be found on the APVMA's website at <http://www.apvma.gov.au/perfreporting/subpage_reporting.shtml>.

Table B.1 Description of product application categories

2 to 3 months	Category 7, 8, 9, 12, 13, 14
5 months	Category 5, 6, 10, 14, 17, 18
6 to 8 months	Category 10,11, 14, 16
9 to 12 months	Category 10, 14, 15
13 to 15 months	Category 1, 10
Withdrawn	Treated as withdrawn by the APVMA, or voluntary withdrawal by the applicant
Cat 10	Cat 10 can be 5 to 15 months, most commonly 6 to 8 months
Cat 14	Cat 14 can be 2 to 14 months, most commonly 5 to 7 months



APPENDIX C: COMMITTEES

Community Consultative Committee

Purpose

The APVMA Community Consultative Committee (CCC) provides a direct link between the Australian community and the Australian Government regulator of pesticides and veterinary medicines. It provides a forum for two-way communication between the APVMA and community representative organisations with an interest in the way pesticides and veterinary medicines are regulated. The committee addresses issues raised with it by the community as well as those referred to it by the APVMA.

For the APVMA to operate to best effect, it is vital that it take into account current and emerging issues of interest and concern that the community has with the regulation of these chemicals. It is equally important that the community be kept fully informed on the rationale that underpins regulatory decisions. The CCC also provides the vehicle for the dissemination of information on such key issues back to the community.

While the regulation of pesticides and veterinary medicines can give rise to some contentious issues, the CCC operates in an atmosphere of shared respect for the different points of view represented in its membership and an acknowledgement of scientific fact as the legitimate basis for decision making.

The committee met in Canberra four times in 2008–09 (September and December 2008 and March and June 2009). Attendance at CCC meetings for 2008–09 is shown in Table C.1.

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, CCC 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 CCC in 2008–09 were:

- continued work on advancing the emerging issues project in pesticide and veterinary medicine regulation
- completion of the development of the guide ‘Choosing the chemical that is right for you’, which is now published on the APVMA website
- continued work on the current educational requirements around pesticide and veterinary medicine use
- presentation on Genetically Modified Organism Process by APVMA and Office of the Gene Technology Regulator.

Table C.1 Membership and attendance at Community Consultative Committee meetings 2008–09

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Dr Heather Yeatman (Chair, January 2008)	Public Health Association of Australia	4	4
Mr Peter Cone	National Farmers' Federation	4	3
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	3	3
Mr John Temperley	Farmsafe Australia Inc	4	4
Mr Joe Elbustani	Greenhouse Vegetables Association, NSW Farmers Association	4	3
Mr Anthony Amis	Friends of the Earth	4	4
Mr David Lawson	Consumers Federation of Australia	4	4

In 2008–09, Dr Raj Bhula was the APVMA's executive advisor to the committee.

Industry Liaison Committee

Purpose

The Industry Liaison Committee (ILC) was established by the APVMA in July 1995. It is the main consultative forum for the APVMA and peak chemical industry organisations representing registrants. The ILC is used to promote active engagement of key industry stakeholders in the strategic planning process, operational issues and associated reforms developed by the APVMA in its role as manager of the National Registration Scheme.



The objectives of the ILC are to:

- provide a forum for industry input through peak chemical industry bodies to APVMA's corporate planning activities, including consideration of current or emerging strategic issues
- provide a forum for formal consultation and discussion with peak chemical industry bodies on APVMA operating policies and programs
- enhance co-operation between industry and APVMA.

Terms of reference

The committee's terms of reference are to:

- obtain the views of industry members on issues of a strategic nature
- provide industry input to APVMA corporate planning processes
- identify opportunities for regulatory reform within the existing framework
- provide a forum for the exchange of information including performance and expectations
- address specific operating policy issues through working groups
- consider the impact of proposed macro-policy changes on APVMA operations and implications for industry.

Highlights

Issues before the ILC in 2008–09 included:

- labelling reform
- projects to reduce elapsed time
- the APVMA's cost recovery review
- nanotechnology
- Ag QA scheme
- providing input assisting the development of the APVMA *Corporate Plan 2009–12* and *Operational Plan 2009–10*
- natural health products
- verification of imports
- revision of fungicide activity groups
- presentation on pesticide impact rating index.

The committee met three times in Canberra during 2008–09 (August and November 2008 and April 2009). Attendance at ILC meetings for 2008–09 is shown in Table C.2.

Table C.2 Membership of and attendance at Industry Liaison Committee meetings 2008-09

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Dr Eva Bennet-Jenkins (Chair)	Australian Pesticides and Veterinary Medicines Authority		3
Mr Geoff MacAlpine	Plastics and Chemicals Industries Association	3	2
Ms Kathy Nolan	ACCORD Australasia	3	3
Ms Dusanka Sabic	ACCORD Australasia	3	3
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	3
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	3
Mr Bernard Lee	Plastics and Chemicals Industries Association	3	3
Ms Stephanie Leach	Plastics and Chemicals Industries Association	3	3
Mr Paul Simons	Swimming Pool and Spa Association of Australia	3	0
Mr Robert Schufft	The Veterinary Manufacturers and Distributors Association Ltd	3	3
Mr Ian Saunders	The Veterinary Manufacturers and Distributors Association Ltd	3	2



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.

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 committee's terms of reference are:

- 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.

Highlights

Issues before the ITC in 2008–09 included:

- reports of ITC working groups and consultation
- the APVMA's AERP
- register of APVMA requirements, guidelines and operational policies under development
- data requirements for natural health remedies
- project management approach to major applications
- adoption of VICH guideline on target animal safety for veterinary live and inactivated vaccines
- use of brilliant blue dye FCF in intramammary antibiotic products
- MRL standard – definition of fat tissue
- development of bioequivalence guideline
- process for developing a standard and revision of an existing standard
- efficacy of veterinary disinfectants
- APVMA Guideline 48 – requirements and guidelines for a particular batch shelf life extension permit for a registered veterinary chemical product
- APVMA Permit 7250 – permit to allow the conduct of small-scale trials with pesticides and veterinary medicines
- compounding of veterinary products – promoting and reiterating relevant arrangements regarding the National Registration Scheme which is operated under the AgVet Code

The committee met three times during 2008–09 (September 2008 and February and June 2009). Attendance at ITC meetings for 2008–09 is shown in Table C.3.

Table C.3 Membership of and attendance at Industry Technical Committee meetings 2008–09

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Mr Martin Holmes (Chair) September 2008	Australian Pesticides and Veterinary Medicines Authority	1	1
Mr James Suter (A/Chair) February 2009 & June 2009		2	2
Ms Kathy Nolan	ACCORD Australia	3	3
Ms Catherine Oh	ACCORD Australia	3	3
Dr Philip Fleming	Aerosol Association of Australia	3	2
Ms Christine Wasiowych	Aerosol Association of Australia	1	1
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	2
Dr Bruce Twentyman	Australian Veterinary Association	3	2
Dr Peter Holdsworth	Animal Health Alliance (Australia) Ltd	3	3
Dr Adrian Harris	CropLife Australia	3	3
Dr Kevin Bodnaruk	Horticulture Australia Limited	3	2
Dr Roger Bektash	Pet Food Industry Association of Australia	3	2
Ms Stephanie Leach	Plastics and Chemicals Industries Association	3	1
Mr Ian Saunders	The Veterinary Manufacturers and Distributors Association	3	3
Mr Robert Schufft		3	3

Manufacturers' Licensing Scheme Industry Liaison Committee

Purpose

The APVMA established the Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC) to provide a forum to discuss strategic and operational issues related to the Manufacturers' Licensing Scheme (MLS) with industry representatives and auditors.



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.

Highlights

Issues considered during 2008–09 included:

- progress with auditing and licensing of veterinary medicine product manufacturers
- feedback from manufacturers on the audit process
- GMP income and cost-recovery
- various GMP issues, including raw material checks, change of source of active ingredients and scheduling of audits
- 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
- minimisation of duplication between the APVMA, the Australian Quarantine and Inspection Service and the Office of the Gene Technology Regulator
- role of MLSILC with Security Sensitive Chemicals
- development of GMP training seminars for industry
- Auditors Workshop

The committee met four times during 2008–09 (in July and October 2008 and in January and April 2009). Attendance at MLSILC meetings is shown in Table C.4.

Table C.4 Membership and attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings 2008–09

MEMBER	ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Dr Bruce Johnson (Chair, July and April)	APVMA	2	2
Mrs Kathryn Winterton (Chair October and January)	APVMA	4	4
Mr James Suter	APVMA	2	1
Ms Toni Pike	APVMA	2	1
Ms Rheannon McNeil (Secretary January to June)	APVMA	2	2
Mr James Deller (Secretary January)	APVMA	1	1
Ms Michelle Elliot (Secretary April)	APVMA	1	1
Mr Andrew Duncum	Animal Health Alliance (Australia) Ltd	4	3
Dr Peter Holdsworth	Animal Health Alliance (Australia) Ltd	4	2
Mr Ian Wheatley	Auditors' representative	4	4
Mr Bill Blackhall	The Veterinary Manufacturers and Distributors Association	4	4

Registration Liaison Committee

Purpose

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, and other relevant Australian government agencies.

The purpose of the RLC is to provide a forum for the development and operational coordination of the National Registration Scheme and for consultation on the development of operational policies, guidelines and protocols in both the APVMA and the signatory organisations. The aim is to allow effective alignment of the pesticide and veterinary medicines 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 chemicals
- 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.

Issues considered

The RLC agendas provide for updates on participating agencies' operational activities, consultation and consideration of topical issues and projects. The APVMA's reports in 2008–09 included pesticides and veterinary medicines registration activities, permits and Minor Use, quality assurance, compliance and chemical review matters. The states, territories and other Australian government departments and New Zealand reported on legislative and policy developments, control of use and regulatory activity within their jurisdictions.

Highlights

Matters considered by RLC during 2008–09 included:

- progress of APVMA chemical reviews including:
 - finalising the chemical review of carbaryl – part 2 agricultural uses
 - regulation of phenoxy herbicides
 - the chemical reviews of 1080, 2,4-D, atrazine, chlorpyrifos, dichlorvos, copper chrome arsenate, triasulfuron and virginiamycin
- the progress of new and continuing APVMA permit and Minor Use activities including:
 - development of a glossary of terms and definitions applicable to agricultural and veterinary chemicals
 - procedures for communicating of changes and updates to permits
 - proposed development of a nationally consistent approach to issuing environmental weeds permits
 - possible adoption of European Plant Protection Organisation extrapolation tables
 - development of a small-scale trial permit
 - progress of the Permits to Label and Registration of Minor Uses project
 - proposed variations to the Guidelines for Determining Minor Uses
 - identification of 'prime' or key states and territories for specialist advice on Minor Use applications
 - the review of transitional state-based off-label permit approvals

- development of data requirements and assessment guidelines for chemicals used in shielded spraying equipment
- development of the APVMA's proposed strategy for managing applications for registration of nanotechnology products
- development of a Model for Registration: Copper Sulphate as an Algaecide in Agricultural Water Storages
- registration requirements for veterinary natural health products
- APVMA disposal instructions for empty agricultural and veterinary chemical containers
- rotational crops: control of pesticide application, MRLs and trade issues
- development of policy for inclusion of export interval information on product labels
- proposals for implementing the Globally Harmonised System of Classification and Labelling of Chemicals in Australia
- development of a Framework for Evaluation of Antimicrobial Resistance for New Antibiotic Products
- a proposed change to the MRL Standard – Definition of Fatty Tissues
- presentations and discussion papers including:
 - APVMA strategic directions
 - progress of the APVMA's cost recovery review project
 - governance procedures for committee member notifications and declarations
 - potential implications for the APVMA of the Productivity Commission Study on Chemicals and Plastics Regulation
 - Monitoring Spray Application using Electronic Equipment
 - the Tasmanian River Catchment Water Quality Initiative
 - the National Chemical Environmental Management process
 - compounding of veterinary products and the United Kingdom cascading system for veterinary prescribing
 - the re-development of the APVMA website
 - control and use of pentobarbitone euthanasia products
 - proposed declaration of pre construction termiticides as Restricted Chemical Products
 - matters to be included in the development of the *Manual of Requirements and Guidelines 2009–10*
 - matters relating to service level agreements between the APVMA, the states and territories and other Australian Government departments
 - APVMA Spray Drift Guidelines – compliance with label requirements
 - removal of fluorine (inorganic salts) MRLs from the MRL standard.
 - Formal meetings of the RLC were held in Canberra in September 2008 and March 2009, and three more meetings were held by teleconference (in July and November 2008 and June 2009). Attendance at RLC meetings is shown in Table C.5.

**Table C.5 Membership and attendance at Registration Liaison Committee meetings and teleconferences 2008–09**

MEMBER	ORGANISATION	MEETINGS ELIGIBLE	MEETINGS ATTENDED
Mr Martin Holmes (Chairperson, September 2008, November 2008) Dr Raj Bhula A/g Chairperson (March 2009, June 2009)	APVMA	3 5	2 5
Mr David Power Ms Stella Williams (November 2007)	Environment Protection, ACT Chief Minister's Department	5	3 1
Mr Lee Cook Mr Mark Scott	Department of Primary Industries, NSW	5	4 2
Mr Andrew Hawkins Ms Patricia Fabiano Ms Carmen Dwyer Mr Ahdy Hanna Mr Roger de Keyzer	Department of Environment and Climate Change, NSW	5	4 1 3 2 1
Ms Sue Duncan Mr George Downing Mr Akau Chan Mr Alan Roberts	Department of Primary Industries, Victoria	5	4 2 1 1
Mr John Kassebaum Ms Petra Lennon	Primary Industries and Resources, South Australia	5	2 3
Mr Ian Parr	Department of Primary Industries and Water, Tasmania	5	5
Mr Vlad Kawaljenko Mr John Alcock	Department of Primary Industry, Fisheries and Mines, Northern Territory	5	4 1
Mr Wayne Thompson Ms Pam Bowles Mr Richard Watts Mr Ian Wells	Department of Primary Industries and Fisheries, Queensland	5	3 1 1 1
Mr Chris Sharpe Mr John Moore	Department of Agriculture and Food, Western Australia	5	3 1
Dr Martin Matisons	Department of Health, Western Australia	5	0
Ms Maree Zinzley Ms Trish Whitaker	Agricultural Chemicals and Veterinary Medicines Group, New Zealand Food Safety Authority	5	2 2
Dr Geoff Thompson Dr Donald Ward Mr Mathew Bulters Dr Gary Buffinton	OCSEH, Australian Department of Health and Ageing	5	1 4 1 1
Mr Greg Plummer Mr Phillip Sinclair Dr Robert Berthon	Chemical Assessment Section, DEWHA	5	1 1 1

APPENDIX D: 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 2008–09

The APVMA received 23 requests for information under the FOI Act during 2008–09. This is ten more requests than were received in 2007–08. The requests covered issues such as:

- analyses, trials and evaluations associated with products
- information supporting specific product claims
- enquiries associated with research
- product formulation details, misplaced by the product owner.

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 2: Organisation Overview.

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 Code 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 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 Code 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

The Minister gave no direction to the APVMA under section 10 of the Administration Act in 2008–09.

Access to information

Website

Information on the APVMA's structure, functions, powers and publications may be obtained from 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, 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:

- monthly APVMA Gazette
- information sheets
- community briefs
- corporate plans and annual operational plans
- annual reports
- service charter
- *People Plan 2006–2009*
- 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 pesticides and veterinary medicines
- review of chemicals
- code of GMP
- 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 these 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 pesticides 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 pesticides and veterinary medicines. For more detail on the APVMA's consultative framework, see Appendix C.



APPENDIX E: CONSULTANCIES

During 2008-09, 30 new consultancy contracts were entered into involving total actual expenditure of \$202,354 (GST inclusive). In addition, 15 ongoing consultancy contracts were active during the 2008-09 year, involving total actual expenditure of \$799,858 (GST inclusive). 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 | up to \$2000 | One verbal quote 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 E.1 Consultancies over \$10 000

NAME	AMOUNT	ACTIVITY	SELECTION PROCESS	JUSTIFICATION
Birubi Agvet Consultancy	\$14 737	Professional services relating to veterinary chemical products/permits.	Direct Sourcing	Specialist skills
Clayton Utz	\$583 217	Legal advice	Legal panel	Specialist skills
Dale Boucher	\$26 500	Legal advice	Direct Sourcing	Specialist skills
Hall Regulatory Consulting	\$12 055	Activity Based Costing study	Direct Sourcing	Specialist skills
Len Early Pty Ltd	\$21 600	Services provided as chair of APVMA Audit Committee	Direct Sourcing	Specialist skills
Pesticides Regulation Consulting	\$22 426	Preparation of briefs and legal supporting documentation	Direct Sourcing	Specialist skills
Price Waterhouse Coopers	\$66 480	Activity Based Costing study	Direct Sourcing	Specialist skills
Resolution Consulting Services	\$41 096	Assistance with preparation of Cost Recovery Impact Statement and with Finance Plan	Direct Sourcing	Specialist skills
Stamford Interact	\$22 248	Web design and development	Direct Sourcing	Specialist skills
Trentora Pty Ltd	\$55 796	Technical services relating to system administration for servers and Web design and development	Direct Sourcing	Specialist skills
University of Wollongong	\$11 423	Peer review services	Direct Sourcing	Specialist skills
Walter Turnbull	\$12 726	Fraud Control Plan	Select Tender	Specialist skills
TOTAL	\$890 303			



APPENDIX F: ADVERTISING AND MARKET RESEARCH

The following table sets out particulars of amounts over \$10 000 (including GST) that the APVMA paid during 2008–09 to advertising agencies or general advertising. The APVMA did not undertake any market research, polling or direct mail activities that cost more than \$10 000.

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

NAME	AMOUNT	ACTIVITY
Farm Guide	\$13 563	AERP advertising and education
TOTAL	\$13 563	

APPENDIX G: CORRECTION OF PREVIOUS REPORT

The APVMA 2007-08 Annual Report was transmitted to the Minister on 29 September 2008

Table G.1: 2007-08 APVMA expenditure by output

	2007-08 ACTUAL	2007-08 BUDGET (PER PBS)	2006-07 ACTUAL
Output 1.1: Regulatory decisions and information	20,709,524	20,712,000	19,240,656
Output 1.2: Chemical product quality	4,141,280	3,243,000	4,001,146
TOTAL RESOURCES FOR OUTCOME 1	24,850,804	23,955,000	23,241,802

The APVMA 2007-08 Annual Report was transmitted to the Minister on 29 September 2008

2007-08 Consultancies

During 2007-08, 25 new consultancy contracts were entered into involving total actual expenditure of \$283,444. In addition, 11 ongoing consultancy contracts were active during the 2007-08 year, involving total actual expenditure of \$393,328.



2007–08 COMPLIANCE INDEX

This Annual Report has been prepared in accordance with the APVMA's statutory obligations. These obligations are outlined in 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 2009 and the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

The reporting requirements have been identified under the legislation or requirements to which they relate, noting that a number of requirements are common to both.

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ACRONYMS

ACRONYM/WORD	TITLE OR MEANING
ACT	Australian Capital Territory
AERP	Adverse Experience Reporting Program (AERP Ag for pesticides and AERP Vet for veterinary medicines)
ANAO	Australian National Audit Office
APS	Australian Public Service
APVMA	The Australian Pesticides and Veterinary Medicines Authority
AWA(s)	Australian Workplace Agreement(s)
CA	Collective Agreement
CCC	Community Consultative Committee (of the APVMA)
CEO	Chief Executive Officer (of the APVMA)
CLA	Common Law Contracts
COAG	Council of Australian Governments
CRP	Chemicals Review Program
DAFF	Department of Agriculture, Fisheries and Forestry (Australia)
DEWHA	Department of the Environment, Water, Heritage and the Arts (Australia)
EARS	Electronic Application and Registration System
EGMU	Expert Group on Minor Uses
EPBC Act	Environment Protection and Biodiversity Conservation Act 1999
FOI	Freedom of Information
GMP	[Code of] Good Manufacturing Practice
HGP(s)	hormonal growth promotants
ILC	Industry Liaison Committee (of the APVMA)
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
MCPA	A herbicide: 2-methyl-4-chlorophenoxyacetic acid

ACRONYM/WORD	TITLE OR MEANING
MCPB	A herbicide: 4-(4-chloro-o-tolyloxy)butyric acid
MLS	Manufacturers' Licensing Scheme (Australia)
MLSILC	Manufacturers Licensing Scheme Industry Liaison Committee (of the APVMA)
MORAG	Manual of Requirements and Guidelines (of the APVMA)
MRL	Maximum Residue Limit
NRS	National Registration Scheme (Australia)
NSW	New South Wales (Australian state)
OCSEH	Office of Chemical Safety and Environmental Health
OECD	Organisation for Economic Co-operation and Development
PACC	Pesticide and Agricultural Chemical Committee
PSIC	Product Safety and Integrity Committee (of the Primary Industries Ministerial Council)
RLC	Registration Liaison Committee (of the APVMA)
SES	Senior Executive Service
TGA	Therapeutic Goods Administration
VICH	International Committee for Harmonisation of Veterinary Drug Registration Requirements
VMEAP	Veterinary Medicines Expert Advisory Panel
WHO	World Health Organization (of the United Nations)

ABBREVIATIONS	GLOSSARY
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	Agricultural and Veterinary Chemicals (Administration) Act 1992
Ag QA Scheme	Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products
Agvet Code	Agricultural and Veterinary Chemicals Code scheduled to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
Agvet Code Regulations	Agricultural and Veterinary Chemicals Code Regulations scheduled to the <i>Agricultural and Veterinary Chemicals Code Regulations 1995</i>
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
Codex	Codex Alimentarius Commission (United Nations)
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
drumMUSTER	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
FOI Act	Freedom of Information Act 1982
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 National Registration Authority) in March 1995
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
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

ABBREVIATIONS	GLOSSARY
nanotechnology	refers to the design, characterisation and application of materials engineered at a molecular (nanometre) 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 nanometre 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
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 <i>Salmonidae</i> , 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)	Review of the Corporate Governance of Statutory Authorities and Office Holders, 2003

2008–09 COMPLIANCE INDEX

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