



CHAPTER 5

APPENDIXES

APPENDIX A ADVISORY BOARD AND AUDIT COMMITTEE

APVMA ADVISORY BOARD

The Chief Executive Officer (CEO) of the APVMA is supported by an Advisory Board.

The Advisory Board does not have decision-making power. It advises the CEO and provides an expert consultative mechanism, either on its own initiative or at the request of the CEO, by providing advice and recommendations on issues relevant to the execution of the functions of the APVMA.

Arrangements for the Advisory Board's appointment, function and procedure, as well as its interaction with the CEO, are prescribed by legislation.

The Advisory Board comprises up to nine part-time members appointed by the Minister for Agriculture for their experience in areas associated with the APVMA's stakeholder community. The individual members are appointed on the basis of their abilities to contribute at the highest level to the national regulation of chemicals in Australia. The experience of members represents, as far as possible, each key stakeholder sector. These are the regulation of chemical products at state and territory level, the agricultural chemical and veterinary medicine industries, primary production, environmental toxicology, protection of consumer interests, public health, and work health and safety. In addition, the minister also has the discretion to appoint a member who has experience in a field relevant to the APVMA's functions.

The Secretary of the Department of Agriculture, or a person authorised by the secretary, may attend meetings. The CEO may also invite a person, other than an Advisory Board member or the secretary, to attend a meeting for the purpose of advising or informing it on any matter.

The Advisory Board comprises the following members, who were appointed for a three-year term commencing on 13 November 2012:

Lyn Fragar AO is a public health physician and an adjunct associate professor with the Australian Centre for Agricultural Health and Safety, University of Sydney. She currently chairs the Hunter New England Local Health District Board. Dr Fragar has been appointed as an Advisory Board member for her expertise in public health, and work health and safety. She has also been appointed to the position of Chair of the Advisory Board.

Sandra Baxendell PSM is the Director of Goat Veterinary Consultancies. She has been a senior lecturer specialising in animal production at Curtin University, and has also worked in agricultural production and industry management roles. Dr Baxendell has extensive Queensland Government experience in a variety of roles, including Regional Director, General Manager (Chemical Use and Food Safety), Director Product Integrity, and Acting General Manager Plant Biosecurity and Product Integrity. Dr Baxendell has been appointed as an Advisory Board member for her experience in the regulation of chemical products under state or territory law.

Bronwyn Capanna is the Executive Director of Accord Australasia, the industry association representing the hygiene, cosmetics and specialty products industry. She has more than 20 years' experience in industry association management, and has held senior positions as a regulatory and technical executive in the not-for-profit and private sectors in Australia and the United Kingdom. She continues to be highly engaged in regulatory reform at a national and international level. Ms Capanna has been appointed as an Advisory Board member for her experience in a field relevant to the APVMA's functions under the optional provisions in the legislation.

John Hassell operates his own farming business, together with off-farm contracting in baling, spraying and clover harvesting. He is also a director of Co-operative Bulk Handling Ltd, Grain Pool Pty Ltd, Bulk West Engineering Pty Ltd and other subsidiaries. Mr Hassell has previously worked as a farm and laboratory assistant with a range of companies. He is an ongoing member of the Western Australian Farmers Federation and is also a member of the Pingelly Land Conservation District Committee. Mr Hassell has been appointed as an Advisory Board member for his experience in primary production.

David Lawson is a financial counsellor, and runs his own consultancy and general counselling business. Mr Lawson was previously a sugarcane farmer, and ran a contracting and farm machinery hire business. He has held a number of senior representative roles in the sugar industry, and has experience representing consumer interests in the areas of financial counselling, telecommunications, energy and banking at a state and national level, including as a representative of the Consumers' Federation of Australia and as a member of the APVMA's Community Consultative Committee. He chairs the management committee of a school for youth who are disengaged from the state school system. Mr Lawson has been appointed as an Advisory Board member for his experience in protecting consumer interests.

Gordon Reidy is the Regional Manager (Asia Pacific Regulatory Development and Toxicology) for the Sumitomo Chemical Company. Dr Reidy has held a range of toxicology-related roles in WorkSafe Australia, AGC Woodward-Clyde Pty Ltd, 3M Asia Pacific and Reckitt Benckiser. He served on the Drugs and Poisons Scheduling Committee and the Basel Hazardous Waste Technical Committee. He has also been a board member of the Australian Consumer Products Industry Association. Dr Reidy has been appointed as an Advisory Board member for his experience in environmental toxicology, including knowledge of the effects of chemicals in ecosystems.

Selwyn Snell is the managing director of Barawyn Pty Ltd. He has extensive experience in agribusiness, including a number of senior roles spanning corporate management, financial and strategic planning, farming research and development. He is the current Chairman of Horticulture Australia Ltd. Mr Snell has been appointed as an Advisory Board member for his experience in the agricultural chemical industry.

Roger Toffolon is the Director of Biosecurity Strategy, Legislation and Performance in the New South Wales Department of Primary Industries. Mr Toffolon has worked as an entomology researcher and has held a number of senior roles in the New South Wales Government as Registrar and Program Leader for Agricultural and Veterinary Chemicals, and Manager of Biological and Chemical Risk Management. He has been appointed as an Advisory Board member for his experience in the regulation of chemical products under state or territory law.

Lisa Wade is Director of Bellmount Consulting Pty Ltd, which provides consulting services to the agricultural and veterinary industries. Dr Wade was previously a veterinarian working in mixed practice both in Australia and the United Kingdom. She has experience in the research and development of a wide range of veterinary therapeutics, and experience with Australian and international regulatory systems. She has been a member of the Animal Health Alliance Issues Management Group and chaired the group's Antimicrobial Resistance Task Force. Dr Wade has been appointed as an Advisory Board member for her experience in the veterinary chemical industry.

Meetings and attendance

Advisory Board meetings were held in July, September and December 2013, and February and April 2014. All meetings were held in Canberra, except the September 2013 meeting, which was held in Sydney. Summaries of the key outcomes of meetings are published on the APVMA website.

Attendance at Advisory Board meetings is shown in Table A1.

Table A1 Attendance at Advisory Board meetings, 2013-14

Members	Meetings eligible to attend	Meetings attended
Lyn Fragar	5	5
Sandra Baxendell	5	4
John Hassell	5	5
David Lawson	5	5
Bronwyn Capanna	5	5
Gordon Reidy	5	5
Selwyn Snell	5	4
Roger Toffolon	5	4
Lisa Wade	5	5
Department of Agriculture representation	5	5

Issues considered

In 2013-14, the Advisory Board advised the CEO in relation to a range of strategic matters, including implementation of the legislative reforms, development of regulatory guidelines to support applicants, effective external consultation, business re-engineering, and aligning regulatory burden with regulatory risk in assessment of applications and compliance.

Presentations

In 2013-14, the Advisory Board received one external presentation from the Australian Government Department of Agriculture on the development of a national antimicrobial resistance framework.

Declarations of interest

Members of the Advisory Board are required under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* to disclose as soon as practicable any direct or indirect financial interests that could conflict with the proper performance of the Advisory Board's function. Any decision made in relation to a disclosure about a matter that is being considered, or about to be considered, at a meeting must be recorded in the minutes of the meeting.

Records of disclosures by Advisory Board members are kept by the APVMA. No conflicts of interest that would conflict with the proper performance of the Advisory Board's functions were declared at any meeting in 2013-14.

APVMA AUDIT COMMITTEE

The APVMA Audit Committee is part of the APVMA governance and risk framework. Its terms of reference are to provide independent assurance and advice to the CEO in relation to the risk control and compliance framework, the APVMA's financial and management responsibilities, and its external accountability responsibilities.

The committee members include an independent chair, a representative from an external organisation, and APVMA executive and non-executive staff members. Committee observers can include representatives from the Australian National Audit Office, an internal auditor and the APVMA Finance Manager.

Meetings and attendance

The committee met four times in 2013-14: in August and November 2013, and February and May 2014. Attendance at Audit Committee meetings is shown in Table A2.

Table A2 Attendance at Audit Committee meetings, 2013-14

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Peter Hoefler	External independent Chair	4	4
Allen Bryce	APVMA Executive Director, Veterinary Medicines	4	4
Tony de la Fosse Dan Webb ^a	APVMA Executive Director, Corporate Services	4	3 1
Claude Gauchat	External organisation representative	4	3
Jan Klaver	APVMA non-executive	4	4

a Dan Webb, APVMA Finance Manager, attended the fourth meeting as Mr de la Fosse's proxy.

Issues considered

In 2013-14, the Audit Committee:

- reviewed the previous year's annual financial statements and Certificate of Compliance
- monitored the schedule for the preparation of annual financial statements for 2013-14
- monitored the financial performance of the APVMA
- monitored and advised on the implementation of the legislative reforms and associated business reforms
- monitored APVMA progress in implementing the *Public Governance, Performance and Accountability Act 2013*
- reviewed the Risk Management Plan and Risk register
- monitored key performance indicators of the committee
- monitored APVMA progress in implementing the Protective Security Policy Framework
- monitored the internal audit program, including audits of the good manufacturing practice licensing scheme, the Adverse Experience Reporting Program, payroll processing, quality of science, and IT security penetration testing.

Presentations

In 2013-14, the Audit Committee received external presentations from Sapere Research Group Ltd on the business process review and reform preparedness.

Declarations of interest

No conflicts of interest that would conflict with the proper performance of the Audit Committee's functions were declared at any meeting in 2013-14.

APPENDIX B LIAISON COMMITTEES

REGISTRATION LIAISON COMMITTEE

The Registration Liaison Committee (RLC) is a consultative forum for the APVMA, representatives of the state and territory signatories of the National Registration Scheme (NRS) for Agricultural and Veterinary Chemicals, and other relevant Australian Government agencies.

The RLC is 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. The RLC allows for effective alignment of the agricultural and veterinary chemical control objectives of the APVMA, and the 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.

Meetings and attendance

RLC meetings were held in Canberra in October 2013 and March 2014. Attendance at RLC meetings is shown in Table B1.

Table B1 Attendance at Registration Liaison Committee meetings, 2013-14

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Kareena Arthy (Chair in October 2013)	APVMA	2	1
Raj Bhula (Chair in March 2014)	APVMA	1	1
David Power	ACT Environment and Sustainable Development Directorate	2	1
Joanna Montague	Australian Government Department of Agriculture	1	1
Lina Tze		1	1
Roisin Mortimer		1	1
Ami Ward	Australian Government Department of the Environment	1	1
Liz Paul		1	1
Christopher Lee	Australian Government Department of Health, Office of Chemical Safety	2	2
Matthew Pitt		1	1
Jenene Kidston	New South Wales Department of Primary Industries	2	2
Andy Hawkins	New South Wales Office of Environment and Heritage	2	2
Maree Zinzley	New Zealand Ministry of Primary Industries ^a	2	1
Glen Bradbury		2	1
Andrew Tomkins	Northern Territory Department of Primary Industry and Fisheries	2	0
Dick Watts	Queensland Department of Agriculture, Fisheries and Forestry	2	1
Russel Scholl		1	1
Kent Andrew	South Australian Department of Primary Industries and Regions	2	2
Stuart Bowman	Tasmanian Department of Primary Industries, Parks, Water and Environment	2	1
Sue Duncan	Victorian Department of Environment and Primary Industries	2	2
George Downing		2	1
Chris Sharpe	Western Australian Department of Agriculture and Food	2	2
Martin Matisons	Western Australian Department of Health	2	2

a Observer organisation

Issues considered

RLC agendas provide for updates on participating agencies' operational activities, consultation, and consideration of topical issues and projects.

In 2013–14, the APVMA provided the committee with operational reports, including reports on pesticides and veterinary medicines registration, permits and minor use activities, adverse experience reporting, compliance, and chemical review matters.

The states and territories, the APVMA, Australian Government partners and New Zealand observers reported on topics including legislative and policy developments, control of use, and regulatory activity within their jurisdictions.

The RLC considered a range of matters, including:

- operational policy relating to service provision agreements
- the progress of chemical reviews
- permits and minor use issues
- compliance activities, and operational policy in relation to information sharing on compliance and enforcement matters
- labelling issues, including the development of label approval procedures and electronic templates for submitting label information for approval
- legislative changes relating to processes for setting maximum residue limits
- preparation for implementation of legislative reforms, including supporting tools and resources.

Presentations

In 2013–14, the RLC received external presentations from:

- Grain Producers Australia and Crop Protection Australia on preparations for the developing mouse plague in South Australia
- Plant Health Australia on the work of the National Working Party on Pesticide Application, including the International Workshop on Pesticide Application held in Brisbane in June 2014
- Australian Environmental Agency Pty Ltd on a proposed new risk assessment methodology for estimating aquatic exposure resulting from pesticide run-off.

Declarations of interest

No conflicts of interest that would conflict with the proper performance of the RLC's functions were declared at any meeting in 2013–14.

MANUFACTURERS' LICENSING SCHEME INDUSTRY LIAISON COMMITTEE

The APVMA established the Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC) to provide a forum to discuss strategic and operational issues relating to the Manufacturers' Licensing Scheme and the Overseas Good Manufacturing Practice (GMP) Scheme with industry representatives and auditors.

Terms of reference

The terms of reference of the MLSILC are to:

- obtain the views of industry members and auditors on issues of an operational, technical or strategic nature
- advance the development and review of operating procedures, manufacturing standards and guidelines relevant to the Australian Manufacturers' Licensing Scheme and the Overseas GMP Scheme
- provide industry input into APVMA operational planning processes relating to manufacturing issues
- identify opportunities for regulatory reform within the existing framework
- consider the impact of proposed policy changes on APVMA operations, and implications for industry
- facilitate communication with industry and other stakeholders.

Meetings and attendance

The committee met three times in 2013-14: in September and November 2013, and April 2014. Membership and attendance at MLSILC meetings are shown in Table B2.

Table B2 Manufacturers' Licensing Scheme Industry Liaison Committee meetings, 2013-14

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Bruce Johnson (Chair)	APVMA	3	3
Kathryn Winterton		3	2
Suzanne Stokes (Secretary)		3	3
Matthew Sherriff	Animal Medicines Australia Ltd (formerly Animal Health Alliance [Australia] Ltd)	3	3
Ian Wheatley	Auditors' representative	3	3
John Aird	Feed Ingredients and Additives Association of Australia	3	3
Bill Blackhall	Veterinary Manufacturers and Distributors Association	3	3

Issues considered

Issues considered in 2013–14 included:

- progress with auditing and licensing of veterinary medicine product manufacturers
- progress with development of risk-based systems for scheduling audits and quantifying audit outcomes
- review of ‘release for supply’ arrangements with third-party toll manufacturers
- updates on APVMA regulatory reform activities
- recognition of the Quality and Safety System for Specialty Feed Ingredients and their Mixtures accreditation
- management and monitoring of inspections of Australian veterinary manufacturers by the Therapeutic Goods Administration (TGA), conducted under a memorandum of understanding between the APVMA and the TGA
- monitoring progress of the Mutual Recognition Agreement between Australia and the European Community.

Declarations of interest

No matters were declared by any member of the MLSILC that would give rise to any personal material conflict of interest.

APPENDIX C

REQUESTS FOR INFORMATION UNDER THE *FREEDOM OF INFORMATION ACT 1982*

The APVMA had 11 requests for information under the FOI Act in hand at the beginning of the year, and received an additional 75 applications during the year. There were 71 requests finalised during the year. These figures reflect a decrease in the number of requests received and completed under the FOI Act during recent years.

ACCESS TO INFORMATION

Website

Information on the APVMA's structure, functions, powers and publications can be obtained from the APVMA website (apvma.gov.au).

Databases and public registers

We maintain databases to record applications for chemical products and active constituents; and store registration and approval details, details of fees and levy payments, mailing lists and other information. Staff details and industry and stakeholder contact details are also stored on databases.

Access to the following public registers is available via the APVMA website, via the free APVMA mobile app for iPhones or by visiting the APVMA office during business hours:

- Register of Agricultural and Veterinary Chemical Products, known as the Public Chemical Registration Information System (PubCRIS), for information on numbers and approved uses of registered pesticide and veterinary medicine products
- Record of Approved Active Constituents for Chemical Products
- Record of Permits.

Files and records

We receive submissions and applications relating to active constituents and chemical products, including data. We maintain this information in accordance with the National Archives of Australia record-keeping guidelines and procedures.

Publications

We produce publications on the National Registration Scheme for Agricultural and Veterinary Chemicals and related matters, including:

- a fortnightly *APVMA Gazette*
- information sheets
- regulatory updates

- community briefs
- corporate plans and annual operational plans
- annual reports
- a Service Charter
- media releases
- a Manual of Requirements and Guidelines (agricultural and veterinary)
- a labelling code of practice
- guidelines on chemistry and manufacturing aspects
- efficacy and safety guidelines
- maximum residue limits
- guidelines for recall of pesticides and veterinary medicines
- a review of chemicals
- a code of good manufacturing practice
- information on how to report adverse experiences with pesticides or veterinary medicines
- agricultural and veterinary public release summaries
- trade advice notices.

Confidential commercial information

Some APVMA documents, particularly individual applications, contain confidential commercial information and may not be disclosed by the APVMA, except in accordance with the provisions of s. 162 of the Agricultural and Veterinary Chemicals Code or under the FOI Act.

Public consultation

Special consideration is given to APVMA mechanisms for consultation with the pesticide and veterinary medicine industries, other relevant specialised industry sectors and community groups. We have a general policy of making the organisation accessible to industry associations and community organisations. We consult on a regular basis with a wide range of groups and organisations with relevant interests, and maintain close contact with rural and service industries, researchers and other government agencies that have an interest in pesticides and veterinary medicines. For more detail about the APVMA consultative framework, see Appendix B.

Information publication scheme

We administer the Information Publication Scheme (IPS) in accordance with s. 8 of the FOI Act, and ensure that information published on our website is accurate, up to date, complete and accessible. Our IPS entry is available on the APVMA website.

We have published the IPS agency plan on the APVMA website. The agency plan describes how we administer and comply with the IPS.