



Australian Pesticides & Veterinary Medicines Authority  
**Appendices**

## A: APVMA Board of Directors

The current Board was appointed on 16 October 2002 for a term expiring on 15 October 2005. The Board met six times in 2003–04. Directors' attendance is detailed in Table A1.

**Table A1. Attendance at APVMA Board meetings in 2003–04**

| Name  | Meetings attended | Meetings eligible to attend |
|---|-------------------|-----------------------------|
| Dr Kevin Sheridan AO (Chairperson appointed 16 Oct. 2002)                                       | 5                 | 6                           |
| Prof John McLean (Director reappointed 16 Oct. 2002)  | 6                 | 6                           |
| Dr Catherine Hollywell (Director appointed 16 Oct. 2002)  | 6                 | 6                           |
| Mr Anthony Bates (Director appointed 16 Oct. 2002)  | 6                 | 6                           |
| Mr Hutch Ranck (Director appointed 16 Oct. 2002)  | 6                 | 6                           |
| Ms Mara Bún (Director appointed 16 Oct. 2002)   | 6                 | 6                           |
| Ms Anne Story (Director appointed 15 Nov. 2002)   | 6                 | 6                           |
| Dr Lyn Fragar AO (Director reappointed 16 Oct. 2002, appointed Deputy Chairperson 18 Dec. 2002) | 6                 | 6                           |
| Dr Gardner Murray (Director appointed 16 Oct. 2002)   | 5                 | 6                           |

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

### Declared interests

Directors are required to declare any potential material personal interests in relation to any matters before the Board. Declarations made by Directors in 2003–04 and the related Board determinations are detailed in Table A2.

Interests are declared and a determination is then made in accordance with Corporate Governance Best Practice and advice received from General Counsel.

**Table A2. Declared interests**

| Board meeting             | Declaration   |
|---------------------------|---|
| APVMA04<br>September 2003 | <p><b>Chemical Reviews of Diazinon and Endosulfan</b></p> <p>Dr Fragar, as Director of the Australian Centre for Agricultural Health and Safety (ACAHS), declared a potential conflict of interest relating to work being undertaken by the ACAHS for the reviews of diazinon and endosulfan. The Board determined that Dr Fragar's association with this work did not give rise to any material conflict of interest and she may therefore participate in discussions and vote on any matters arising.</p> <p><b>National Chemical Training Competencies</b></p> <p>Dr Hollywell, as an officer of the Victorian Department of Primary Industries, declared a potential conflict of interest relating to her responsibilities under State control-of-use laws concerning planned discussions about national chemical training competencies. The Board determined that Dr Hollywell's association with this work did not give rise to any material conflict of interest and she may therefore participate in discussions and vote on any matters arising.</p> |

|                          |  |
|--------------------------|--|
| APVMA05<br>November 2003 | <p><b>Chemical Review of Endosulfan</b></p> <p>Dr Fragar declared a potential conflict of interest relating to the review of endosulfan. As Director of ACAHS Dr Fragar is associated with work being undertaken by the ACAHS to generate worker exposure data and discussions relating to the draft OHS risk assessment of endosulfan. The Board determined that Dr Fragar's association did not give rise to any material conflict of interest and she may therefore participate in discussions and vote on the matter.</p> <p><b>Management of Trade Risk—Development of Export Intervals</b></p> <p>Dr Murray declared a potential conflict of interest relating to planned discussions about export intervals in his capacity as a member of the Safemeat Partnership. The Board determined that Dr Murray's association did not give rise to any material conflict of interest and he may therefore participate in discussions and vote on the matter.</p> |
| APVMA06<br>February 2004 | <p><b>Chemical Reviews of Benomyl and Endosulfan</b></p> <p>Potential conflicts of interest were declared by Mr Ranck concerning the Board's consideration of the chemical review of benomyl and Dr Fragar concerning the chemical review of endosulfan. Mr Ranck is the Managing Director of DuPont (Australia) Ltd, a company which provided a submission in response to the OCS's draft report on benomyl and had previously been the registrant of a product and approval holder of the active constituent. Dr Fragar, as Director of the ACAHS, is associated with work being undertaken by the ACAHS to generate worker exposure data for the endosulfan review. The Board determined that neither Director's association with the above matters gives rise to any material conflict of interest and that both may therefore participate in discussions and vote on matters arising.</p>   |
| APVMA07<br>April 2004    | <p><b>Chemical Reviews of Endosulfan and Virginiamycin</b></p> <p>Potential conflicts of interest were declared by Dr Fragar relating to the Board's consideration of the chemical review of endosulfan and by Professor McLean concerning the chemical review of virginiamycin. Dr Fragar, as Director of the ACAHS, is associated with consultancy work being undertaken by the ACAHS to generate worker exposure data for the endosulfan review. Professor McLean is a member of the Australian Veterinary Association, which has written to the APVMA concerning possible virginiamycin review outcomes. The Board determined that neither Director's association with the above matters gives rise to any material personal conflict of interest and that both may therefore participate in discussions and vote on matters arising.</p>  |
| APVMA08<br>June 2004     | <p><b>Performance Outcomes for the Registration of Agvet Products—Draft Project Report</b></p> <p>Dr Fragar disclosed a potential conflict of interest concerning the above draft report. Dr Fragar advised that her interest relates to her position as Director of ACAHS. The ACAHS was commissioned by the APVMA to collate and review data for the report. The Board considered Dr Fragar's declared association with the preparation of the Performance Outcomes report and determined that it did not give rise to any material personal interest. Dr Fragar may therefore participate in discussions and vote on any matters arising.</p>   |

## Indemnities and insurance

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

The APVMA maintains directors' and officers' liability insurance as set out in Table A3. The nature of the liabilities covered and the amount of premium payable under the contract of insurance are confidential under the terms of the policy.

**Table A3. Indemnities and insurance for APVMA directors and officers in 2003–04**

|  | Indemnity | Directors and officers liability insurance |
|--|-----------|--|
| Dr Kevin Sheridan AO Chairperson   | Y         | Y  |
| Dr Catherine Hollywell Director  | Y         | Y  |
| Prof John McLean Director  | Y         | Y  |
| Mr Anthony Bates Director  | Y         | Y  |
| Mr Hutch Ranck Director  | Y         | Y  |
| Ms Mara Bún Director   | Y         | Y  |
| Ms Anne Story Director   | Y         | Y  |
| Dr Lyn Fragar AO Deputy Chairperson  | Y         | Y  |
| Dr Gardner Murray Director   | Y         | Y  |
| Dr Alison Turner (CEO until 20 Aug. 2003)  | Y         | Y  |
| Dr Joe Smith (from 21 Aug. 2003)   | Y         | Y  |
| Mr Peter Raphael Program Manager, Quality Assurance and Compliance (until 31 March 2004) | N         | Y  |
| Dr Martin Holmes Program Manager, Veterinary Medicines                                   | N         | Y  |
| Dr Tim Dyke Program Manager, Quality Assurance and Compliance                            | N         | Y  |
| Mr Tony de la Fosse Program Manager, Corporate Services                                  | Y         | Y  |
| Mr James Suter General Counsel   | Y         | Y  |
| Dr Eva Bennet-Jenkins Program Manager, Pesticides  | N         | Y  |
| Dr Trevor Doust Program Manager, Chemistry and Residues                                  | N         | Y  |

## Audit Committee

The primary objective of the Audit Committee is to assist with the Board's responsibilities relating to the APVMA's financial accounting and reporting practices. The current committee was appointed on 29 November 2002. The Audit Committee comprises Dr Lyn Fragar (Chairperson), Ms Anne Story and Mr Hutch Ranck. Five Audit Committee meetings were held in 2003–04: on 27 August and 31 October 2003 and on 23 and 30 March and 6 April 2004. All committee members attended each meeting. Meetings coincided with key financial year milestones for provision of advice and reports to the Board. A revised Audit Committee charter to include responsibility for certain non-financial risk assessment and quality assurance functions was approved by the Board in November 2003.

## B: Committees

### Community Consultative Committee

#### Purpose

The APVMA's Community Consultative Committee provides a vehicle for effective two-way communication between the national chemical regulator and community representatives concerned about pesticides and veterinary medicines.

For the APVMA to operate to best effect it is vital that it be able to respond to current and emerging issues and concern that the community has with the regulation of these chemicals. It is equally important that the community be kept fully informed of the rationale that underpins regulatory decisions. The committee provides a valuable means for disseminating information among the community.

#### Terms of reference

The committee's terms of reference require it to:

- communicate community views to the APVMA on issues concerning 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

The committee met five times during 2003–04: in July, September and November 2003 and February and May 2004. At each meeting, members provided a report to the APVMA about committee-related activities and details of any significant community issues of concern. The APVMA reports at each meeting cover registration, chemical review and quality assurance and compliance. The committee also progressed major work program items during the year.

## Highlights

Significant achievements for the committee during 2003–04 were:

- active involvement in the development of the Adverse Experience Reporting Program for pesticides
- improved communication mechanisms for the committee and the development of a dedicated community web page and e-bulletin
- input to the APVMA communication strategy, development of spray drift data requirements and the APVMA labelling project.

**Table B1. Membership of and attendance at Community Consultative Committee meetings in 2003–04**

| Member                | Organisation  | Meetings eligible to attend | Meetings attended |
|-----------------------|---|-----------------------------|-------------------|
| Ms Jenni Mack (Chair) | Australian Consumers Association  | 5                           | 5                 |
| Mr Ben Cole           | Total Environment Centre,<br>Friends of the Earth                             | 4                           | 4                 |
| Mr Andrew Duncan      | WA Farmers Federation   | 5                           | 4                 |
| Ms Jane Fuller        | Rural Women's Network   | 5                           | 4                 |
| Mr Sam Beechey        | Australian Workers' Union   | 5                           | 3                 |
| Ms Alison Brinson     | Chemcert Australia  | 5                           | 4                 |
| Ms Liz Hanna          | Public Health Association of Australia,<br>Royal College of Nursing Australia | 5                           | 4                 |
| Ms Anne Stanton       | National Toxics Network   | 5                           | 4                 |
| Mr Sid Cowling        | Organic Federation of Australia,<br>Independent Organic Inspectors Australia  | 5                           | 3                 |
| Dr Joe Smith          | APVMA Advisor   | 1                           | 1                 |
| Dr Eva Bennet-Jenkins | APVMA Advisor   | 4                           | 4                 |

Contact: Kathleen Allan, APVMA (02) 6272 3794

## Registration Liaison Committee

During 2003–04, the Registration Liaison Committee held two formal meetings in Canberra on 15–16 October 2003 and 24–25 March 2004. In keeping with APVMA efforts to improve the effectiveness of its consultative committees, two additional meetings were held by teleconference on 19 February and 30 June 2004.

### Purpose

The Registration Liaison Committee is the main consultative forum between the APVMA, the States, Territories and Australian Government agencies relating to operational management of the National Registration Scheme. The committee works to ensure an efficient and coordinated approach to the APVMA's responsibilities for regulating the supply of pesticides and veterinary medicines up to and including the point of retail sale and State and Territory responsibilities for control of use. It also works to ensure a uniform approach to the APVMA's compliance activities that monitors the supply of pesticides and veterinary medicines to ensure that only registered products bearing approved labels are sold in Australia.

The Department of Agriculture, Fisheries and Forestry, the Department of the Environment and Heritage and the OCS in the Australian Government Department of Health and Ageing represent the Australian Government on the committee. The Advisory Committee on Pesticides and Health in the OCS withdrew as an observer in late 2003.

### Terms of reference

The committee's terms of reference are to:

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



## Issues considered

The APVMA's reports to the committee covered registration, permit, quality assurance, compliance and chemical review programs. The States, Territories, Australian Government agencies and the New Zealand regulator of pesticides and veterinary medicines also provided regulatory activity reports. Department of Agriculture, Fisheries and Forestry briefings covered National Registration Scheme policy, legislative changes and Australian participation in international forums, treaties and conventions.

## Highlights

Highlights were:

- agreement to appoint a representative from the Department of Health WA to the committee in recognition of that agency's particular role in controlling use of pesticides in WA
- development of data requirements for crop stubble residues
- consideration of domestic chemical use issues
- State/Territory, Australian Government and APVMA input to the review of labelling, proposals for chemical user training and accreditation, developing requirements for translating permitted uses to approved labels and developing dip disposal and spray drift guidelines
- consultation and feedback on chemicals under review and the effective implementation of training requirements and other control-of-use outcomes
- progression of negotiation of Service Level Agreements for efficacy reviews with the States/Territories
- review of procedures for consulting the States and Territories prior to the APVMA issuing permits
- agreement to allow permit holders to advertise permitted off-label use patterns
- agreement on actions to address discrepancies between State and Australian Government legislation such as for the regulation of Restricted Chemical Products
- consultation on developing electronic business and information systems
- regular provision to members of tabulated updates on State and Territory control-of-use legislation.

**Table B2. Membership of and attendance at Registration Liaison Committee meetings in 2003–04**

| Member                                | Organisation  | Meetings eligible to attend | Meetings attended |
|---------------------------------------|---|-----------------------------|-------------------|
| Mr Martin Holmes (Chair)              | APVMA   | 4                           | 4                 |
| Mr David Power                        | Environment ACT   | 4                           | 2                 |
| Mr Lee Cook                           | NSW Agriculture   | 4                           | 4                 |
| Mr Jud Agius                          | NSW Department of Environment and Conservation  | 4                           | 4                 |
| Mr Kevin Hiser                        | Victorian Department of Primary Industries  | 4                           | 4                 |
| Mr John Kassebaum                     | Department of Primary Industries and Resources South Australia                                      | 4                           | 4                 |
| Mr Mike Norman/<br>Mr John Mollison   | Tasmanian Department of Primary Industries, Water and Environment                                   | 4                           | 4 <sup>1</sup>    |
| Mr Vlad Kawaljenko                    | Northern Territory Department of Business Industry and Resource Development                         | 4                           | 4                 |
| Mr Wayne Thompson                     | Qld Department of Primary Industries  | 4                           | 4                 |
| Mr Chris Sharpe                       | Department of Agriculture WA  | 4                           | 4                 |
| Mr Martin Matisons                    | Department of Health WA   | 2                           | 1 <sup>2</sup>    |
| Mr Andre Mayne                        | Australian Government Department of Agriculture, Fisheries and Forestry                             | 4                           | 3 <sup>3</sup>    |
| Mr Brian Pidford/<br>Ms Maree Zinzley | NZ Agricultural Chemicals and Veterinary Medicines Group  | 4                           | 4                 |
| Dr Wafa El-Adhami                     | OCS, Australian Government Department of Health and Ageing  | 4                           | 4 <sup>4</sup>    |
| Dr Geoff Lovell                       | National Occupational Health and Safety Commission, OCS   | 4                           | 2                 |
| Mr Graeme Barden                      | Australian Government Department of the Environment and Heritage                                    | 4                           | 3                 |
| Dr Brian Radunz                       | Animal Health Committee—<br>Australian Government Department of Agriculture, Fisheries and Forestry | 4                           | 0                 |
| Dr Graeme Hamilton                    | Plant Health Committee—Department of Agriculture, Fisheries and Forestry                            | 4                           | 2 <sup>5</sup>    |
| Ms Melanie Buckley                    | Aquaculture Committee—Department of Agriculture, Fisheries and Forestry                             | 4                           | 0                 |
| Dr Mathew O'Mullane                   | Advisory Committee on Pesticides and Health   | 1                           | 0                 |

Contact: Alan Hill, APVMA (02) 6272 5238

- 1 Mr Mollison represented Tasmania following Mr Norman's retirement.
- 2 Mr Matisons was appointed March 2004.
- 3 The Department was represented by Ms Julia Rymer at the February 2004 teleconference and by Mr Scott McKenzie on Day 2 of the March 2004 meeting.
- 4 OCS was represented by Dr Utz Meuller at the March 2004 meeting.
- 5 Plant Health Committee was represented by Ms Fiona Macbeth at the October 2003 meeting and the February 2004 teleconference.

## Industry Liaison Committee

The Industry Liaison Committee was established in 1995 and is the main consultative forum between the APVMA and peak chemical industry organisations representing registrants of pesticides and veterinary medicines.

### Purpose

The purpose of the committee is to:

- provide a forum for formal consultation and discussion with peak chemical industry bodies on APVMA operating policies and programs
- enhance cooperation 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
- provide a forum for reporting by the APVMA to industry on APVMA's performance
- address specific operating policy issues through working groups
- consider the impact of proposed macro-policy changes on APVMA operations and implications for industry.

### Issues considered

The committee considered:

- label Disposal Requirements
- *drumMUSTER* Label Disposal Statement
- label approvals in the light of legislative amendments
- Globally Harmonized System of Classification and Labelling of Chemicals
- APVMA Stakeholder Communications Plan
- spray drift Registration Requirements
- review of sheep ectoparasiticides
- levy assessment notices
- APVMA consultation with registrants about permits
- activities of the Chemicals and Plastics Leadership Group

- *Chemclear* program of Agsafe
- data protection aspects of the United States–Australia Free Trade Agreement
- reforms to the Manufacturers' Licensing Scheme
- industry input to APVMA planning.

### Highlights

Highlights were:

- Quality Assurance Scheme for Agricultural Active Constituents
- Low Regulatory Requirements products
- seminars for new APVMA legislation
- Adverse Experience Reporting Program (*Ag*)
- framework, terms of reference and operation of the committee
- communication of Trade Risk.

**Table B3. Membership and attendance at Industry Liaison Committee meetings in 2003–04**

| Member                         | Organisation   | Meetings eligible to attend | Meetings attended |
|--------------------------------|--|-----------------------------|-------------------|
| Dr Alison Turner (Chairperson) | APVMA  | 1                           | 1                 |
| Dr Joe Smith (Chairperson)     | APVMA  | 2                           | 2                 |
| Mr Lindsay Showyin             | Aerosol Association of Australia Inc                   | 3                           | 3                 |
| Mr Philip Fleming              | Aerosol Association of Australia Inc                   | 3                           | 3                 |
| Mr Geoff MacAlpine             | Australian Consumer and Specialty Products Association | 3                           | 3                 |
| Dr Peter Holdsworth            | Avcare Ltd   | 3                           | 3                 |
| Dr Fay Stenhouse               | Avcare Ltd   | 2                           | 2                 |
| Dr Ross Rainbird               | Generic Agricultural Chemical Association              | 1                           | 0                 |
| Mr Richard de Vos              | Nursery and Garden Industry Australia                  | 3                           | 0                 |
| Mr Peter Nobbs                 | Pet Industry Association of Australia Ltd              | 3                           | 2                 |
| Mr Bernard Lee                 | Plastics and Chemicals Industries Association          | 1                           | 1                 |
| Mr Greg Healey                 | Plastics and Chemicals Industries Association          | 2                           | 2                 |
| Mr Andrew Simons               | Swimming Pool and Spa Association of Australia         | 3                           | 1                 |

**Table B3. Membership of and attendance at Industry Liaison Committee meetings in 2003–04** *continued*

| Member            | Organisation  | Meetings eligible to attend | Meetings attended |
|-------------------|---|-----------------------------|-------------------|
| Mr Robert Schufft | Veterinary Manufacturers and Distributors Association | 3                           | 3                 |
| Mr Jim Adams      | Veterinary Manufacturers and Distributors Association | 3                           | 2                 |
| Mr Mike Craft     | Veterinary Manufacturers and Distributors Association | 3                           | 3                 |

Contact: David Hutchison, APVMA (02) 6271 6384

## Industry Technical Committee

### Purpose

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

The objectives of the committee are to:

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

During 2003–04, the Industry Technical Committee met four times in Canberra, in August and November 2003 and April and June 2004.

### Terms of reference

The committee was created by the Industry Liaison Committee to:

- improve the functioning of the Industry Liaison Committee both 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 considered by the committee during 2003–04 included:

- progress on listed registration
- amendment to the registration certificate to change the term 'Registration ends'
- stability testing of veterinary vaccines

- status of Avcare resistance management strategies
- consistency in chemistry requirements
- APVMA preparation for impending changes to data protection legislation
- dip disposal guidelines
- spray drift guidelines
- implementation of amendments to the AgVet Code
- draft guidelines on stability testing of immunobiologicals
- guidelines on injectable veterinary products
- category 50 draft guidelines and regulatory science quality
- APVMA collection of active constituent data
- Quality Assurance Scheme for agricultural active constituents and products
- revised terms of reference for the committee
- new application categories
- efficacy reviews
- a proposal to review APVMA's Submit Once Review Once policy
- APVMA market research
- labelling issues.

**Table B4. Membership of and attendance at Industry Technical Committee meetings in 2003–04**

| Representative           | Organisation   | Meetings eligible to attend | Meetings attended |
|--------------------------|--|-----------------------------|-------------------|
| Mr Martin Holmes (Chair) | APVMA  | 4                           | 4                 |
| Dr Eva Bennet-Jenkins    | APVMA  | 4                           | 4                 |
| Ms Laura Lollback        | Aerosol Association of Australia                       | 4                           | 2                 |
| Ms Kathy Nolan           | Australian Consumer and Specialty Products Association | 4                           | 0                 |
| Mr Geoff McAlpine        |  |                             | 2                 |
| Dr Craig Suann           | Australian Racing Board                                | 4                           | 1                 |
| Dr John McCaffrey        |  |                             | 1                 |
| Ms Ruth Davis            | Australian Veterinarians in Industry                   | 4                           | 3                 |
| Dr Finola McConaghy      |  |                             | 1                 |
| Dr Bill Darmody          | Australian Veterinary Association                      | 4                           | 3                 |
| Dr Tom Grimes            | Australian Veterinary Poultry Association              | 4                           | 0                 |
| Dr Peter Holdsworth      | Avcare   | 4                           | 4                 |
| Dr Fay Stenhouse         |  |                             | 3                 |
| Dr Les Davies            | OCS  | 4                           | 4                 |
| Mr Shane Walsh           | Pet Food Industry Association of Australia             | 4                           | 3                 |

**Table B4. Membership of and attendance at Industry Technical Committee meetings in 2003–04** *continued*

| Representative                                     | Organisation  | Meetings eligible to attend | Meetings attended |
|--|---|-----------------------------|-------------------|
| Mr Neil McMahon<br>Mr Peter Nobbs                  | Pet Industry Association of Australia Ltd             | 4                           | 1<br>1            |
| Ms Stephanie Leach                                 | Plastics and Chemicals Industries Association         | 4                           | 4                 |
| Mr Andrew Simons<br>Mr Greg O'Connell              | Swimming Pool and Spa Association of Australia        | 4                           | 0<br>0            |
| Mr Mike Craft<br>Mr Robert Schufft<br>Mr Jim Adams | Veterinary Manufacturers and Distributors Association | 4                           | 4<br>4<br>4       |

Contact: thea Reiman, APVMA (02) 6272 3744

## Manufacturers' Licensing Scheme Industry Liaison Committee

### Purpose

The Manufacturers' Licensing Scheme Industry Liaison Committee was established to provide a forum for the APVMA to discuss strategic and operational issues related to the Manufacturers' Licensing Scheme with industry representatives. The committee met four times in 2003–04.

**Table B5. Membership of and attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings in 2003–04**

| Member                         | Organisation  | Meetings eligible to attend | Meetings attended |
|--------------------------------|---|-----------------------------|-------------------|
| Dr Bruce Johnson (Chair)       | APVMA   | 4                           | 4                 |
| Mrs Kathy Winterton            | APVMA   | 4                           | 4                 |
| Mr Michael Nagajek             | APVMA   | 4                           | 3                 |
| Dr Peter Holdsworth            | Avcare  | 4                           | 1                 |
| Mr Ian Wheatley                | Avcare  | 4                           | 4                 |
| Mr Bill Blackhall              | Veterinary Manufacturers and Distributors Association | 4                           | 4                 |
| Mr Bruce Graham                | Auditors' representative                              | 4                           | 4                 |
| Mr Allan Smalley (Secretariat) | APVMA   | 4                           | 4                 |

Contact: Bruce Johnson, APVMA (02) 6272 4924

## Highlights

The revision of the Code of GMP for veterinary medicines dominated the activities of the committee during the year. A working group was formed and met regularly. The manufacturing principles and the core chapters of the code relevant to all manufacturers were prepared and circulated within the APVMA prior to release for public comment. The annexes, providing sector-specific guidance to manufacturers of distinct product types, were drafted and are currently being reviewed prior to release.

Other issues considered during the year included:

- progress with auditing and licensing of veterinary medicine manufacturers
- the introduction of unannounced audits and short-notice audits
- the availability of auditors and the Auditors' Workshop
- further GMP training seminars for industry
- improving communications with industry
- the operation and management of mutual recognition agreements.

## Residues Advisory Committee

The Residues Advisory Committee provides expert technical advice to the APVMA on issues and policy associated with chemical residues in food. Mr Tom McEwan retired from the committee in 2003. In 2004–05 it is proposed to review the membership in light of the Review into the Advisory Committee on Pesticides and Health and the APVMA Science Fellows Program.

Contact: Dr Trevor Doust, APVMA (02) 6272 3208



## 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 detailed information on its organisation, functions and powers and on arrangements for public involvement in the formulation of agency policy or administration of any enactment or scheme. This statement, together with the information contained in this report, is intended to meet the requirements of the FOI Act.

### Organisation and structure

The APVMA operates nationally under the direction of a Board of Directors. Further details about the APVMA Board are in the section headed The Organisation, and at Appendix A.

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

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

#### Postal address

PO Box E240  
Kingston ACT 2604

### APVMA's functions and powers

The APVMA is responsible for assessing and registering 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
- to 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
- to keep records and statistics of approvals and registrations it has granted, and permits and licences it has issued, under the Agvet Code

- to evaluate the effects of the use of chemical products in the States and participating Territories
- to 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, to develop codes of practice, standards and guidelines for, and to recommend precautions to be taken in connection with, the manufacture, export, import, sale, handling, possession, storage, disposal and use of chemical products in the States and participating Territories
- to collect, interpret, disseminate and publish information relating to chemical products and their use
- to encourage and facilitate the application and use of results of evaluation and testing of chemical products
- to exchange information relating to chemical products and their use with overseas and international bodies having functions similar to those of the APVMA
- when requested by the Minister, or on its own initiative, to report to or advise the Minister on any matter relating to chemical products or arising in the course of the performance of its functions
- to encourage and facilitate the introduction of uniform national procedures for the control of the use of pesticides and veterinary medicines
- to fund, and cooperate in, a program designed to ensure that active constituents for proposed or existing chemical products, registered chemical products, and labels for containers for chemical products, comply with the Agvet 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, 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 enabling legislation, the Administration Act, the Australian Government Minister responsible for administering agvet chemicals legislation may direct the APVMA in writing in relation to the functions or powers that have been conferred on it under applicable Commonwealth or State laws. The APVMA must comply with any such direction. During 2003–04, the Minister gave no such direction.

## Access to information

### Web site

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

### Public registers

The APVMA maintains databases to store, manipulate and record product applications, to track submissions, and for product registration details, financial records, mailing lists and other information. Some other information, such as staff details, and industry and stakeholder contact details, is stored on databases. Access to the following public registers is possible by arrangement, by visiting the APVMA offices, or through the APVMA's web site:

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

### Files and records

The APVMA maintains files on specific chemicals and on a range of topics relating to 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 a range of publications on the National Registration Scheme and related matters. These publications include:

- *APVMA News* (regular newsletter)
- *Agricultural and Veterinary Chemicals Gazette* (monthly Australian Government gazette)
- APVMA information sheets
- APVMA community briefs
- APVMA Corporate Plan and Operational Plan
- APVMA Annual Report
- APVMA Service Charter
- media releases
- agricultural registration requirements series
- veterinary registration requirements series
- labelling code of practice
- guidelines 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 chemicals
- 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 Relations Section

Ph: (02) 6272 3794

Fax: (02) 6272 5811

Email: [contact@apvma.gov.au](mailto:contact@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 Freedom of Information.

## Public consultation

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

## Requests for information under the FOI Act in 2003–04

Six requests for information under the FOI Act were received during 2003–04.

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

### FOI Coordinator

Australian Pesticides and Veterinary Medicines Authority  
PO Box E240  
Kingston ACT 2604

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

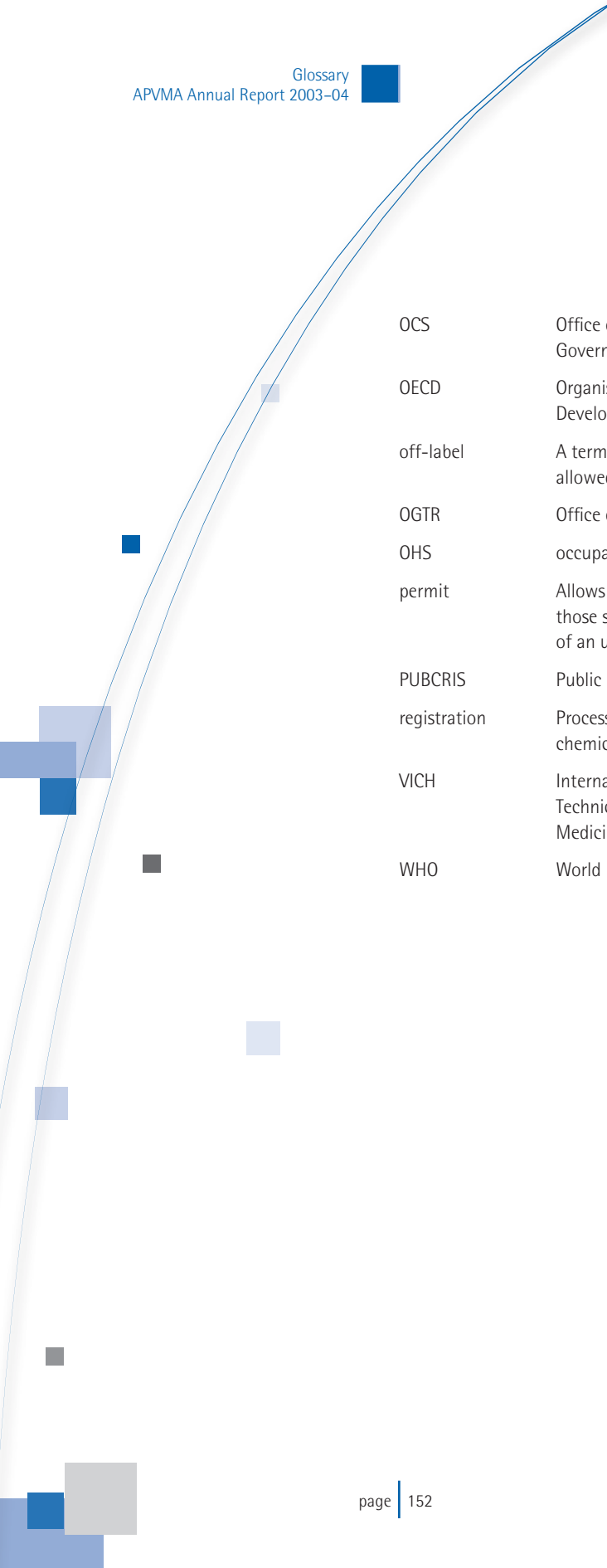
## D: Consultancies

In 2003–04, the APVMA spent a total of \$342 955 on consultants, with 28 consultancy contracts let 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 year. The reason for engaging the consultancy services was a requirement for specialist expertise not available within the APVMA.

| Consultant   | Activity   | Amount           |
|--|--|------------------|
| Clayton Utz Lawyers  | Legal advice   | \$49 461         |
| Deloitte Touche Tohmatsu   | Fraud Control Plan and Risk Assessment   | \$12 364         |
| Dr James Renwick   | Legal advice and representation  | \$17 789         |
| Graham Savage  | Revision of Australian GMP Codes   | \$11 000         |
| Queensland Health Pathology and Scientific Services                                | Analysis of multi-residue air monitoring of pesticides in urban cotton centres | \$16 981         |
| Solutions Marketing and Research Pty Ltd   | Market research of chemical product registrants and the general community      | \$82 500         |
| Sparke Helmore   | Legal advice   | \$29 285         |
| Spooner and Hall   | Legal advice   | \$44 880         |
| the State of Qld acting through its Department of Primary Industries and Fisheries | Review of residues processes   | \$20 000         |
| <b>Total</b>   |  | <b>\$284 260</b> |

## Glossary

|                    |   |
|--------------------|---|
| ACAHS              | Australian Centre for Agricultural Health and Safety  |
| actives            | active constituents   |
| Administration Act | <i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>  |
| AERP Ag            | Adverse Experience Reporting Program for agricultural products  |
| AERP Vet           | Adverse Experience Reporting Program for veterinary chemicals   |
| agvet chemicals    | agricultural and veterinary chemicals   |
| Agvet Code         | Agricultural and Veterinary Chemicals Code  |
| AHRI               | Australian Human Resources Institute  |
| APVMA              | Australian Pesticides and Veterinary Medicines Authority (formerly National Registration Authority for Agricultural and Veterinary Chemicals) |
| CAC Act            | <i>Commonwealth Authorities and Companies Act 1997</i>  |
| CCA                | copper chrome arsenate  |
| CEO                | Chief Executive Officer   |
| Code Act           | <i>Agricultural and Veterinary Chemicals Code Act 1994</i>  |
| Codex              | Codex Alimentarius Commission   |
| EEO                | equal employment opportunity  |
| FAO                | Food and Agriculture Organization   |
| FOI                | freedom of information  |
| FSANZ              | Food Standards Australia New Zealand  |
| GMP                | Good Manufacturing Practice   |
| HGP                | hormonal growth promotant   |
| ISO                | International Organisation for Standardization  |
| MGA                | melengesterol acetate   |
| NOHSC              | National Occupational Health and Safety Commission  |
| NRA                | National Registration Authority for Agricultural and Veterinary Chemicals (now Australian Pesticides and Veterinary Medicines Authority)      |



|              |   |
|--------------|---|
| OCS          | Office of Chemical Safety (within the Australian Government Department of Health and Ageing)  |
| OECD         | Organisation for Economic Cooperation and Development   |
| off-label    | A term used to describe the different use patterns allowed under a permit   |
| OGTR         | Office of the Gene Technology Regulator   |
| OHS          | occupational health and safety  |
| permit       | Allows the legal use of a chemical in ways different to those specified on the product label or the limited use of an unregistered chemical |
| PUBCRIS      | Public Chemicals Registration Information System  |
| registration | Process of assessment and evaluation to determine a chemical's safety and efficacy  |
| VICH         | International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products                      |
| WHO          | World Health Organization   |



# Compliance index

This annual report has been prepared in accordance with the *Commonwealth Authorities and Companies (Report of Operations) Orders 2002* and the Requirements for Annual Reports revised by the Department of the Prime Minister and Cabinet in June 2004.

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