A: APVMA BOARD OF DIRECTORS

Attendance

The current Board was appointed on 16 October 2002 for a term expiring on 15 October 2005. The Board met six times in 2004–05. Directors’ attendance is shown in Table A1.

Declared interests

Directors are required to declare any potential material personal interests in relation to any matters before the Board. Declarations by Directors in 2004–05 and the related Board determinations are detailed in Table A2.

Table A1 Attendance at APVMA Board meetings in 2004–05

<table>
<thead>
<tr>
<th>Name</th>
<th>Meetings attended</th>
<th>Meetings eligible to attend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Kevin Sheridan AO (Chairperson appointed 16 Oct. 2002)</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Dr Lyn Fragar AO (Director reappointed 16 Oct. 2002, appointed Deputy Chairperson 18 Dec. 2002)</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Prof. John McLean (Director reappointed 16 Oct. 2002)</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Dr Catherine Hollywell (Director appointed 16 Oct. 2002)</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Mr Anthony Bates (Director appointed 16 Oct. 2002)</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Mr Hutch Ranck (Director appointed 16 Oct. 2002)</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Ms Mara Bùn (Director appointed 16 Oct. 2002)</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Ms Anne Story (Director appointed 15 Nov. 2002)</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Dr Gardner Murray (Director appointed 16 Oct. 2002)</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

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

APPENDICES

Interests so declared are considered and determined by the Board in accordance with Corporate Governance principles and advice provided by General Counsel.

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.

Audit Committee

The primary objective of the Audit Committee is to assist with the Board’s responsibilities relating to the APVMA’s annual budget, financial accounting and reporting practices. The current committee was appointed on 3 December 2004. The Audit Committee comprises Dr Lyn Fragar (Chairperson), Ms Anne Story and Mr Hutch Ranck. Audit Committee meetings in 2004–05 were held on 13 August and 29 October 2004 and on 1 April 2005. All three committee members attended each meeting. Meetings coincided with key financial year milestones for provision of advice and reports to the Board.
Table A2 Declared interests

<table>
<thead>
<tr>
<th>Board meeting</th>
<th>Declaration</th>
</tr>
</thead>
<tbody>
<tr>
<td>APVMA10</td>
<td>Chemical Review of Virginiamycin</td>
</tr>
<tr>
<td></td>
<td>Professor McLean declared his interest as a member of the Australian Veterinary Association (AVA) in relation to the regulatory outcomes of the review of virginiamycin.</td>
</tr>
<tr>
<td></td>
<td>The Board determined that Professor McLean's membership of the AVA did not constitute a material conflict of interest and therefore he could be present for and participate in discussions concerning the APVMA's regulatory approach arising from the review of virginiamycin.</td>
</tr>
<tr>
<td>APVMA13</td>
<td>Chemical Review of Diuron</td>
</tr>
<tr>
<td></td>
<td>Mr Ranck declared his interest as Managing Director of DuPont (Australia) regarding any discussion of possible interim action to suspend herbicide products, including those registered to DuPont, containing the active constituent diuron.</td>
</tr>
<tr>
<td></td>
<td>The Board determined that Mr Ranck may be present for discussions regarding diuron. There were no decisions arising from those discussions.</td>
</tr>
<tr>
<td>APVMA14</td>
<td>Chemical Review of Endosulfan—Final Regulatory Decision</td>
</tr>
<tr>
<td></td>
<td>Dr Fragar declared her interest as Director of the Australian Centre for Agricultural Health and Safety which undertook worker exposure studies for the endosulfan review under her supervision.</td>
</tr>
<tr>
<td></td>
<td>Chemical Review of Diuron—Preliminary Review Findings</td>
</tr>
<tr>
<td></td>
<td>Mr Ranck declared his interest as Managing Director of DuPont (Australia) regarding the review of diuron, the active constituent of herbicide products registered to Dupont.</td>
</tr>
<tr>
<td></td>
<td>The Board determined that Dr Fragar and Mr Ranck may be present for discussions but they would abstain from voting on recommendations concerning the endosulfan and diuron reviews respectively.</td>
</tr>
</tbody>
</table>

Table A3 Indemnities and insurance for APVMA directors and officers in 2004–05

<table>
<thead>
<tr>
<th>Indemnity</th>
<th>Directors' and officers' liability insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Kevin Sheridan AO, Chairperson</td>
<td>Y</td>
</tr>
<tr>
<td>Dr Lyn Fragar AO, Deputy Chairperson</td>
<td>Y</td>
</tr>
<tr>
<td>Dr Catherine Hollywell, Director</td>
<td>Y</td>
</tr>
<tr>
<td>Prof. John McLean, Director</td>
<td>Y</td>
</tr>
<tr>
<td>Mr Anthony Bates, Director</td>
<td>Y</td>
</tr>
<tr>
<td>Mr Hutch Ranck, Director</td>
<td>Y</td>
</tr>
<tr>
<td>Ms Mara Bün, Director</td>
<td>Y</td>
</tr>
<tr>
<td>Ms Anne Story, Director</td>
<td>Y</td>
</tr>
<tr>
<td>Dr Gardner Murray, Director</td>
<td>Y</td>
</tr>
<tr>
<td>Dr Joe Smith, CEO</td>
<td>Y</td>
</tr>
<tr>
<td>Dr Martin Holmes, Program Manager, Veterinary Medicines</td>
<td>Y</td>
</tr>
<tr>
<td>Dr Tim Dyke, Program Manager, Quality Assurance &amp; Compliance</td>
<td>Y</td>
</tr>
<tr>
<td>Mr Tony de la Fosse, Program Manager, Corporate Services</td>
<td>Y</td>
</tr>
<tr>
<td>Mr James Suter, General Counsel</td>
<td>Y</td>
</tr>
<tr>
<td>Dr Eva Bennet-Jenkins, Program Manager, Pesticides</td>
<td>Y</td>
</tr>
<tr>
<td>Dr Trevor Doust, Program Manager, Chemistry and Residues</td>
<td>Y</td>
</tr>
</tbody>
</table>
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 concerns 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

<table>
<thead>
<tr>
<th>Member</th>
<th>Organisation</th>
<th>Meetings eligible to attend</th>
<th>Meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Jenni Mack (Chair)</td>
<td>Australian Consumers Association</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Andrew Duncan</td>
<td>WA Farmers Federation</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>(retired April 2005)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ms Jane Fuller</td>
<td>Rural Women’s Network</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>(retired April 2005)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mr Sam Beechey</td>
<td>Australian Workers’ Union</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>(reappointed May 2005)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ms Alison Brinson</td>
<td>Chemcert Australia</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>(retired April 2005)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ms Liz Hanna</td>
<td>Public Health Association of Australia, Royal College of Nursing Australia</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Ms Anne Stanton</td>
<td>National Toxics Network</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Sid Cowling</td>
<td>Organic Federation of Australia, Independent Organic Inspectors Australia</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Ms Jo Immig</td>
<td>National Environmental Consultative Forum</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>(appointed July 2004)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mr Peter Cone</td>
<td>National Farmers Federation</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>(appointed May 2005)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mr Don Sutherland</td>
<td>Farm Safe</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>(appointed May 2005)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr Eva Bennet-Jenkins</td>
<td>APVMA Liaison</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Contact: Kathleen Allan, APVMA (02) 6272 3794</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 four times during 2004–05; in August, December, March and June. At each meeting, members report to the APVMA about committee-related activities as well as details of any important community issues of concern. The APVMA provides reports to each meeting detailing registration and review activities for pesticides and veterinary medicines as well as quality assurance and compliance matters. The committee progressed a number of major work program items during 2004–05.

Highlights
Significant achievements for the committee during 2004–05 were:

■ input to the APVMA labelling project and discussion of wider issues through a committee project looking at the management of agvet chemical containers

■ ongoing involvement in the AERPAg with particular interest in promotion of the program

■ the completion of a major review of the APVMA chemical review program aimed at improving transparency and community involvement in the process.

Registration Liaison Committee
During 2004–05, the Registration Liaison Committee (RLC) met in Canberra on 14–15 September 2004 and 16–17 March 2005. RLC also met by teleconference on 13 December 2004 and 8 June 2005.

Purpose
The Registration Liaison Committee is the main consultative forum between the APVMA and 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 between 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 monitor the quality and 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 Office of Chemical Safety in the Department of Health and Ageing are also represented on the committee.

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 operational activities relating to pesticides and veterinary medicines registration, permits and minor use, quality assurance, compliance and chemical review. The States, Territories, other Australian Government departments and the New Zealand regulator of pesticides and veterinary medicines also provided regulatory activity reports. The Department of Agriculture, Fisheries and Forestry briefings covered National Registration Scheme policy, legislative changes and Australian participation in international forums, treaties and conventions.
Highlights

Key issues considered by RLC during the reporting period included:

- RLC input to the APVMA Operational Plan 2005–06
- Agreement of priority issues for the RLC Workplan including the development of guidelines for spray drift, disposal of chemical dip solutions and an efficacy and target animal/crop safety manual
- Regulatory cooperation between the APVMA and affected States in response to incidents of off-target spray drift involving 2,4-D
- Endorsement of proposed regulatory reforms to the minor use system including requirements for model permit templates
- Consideration of labelling issues including revised procedures for varying labels, industry perspectives on labelling and APVMA policy on unenforceable label directions and statements
- Consultations on revised processes for nominating and finalising chemical reviews, draft APVMA policy on consequential label claims, revisions to Regulation 8 of the Agvet Code and adopting the JECFA approach to setting MRLs
- Endorsement of a review of Restricted Chemical Products and development of the new APVMA Manual of Requirements and Guidelines
- Consultations on regulatory approaches for inter-row shield spraying and the use of liquid fertilisers as diluents, revisions to labels for pentobarbitone products and the use of colourings to identify arsenic trioxide products
- Negotiation of Service Level Agreements for efficacy reviews with the States/Territories
- Agreement to amend procedures for conducting RLC meetings and consultations on the APVMA review of consultative committees.

Table B2. Membership of and attendance at Registration Liaison Committee meetings in 2004–05

<table>
<thead>
<tr>
<th>Member</th>
<th>Organisation</th>
<th>Meetings eligible to attend</th>
<th>Meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr Martin Holmes (Chairperson)</td>
<td>APVMA</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Dr Jonathan Taylor (Acting Chairperson)</td>
<td>Environment Protection, ACT Government</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Mr David Power</td>
<td>Environment Protection, ACT Government</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Mr Lee Cook</td>
<td>NSW Agriculture</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Jud Agius</td>
<td>Department of Environment and Conservation (NSW)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Andrew Hawkins</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Mr Kevin Hiser</td>
<td>Victorian Department of Primary Industries</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mr Geoff Bennett</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Ms Sue Duncan</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Mr John Kassebaum</td>
<td>Department of Primary Industries and Resources South Australia</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Ian Parr</td>
<td>Tasmanian Department of Primary Industries, Water &amp; Environment</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Vlad Kawaljenko</td>
<td>Northern Territory Department of Business Industry &amp; Resource Development</td>
<td>4</td>
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</tr>
<tr>
<td>Mr Wayne Thompson</td>
<td>Queensland Department of Primary Industries</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>
### Table B2. Membership of and attendance at Registration Liaison Committee meetings in 2004–05

<table>
<thead>
<tr>
<th>Member</th>
<th>Organisation</th>
<th>Meetings eligible to attend</th>
<th>Meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr Chris Sharpe</td>
<td>Department of Agriculture WA</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Dr Martin Matisons</td>
<td>Department of Health WA</td>
<td>4</td>
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</tr>
<tr>
<td>Mr Andre Mayne</td>
<td>Department of Agriculture, Fisheries and Forestry</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Mr Ian Mortimer</td>
<td></td>
<td>1</td>
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<tr>
<td>Mr Daniel Quinn</td>
<td></td>
<td>1</td>
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</tr>
<tr>
<td>Ms Janet Kerr</td>
<td></td>
<td>2</td>
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</tr>
<tr>
<td>Ms Julia Rymer</td>
<td></td>
<td>1</td>
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</tr>
<tr>
<td>Mr Brian Pidford</td>
<td>NZ Agricultural Compounds and Veterinary Medicines Group</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Ms Maree Zinzley</td>
<td></td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Dr Wafa El-Adhami</td>
<td>Office of Chemical Safety, Department of Health and Ageing</td>
<td>4</td>
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</tr>
<tr>
<td>Dr Les Davies</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mr Graeme Barden</td>
<td>Department of the Environment and Heritage</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Mr Phil Sinclair</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dr Ian Pitt</td>
<td></td>
<td>1</td>
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</tr>
<tr>
<td>Mr Justin Gilligan</td>
<td>Standing Committee on Fisheries and Aquaculture—Department of Agriculture, Fisheries and Forestry</td>
<td>3</td>
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</tr>
<tr>
<td>Dr Ingo Ernst</td>
<td>Aquatic Animal Health Unit—Department of Agriculture, Fisheries and Forestry</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Contact: Mr Alan Hill, APVMA, (02) 6272 5238

### Industry Liaison Committee

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

### Purpose

The purpose of the committee is to:

- provide a forum for formal consultation and discussion with peak chemical industry 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
- report via the APVMA to industry on its performance
- address specific operating policy issues through working groups
- consider the impact of proposed macro-policy changes on APVMA operations and implications for industry.
<table>
<thead>
<tr>
<th>Member</th>
<th>Organisation</th>
<th>Meetings eligible to attend</th>
<th>Meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Joe Smith</td>
<td>APVMA</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>(Chairperson)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Geoff MacAlpine</td>
<td>ACCORD Australia (previously ACSPA)</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Kathy Nolan</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lindsay Showyin</td>
<td>Aerosol Association of Australia Inc</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Philip Fleming</td>
<td></td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Dr Peter Holdsworth</td>
<td>Avcare Ltd</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Claude Gauchat</td>
<td></td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>John Firth</td>
<td>Generic Agricultural Chemical Association</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Richard de Vos</td>
<td>Nursery and Garden Industry Australia</td>
<td>3</td>
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<tr>
<td>Kevin Bodnaruk</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Peter Nobbs</td>
<td>Pet Industry Association of Australia Ltd</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Bernard Lee</td>
<td>Plastics and Chemicals Industries Association</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Andrew Simons</td>
<td>Swimming Pool and Spa Association of Australia</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Peter Drummond</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Robert Schufft</td>
<td>Veterinary Manufacturers and Distributors Association</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Tony McGloin</td>
<td></td>
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<td>0</td>
</tr>
<tr>
<td>Jim Adams</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Neil Sammons</td>
<td></td>
<td>1</td>
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</tr>
<tr>
<td>Mike Craft</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Contact: David Hutchison, APVMA (02) 6271 6384
**Issues considered**

- Reports of APVMA program operational and financial performance
- Reservation of sanitiser products
- Rotterdam and Stockholm conventions
- Trans-Tasman harmonisation of regulatory measures in agvet arena
- APVMA market research of registrants and the public
- Globally Harmonized System of Classification and Labelling of Chemicals
- Uhlig review of governance of statutory authorities
- Legislative change for quality of agricultural actives
- Development of standards and conditions for the lower regulatory requirements regime
- Correctness of labels submitted to APVMA by applicants
- Evaluation by the APVMA of export intervals on labels.

**Highlights**

- Review of APVMA consultative committees
- Implementation of new data protection framework
- Development of an APVMA Standard on Good Regulatory Science Practice
- Development of a guideline on dispute resolution mechanisms in the APVMA.

**Industry Technical Committee**

**Purpose**

The Industry Technical Committee (ITC) 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 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 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 before the committee in 2004–05 included:

- proposed survey questionnaire on APVMA reviews
- timing of discussion/consultation on issues and presentation of option papers
- infringements letters on advertising complaints
- APVMA communication with registrants and approved persons
- progress on APVMA credit card/electronic payment option
- general labelling issues
- standards for listed registration
- Veterinary Guideline No. 49—Extension of use or formulation change to an immunobiological product.
- new draft guidelines for immunobiologicals
- export intervals (EIs)
- globally harmonized system for hazard labelling
- dates for APVMA registration seminars for 2005
- release of supply under GMP
- Terms of Reference for the ITC Labelling Group.
### Table B4 Membership of and attendance at Industry Technical Committee meetings in 2004–05

<table>
<thead>
<tr>
<th>Member</th>
<th>Organisation</th>
<th>Meetings eligible to attend</th>
<th>Meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr Martin Holmes (Chair)</td>
<td>APVMA</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Ms Kathy Nolan</td>
<td>ACCORD Australia (previously ACSPA)</td>
<td>3</td>
<td>1</td>
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<tr>
<td>Mr Geoff McAlpine</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Ms Laura Lollback</td>
<td>Aerosol Association of Australia</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Mr Philip Fleming</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Mr Michael HR Hambrook</td>
<td>Australian Paint Manufacturers’ Federation</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Dr John McCaffrey</td>
<td>Australian Racing Board</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Dr Finola McConaghy</td>
<td>Australian Veterinarians in Industry</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Dr Bill Darmody</td>
<td>Australian Veterinary Association</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Dr Kevin Doyle</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Dr Peter Holdsworth</td>
<td>Avcare</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Mr Kevin Bodnaruk</td>
<td>Horticulture Australia Limited</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dr Les Davies</td>
<td>Office of Chemical Safety</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Mr Shane Walsh</td>
<td>Pet Food Industry Association of Australia</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Mr Peter Nobbs</td>
<td>Pet Industry Association of Australia Ltd</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Ms Stephanie Leach</td>
<td>Plastics and Chemicals Industries Association</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Mr Andrew Simons</td>
<td>Swimming Pool and Spa Association of Australia</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Mr Greg O’Connell</td>
<td></td>
<td></td>
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</tbody>
</table>

2 of:

<table>
<thead>
<tr>
<th>Member</th>
<th>Organisation</th>
<th>Meetings eligible to attend</th>
<th>Meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr Mike Craft</td>
<td>Veterinary Manufacturers and Distributors Association</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Mr Neil Sammons</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mr Robert Schufft</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mr Jim Adams</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Manufacturers’ Licensing Scheme Industry Liaison Committee

**Purpose**

The Manufacturers’ Licensing Scheme Industry Liaison Committee (MLSILC) was established to provide a forum for the APVMA to discuss strategic and operational issues related to the Manufacturers’ Licensing Scheme (MLS) for manufacturers of veterinary medicines with industry representatives and auditors. The committee met four times in 2004–05.

**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
- progressing 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**

The revision of the Australian Code of Good Manufacturing Practice for Veterinary Medicines again dominated the activities of the committee during the year. The Working Group, formed in 2003 to consider Code revisions, continued to meet regularly and agreed to a draft Code that was released to Australian veterinary manufacturers for preliminary comment.

Other issues considered during the year included:

- progress with auditing and licensing of veterinary medicine manufacturers
- availability of auditors and the Auditors’ Workshop
- further GMP training seminars for industry
- clarification of APVMA requirements, including pre-employment medical checks, and release for sale
- operation and management of mutual recognition agreements.

During the year, Mr Bruce Graham resigned from the committee. The committee would like to acknowledge Mr Graham’s valuable contribution to both the MLS-ILC and the Code Review Working Group.

---

**Table B5 Membership of and attendance at Manufacturers’ Licensing Scheme Industry Liaison Committee meetings in 2004–05**

<table>
<thead>
<tr>
<th>Member</th>
<th>Organisation</th>
<th>Meetings eligible to attend</th>
<th>Meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Bruce Johnson (Chair)</td>
<td>APVMA</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Michael Johnson</td>
<td>APVMA</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Mrs Kathy Winterton</td>
<td>APVMA</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Michael Nagajek</td>
<td>APVMA</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Dr Peter Holdsworth</td>
<td>Avcare</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Mr Ian Wheatley</td>
<td>Avcare</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Bill Blackhall</td>
<td>Veterinary Manufacturers and Distributors Association</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mr Bruce Graham</td>
<td>Auditors’ representative</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Contact: Bruce Johnson, APVMA, (02) 6272 4924
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 Section 5, 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

■ provide information to the Australian Government and its agencies and the States and participating Territories about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for such products, and to cooperate with those Australian Government agencies on matters relating to the management and control of chemical products

■ keep records and statistics of approvals and registrations it has granted, and permits and licences it has issued, under the Agvet Code

■ evaluate the effects of the use of chemical products in the States and participating Territories

■ cooperate with the Australian Government and its agencies and the States and participating Territories, to facilitate a consistent approach to the assessment and control of chemicals

■ in cooperation with the Australian Government and its agencies and the States and participating Territories, develop codes of practice, standards and guidelines for, and to recommend precautions to be taken in connection with, the manufacture, export, import, sale, handling, possession, storage, disposal and use of chemical products in the States and participating Territories

■ collect, interpret, disseminate and publish information relating to chemical products and their use

■ encourage and facilitate the application and use of results of evaluation and testing of chemical products

■ exchange information relating to chemical products and their use with overseas and international bodies having functions similar to those of the APVMA

■ when requested by the Minister, or on its own initiative, 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

■ encourage and facilitate the introduction of uniform national procedures for the control of the use of pesticides and veterinary medicines

■ fund, and cooperate in, a program designed to ensure that active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products, comply with the Agvet Code and the Agvet Regulations.

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

acquiring, holding and disposing of real and personal property

occupying, using and controlling any land or building owned or held under lease by the Commonwealth, 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 2004–05, the Minister gave no such direction.

Access to information

Website

Information on the APVMA’s structure, functions, powers and publications may be obtained via the APVMA’s website at 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 website:

- 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)
- 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 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
- Manual of Requirements and Guidelines (Ag and Vet)
- labelling code of practice
- guidelines for pesticides
- guidelines for veterinary medicines
- guidelines on chemistry and manufacturing aspects
- specific guidelines
- efficacy and safety guidelines
- setting maximum residue limits
- guidelines for recall of agricultural and veterinary 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

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 2004–05
Thirteen requests for information under the FOI Act were received during 2004–05.

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 and some section managers. The CEO has internal review powers. Initial enquiries may be made by telephoning (02) 6272 3896.

D: CONSULTANCIES
In 2004–05, the APVMA spent a total of $330,117 on consultants, with 27 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.

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<tr>
<th>Consultant</th>
<th>Activity</th>
<th>Amount</th>
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<tr>
<td>CITEC</td>
<td>Development of online payment facility</td>
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<td>Clayton Utz Lawyers</td>
<td>Legal advice</td>
<td>$99,638</td>
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<tr>
<td>Corporate Network Solutions</td>
<td>External penetration testing of network</td>
<td>$11,880</td>
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<td>Dr James Renwick</td>
<td>Legal advice and representation</td>
<td>$22,597</td>
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<td>Elizabeth Hutchings Editing</td>
<td>Editing of corporate documents</td>
<td>$13,422</td>
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<tr>
<td>Sparke Helmore</td>
<td>Legal advice</td>
<td>$11,158</td>
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<td>Spectrum Graphics</td>
<td>Graphic design of annual report</td>
<td>$10,963</td>
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<tr>
<td>Spooner &amp; Hall</td>
<td>Legal advice</td>
<td>$34,176</td>
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<td>The State of Qld acting through its Department of Primary Industries and Fisheries</td>
<td>Review of residues processes</td>
<td>$20,000</td>
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<td>Workplace Research Associates</td>
<td>Staff attitude survey</td>
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<td><strong>Total</strong></td>
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### Glossary

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<th>Term</th>
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<td>1080</td>
<td>sodium fluoroacetate</td>
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<td>ACA</td>
<td>Australian Consumers’ Association</td>
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<td>ACCORD Australia (previously ACSPA)</td>
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<td>active constituents</td>
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<td>ADI</td>
<td>acceptable daily intake</td>
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<td>Administration Act</td>
<td>Agricultural and Veterinary Chemicals (Administration) Act 1992</td>
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<td>AERP Ag</td>
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<tr>
<td>AERP Vet</td>
<td>Adverse Experience Reporting Program for veterinary products</td>
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<td>AgQA</td>
<td>Quality Assurance Scheme for Agricultural Actives and Products</td>
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<td>agvet chemicals</td>
<td>agricultural and veterinary chemicals</td>
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<tr>
<td>Agvet Code</td>
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<td>AHRI</td>
<td>Australian Human Resource Institute</td>
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<td>AME</td>
<td>Application Management and Enquiries</td>
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<td>ANAO</td>
<td>Australian National Audit Office</td>
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<td>APVMA</td>
<td>Australian Pesticides and Veterinary Medicines Authority (formerly National Registration Authority for Agricultural and Veterinary Chemicals)</td>
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<td>AQIS</td>
<td>Australian Quarantine and Inspection Service</td>
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<td>AAT</td>
<td>Administrative Appeals Tribunal</td>
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<td>AVA</td>
<td>Australian Veterinary Association</td>
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<tr>
<td>CCA</td>
<td>copper chrome arsenate</td>
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<td>Community Consultative Committee</td>
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<td>Codex Committee on Pesticide Residues</td>
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<td>Chief Executive Officer</td>
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<td>Codex</td>
<td>Codex Alimentarius Commission</td>
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<tr>
<td>CSIRO</td>
<td>Commonwealth Scientific and Industrial Research Organisation</td>
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<tr>
<td>CVM</td>
<td>Center of Veterinary Medicine (US)</td>
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<td>DAFF</td>
<td>Department of Agriculture, Fisheries and Forestry</td>
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<td>DEH</td>
<td>Department of the Environment and Heritage</td>
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<td>EI</td>
<td>export interval</td>
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<td>EMS</td>
<td>Environmental Management System</td>
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<td>Environmental Protection Agency</td>
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<td>FAO</td>
<td>Food and Agriculture Organization</td>
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<td>FDA</td>
<td>US Food and Drug Administration</td>
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<td>Freedom of Information Act 1982</td>
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<td>FSANZ</td>
<td>Food Standards Australia New Zealand</td>
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<td>GAP</td>
<td>Good Agricultural Practice</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>HAL</td>
<td>Horticulture Australia</td>
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<tr>
<td>HGP</td>
<td>hormonal growth promotant</td>
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<tr>
<td>ILC</td>
<td>Industry Liaison Committee</td>
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<tr>
<td>IPAD</td>
<td>Individual Performance and Development</td>
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<tr>
<td>IPM</td>
<td>Integrated Pest Management</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<tr>
<td>ITC</td>
<td>Industry Technical Committee</td>
</tr>
<tr>
<td>JECFA</td>
<td>Joint FAO/WHO Expert Committee on Food Additives</td>
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<td>MLS</td>
<td>Manufacturers’ Licensing Scheme</td>
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<td>MLSILC</td>
<td>Manufacturers’ Licensing Scheme Industry Liaison Committee</td>
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<td>MORAG</td>
<td>Manual of Requirements and Guidelines</td>
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<td>MOU</td>
<td>Memorandum of Understanding</td>
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<td>MRL</td>
<td>maximum residue limit</td>
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<td>NAA</td>
<td>National Archives of Australia</td>
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</table>
National Registration Scheme
This Scheme sets out the regulatory framework for the management of pesticides and veterinary medicines in Australia.

NRA
National Registration Authority for Agricultural and Veterinary Chemicals (now Australian Pesticides and Veterinary Medicines Authority)

NRS
National Registration Scheme

NZFSA
New Zealand Food Safety 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

PACIA
Plastics and Chemical Industry Association

permit
allows the legal use of a chemical in ways different from those specified on the product label or the limited use of an unregistered chemical

PIRSA
Department of Primary Industries and Resources of South Australia

PMRA
Pest Management Regulatory Agency (Canada)

PSIC
Product Safety Integrity Committee

PUBCRIS
Public Chemicals Registration Information System

QA
Quality assurance

registration
process of assessment and evaluation to determine a chemical’s safety and efficacy

RLC
Registration Liaison Committee

SLA
Service Legal Agreement

TRIPS
Trade-Related Aspects of Intellectual Property Rights

TT
triazine-tolerant

USDA
United States Department of Agriculture

USFTA
US Free Trade Agreement Implementation Act 2004

VDD
Veterinary Drugs Directorate (Canada)

VICH
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

VMDA
Veterinary Manufacturers and Distributors Association

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.

Requirement

- Annual operational plan: 7, 8
- Audit committee: 98
- Certification: iii
- Commonwealth Disability Strategy: 61
- Corporate Plan: 7, 8

Developments since end of financial year, affecting:
- operations in future financial years: N/A
- results of those operations in future financial years: N/A
- state of affairs in future financial years: N/A

Directors
- particulars: 55–56
- meetings held: 47–48
- meeting attendance: 98

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- Major investing and financing activities: 11–12
- Key financial and non-financial performance indicators: 7, 8, 11–12

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- efficiency and effectiveness in producing outputs: 7–10, 14–41
- clear links between outcomes, strategies and principal outputs: 7–10

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  - Corporate plan: 48
  - Principal outputs and contribution to outcomes: 48

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  - Factors, events or trends: 4–6, 14–41
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Enabling legislation requirements

- Significant changes in state of affairs and/or principal activities: N/A
- Significant events (as referred to in s.15 of the CAC Act): N/A
- Stakeholders: 2
- Subsidiaries: N/A

Other reporting requirements

- Funding of consultation costs for industry representative organisations: N/A

Other legislative requirements

- Ecologically sustainable development and environmental performance: 52
- Freedom of information: 108–110
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