Australian Pesticides & Veterinary Medicines Authority

Performance against outputs

PERFORMANCE AGAINST OUTPUTS

PRINCIPAL GOAL 1: PRODUCT REGISTRATION

Stakeholder confidence that independent product assessment protects public health, environment and trade

OVERVIEW

All manufacturers of pesticides and veterinary medicines must apply for registration of their products and approval of their labels with the APVMA before they can be supplied, sold, distributed or used in Australia.

Companies or individuals who hold a registration for a pesticide or veterinary medicine must also seek approval for any variation made to the product, additional claims made about the product or other changes to its label.

The purpose of registration is to provide a rigorous and independent assessment of scientific information concerning the safety and efficacy of a product. Registration is granted provided the assessment of that information has concluded that the use of the product is unlikely to be harmful to the target crops or animals, to the users, the consumers and the environment; that the product is efficacious and suitably formulated; and that its label contains adequate instructions. The APVMA must also assess whether use of the product may unduly prejudice trade.

By this process of careful evaluaton, users of pesticides and veterinary medicines and the general community can be confident that, when used according to label instructions, the products are safe and effective.

The APVMA employs three key strategies in its efforts to build stakeholder confidence in the assessment of pesticides and veterinary medicines.

Strategy 1: Conduct independent risk-based assessments that are both efficient and effective, of pesticides and veterinary medicines.

Strategy 2: Provide targeted information and develop key links with stakeholders to enhance system outcomes and build stakeholder confidence.

Strategy 3: Support development of relevant government policy.

Strategy 1: Conduct independent risk-based assessments that are both efficient and effective, of pesticides and veterinary medicines

Performance:

Pesticide applications

The Pesticides Program began the year with an increased number of applications in process carried over from the previous year. A reduced number of applications submitted throughout the year and maintenance of a similar number finalised to last year has resulted in a slight reduction in the number carried over to next year. These are detailed in Table 1 and include applications granted for product registrations and/or label approval, refusals of applications and withdrawals of applications.

The overall complexity of applications handled by evaluators continues to increase, with some of the less complex administrative applications being consolidated or transferred to a general permit. While this has improved the throughput of these types of applications, this added complexity, coupled with the ongoing effect of new label approval and data protection legislative requirements, has continued to challenge timeframe performance (see Table 2).

Table 1 Pesticide product applications

	2004–05	Change from 2003–04	2003–04
Commencing number of applications in progress	1118	+ 34%	833
Applications received	1398	– 15%	1763
Applications finalised	1429	– 3%	1478
Closing number of applications in progress	1087	– 3%	1118

Table 2 Registrations and approvals of pesticides

Class of application	Total no. registered or approved	No. finalised or approved vs statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		Within timeframe	Up to 20% above timeframe	More than 20% above timeframe		
15 month	3	1	0	2	17.6	34.7
13 month	1	1	0	0	12.1	17.5
12-month	7	4	2	1	12.7	18.7
8 month	64	32	14	18	8.8	20.8
6 month	5	0	1	4	9.1	14.3
5 month	62	26	14	22	6.4	15.3
3 month	1081	975	25	81	1.9	6.2
Total	**1223**	**1039 (85%)**	**56**	**128**		

Veterinary medicines applications

The number or applications received for registration, variation to registration, or label approval was slightly reduced compared with 2003–04.

The number of applications finalised was 24 per cent fewer than 2003–04 (see Table 3). This was primarily due to the increase in complexity in processing applications associated with the introduction of data protection on 1 January 2005. Despite this, 98.5 per cent of all applications received were finalised within statutory timeframes, a performance which is 4 per cent better than during 2003–04 (see Table 4).

The APVMA continues to implement process improvements which will assist both applicants and APVMA evaluators.

Table 3 Veterinary product applications

	2004–05	Change from 2003–04	2003–04
Commencing number of applications in progress	579	– 16%	689
Applications received	979	– 6%	1038
Applications finalised	871	– 24%	1148
Closing number of applications in progress	687	+ 19%	579

Table 4 Registrations and approvals of veterinary medicines

Class of application	Total no. registered or approved	No. finalised or approved vs statutory timeframe: Within timeframe	Up to 20% above timeframe	More than 20% above timeframe	Average clock time to finalise (months)	Average elapsed time to finalise (months)
15 month	4	4	0	0	12.6	21.4
12-month	1	1	0	0	9.0	18.0
8 month	45	44	0	1	6.4	20.3
5 month	161	161	0	0	3.5	9.9
3 month	520	510	3	7	1.4	6.0
Total	**731**	**702 (98.5%)**	**3**	**8**		

IRAQ REHABILITATION ASSISTANCE

The APVMA hosted four Iraqi Government veterinarians who were on an AusAid Iraq Rehabilitation Assistance Facility Program managed by the Department of Agriculture, Western Australia and Curtin University. The Australian Government, as part of its assistance for reconstruction in Iraq, is assisting the Iraqi agriculture sector through the provision of a short-term training and education program in Australia.

The APVMA provided a two-week intensive course on the regulation of veterinary medicines in Australia. The course covered areas such as:

- the role of the APVMA and other Australian Government agencies involved in the National Registration Scheme
- the relationship between the States and the Commonwealth in the regulation of veterinary medicines
- the quarantine role of the Australian Quarantine and Inspection Service (AQIS) in the importation of veterinary biological materials, and
- States' legislation.

The APVMA also organised a study tour of two veterinary vaccine and two pharmaceutical manufacturing plants.

CHEMISTRY AND RESIDUES PROGRAM

The Chemistry and Residues Program within the APVMA plays an important role in evaluating applications for registration and approval of permits. The APVMA must be satisfied that the constituents and manufacturing process for a product are appropriate prior to registering or approving the product. New and generic chemicals are evaluated before their approval for sale.

Residues and trade aspects of the product application are also evaluated to determine whether products can be used safely and properly in the marketplace, without concern about potential residues in food. A dietary intake evaluation is conducted to see that the use of a product on food animals or crops will satisfy the relevant health standards, namely the Acceptable Daily Intake and the Acute Reference Dose. No product is registered unless food safety standards are satisfied. A key objective of trade evaluations is to ensure that Australian trade to other countries will not be prejudiced unduly as a result of product registration. Residues and chemistry data are also evaluated for active constituents and products under chemical review. The Chemistry and Residues Program maintains the Record of Approved Active Constituents for Chemical Products and publishes the Standard for Maximum Residue Limits.

Efficient and effective risk assessment

The APVMA maintained its focus on performing efficient and effective risk assessments of applications for approval of new active constituents, registration of products, approval of labels, or variations to existing approvals and registrations.

The risk criteria which the APVMA must assess are provided in the Agvet Code—these relate to the risk that an application may cause harm to users, consumers, other people, the environment, overseas trade, or target animals or crops. The APVMA also assesses whether the product will be effective for the purposes claimed.

In assessing these risks the APVMA seeks advice from several external experts. Toxicology and occupational health and safety (OHS) advice is provided by the Office of Chemical Safety in the Department of Health and Ageing. Advice on environmental safety is provided by the Department of the Environment and Heritage, while advice on efficacy and target animal or crop safety is provided by State Departments of Agriculture, or universities, the CSIRO, or other experts. The APVMA integrates this expert advice with its own assessment of chemistry and manufacture and the likely residues profile arising from use of the product. After consideration of all the individual assessments, the APVMA decides whether to grant the application and, if so, under what conditions.

During 2004–05 the APVMA has improved its risk assessments by strengthening the administrative and scientific arrangements with its external advisers. Service Level Agreements have been negotiated with the State Departments of Agriculture or Primary Industries and existing SLAs with the Department of Health and Ageing

COMMUNICATION OF TRADE ADVICE

Following stakeholder discussions in 2003–04, the APVMA decided that Export Slaughter Intervals should be determined by the APVMA in consultation with the applicant and the relevant producer industry and that the APVMA must be satisfied that the relevant trade advice is communicated effectively by the use of label statements, websites, brochures, or a combination of methods. As a result, Part 5B of the Agricultural and Veterinary Requirement Series, *Overseas Trade Aspects of Residues in Food Commodities*, was amended and implemented in 2004–05. These requirements detail the data required for submission by applicants for evaluation and communication of trade risk. Trade advice on labels is an essential part of the whole of food chain quality assurance enabling the livestock producer to accurately complete the National Vendor Declaration under Meat and Livestock Australia's Livestock Production Assurance Scheme. To assist greater communication of trade advice the APVMA updated the former Meat and Livestock Australia's Export Slaughter Interval Database and posted it on the APVMA website where it is now updated monthly.

STOCKFEED GUIDELINES

This year, the APVMA completed a four-year project preparing a series of stockfeed guidelines. Thirty-three guidelines have been completed and posted on the APVMA website. These guidelines determine acceptable feeding levels for animals consuming a commodity treated with chemicals. They enable farmers and stockfeed manufacturers to make informed decisions about the residue status of feed commodities and how they should be incorporated into the livestock diet. Appropriate use of the guidelines will facilitate risk management of diets containing chemically treated commodities, and will reduce the risk of breaching residue limits for animal produce.

ACTIVE CONSTITUENTS

During 2004–05, 96 applications for active constituent approval were finalised, 96 per cent within legislative timeframes. The APVMA implemented the new scheme for agricultural chemical active constituents. This scheme involves assessing the quality of the active constituent in a product at the time of product registration and keeping records verifying active constituent quality post registration. The new scheme emphasises the quality of the active constituent and increases the robustness of the regulatory framework for agricultural chemical products. As part of this process, the APVMA established 403 standards and updated the relevant data requirements. During the year 25 new or amended standards for active constituents were determined.

MAXIMUM RESIDUE LIMITS

During 2004–05 the APVMA evaluated residue data for 59 applications for product registration, 161 applications for permits and 15 Chemical Reviews, producing 779 amendments to the MRL Standard.

and the Department of the Environment and Heritage have been revised. SLAs provide both parties with clear commitments relative to cost, timeframe and performance.

The APVMA has also striven to improve the efficiency and effectiveness of its assessments through comprehensive review of the application categories and data requirements. This was driven by the release of the new fees structure on 1 July 2005, in which the existing 50 application categories have been changed to 25 application categories, with revised fees. The revised application categories and data requirements are published on the APVMA website in the new Manual of Requirements and Guidelines.

Greater efficiency will also be an outcome of the restructure of the Registration Client Services team and the Registration Finalisation and Information team to form a single team called Application Management and Enquiries (AME). This restructure provides a greater focus on efficiently processing application files, updating the registration database, sending notices to applicants and providing information about applications. AME officially commences in early July 2005. One of the important tools the APVMA now uses to provide information is the Service Centre on the APVMA website. This advanced piece of software provides answers and website links for commonly asked questions.

Permits and minor uses

Pesticides

The Pesticides Program commenced the year with 443 permit applications in process. During this period 771 applications were received, of which 609 (79 per cent) were for minor or emergency use and 162 (21 per cent) for research purposes.

MORAG: INCREASED INFORMATION FOR REGISTRANTS

During 2004–05 the APVMA prepared the Manual of Requirements and Guidelines (MORAG), to be ready for commencement on 1 July 2005. MORAG is necessary because the existing 50 application categories have all changed as part of the review of fees and levies, which also comes into effect on 1 July.

MORAG replaces the existing Ag and Vet Requirements Series. The APVMA has taken the opportunity to update the style of presentation of information in MORAG so that requirements, which are the mandatory parts of an application for registration or approval of a product, active constituent or label, are clearly identified.

The guiding principle during the writing of MORAG was to make information precise, clear and easily available for registrants and APVMA staff. A working group comprised of representatives from Avcare, VMDA, PACIA and ACCORD made an invaluable contribution to the writing of MORAG.

MORAG will be divided into five volumes:

- Volume 1 Legislation and applications
- Volume 2 Application categories
- Volume 3 Data requirements and guidelines
- Volume 4 Specific product guidelines
- Volume 5 Labelling

MORAG will be located on the APVMA website and updates to the MORAG chapters can be downloaded from there. By basing MORAG on the website, chapters which are updated are always accessible.

The APVMA has produced a binder containing dividers for each volume and chapter. In this way, applicants can download the relevant chapters from the website and store them in the binder. However, by using MORAG on the website, registrants can use features such as extensive links between MORAG chapters, and the module calculator.

The APVMA plans also to publish MORAG on CD.

In June 2004 the APVMA held seminars on MORAG and the revised fees and levies, for registrants in Brisbane, Sydney, Melbourne, Adelaide and Perth.

DEVELOPING A STRATEGIC FRAMEWORK FOR MINOR USE

The Minor Use Task Force was established to progress reforms identified at the Minor Use Stakeholder Forum convened by the APVMA in November 2003. It comprises representatives from the chemical industry, agricultural users, agricultural consultants, the States, the APVMA and DAFF.

During 2004–05 the Task Force analysed the minor use situation in Australia and assessed successful international schemes, and developed a strategic framework and reform initiatives to address Australia's minor use needs.

The strategic framework is based on the following principles:

Minor use needs are:

- nationally coordinated, appropriately funded and driven by the user industry
- targeted at the development of new chemistry to enhance IPM adoption, resistance management, food safety, occupational health, the environment and trade.

Regulatory processes are:

- independent, risk based, efficient, effective and enhanced via the use of international collaboration and crop grouping schemes
- structured to encourage the introduction of new chemistry and the approval of more minor uses on product labels.

Communication processes are:

- clear, concise, consistent and the responsibility of all stakeholders
- enhanced via established minor use networks.

Five key strategies (underpinned by specific initiatives) are proposed to achieve this framework:

- enhancing the approval of more minor uses on product labels
- increasing industry collaboration and coordination
- enhancing the availability of new and reduced-risk chemistry
- enhancing international collaboration
- improving communication.

The framework and key strategies have been endorsed in principle by the APVMA Board and the Product Safety Integrity Committee (PSIC). Various actions are underway to implement them, particularly aimed at agreeing a mechanism for the establishment of an Australian Minor Use and Specialty Crops Development Unit to enhance industry collaboration, prioritisation of minor use research and linkages to existing

For this period, the APVMA finalised 676 applications, with the total number of unfinalised applications at the end of the year being 538. While the number of applications in process increased by 95 (443 versus 538) for the year, it is noted that 163 (21 per cent) of total applications were received in June 2005, most likely attributable to the introduction of an administrative fee for minor use permits from 1 July 2005.

Of the permit applications finalised, 505 permits were issued, 105 applications were withdrawn, three applications were refused and a permit was not required on 63 occasions.

A total of 76 emergency use applications were finalised in the period, including permits for citrus canker, lettuce aphid, Sclerotinia, Red Imported Fire Ants, Yellow Crazy Ants, silverleaf whitefly and plague locusts.

Approximately 78 per cent of applications were finalised within their statutory timeframe. The average time taken to finalise applications for minor use permits requiring a non-technical assessment was 70 days and applications requiring a major technical assessment, 165 days

Veterinary medicines

At 1 July 2004 the Veterinary Medicines Program had 69 permit applications in process. During the year 195 applications were received and a total of 199 applications were finalised. Of the permit applications finalised, 175 permits were issued, 17 applications were withdrawn, three applications were refused and a permit was not required on four occasions. Ninety-four per cent of permits were issued within statutory timeframes.

The majority (59 per cent) of permits issued were for minor uses (including off-label use of registered veterinary medicines, autogenous vaccines and shelf-life extensions). Twenty-four per cent of permits issued were for the generation of safety and efficacy data to support applications for registration; 15 per cent of permits were to allow export of unregistered veterinary chemicals and 2 per cent were for emergency uses.

Other activities—Minor Use Task Force, international activities and stakeholder relations

During the period the APVMA-initiated Minor Use Task Force developed a strategic framework for reform of minor uses, of which a major proposal was for the establishment of a Minor Use and Speciality Crops Development Unit. The three working groups reporting to the task force also progressed reforms relating to policy, operational issues and communications. Of particular note is the release of a Minor Use Communications Strategy developed by Growcom in consultation with the Communications Working Group, minor use stakeholders and DAFF. The Operational Issues Working Group, chaired by the APVMA, further progressed reforms including consolidating permits by active constituent and label reviews focused on crop grouping.

The APVMA also presented a paper outlining proposed initiatives for minor use to the OECD Working Group on Pesticides and continued participation in the International Crop Grouping Consulting Committee convened by the USA IR-4 program, contributing to reviews of crop groups, including tropical fruits, bulb vegetables, small (berry) fruits, cereals, forage and fodder crops.

The APVMA continued to strengthen links with several peak industry groups and associations throughout the year, including regular meetings with the HAL Minor Use Coordinator in relation to the fruit and vegetable industries and the ACA Project Team (on behalf of the Grains Research Development Corporation) for the grains industry. These interactions focused on informing industries of data requirements and on specific identified priorities with a view to enabling those industries to effectively address their minor use needs.

Regulatory science quality

The objectives of the Principal Scientist Program are to:

- improve the quality of scientific work within the APVMA
- increase domestic and international awareness and scientific credibility
- effectively manage science-related projects and issues within the APVMA.

Substantial progress was made in each of these areas during 2004–05.

First, several measures targeted improving the quality of scientific work undertaken by the APVMA. The Principal Scientists audited the regulatory science quality of evaluation reports prepared by staff. Development of the APVMA Science Fellows Program and the APVMA Standard of Good Regulatory Science Practice were also progressed. The Principal Scientist, Residues and Veterinary Medicines presented 12 training sessions to APVMA staff and presented risk assessment methodologies to the Expert Advisory Group on Antibiotic Resistance and the Office of Chemical Safety. External experts provided training to APVMA staff in the principles of Good Laboratory Practice, formulation chemistry, technical writing and editing skills, spray drift risk assessment methodologies and current concepts in general risk assessment approaches and mentored APVMA staff preparing to sit the membership examinations of the Australian College of Veterinary Scientists in veterinary pharmacology.

Second, the domestic and international scientific credibility of the APVMA was enhanced through various initiatives. Both Principal Scientists made presentations to the ChemCert National Conference. The Principal Scientist, Residues and Veterinary Medicines made presentations to the GLP workshops hosted by the Veterinary Manufacturers and Distributors Association, an APVMA workshop on the JECFA approach to setting MRLs for veterinary drugs, the AVA Conference and the FDA Minor Use and Minor Species workshop, as well as delivering invited university lectures and publishing in the international refereed literature. The Principal Scientist for Agricultural Chemicals helped organise and chaired sessions in the major international spray drift conference of 2004 and delivered invited presentations to numerous other external conferences.

Third, both Principal Scientists effectively managed numerous technical issues and led several science-related projects throughout the year. The projects included Performance Outcomes Monitoring, a review of the agricultural and veterinary chemical substances in Appendix J of the Standard for the Uniform Scheduling of Drugs and Poisons with an evaluation of products containing these substances for Restricted Chemical Product status, a proposal to adopt the JECFA approach to setting MRLs for veterinary drugs in Australia, the development of new efficacy guidelines for pool

sanitisers and a major reassessment of the APVMA's approach to spray drift risk management.

Standard on Good Regulatory Science Practice

The objective of the APVMA Standard on Good Regulatory Science Practice is to support science quality and science-based decision-making in the regulation of agricultural and veterinary chemicals in Australia. Compliance with the standard will strengthen the regulatory science quality that underpins regulatory decisions made by the APVMA. The Principal Scientists explored the perceptions of regulatory science quality with representatives of the community in 2003 and with chemical industry groups in 2004. The principles identified in these consultations formed a framework for the standard, a draft of which was provided to the APVMA's Industry Liaison Committee. The standard is now being finalised taking into account the comments received.

Science Fellows Program

The APVMA Science Fellows Program also aims to enhance regulatory science quality and to build public confidence in the APVMA by involving external scientists. Since it provides flexible delivery of expert scientific advice, it is an excellent vehicle for addressing any needs identified by audits of regulatory science quality conducted by APVMA Principal Scientists. To date, technical staff from the Chemistry and Residues Program have completed training in science writing and editing, while evaluation staff from the Veterinary Medicines Program have commenced additional training in formulation chemistry. Staff from the Pesticides Program have been trained in general risk assessment methodologies with particular training in relation to spray drift risk. Experts in other areas have been identified and invited to become APVMA Science Fellows. Training delivered by the APVMA Principal Scientists complements the Science Fellows Program.

APVMA processes

The APVMA continues to control its system of processes in accordance with its obligations as detailed in the legislation and within the framework of its externally accredited certification to the international ISO 9000 quality systems series.

Review of residue evaluation processes

The residue evaluation processes of the APVMA were reviewed in 2004 by an external review team. The review made recommendations, the most important being that Australia adopt the process used by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for setting MRLs for veterinary drugs. This proposal will bring the Australian approach into line with the JECFA process being used by other countries, build additional rigour and transparency into the current residues evaluation process by using a statistical method and enhance Australia's ability to provide input to, and influence, international forums dealing with the use and regulation of veterinary medicines.

A stakeholder forum was held in May 2005 and a Regulatory Impact Statement on the JECFA approach to setting MRLs for veterinary medicines will be prepared for consideration later in 2005.

Listed registration and reservation from registration

Amendments to the Agvet Code introduced in October 2003 now allow for a three-tiered regulatory framework for pesticides and veterinary medicines. Under this framework, products which require registration according to the criteria in the Agvet Code, but whose risk profile is low and well known, may be given listed registration if they conform to a predefined standard.

A draft standard for listed registration of certain products which modify the health of joints in dogs and horses was gazetted in December 2004. The APVMA has published draft standards for the listed registration of products containing chlorine that are used to treat water in swimming pools and spas. Comments on these standards have been received and are under consideration.

The third tier of the regulatory framework is reservation from registration. In this case, products which are used for very low-risk agvet uses, may be reserved from registration if they conform to predefined conditions. The APVMA has also published draft conditions for reservation for certain general purpose sanitisers and disinfectants and has received comments on these proposals. Several other substances have been identified for consideration for the development of standards for listed registration or conditions for reservation.

DATA PROTECTION

In 2004–05 the APVMA was required to implement a new data protection scheme as a result of the *US Free Trade Agreement Implementation Act 2004* (USFTAI Act), which was given royal assent on 16 August 2004. The new scheme provides intellectual property protection for information provided with applications for active constituents and products. It is separate from the current data protection schemes (i.e. provided by chemical reviews and TRIPS) in both legislation and administration, requiring the APVMA to run three separate data protection schemes.

In July 2004 the APVMA created a Data Protection Establishment Unit to develop the necessary documentation (i.e. requirements, guidelines and forms), IT infrastructure (e.g. databases) and internal processes to be ready for commencement on 1 January 2005. This included consultation with, and seminars for, stakeholders.

This year has seen the scheme implemented smoothly with minor changes made to fine-tune the process.

In addition to the data protection requirements, the USFTAI Act also requires the APVMA to be more transparent in declaring the types of applications before it and the types of information required to make regulatory decisions. To this end the APVMA is now required to publish a summary of certain applications which have been accepted for evaluation as well as summaries of advice received by the APVMA (from persons or bodies consulted) for applications which have been granted. The APVMA is publishing these summaries on the APVMA website.

Label quality

Work has continued on the review of the Agricultural and Veterinary Chemicals Labelling Codes, in conjunction with the States and other stakeholders. The aims of this review are to facilitate compliance with State control-of-use legislation and improve consistency and clarity of labels for users of pesticides and veterinary medicines.

The review has so far resulted in the development of key labelling principles and drafting of various example labels. Following consultations on the principles, the APVMA will now look to agree further necessary reforms.

The APVMA also reached agreement with manufacturers of paints used as marine antifoulants on improvements to the labelling of these products.

Spray drift

Spray drift is an issue of great interest to the community and one that the APVMA takes very seriously. The APVMA keeps abreast of the latest national and international developments in methods to assess spray drift risk and manage potential spray drift.

The APVMA has been reviewing and strengthening its approach to spray drift risk assessment during the last several years. A discussion paper published in 2003 has been the stimulus for many useful written submissions from industry and the community and has been the basis of a significant number of helpful meetings such as a national industry forum held in February 2005 to discuss spray drift issues.

Information from sources such as this combined with new information from overseas regulators and other international sources, such as a major international spray drift conference held last year, have enabled the APVMA to substantially revise and update its original discussion paper. This revised discussion paper with its proposals will be made available for another round of public comment during August through to 21 October 2005. The APVMA will carefully consider all new submissions and plans to move toward finalising its proposals by early 2006.

Service Level Agreements

In evaluating applications for registration, the APVMA receives advice on human toxicology, occupational health and safety, the environment, efficacy, target animal and crop safety and genetically modified products and organisms from various Australian Government and State and Territory government agencies. Formal Service Level Agreements are in place between the APVMA and these agencies to ensure that advice is provided in an accountable financial framework and has relevant performance measures.

The agreements provide a framework for cost-effective and timely advisory services that are of appropriate and consistent quality.

Throughout 2004–05, the APVMA maintained and revised Service Level Agreements with the Department of the Environment and Heritage (DEH) and the Office of Chemical Safety (OCS) in the Department of Health and Ageing for the provision of scientific assessment services. Services include assessments for registration and permit

applications, assessments of chemicals under review and other professional advice. Both DEH and OCS delivered 95 per cent of application assessments within timeframes.

The APVMA also has a Memorandum of Understanding with the Office of the Gene Technology Regulator (OGTR) that provides a framework for cooperation between the two organisations. The OGTR advises the APVMA on the impact of pesticides and veterinary medicines on genetically modified organisms and on genetically modified organisms that are part of pesticide and veterinary medicine products. The APVMA also provided comment on relevant draft risk assessments prepared by the OGTR.

The APVMA finalised negotiations for SLAs with some State and Territory departments regarding the provision of efficacy and target safety advice for product registration or minor use applications. The APVMA signed new or revised SLAs with the Tasmanian Department of Primary Industries, WA Agriculture and the NSW Department of Primary Industries.

Strategy 2: Provide targeted information and develop key links with stakeholders to enhance system outcomes and build stakeholder confidence

Performance:

Communication strategy

Throughout 2004–05 the APVMA continued to implement a comprehensive communication plan which was approved by the APVMA Board in 2003. The plan aims to build confidence in the APVMA and the regulatory system among the identified key audiences: the community, chemical industry, chemical users and government.

The three key objectives that the APVMA plans to achieve through its communication strategies outlined in the communication plan are to:

- identify current community attitudes and emerging issues concerning the use of agvet chemicals
- develop and maintain excellent communications with peak representative bodies
- provide easily accessible public information.

A number of significant activities were conducted as part of the plan in 2004–05. These include an upgrade to the APVMA website including the addition of the self-help service centre, development of the new electronic APVMA Newsletter, launch of the Account Manager Scheme and conducting several meetings and seminars for APVMA stakeholders. Topics covered by these meetings include data protection, the new cost-recovery framework and APVMA fee structure as well as the development and roll-out of MORAG. The APVMA also conducted a comprehensive stakeholder research program with the community and chemical industry. The results of this research will guide communication activities of the APVMA in the future.

Stakeholder interaction

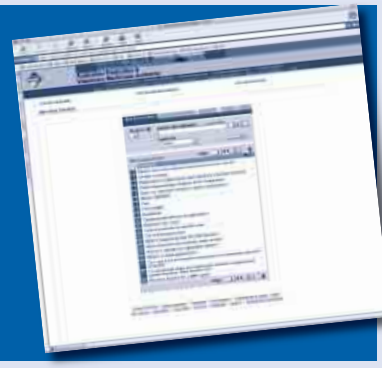
In accordance with the APVMA's corporate goal to build and maintain stakeholder confidence, the APVMA has continued to strengthen relationships and communication efforts with key stakeholders during 2004–05.

Throughout 2004–05, the APVMA continued to engage stakeholder groups through consultative committees that ensure effective two-way communication with such groups.

During the year, the APVMA launched the Account Manager Scheme. This scheme involves senior staff having responsibility for managing relationships with particular stakeholder organisations. APVMA Account Managers currently liaise with a range of organisations representing rural producers, commodity groups and professional bodies. The Account Manager Scheme will improve stakeholder relationships and awareness of agvet chemical issues. The CEO continued to meet with senior personnel from a range of organisations throughout Australia to increase understanding of the APVMA.

The APVMA continued to build awareness of the Adverse Experience Reporting Program with a number of target organisations including the medical profession and local government.

The use of electronic media is an important communication tool for the APVMA. Further enhancements were made to the APVMA website in 2004–05. These include major improvements to PUBCRIS (our public agvet chemicals database) as well as the addition of a customer enquiry management system. The APVMA's email subscription service was also used



APVMA SERVICE CENTRE

The APVMA launched an on-line Service Centre on 10 January 2005. The Service Centre allows visitors to search and view APVMA information and submit enquiries directly to the Enquiries Unit. These enquiries can be tracked, stored and updated by the user. Further, users can indicate their interest in any updates to information contained in the Service Centre.

In the first five months of operation almost 12 000 pages have been viewed and 2800 searches performed in over 3800 sessions. There have been about 620 enquiries submitted by just over 400 registered users.

The Service Centre may be accessed by clicking on 'Ask Enquiries Unit' on the left-hand menu of the APVMA home page.

increasingly to disseminate targeted information via email announcements in 2004–05.

A major achievement for 2004–05 has been the introduction of the electronic APVMA Newsletter. The APVMA Newsletter, distributed via email, replaces the former hard-copy APVMA News magazine that was published three times per year. The electronic format, published more frequently is a far more effective mechanism to communicate with a range of stakeholders.

During 2004–05 the APVMA hosted a number of issues-focussed meetings or seminars tailored to specific stakeholder groups. A Chemical Review Users Forum was held in November 2004. The APVMA also held seminars outlining new data protection arrangements, proposals relating to the management of spray drift, the new cost-recovery framework and APVMA fee structure and the development of MORAG.

Throughout the year, the APVMA staff attended and gave presentations at stakeholder meetings, field days, conferences and seminars. These activities increase awareness of the APVMA and its requirements and improve stakeholder awareness of the regulatory system. A summary of these activities is provided in Table 5.

Table 5 APVMA presentation summary

Month	Conference or seminar name	Topic of presentation
July 2004	Australian College of Veterinary Scientists Annual Conference	APVMA AERP Vet program
August 2004	ChemCert National Conference	APVMA AERP Ag program
August 2004	ChemCert National Conference	Performance Monitoring
August 2004	ChemCert National Conference	The national regulator's view
August 2004	ChemCert National Conference	Spray Drift Lessons from Case Studies
August 2004	Australian Ground Sprayers Annual General Meeting	APVMA AERP Ag program
August & September 2004	Various	Three APVMA seminars on the Ag QA scheme
August 2004	Industry meeting	The AgQA Scheme—Chemistry aspects
August 2004	Soil Biology in Agriculture Workshop	Registration of Soil Biological Products
August 2004	Australian Groundsprayers Association Annual Conference	Spray Drift Risk Management

Table 5 APVMA presentation summary

Month	Conference or seminar name	Topic of presentation
August 2004	Red Imported Fire Ant Workshop	APVMA Permit Process and the Fire Ant Eradication Program
September 2004	Invited lecturers, University of Sydney	Food Safety—Chemical Residues
September 2004	Australian Society for Microbiology Conference	Heritage Pharmacy in a Low Regulatory Environment: a case study in developing a standard for ornamental aquarium antiseptic products
September 2004	CSIRO Endocrine Disruptor Chemicals Conference	APVMA Approach to Risk Assessment for Endocrine Disruptor Chemicals
September 2004	Second Australian New Crops Conference	Regulation of Agricultural Chemicals in Relation to New Chemicals and Minor Uses
October 2004	FDA International Workshop on Minor Uses and Minor Species, Washington DC	An Australian Perspective—Minor Uses and Minor Species
October 2004	VMDA GLP Workshop, Sydney	GLP Residues Data—An APVMA Perspective
October 2004	Avcare Summit	Taking a closer look—changing risk paradigms
October 2004	International Conference for Pesticide Application for Drift Management	Australia—Regulatory Goals and Approaches to Spray Drift Risk Management
October 2004	National Peanut Update Conference	Chemical Registration and Crop Protection Product Labels
November 2004	International Dairy Federation World Dairy Summit	Global trends in antibiotic resistance and availability—a regulator's perspective
February 2005	National Health and Medical Research Council Expert Advisory Group on Antibiotic Resistance	Maximum Residue Limits, dietary exposure and antibiotic resistance
February 2005	OECD	APVMA organisation structure and assessment process
February 2005	OECD	Structure of Australian residues evaluation reports
February 2005	APVMA Industry and State National Spray Drift Forum	The APVMA and Spray Drift Risk Management
February 2005	ChemCert NSW Professional Development Workshop	Legislation and Product Labels
March 2005	New Zealand Timber Preservation Council Conference	The APVMA's Decision on CCA Timber Treatments
April 2005	Agricultural Crop Sprayers Association of SA Annual Conference	Managing Spray Drift Risks
May 2005	Australian Veterinary Association Annual Conference	Consideration of Antibiotic Resistance and Dietary Exposure when Setting Maximum Residue Limits for Veterinary Antibiotics
May 2005	Australian Veterinary Association Annual Conference	The JECFA approach to setting MRLs for veterinary drugs
May 2005	Animal health industry workshop	JECFA MRL-setting process for veterinary drugs
May 2005	Communicable Diseases Control Conference	Rapid response regulatory options for zoonotic diseases
May 2005	VMDA GLP Workshop, Melbourne	GLP Residues Data—An APVMA Perspective
April & May 2005	Invited lecturers, Monash University	Veterinary Dosage Forms

Table 5 APVMA presentation summary

Month	Conference or seminar name	Topic of presentation
May 2005	Product Safety and Integrity Committee	Performance Outcomes Monitoring
May 2005	NSW Apiarists Association Conference	Update on labelling review and general residues issues
May 2005	Australian Veterinary Association Conference	APVMA Efficacy Trial Data Requirements
May 2005	Communicable Diseases Control Conference	Rapid Response Regulatory Options for Zoonotic Diseases
May 2005	Australian Veterinary Association Conference	Generic Equivalence and Bioequivalence
May 2005	National Working Party on Grain Protection	Update on Regulation of Agricultural Chemicals
May 2005	Avcare Crop Protection Subcommittee	AgQA Scheme Auditing and Testing
May 2005	PIRSA Regional Chemical Trespass Officer Seminar	APVMA AERP Ag program
May 2005	ChemCert and Farmcare Professional Development Workshop	APVMA AERP Ag program
June 2005	Office of Chemical Safety	Metabolism studies—the link between toxicology and the monitoring of residues in food
June 2005	Pharmacology Candidates Workshop, Australian College of Veterinary Scientists Science Week	Generic Equivalence: pharmacoequivalence and bioequivalence
June 2005	Pharmacology Candidates Workshop, Australian College of Veterinary Scientists Science Week	APVMA Efficacy Trial Data Requirements
June 2005	Aerial Agricultural Association of Australia Annual Conference	Update on Current Activities Relating to Labelling
June 2005	Australian Timber Preservation Industry Conference 2005	The Reasons for the APVMA Decision on CCA
June 2005	Avcare/VMDA Seminar	APVMA AERP Vet program

Throughout the year, the APVMA continued to produce a range of information materials tailored to meet the needs of specific audiences on particular issues. The APVMA has developed an 'Information Pack' suitable for a range of stakeholder audiences. This pack includes the recently developed corporate credentials document 'Introducing the APVMA' as well as the corporate CD that includes popular web links and information sheets. The APVMA also commenced publishing a summary of APVMA Board meetings on the website.

Working with the media

The work of the APVMA continued to attract considerable media interest throughout 2004–05. As in previous years, most was a result of APVMA chemical review activities. Announcements relating to arsenic timber treatments, 1080, atrazine and virginiamycin attracted significant attention. The APVMA issued six media releases in 2004–05 all of which generated significant media interest. The APVMA CEO, Program Managers and Principal Scientists continued to act as spokespeople for the APVMA. The APVMA also responded to a number of general media inquiries.

International engagement—building relationships with overseas regulatory agencies

Under the umbrella of overall Australian Government participation, the APVMA actively participates in a number of key international forums.

OECD

The APVMA is engaged in the work of the OECD Working Group on Pesticides (WGP) and its related committees

(the Registration Steering Group, the Risk Reduction Steering Group and the Biopesticides Steering Group). Through these OECD groups the APVMA focuses on achieving greater efficiency in registration processes, improving harmonisation of registration requirements and guidelines, promoting and participating in exchange of assessments, work sharing, improving the scientific basis for and continuing to reduce risks to people and the environment.

The WGP aims to facilitate common international approaches to pesticide regulation through development of common evaluation and testing guidelines and promoting work sharing among member countries. The APVMA and representatives from its health and environment advisory agencies took a leading role in the OECD Workshop to Advance Work Sharing of Agricultural Pesticide Reviews Work held in early 2005. The aim of the workshop was to discuss specific barriers to work sharing, develop recommendations to eliminate and reduce such barriers, and to promote work savings by increasing the experience and confidence of evaluators and registrants in using and sharing dossiers and monographs.

During 2005 the APVMA also presented a minor use discussion paper to the WGP as a follow-up to the Risk Reduction Steering Group Minor Use Seminar held in Canberra in November 2003. The paper proposes some key objectives and actions to help harmonise regulatory requirements for minor uses and improve opportunities for conducting joint reviews and acceptance of international data, including improving opportunities for the generation of data in an international context by user industries.

In the area of guideline development the APVMA is supporting the work of the Office of Chemical Safety in leading an OECD project on the development of a guidance document on the analysis of dermal absorption studies, with a focus on the use of such studies for occupational health risk assessment purposes. During 2004–05 work on the development of test guidelines and guidance documents on residue chemistry also began and the APVMA is taking a leading role in this project. To date the Expert Group on Pesticide Residue Chemistry has finalised five guidelines and two guidance documents for comment.

The development of a livestock feeding guideline was particularly important for the recognition of Australian MRLs for meat and animal commodities by our major trading partners.

United Nations FAO/WHO Codex Committees on Pesticide Residues and Residues of Veterinary Drugs in Food

The APVMA provides technical advice for the Codex Committee on Pesticide Residues and the Codex Committee on Residues of Veterinary Drugs in Food. These committees and the FAO/WHO expert evaluation panels, the Joint Meeting on Pesticide Residues and the Joint Expert Committee on Food Additives are responsible for determining the MRLs that underpin the trade in food commodities.

The APVMA contributed to the Australian delegation to the Codex Committee Meeting on Pesticide Residues (CCPR) in April 2005. Key issues for Australia included prioritisation of the evaluation of the new chemicals aminopyralid, difenoconazole and thiacloprid, refining the variability factor in estimating acute dietary exposure, probabilistic modelling for Codex MRL setting, the proposed draft risk analysis principles applied by the CCPR, the use of alternative Good Agricultural Practices (GAPs) where acute dietary risk concerns are raised with the reviewed GAPs and the Pilot Project for National MRLs as Interim Codex MRLs for safer replacement pesticides.

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

The principal objective of VICH is to provide an international forum for regulators and the veterinary medicinal products industry to harmonise technical requirements for product registration. The members of VICH are drawn from the European Union, Japan and the United States. Australia and New Zealand have combined observer status at VICH. VICH working groups develop guidelines that are progressively adopted by the APVMA.

The APVMA will be the Australia/New Zealand representative on the VICH Steering Group for the period 2005–2008.

During 2004–05 the APVMA adopted evaluation guidelines on the generation of storage stability data for veterinary chemical products and guidelines for the validation of analytical methods. A third important guideline adopted was the second phase of guidelines on environmental safety. The first phase was adopted in 2001. The Department of the Environment and Heritage and the APVMA made a significant contribution towards writing these two environmental guidelines.

APVMA and other Australian Government staff participated in working groups on antimicrobial resistance and ecotoxicity.

Other international activities

The Principal Scientist for Agricultural Chemicals met with various staff members of the US Environmental Protection Agency (EPA), The Canadian Pest Management Regulatory Agency and the California Environmental Protection Agency in October 2004. Common issues of concern that were discussed related to spray drift risk management, occupational health and safety risk assessment methods, the efficacy of pool sanitisers and the health risks from copper chrome arsenate (CCA) timber treatments.

Strategy 3: Support development of relevant government policy

Performance:

Informing policy

The APVMA's key responsibility is for the regulation of pesticides and veterinary medicines according to its governing legislation. It does not have a primary role in development of government policy. However, because of its extensive and unique knowledge, the APVMA plays a vital role in informing development of policy impacting on regulation of pesticides and veterinary medicines.

Against this background, the APVMA contributed to policy development and reform in several important areas, including:

- the policy and legislative programs coordinated by the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) related to the regulation of pesticides and veterinary medicines. Particularly significant were amendments to the APVMA cost-recovery framework and the new data protection legislation associated with applications to register (now in place) and review of existing agvet chemical products (revised legislation under development)
- the work of the Product Safety and Integrity Committee of the Primary Industries Standing Committee, with key projects including training and accreditation of chemical users, development of performance outcome measures for Australia's agvet chemicals management system and collection of chemical use information

MEMORANDA OF UNDERSTANDING WITH OVERSEAS REGULATORS

During 2004–05 the APVMA finalised several Memoranda of Understanding with overseas regulators. They are with:

- New Zealand Food Safety Authority (NZFSA) Agricultural Compounds and Veterinary Medicines Group. This MOU formalises processes for the mutual acceptance of licences for the manufacture of veterinary medicines following Good Manufacturing Practice principles
- Veterinary Drugs Directorate (VDD) of Health Canada. This MOU includes information exchange on veterinary medicines regulatory matters, staff exchange, and common approaches and cooperation in risk assessment and in the use of information technology
- Pest Management Regulatory Agency (PMRA) of Health Canada. This MOU has a similar scope to the MOU with the VDD.

During 2005–06 the APVMA expects to conclude similar MOUs with the Center of Veterinary Medicine (CVM) in the United States Food and Drug Administration and the Office of Pesticides Program in the US EPA.

The MOUs add an important extra dimension to the APVMA's already extensive international engagement. They will enable the APVMA to benchmark its performance against the best international standards and through cooperation and work sharing will lead to quality and efficiency gains for all agencies involved.

- input to the activities of the Environment Protection and Heritage Council Working Group on Environmental Risk Management of Chemicals
- contributing to government consideration of issues related to chemicals security and proposals identified by the Chemicals and Plastics Leadership Group
- in conjunction with DAFF and Food Standards Australia New Zealand (FSANZ) working to optimise interaction between APVMA and FSANZ on incorporating maximum residue limits into the Australian Food Standards Code
- pursuing reforms regarding policies impacting the availability of adequate safe and effective chemicals for minor use in Australian agriculture.

As part of overall Australian Government engagement, the APVMA has maintained a strong focus on working proactively with international agencies such as the OECD Working Group on Pesticides, VICH and Codex. The key aims of this are to ensure Australia remains aware of, influences and adopts international best practice in the regulation of pesticides and veterinary medicines. Within OECD, APVMA is taking a lead role in advancing international reform in minor use, harmonised residue guidelines and overcoming barriers to acceptance of country evaluation reports by other OECD member countries.

We have also strengthened our bilateral liaison through the signing of Memorandums of Understanding with the Canadian PMRA and VDD and the New Zealand FSA.

SUMMARY

Progress towards achieving the goal of stakeholder confidence that independent product assessment of pesticides and veterinary medicines protects public health, the environment and trade has been a major focus for the APVMA during 2004–05. This has been achieved through the APVMA's commitment to ensuring that registered products in the marketplace meet legislative requirements for performance, safety and trade as a result of high quality and scientifically sound decision-making.

During the year more than 90 per cent of registration decisions were made within statutory timeframes while major reforms were made to registration processes. The APVMA implemented a number of measures to ensure that information provided contributes to an informed public debate and the development of robust government policy in relation to the regulatory framework for pesticides and veterinary medicines.

PRINCIPAL GOAL 2: QUALITY ASSURANCE AND COMPLIANCE

Ongoing product quality supported by effective intelligence, quality assurance and compliance and enforcement programs

OVERVIEW

Pesticides and veterinary medicines may not be registered forever. The APVMA manages four programs that monitor the ongoing quality and safety of registered products to ensure that the high standards of registration are maintained. These programs have the capacity to take regulatory action if the registration standards are not maintained or if new information becomes available that dictates the need to reconsider a product's registration.

The four APVMA programs dedicated to maintaining the high standards of registration are the Chemical Review Program, the Compliance Program, the Adverse Experience Reporting Programs and the Manufacturers' Licensing Scheme.

The APVMA employs three key strategies to ensure the ongoing quality of pesticides and veterinary medicines:

Strategy 1: Achieve system excellence through enhanced intelligence, feedback loops, monitoring and reporting.

Strategy 2: Review chemical safety, quality and performance against contemporary standards.

Strategy 3: Ensure product quality through risk-based compliance strategies.

Strategy 1: Achieve system excellence through enhanced intelligence, feedback loops, monitoring and reporting

Performance:

AERP

The programs

The Adverse Experience Reporting Program for agricultural (AERP *Ag*) and veterinary chemicals (AERP *Vet*) are post-registration feedback loops established by the APVMA to facilitate responsible management of agricultural and veterinary chemical products throughout their lifecycle. The programs provide a means for identifying actions necessary to assure continued safety, quality and effectiveness of registered chemical products.

The aim of the AERP *Ag* and AERP *Vet* is to provide the APVMA with feedback about the quality and performance

of agricultural and veterinary chemical products in the field to ensure that registration decisions being made by the APVMA continue to remain appropriate and to promote and maintain public confidence in the National Registration Scheme.

AERP *Ag*

As the AERP *Ag* program is still relatively new, there was a focus on promoting the AERP *Ag* to various community, farming and pesticide working groups throughout 2004–05. Activities undertaken to raise awareness of the program include:

- meetings with the New South Wales Department of Environment and Conservation, South Australian Department of Primary Industries and Resources, Western Australian Department of Health, Australian Groundsprayers Association, ChemCert National Conference.
- contribution to the *Wildlife Health in Australia Newsletter*, **1**(2)
- an insert for the National ChemCert Training Manual
- communicating with the Australian Local Government Association, Australian Medical Association and various other medical and community groups
- a submission to the South Australian Parliamentary Enquiry on Multiple Chemical Sensitivity.

There were 159 adverse experience reports assessed and classified during the 2004–05 financial year. Of these reports, 85 per cent were finalised within three months of receipt. Numerous enquiries were also received from members of the public.

Adverse experience reports involving crops constituted approximately 73 per cent of the reports. Human adverse experience reports comprised 13 per cent of all reports. The three most common groups of agricultural chemicals implicated in the reports were the insecticides (84 per cent), molluscides (6 per cent) and herbicides (5 per cent).

The quality of information provided in the reports to date has generally been of an acceptable standard, but there is a lack of detail provided in some reports. Registrants of implicated products were involved in the investigations. Based on assessments of information received, a number of corrective actions are currently underway.

Although in its infancy, the program has received positive feedback. It is important that the community, the medical profession, government departments and industry submit suspected adverse experience reports to the program so that appropriate actions can be taken to maintain the continued quality of agricultural chemicals in Australia.

AERP *Vet*

Activities undertaken to raise awareness of the AERP *Vet* program include:

- a presentation at the Australian College of Veterinary Scientists' annual conference in July 2004
- publication of a peer-reviewed scientific paper titled 'The Veterinary Pharmacovigilance Program of the APVMA'. *Australian Veterinary Journal* **83**(1&2): 32, 2005
- publication of an article titled 'Appropriate Treatment for Multicrop Multiguard® Affected Dogs'. *Australian Veterinary Journal* **82**(11): 675, 2004
- an article in the WA Australian Veterinary Surgeons' Board newsletter.

There were 1276 adverse experience reports assessed during 2004–05. Of these 98.8 per cent were finalised within three months of receipt. There were slightly fewer reports than in 2003–04 (1438). In addition, numerous enquiries were received from both veterinarians and members of the public.

Eighty per cent of adverse experience reports involved animal safety, 15 per cent involved lack of efficacy and 5 per cent involved human health issues. The two most common groups of veterinary medicines implicated in the reports were parasiticides (58 per cent) and vaccines (19 per cent).

Corrective actions taken include:

- additional warning, precautionary or restraint statements placed on seven product labels, including changes to First Aid Instructions and Safety Directions for two products, and
- a formulation change was made to one product.

The quality of the information provided in the reports was generally of a high standard, which in part reflects the very active relationships the AERP *Vet* staff have maintained with product registrants. This has been a year

of consolidation after recent staff changes and extensive process re-engineering during 2003–04.

The AERP *Vet* is an essential part of a quality assurance program, providing veterinarians and other users of veterinary products with feedback about the performance of these products in the field.

Performance outcomes monitoring

The APVMA completed a Performance Outcomes Monitoring project that looked at how the overall agricultural and veterinary chemicals management system is performing in relation to public health, worker exposure, the environment and trade outcomes. Readily available data and information were reviewed to determine the scope of the monitoring that is currently undertaken, to draw conclusions regarding any adverse effects of agricultural and veterinary chemicals on these measures, and to propose initiatives for improving the performance outcomes of the overall chemicals management system and the monitoring of those performance outcomes.

The project proposed a set of reporting measures that aim to:

1. provide the information that is required for the agricultural and veterinary chemical management system to implement feedback mechanisms
2. enhance the transparency of the decision-making process by placing more information in the public domain
3. facilitate improved consultation by stakeholders and the community
4. build public confidence in the system.

The project has affirmed that the case for nationally integrated outcomes monitoring of the regulatory system for agricultural and veterinary chemicals in Australia is compelling. The findings of the project will make a

SAFETY OF AUSTRALIA'S FOOD SUPPLY

Australia conducts various programs to assess and mitigate trade risks and maintain access to markets for agricultural produce. The most significant of these in relation to residues of pesticides and veterinary medicines are the National Residues Survey conducted by the Department of Agriculture, Fisheries and Forestry and the Australian Total Diet Survey conducted by Food Standards Australia New Zealand.

In 2004–05 the National Residue Survey conducted analyses on a total of 210 224 chemical-commodity combinations in the meat products, honey, grains, horticulture and fisheries/aquaculture programs. The incidence of residues in excess of MRLs reported in these surveys is very low (see Table 6). This reflects the success of the measures put in place by government and industry to mitigate trade risks, a key element of which is the chemical product registration scheme operated by the APVMA.

Food Standards Australia New Zealand conducted the 20th Australian Total Diet Survey in 2000–01. The survey confirmed the overall safety of the Australian food supply and demonstrated that pesticide residues, metals and selected antibiotics, aflatoxins and ochratoxins are either absent or present in low amounts.

Table 6 Percentage compliance with MRLs for pesticides and veterinary medicines in the National Residues Survey

Commodity group	2000–01	2001–02	2002–03	2004–05
Meat products	99.98	99.87	99.99	99.99
Grain products	99.98	99.65	99.99	99.98
Horticultural products	99.96	98.83	100.00	99.99
Fisheries products	100.00	100.00	100.00	99.94
Honey	99.98	100.00	100.00	100.00

valuable contribution to the continuous improvement of the chemicals management system in Australia.

Strategy 2: Review chemical safety, quality and performance against contemporary standards

Performance:

Effective regulation through chemical review

APVMA chemical reviews reconsider the registration of pesticides and veterinary medicines in the marketplace where potential risks to safety and performance have been identified. A review may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical or product.

Under the program, reviews may be based on one or more areas of concern (such as environmental safety, worker safety, public health, residues or trade) or may be comprehensive, covering all aspects of the product's registration.

During a chemical review, the APVMA draws on the specialist expertise of its own staff and that of other advisory agencies, as it does in the registration process. The review process also generally includes extensive consultation with the chemical industry, users and the community. At the completion of a chemical review, for a chemical to continue to be registered the APVMA must be assured that the product remains safe and effective when used according to the label.

At 30 June 2005, the Chemical Review Program had 34 (33 in 2003–04) ongoing reviews. Twelve of these are comprehensive reviews—shown in Table 7 as (c)—covering all aspects of the respective active constituent, product and labels. The remaining 22 reviews focus on more specific aspects of products and/or their labels.

During 2004–05, four reviews were concluded—benomyl, arsenic timber treatments, endosulfan and virginiamycin—and six Preliminary Review Findings were released for public consultation—atrazine, carbon disulfide, dimetridazole, diuron, methiocarb and sodium fluoroacetate (1080). These reports are available on the APVMA website.

A new chemical review was initiated in 2004–05 for procymidone. A review scope document was prepared and is available from the APVMA website. The scope document details the background to a review including the reasons for review and the aspects of active constituent approval, product registration and/or labels that are to be examined.

Table 7 Chemicals under review in 2004–05

1080	Dichlorvos	Maldison
2,4-D	Dimethoate	Methamidophos
Arsenic timber treatments (complete)	Dimetridazole	Methidathion
Atrazine (c)	Diquat (c)	Methiocarb (c)
Azinphos methyl (c)	Diuron	Molinate
Benomyl (complete)	Endosulfan (c) (complete)	Omethoate
Carbaryl	Fenamiphos (c)	Paraquat (c)
Carbon disulfide	Fenitrothion	Parathion methyl (c)
		Procymidone
Chlorfenvinphos (c)	Fenthion (c)	Sheep ectoparasiticides
Chlorpyrifos (c)	Fipronil	Temephos
Diazinon (c)	Macrolides	Virginiamycin (complete)

Arsenic-based timber treatments

Arsenic-based timber treatments—copper chrome arsenate (CCA) and arsenic trioxide—are used to protect timber from insect pests and microbial decay. This review examined the potential for human health risks, particularly for children exposed to CCA-treated timber structures. It also considered environmental effects from the use and disposal of CCA-treated timber products, and the adequacy of instructions and warnings on product labels.

There was a high level of community, industry, media and public attention on this review. These related mainly to the concerns about possible health effects, particularly for children who may have a high level of contact from play equipment.

The final report for the review of arsenic timber treatments was released in March 2005. The review required labels on containers of CCA products to display revised instructions for use. Timber treatment facilities are to be designed and operated to meet appropriate Australian Standards, and the use of CCA will be prohibited on timber intended for structures such as children's play equipment, garden furniture, picnic tables, exterior seating, patio and domestic decking, and handrails. In addition, timber treated with CCA for permitted uses must be clearly labelled.

The review made no recommendations to remove existing structures constructed from CCA-treated timber. This is consistent with the approach already taken in other countries such as the USA, Canada and the European Union. The APVMA has no jurisdiction over existing structures but will provide all available information to the relevant agencies to assist them in making their own regulatory decisions.

There will be a 12-month phase-in period to enable industry to implement process and other changes required to meet the outcomes of the review. A copy of the report and frequently asked questions can be found on the APVMA website.

This review is now concluded and the outcomes are being implemented during the phase-in period.

Endosulfan

Endosulfan is a broad-spectrum chemical that has been used in Australia for over 35 years. It is used for the control of a range of insect pests in horticultural and agricultural crops including cotton, cereals, oilseeds, fruit and vegetables.

The review was undertaken to assess concerns relating to human health, environment, residues, and worker exposure. There were also some significant concerns for trade because of the potential for residues in meat that may result from cattle eating contaminated feed.

During progress of the review, the APVMA made a number of changes to the way that endosulfan may be used, to reduce risks. These included restricting access to endosulfan to authorised people, limiting the number of times it could be sprayed during a season, and other control measures.

The APVMA concluded the Review Findings and Regulatory Outcomes for endosulfan in June and released its report in early July.

A key issue for the review was the potential for by-products of cotton that have been treated with endosulfan to be fed to livestock and the consequent potential for residue violations in the meat. Such violations, if they occurred, could significantly impact on Australia's export trade.

The review has endorsed the continued use of endosulfan in cotton. The APVMA is satisfied that effective safeguards have been put in place to protect against possible residue concerns. This includes a Memorandum of Understanding between key industry organisations (Cotton Australia, Cotton Ginners Association, Cattle Council of Australia, Australian Lot Feeders Association), which specifies management practices, and codes of conduct to be used by industry to manage endosulfan residue risks.

A number of other important uses of endosulfan have been retained, while changes have been made to the use of endosulfan in a range of other situations. These changes include removal of uses where residue and trade concerns cannot be resolved and the addition of new label instructions including new withholding periods, safety directions and worker re-entry periods.

This review is now concluded.

Virginiamycin

Virginiamycin is an antibiotic that is used in feed rations for poultry, pigs, sheep and cattle. The registered uses in poultry include growth promotion and prevention of the disease known as necrotic enteritis. The registered uses in pigs include improved feed conversion efficiency and growth promotion. The registered uses in sheep and cattle are to reduce the risk of rumenal acidosis when feeding grain.

Virginiamycin is not used for humans, but is closely related to an antibiotic which is used for humans as an 'antibiotic of last resort' to treat infections which are resistant to other antibiotics.

The APVMA published its Review Findings in November 2004 and in February 2005 the APVMA Board made its regulatory decisions to cancel the registration of products

whose sole purpose is growth promotion, and to vary the labels of products whose purpose is prevention of lactic acidosis in cattle and sheep and prevention of necrotic enteritis in poultry, so that usage is restrained to a maximum of 21 days in poultry and 28 days in cattle and sheep. An additional restraint is that the product may be used only once in a 12-month period and may not be used for any other animal species.

The major registrant of virginiamycin products has sought review of the APVMA's decisions in the Administrative Appeals Tribunal.

1080

Sodium fluoroacetate (commonly known as 1080) is used in Australia for the control of vertebrate pests in agricultural production, as well as for biodiversity conservation.

Sodium fluoroacetate was put under review because of concerns relating to persistence of 1080 in baits and poisoned animals and effects on non-target animals. The review assessed the adequacy of current labels and associated extension materials, and also considered some community concerns about the humaneness of 1080.

The report of the Preliminary Review Findings for 1080 was released for public comment in May 2005. The report recommended a number of changes to product labels and new conditions of registration aimed at achieving more effective regulatory controls on 1080. The new requirements included neighbour notification and better signage of bait locations; minimum distance requirements for placement of baits; and requirements for bait preparation, dose rates, bait materials and size, storage and transport.

The review will be concluded following receipt and consideration of public submissions.

Atrazine

Atrazine is a selective herbicide that can be used both pre- and post-emergence for the control of grass and broadleaf weeds for a range of crops, including sorghum, maize, sugar cane, lupins and triazine-tolerant (TT) canola. It is also important in the establishment of pine and eucalypt plantations and is used for control of Parthenium weed.

The review was undertaken to assess concerns relating to human health and toxicity, environmental contamination and efficacy.

The APVMA released an interim report in November 1997 that concluded that there were no major toxicological concerns relating to the use of atrazine and, moreover, that atrazine poses no undue hazard to most users. New conditions for use of atrazine were implemented in order to reduce chemical handling by workers, and to reduce drift and runoff into water bodies. Additional environmental and residue data were required to address remaining concerns related to the potential risk its use poses to the environment and the validity of a number of maximum residue limits.

The APVMA released a Preliminary Review Findings report in October 2004 for public consultation. This discussed action taken since the release of the 1997 interim report and the assessment of new information (residues and environment). The report also discussed new reports relating to potential adverse developmental and reproductive effects in frogs. Based on the weight of available evidence, it was determined that atrazine is not likely to be carcinogenic, nor is it likely to be an endocrine disruptor in humans.

The public comments received in response to the release of this report are currently being assessed.

Benomyl

Benomyl is a fungicide that is widely used in Australia in the horticultural industry.

The review was undertaken to assess potential toxicology and OHS concerns, particularly for pregnant women. At the same time all product registrations and approvals for benomyl were suspended and new instructions for use were issued for continuing supply and use.

The review was concluded in December 2004, following voluntary cancellation of the registration for the remaining benomyl product.

Carbon disulfide

At commencement of the review, carbon disulfide was used in Australia as a grain fumigant and in a pig poison product. The APVMA undertook the review of carbon disulfide because of toxicological, residues and OHS concerns.

The report of the Preliminary Review Findings was released in August 2004. The registration of the grain fumigant product was subsequently voluntary cancelled in December 2004. The review continued for the remaining carbon disulfide product, which is registered as a pig poison.

The Review Findings for the pig poison were concluded in April 2005. These will require product registrants to update product labels to include comprehensive information relating to distance restrictions, neighbour notification, disposal of baits and carcasses at the end of a baiting campaign, placement of poison signs, updated first aid instructions and safety directions, and clearer directions for the amount of product to be applied.

Subject to the registrant updating the product label, the review will be concluded.

Diuron

Diuron is a broad-spectrum residual herbicide used for control of both broadleaf and grass weeds in a variety of situations including broadacre crops and horticulture.

The review of diuron was undertaken in response to concerns about potential environmental contamination of waterways as a result of diuron run-off from agricultural areas, particularly into marine environments. There were also some human health concerns about the toxicity of some impurities in the active constituent.

The APVMA completed the Preliminary Review Findings for diuron in June and released its report for public consultation in early July 2005.

The APVMA's preliminary findings were that the toxic impurities in the active constituent at the current very low concentration levels do not pose a risk to human health. There is a risk, however, to the environment caused by diuron in water and soil run-off from use in sugar cane, citrus, horticulture, irrigation channels and drainage ditches. These risks can be reduced by decreasing the amount of diuron used. It was also found that labels for products containing diuron did not contain instructions for spray drift buffers.

In response to these findings the APVMA recommended that the use of diuron on broadacre crops continue but that the amount of product used in sugar cane, cotton, citrus and horticulture crops be reduced, perhaps by altering the label rate or through a change in agricultural practice. The APVMA, however, recommended that the use of diuron in irrigation channels and drainage ditches not be permitted due to the unacceptable risk this poses to the environment.

While the majority of these findings did not warrant immediate action at that time, the APVMA is considering interim action on the uses of diuron in sugar cane. This is being done in association with registrants, advisory agencies, States and the sugar industry.

The review will be concluded following receipt and consideration of public submissions.

Dimetridazole

The review was initiated in July 2002 because of concerns over public health. Dimetridazole has been withdrawn from use in food-producing animals in several countries, primarily due to unresolved concerns regarding its potential carcinogenicity. There is also uncertainty surrounding the longevity of residues in treated animals. In addition, the review includes a reconsideration of the existing labels for products containing dimetridazole, as inconsistencies in label instructions exist.

In September 2004 the APVMA released a draft review report for the reconsideration of the registration and label approvals of products containing dimetridazole. Dimetridazole is currently approved for treatment of histomoniasis (blackhead) infection in turkeys and poultry. Products containing dimetridazole are also registered for use in the treatment of swine dysentery in pigs, and for the treatment of canker in pigeons and caged birds.

The review found that there is an incomplete toxicological database and insufficient available information to determine whether dimetridazole is or is not a potential carcinogen. On this basis the Office of Chemical Safety reported that an acceptable daily intake (ADI) for dimetridazole is no longer supportable. The draft review report proposes that the registration of products currently used in food-producing animals will be cancelled as a result of the cancellation of the ADI. Although dimetridazole has been designated a potential genotoxic carcinogen, options exist that could enable the continued limited use of dimetridazole in breeder poultry, provided that such use does not result in residues of dimetridazole entering the human food chain. The

draft review report also proposes that labels will be varied to specify appropriate instructions for use, including appropriate protective equipment for workers handling product containing a potential genotoxic carcinogen.

Methiocarb

Methiocarb is registered for the control of snails, slugs, wireworm and birds in a range of agricultural and domestic (the home garden) situations. Major agricultural uses of methiocarb include grapevines, citrus, berries, pastures, cereals and ornamentals.

The review was undertaken to assess concerns relating to residues in food and trade, and worker and environmental exposure. There were also some adverse experience reports relating to domestic animals that were investigated by State departments.

The report of the Preliminary Review Findings for methiocarb was released for public comment in May 2005. The proposed outcomes of the review are that labels be varied to remove all uses for food and animal feed-producing crops, because of a lack of residues data. Soil drench uses for ornamental plants are also proposed to be removed because of concerns over worker safety. In addition, labels are to be updated to include revised safety directions and warning statements, new instructions in relation to personal protective equipment and re-entry to treated crops, and new instructions in relation to environmental protection.

The review will be concluded following receipt and consideration of public submissions.

Procymidone

Procymidone is a fungicide used widely in horticulture as both a pre- and post-harvest chemical as well as in turf, ornamentals and pulse crops.

The review was initiated in November 2004 following advice that procymidone had been rescheduled to an S7 poison, and that the associated health standards had been revised. These changes raised concerns for dietary exposure for some products, human health, occupational health and safety, residue, and trade. At the same time, all registrations and label approvals for products containing procymidone were suspended and recall action was initiated to ensure that all products in the marketplace contained adequate instructions to protect health and worker safety and to ensure that residues in food were within acceptable levels.

The new instructions deleted uses where dietary exposure was considered unacceptable, increased withholding periods for remaining uses, updated signal headings and safety directions, included re-entry period statements and a new warning statement about birth defects. These instructions will remain in place pending the outcomes of the review.

Since this decision, registrants have voluntarily cooperated with the APVMA to ensure that new instructions for use appear on labels still in the market. Several applications have been received for approval of updated labels consistent with those instructions and in these circumstances suspensions have been revoked.

Data submitted by registrants and other stakeholders will be assessed prior to release of the Preliminary Review Findings for public consultation.

Other achievements

In 2003–04, new project management procedures and a comprehensive review of process documentation were implemented for chemical reviews to improve efficiency and targeting of resources and to capture recent legislative change. This has contributed to a greater throughput of reviews in 2004–05, with four reviews being concluded and a further six released for public consultation.

Following an evaluation of the potential implications of chemical reviews, greater attention is now given to the needs of chemical users in the review process. Reviews will identify potential impacts on user industries early in the process. This provides an opportunity for users to provide data or information to help address concerns with the chemical or to identify alternative pest control measures. To further develop this approach a User Forum was conducted in November 2004 that brought together a broad cross-section of user groups to discuss how to best communicate with this important stakeholder.

Strategy 3: Ensure product quality through risk-based compliance strategies

Performance:

Compliance procedures

To further enhance the effectiveness of its enforcement actions the APVMA has put procedures in place to ensure clear distinction between accountability for compliance and technical decisions associated with particular products. The APVMA's Regulatory Compliance Committee, which includes senior management from different programs, has continued to provide guidance to the Compliance Section and the APVMA in optimising its approaches to addressing non-compliance.

Reports of non-compliance

The APVMA encourages industry and the public to report the advertising and supply of unregistered and unapproved chemicals or promotion of products inconsistent with approved labels. All reports received are acknowledged and assessed for action on the basis of the risk posed by the chemicals involved. Risk is based on the potential or actual harm to the environment, human, plant or animal health, or trade with other countries.

Reports assessed as representing a potential or actual high risk are dealt with by an inquiry that may escalate to an investigation, with a view to prosecution or product recall. Those assessed as representing a low-to-medium or continuing risk are dealt with mainly by warnings and negotiation to achieve compliance. During the year 297 new reports were received. Of these 79 per cent were assessed as low risk. A total of 314 reports were finalised during the year through warnings and negotiated compliance. Seven resulted in product recall, two led to monitoring visits, and one report was referred to another agency. Eighty per cent of all non-compliance reports were completed within three months of receipt.

Investigations and recalls

During 2004–05, the APVMA finalised five investigations carried over from 2003–04. No new investigations were initiated this year. Three investigations resulted in a warning letter, one led to recall of product and one was found to be inconclusive. One of these investigations resulted in a warning letter after referral of a brief of evidence and consultation with the Commonwealth Director of Public Prosecutions.

In 2003–04 the APVMA reported the successful prosecution of the company Group A Health Care and its director for advertising and supply of unregistered products. In August 2004 Hobart Magistrates Court handed down penalties to Group A Health Care of

Figure 6 APVMA compliance offence statistics

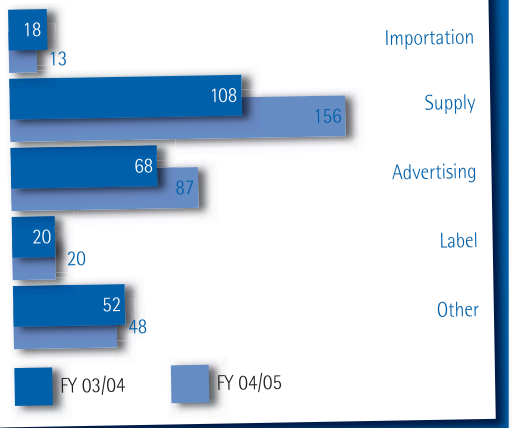
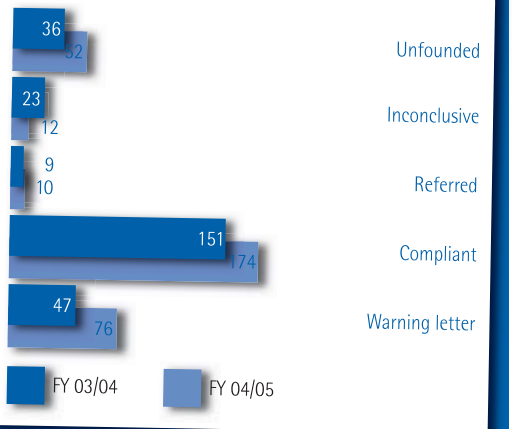


Figure 7 APVMA compliance outcome statistics



- Unfounded—no offence committed
- Inconclusive—insufficient information presented
- Referred—to formal investigation, recall or another agency
- Compliant—corrective action has been taken to achieve compliance
- Warning letter—where a non-ongoing offence has occurred and a letter advising of future legal requirements is sent

$10 000 on all charges, and penalties for the director, including $10 000 on advertising and supply charges.

During 2004–05 the APVMA managed 27 recalls as follows.

Compulsory recalls

In March 2004, following a review of scientific literature, the APVMA decided it could not be satisfied that pool and spa sanitising devices or systems that are based solely on silver or silver and copper are adequate in controlling harmful micro-organisms that can grow in pools and spas. The APVMA decided that such products are only safe and effective if they are used in conjunction with other, APVMA-registered, pool sanitisers.

As a result the APVMA issued compulsory recall notices for 11 pool ioniser products and sent one warning letter requiring the suppliers to cease supply and to warn all owners of such devices to use registered sanitisers in conjunction with the ionising devices. Since being issued with the recall notices and warning letter all but two suppliers have either complied with the recall notice or have applied for and been granted a permit to allow continued supply and use under specified conditions. The APVMA is continuing with compliance action on the remaining two non-compliant companies.

The APVMA also concluded a compulsory recall of an unregistered gibberellic acid product supplied by a table grape producer in Victoria. The grower applied for, and was subsequently granted, a permit to conduct trials with the recalled gibberellic acid.

Recall by deed poll undertaking

Deed pool undertakings have been developed and used as an alternative means of recalling non-compliant product in the marketplace. Companies enter into an undertaking with the APVMA to take agreed steps to deal with a non-compliant aspect of a marketed chemical product. Such undertakings provide more control for the APVMA over a voluntary recall but are less restraining than a compulsory recall. In contrast to voluntary undertakings, deed polls are enforceable and legally binding for the person executing the deed. The APVMA can proceed to compulsory recall action if necessary. The APVMA agreed to eight deed poll undertakings in 2004–05 as follows:

- recall of batches of insecticide ear tags for cattle, which were identified as leaking the diazinon active ingredient. The APVMA considered that leakages were likely to pose a risk of harm to persons handling the tags and their packaging as well as posing a risk to animals fitted with the tags because of a degradation impurity
- six companies entered into deed poll undertakings as a direct result of the APVMA suspending the approved labels for products containing procymidone. This action was taken on the basis of human health, dietary exposure and occupational exposure concerns. The deed poll undertaking required the companies to locate all product in the marketplace and attach a new label with appropriate warnings
- one company manufacturing a pool ioniser entered into a deed poll undertaking to recall its product from the marketplace.

Voluntary recalls

The APVMA monitored seven voluntary recalls, five of which were agricultural chemical products and two were veterinary chemical products. Products were voluntarily recalled due to non-compliant formulations (three), errors in manufacture or labelling (two) or because they were not registered (two).

Quality Assurance Scheme for Agricultural Actives and Products (AgQA)

In May 2004, the APVMA introduced a new quality assurance scheme, requiring registrants to keep certain records, and introduced product testing to help ensure the ongoing quality of active constituents used in agricultural chemical products. The scheme required the introduction of revised data requirements for chemistry and manufacturing, development of APVMA Standards for Agricultural Active Constituents and application of new conditions for product registration/active constituent approval.

Products currently registered were required to have new conditions set following a review. New conditions of registration were imposed via chemical review on 3461 agricultural chemical products and 1117 active constituents. The APVMA also published 402 new Standards for Active Constituents.

To facilitate the implementation of the scheme, the APVMA conducted an industry awareness program to familiarise participants with the new conditions and record-keeping requirements. The program consisted of industry seminars in capital cities, website news

releases and a Q&A page. To provide both the APVMA and industry with a better understanding of the issues involved and requirements for record keeping APVMA staff visited four companies in both Melbourne and Sydney, and six companies in Perth to examine records kept by them. Data was called in from 11 companies.

Issues identified during these visits were administrative (manufacturer not identified, batch numbers not matching on all records) and the procurement of data held by third parties (analytical method details and validation data). Similar issues were observed from the data call-in records.

The official audits and data call-ins will now commence during the 2005–06 financial year.

The product testing component of the AgQA scheme began with the testing of chlorothalonil products for the toxicologically significant impurities hexachlorobenzene and decachlorobiphenyl, and trifluralin products for N-nitroso-di-n-propylamine, during the first half of 2005. Thirty products were analysed and records for the batches tested were called in and audited.

Hormonal growth promotants

The European Union requires continued assurance from Australia that beef and beef products imported to its member States have not been treated with hormonal growth promotant (HGP) products. To provide this assurance, the Australian Government and State and Territory governments have put in place the National Hormonal Growth Promotant Monitoring and Control System.

The system enables Australian authorities to account for the importation, supply and use of HGPs. The APVMA plays a significant role in the operation and management of the system by authorising importers and resellers, and requiring that accurate records of supply be kept. At 30 June 2005, there were 232 APVMA–authorised suppliers.

The APVMA continued to operate a compliance audit program of authorised HGP suppliers. The frequency of audit is determined on a risk basis and includes verification or a follow-up audit to confirm implementation of major corrective actions identified during the first visit. During the year, the APVMA audited 62 HGP authorised suppliers (both retailers and wholesalers). A total of 77 per cent of the suppliers were found to be compliant on the first visit, with 23 per cent being issued with a warning and being subject to an increased audit frequency. All suppliers audited for a second time were found compliant.

Consent to import

The APVMA monitors the 'import barrier' to limit the potential distribution of unregistered and unapproved chemicals in the Australian marketplace. In 2004–05 it conducted enquiries into 13 matters involving importation. The APVMA issues Consents to Import for unregistered and unapproved chemicals where a legitimate reason exists for a person or a company to have possession of the chemicals in Australia. The APVMA assessed 272 applications and issued 219 Consents to Import. Of these, 108 were issued for permit applications, 105 to veterinarians and six for other purposes. Forty-six applications for consent were not approved or were found to be unnecessary.

Inter-agency liaison

APVMA Compliance continued to maintain liaison with law enforcement areas in other agencies. During the year Compliance staff assisted the Australian Customs Service in developing a standardised data set for importers and exporters, attended government enforcement agency liaison functions and visited other agencies to improve understanding of emerging trends in non-compliance. Staff also participated in the National Working Group on the Prevention of the Diversion of Precursor Chemicals into Illicit Drug Manufacture chaired by the Australian Attorney-General's Department.

Manufacturers' Licensing Scheme —maintaining GMP compliance

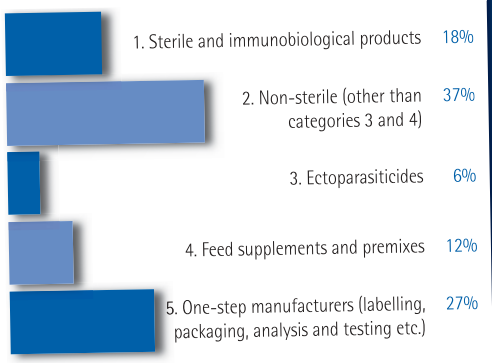
The Manufacturers' Licensing Scheme (MLS) is a quality assurance program that was established in 1996 in response to concerns over the quality of veterinary chemical products. Industry and government recognised that quality needs to be 'built into' rather than 'tested into' products. The primary objective of the scheme is to assure (and give confidence in) the quality of veterinary chemical products manufactured and supplied in Australia. To obtain and maintain a licence under the scheme, manufacturers must demonstrate compliance with the APVMA's Manufacturing Principles and the relevant Australian Code of Good Manufacturing Practice (GMP). Compliance is confirmed by regular audits by

APVMA–authorised auditors or specified authorities recognised by the APVMA. During the year APVMA–authorised auditors conducted 82 routine GMP audits.

At 30 June 2005, the number of Australian–based manufacturers licensed or being assessed for a licence was 238, a slight increase from 231 in the previous financial year. Approximately 9 per cent of manufacturers were in the process of either applying for a new licence, changing site or changing ownership as a result of significant corporate activity within the veterinary chemical manufacturing industry.

Figure 8 shows manufacturers distributed according to licence category.

Figure 8 Percentage of manufacturers licensed, or being assessed for a licence, under the Manufacturers' Licensing Scheme, by category, at 30 June 2005



The management of the Manufacturers' Licensing Scheme is closely integrated with the APVMA's recall, adverse experience and compliance programs and a firm approach continues to be taken with manufacturers who fail to comply with required standards. More stringent conditions continued to be imposed on all new and existing licences to improve compliance and overcome delays in responding to audit findings. An Auditors' Workshop was held in May 2005 as part of the Authority's quality assurance program for this key function.

An APVMA/Industry Working Group recently revised the APVMA's Manufacturing Principles and the Australian Code of Good Manufacturing Practice for Veterinary Medicines in order to bring them up to date with contemporary standards and to provide greater transparency for both manufacturers and auditors. The documents will be released in 2005 for public comment. Members of industry have actively supported the revision of the Code.

The APVMA continued to provide assistance to manufacturers, primarily through feedback to enquiries and follow-up to audits.

Imported veterinary products

For veterinary chemical products manufactured overseas, applicants for product registration must demonstrate that the product is manufactured to quality standards comparable to those applying to veterinary chemical products manufactured in Australia. During 2004–05, 273 overseas manufacturing sites were assessed for compliance with Australian manufacturing standards. This represents an increase of more than 50 per cent on the previous year. In addition, evidence for another 10 manufacturing sites was evaluated in anticipation of an application being submitted.

Export assistance

Many foreign governments require evidence of compliance with GMP to be provided before veterinary medicinal products can be imported. The APVMA has endeavoured to assist the export of Australian-made veterinary products by providing certificates of manufacture, upon request. Such certificates confirming

OVERSEAS GMP SCHEME

In order to provide greater ongoing assurance of, and confidence in, the quality of imported veterinary products being supplied to Australian consumers, the Overseas GMP Scheme was introduced in February 2005 to ensure that overseas manufacturers remain GMP compliant for as long as they are providing product for the Australian marketplace. A Regulation Impact Statement about the scheme was published in February 2005, after public consultation. Under the scheme, conditions of product registration require that registrants maintain evidence of ongoing GMP compliance. Existing veterinary products that are manufactured overseas are being reviewed, so that these conditions can be formally applied to their product registration. The conditions will also be routinely added to new product registrations.

the licensing status of Australian manufacturers have been recognised and accepted by many countries including Brazil, Egypt, Indonesia, Malaysia, the Philippines, Saudi Arabia, Singapore, South Korea, Taiwan and Thailand. Countries within the European Community and the European Free Trade Association also accept certificates issued under the terms of two Mutual Recognition Agreements.

During the financial year, 51 export certificates were issued for compliance with Australian manufacturing standards. Of these, one was issued under the Mutual Recognition Agreement with the European Community.

SUMMARY

APVMA activities throughout 2004–05 contributed to ensuring the ongoing quality of pesticides and veterinary medicines available for sale in Australia. This has been achieved through a number of improvements to the regulatory framework as a result of new information, feedback and process enhancements. Product quality has also been supported through the timely review of a number of chemicals of possible concern. Quality assurance programs along with risk-based compliance strategies have worked to ensure that registered products in the marketplace continue to meet acceptable standards.

OUTCOME ACHIEVEMENTS

The APVMA continued to provide a world-class registration scheme for pesticides and veterinary medicines in 2004–05.

Its capacity to achieve this output was supported by the pursuit of the three key strategies of building stakeholder confidence, improving operational excellence and informing policy.

The APVMA has maintained high standards in its provision of chemical registration services in an increasingly complex operational environment. At the same time it has implemented several initiatives to help enhance the quality of pesticides and veterinary medicines available in the Australian marketplace. In all of these efforts, the APVMA has continued to strengthen its commitment to making regulatory decisions based on the best current scientific information available.

Through the operation of a world-class registration scheme for pesticides and veterinary medicines, the APVMA achieves its mission to protect the health and safety of people and animals, the environment and trade and to support Australian agriculture through science-based, effective and efficient regulation of pesticides and veterinary medicines.