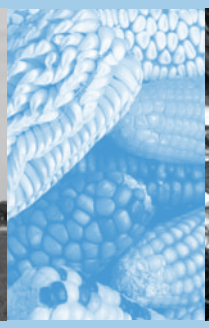




CHAPTER 2

Performance against outputs

Output 1: Regulatory decisions and information

Regulatory decisions and information supported by evidence-based risk assessments that are consistent with national and international standards

Overview

Anyone who wishes to supply pesticides and veterinary medicines must apply to the APVMA to register the products and approve the labels for product containers before the products 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 to the product, additional claims made about the product or changes to its label.

Registration is based on a rigorous and independent evaluation of scientific information about the safety and efficacy of a product. The APVMA grants registration if its evaluation has shown that 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 using the product may unduly prejudice trade.

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

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

Strategy 1: Evaluate and consider applications to approve active constituents, register chemicals, approve labels and provide regulatory consents such as permits following scientific evaluation

Strategy 2: Engage stakeholders to improve awareness and inform policy development and to optimise the regulatory framework within which APVMA operates

Strategy 3: Review registered chemicals on the basis of their risk

Strategy 1: Evaluate and consider applications to approve active constituents, register chemicals, approve labels and provide regulatory consents such as permits following scientific evaluation

Throughout 2006–07, the APVMA has focused on using the highest quality and standards of regulatory science to assess applications, while finalising them within the statutory timeframe. The APVMA introduced monitoring and reporting tools that allow it to identify classes of applications most likely to take a long time to complete.

The APVMA has a process reform program to maximise the efficiency of assessments. The ANAO's review of recommendations and meetings with industry groups assisted this program. In 2006–07 to improve processes further, the APVMA began a complete

overhaul of its registration processes. This overhaul will result in the publication on the APVMA's website in 2007–08, of flowcharts and information on the organisation's registration processes. When these flowcharts and registration information are used with the EARS, applicants will have access to better information on the processing and progress of their applications.

Performance

The APVMA benchmarks its registration timeframe performance against applications that we received after 1 July 2005. On that date, new application categories, new fees and new timeframes came into force and replaced those that applied before 1 July 2005.

Measuring the time to process

The APVMA must finalise applications for registration within a timeframe set out in Schedules 6 and 7 of the Agvet Code Regulations. This statutory timeframe depends on the nature of the application, and varies from three months for a simple variation to an already-registered product, to 15 months for a new product that uses a new active constituent.

The APVMA has a good record in meeting statutory timeframes. During 2006–07 the APVMA finalised 2096 applications out of the 2279 received within the statutory timeframe. Of these finalised applications, 259 were withdrawn, treated as having been withdrawn, or refused.

There is a difference between the statutory timeframe for an application and the elapsed time (real time) it takes to finalise an application. Elapsed time is the time that passes between the applicant posting the application to the APVMA, and the APVMA posting back a notice of registration to the applicant.

The APVMA measures statutory time by means of clocks in its application tracking system. The clock is turned ON when the application arrives at the APVMA. It is turned OFF when the APVMA asks the applicant to correct a mistake in the application, clarify some of the information, provide missing information or send in the final version of product labels for approval.

However the elapsed time is almost always longer than clock time because of long periods of time when the statutory clock is turned off while the applicant responds to APVMA requests, such as amendment of the application, more information, or provision of labels.

Reducing elapsed time

The APVMA is focusing on reforms aimed at reducing elapsed time for product applications. These include activities in response to ANAO recommendations as well as specific initiatives that are being advanced by APVMA/industry working groups.

Other developments such as continuous upgrades to MORAG and the introduction of electronic applications (EARS and e-labels) will make a great contribution to reducing elapsed time for applications.

Pesticides product applications

During 2006–07, the Pesticides Program received approximately 10 per cent more applications than during 2005–06 and hence the number of applications in train carried over from the previous year was higher than in 2005–06 (see Table 4).

Finalisation against statutory timeframes overall has improved since last year. Ninety per cent of applications were completed within the statutory timeframe during 2006–07 compared to 87 per cent during 2005–06 (see Table 5). The finalisation statistics for pesticide applications received after 1 July 2005 are shown in Table 6. Approximately 93 per cent of finalisations were within statutory timeframes.

Table 4: Pesticide product applications for product registration or variation for 2006–07

Applications	2006–07	2005–06	Change from 2005–06 %
Commencing number of applications in progress	1129	1087	+ 3.7
Applications received	1551	1402	+ 9.6
Applications finalised	1362	1462	– 7.3
Closing number of applications in progress	1207	1024	+ 15.0

Table 5: Pesticide finalisations of all applications for product registration or variation 2006–07

Class of Application	Total finalised	Number finalised *vs* statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		<100%	100–120%	>120%		
13 to 15 months	14	11	2	1	10.1	28.9
9 to 12 months	3	2	1	0	12.6	37.9
6 to 8 months	85	51	15	19	8.3	15.5
5 months	167	110	23	34	5.1	12.7
2 to 3 months	1093	1054	11	28	1.1	6.0
Total	1362	1228 (90.2%)	52	82		

Of the 1362 pesticide product applications that were finalised, 117 were withdrawn by the applicant, treated by the APVMA as having been withdrawn by the applicant, or refused by the APVMA.

Table 6: Pesticide product finalisations for 2006–07, for applications received after 1 July 2005

Class of Application	Total finalised	Number finalised *vs* statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		<100%	100–120%	>120%		
13 to 15 months	2	2	0	0	7.2	20.5
9 to 12 months	0	0	0	0	-	-
6 to 8 months	59	39	12	8	7.4	11.8
5 months	138	96	20	22	4.8	10.4
2 to 3 months	1019	994	7	18	1.1	4.2
Total	1218	1131 (92.8%)	39	48		

Veterinary medicines product applications

The Veterinary Medicines Program received 10 per cent more applications in 2006–07 than during 2005–06 and completed 15 per cent more, resulting in fewer applications in progress (see Table 7). We completed 94 per cent within statutory timeframes (compared with 96 per cent in 2005–06).

The completion rates within statutory timeframes for applications received before 1 July 2005 and after 1 July 2005 are now approximately equal at 95 per cent (see Tables 8 and 9).

Table 7: Veterinary medicines applications for product registration or variation 2006–07

Applications	2006–07	2005–06	Change from 2005–06 %
Commencing number of applications in progress	696	687	+1
Applications received	888	804	+10
Applications finalised	917	799	+15
Closing number of applications in progress	667	692	-4

Table 8: Veterinary medicines finalisations of all applications for product registration or variation 2006–07

Statutory timeframe of application	Total finalised	Number finalised vs statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		<100%	100–120%	>120%		
13 to 15 months	7	7	0	0	5.9	26.2
9 to 12 months	0	0	0	0	0.0	0.0
6 to 8 months	46	43	2	1	4.7	18.5
5 months	204	172	12	20	4.1	13.7
2 to 3 months	660	646	5	9	0.6	6.5
Total	917	868 (94.7%)	19	30		

Of the 917 veterinary medicines product applications that were finalised, 142 were withdrawn by the applicant, treated by the APVMA as having been withdrawn by the applicant, or refused by the APVMA.

Table 9: Veterinary medicine product finalisations for 2006–07, for applications received after 1 July 2005

Class of Application	Total finalised	Number finalised vs statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		<100%	100–120%	>120%		
13 to 15 months	1	1	0	0	3.2	20.8
9 to 12 months	0	0	0	0	-	-
6 to 8 months	27	25	1	1	4.5	12.8
5 months	155	130	11	14	4.1	8.8
2 to 3 months	620	610	3	7	0.6	4.7
Total	803	766 (95.4%)	15	22		

Permits and minor uses

Pesticides

During 2006–07, a total of 434 pesticide permits were finalised, of which 83 per cent were completed within the statutory timeframe. Almost 70 per cent of finalised permit applications were minor use permits and renewals; 54 emergency permits were finalised. The emergency permits that were issued included control of Australian plague locusts and wingless grasshoppers in broad acre situations in several states, mite control in various situations, control of electric ants in cropping and non-cropping situations and termites in various situations.

In 2006, the APVMA Board approved an initiative to assess and consolidate pre-NRS state-based approvals. Several hundred permits require assessment, the outcomes of which are renewal of the permit, cancellation of the permit, or consolidation of the uses on to registered product labels. The project has been running for six months, during which time permits requiring priority action were identified. To date, 31 permits have been cancelled. Some of these dated back to the 1970s and involved 14 active constituents, most of which no longer had active approvals or registered products.

Veterinary medicines

During 2006–07 the Veterinary Medicines Program finalised 197 permit applications, of which 195 (99 per cent) were finalised within the statutory timeframe.

The majority of permits issued during 2006–07 were for extension of shelf life of a particular batch of products and for reissue or extension of previously issued permits.

Scope of products under the National Registration Scheme

During 2006–07 the APVMA has played a major role in a Working Group that established a process undertaken by the Product Safety and Integrity Committee (PSIC) to review the scope of products the APVMA registers under the NRS. The PSIC is a committee that reports to the Primary Industries Standing Committee, that in turn reports to the Primary Industries Ministerial Council.

The NRS is a cooperative activity between the APVMA and the states and territories, in which the APVMA is responsible for national registration of agricultural and veterinary chemical products, and the states and territories are responsible for controlling their use.

There has not been a review of the scope of products that the APVMA registers under the NRS since it was set up in 1992. As part of this process, the Working Group assessed more than 40 classes of products registered by the APVMA because they fell within the scope of the NRS. The assessment asked whether the products should be registered at all, or whether there is a better approach to regulating them than by registration. The products evaluated included:

- animal feed products
- animal cosmetic products
- insect repellents and head lice products for humans
- water treatments for agricultural use, domestic use and industrial use.

The PSIC conducted a public seminar in May 2007 to discuss the evaluations and, as a result, endorsed a revision of the regulatory treatment of these classes of products. Some were identified as coming within the scope of the NRS and so should continue to be registered by the APVMA. Others were identified as coming within the scope of the NRS, but should not be registered if they conform to certain conditions. For other products, the PSIC agreed that they should not fall within the scope of the NRS and do not need APVMA registration.

Work has begun on implementing the review recommendations. The revision of the scope of the NRS will continue during 2007–08 and will give much greater clarity to manufacturers and the public about whether or not a product must be registered.

Chemistry and residues

In evaluating applications to register products and seek approval for permits, the APVMA must be satisfied that the constituents and manufacturing process for a product are appropriate, and that products can be used safely without concern about potential residues in food. A dietary intake evaluation is conducted to establish if 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 unduly prejudiced as a result of product registration.

Chemistry Data Quality

A review in early 2006 of the efficiency of chemistry processes revealed that the greatest impediment to timely evaluation of chemistry data was the poor quality of submissions submitted by applicants. In 2005–06, 79 per cent of the chemistry data applicants submitted was deficient. Measures implemented in 2006–07 to address the poor quality of data submissions include clarification and amendment of the APVMA's Chemistry and Manufacture Requirements (MORAG Part 2), Chief Executive Officer visits to the top ten companies with poor chemistry data submissions, and letters to more than 200 companies, with poor data submission, inviting their staff to attend chemistry data submission workshops. Two hundred and fifty registrants and consultants attended six workshops conducted in Perth, Sydney, Brisbane and Melbourne. The interactive workshops were designed to assist industry personnel with the chemistry requirements for the approval of active constituents, the registration of agricultural and veterinary chemical products, the compliance of registered agricultural products with conditions of registration and the Manufacturers' Licensing Scheme (MLS) for veterinary products.

Communication of trade advice

Trade advice on labels is an essential part of the whole-of-food-chain quality assurance process, enabling the livestock producer to accurately complete the National Vendor Declaration under Meat and Livestock Australia's Livestock Production Assurance Scheme. Export slaughter intervals (ESIs) are set by the APVMA in collaboration with the registrant and the relevant producer industry. In 2006–07 the APVMA continued its initiatives to enhance communication of trade risk advice.

Following a red meat stakeholders' meeting in March 2006, the APVMA negotiated with the veterinary chemical industry to update labels with trade advice statements by May 2009. Part 5B of the MORAG 'Overseas Trade Aspects of Residues in Food Commodities' has been amended to include these statements.

New statistical software for determining export slaughter intervals

In Australia, meat exports make up a higher proportion of total meat production than in almost any other country and market access for exports is important. Australia therefore needs to ensure that residue concentrations in our exported meat comply with the residue standards of importing countries. The ESI is the primary tool Australia uses to give this assurance. The APVMA uses an ESI methodology about which stakeholders have been consulted and on which they have agreed.

Existing statistical techniques developed for determining withholding periods have some shortcomings when used for determining ESIs. In 2006 the APVMA engaged consultants from the Australian National University (ANU) and the Bureau of Rural Sciences (BRS) to help develop and refine statistical approaches to determine ESIs.

New ESI software demonstrated

On 2 March 2007, the APVMA held a workshop to demonstrate its new prototype statistical software. Stakeholders from government authorities, animal production industries, the animal health industries, regulatory consultants, and academic and research institutions attended. The statistical basis of the new software was explained and results from the new software were compared to results from existing methods. The new APVMA software demonstrated clear advantages over existing methods. Stakeholders strongly supported further development of the software for a version that could be made available to help them prepare applications for ESIs.

The APVMA is engaging consultants to develop this version of the software and make it available to all interested stakeholders in 2007–08.

In 2006–07 the APVMA met with Australian Pork Limited (APL) to discuss determining ESIs for the products registered for use in pigs. The APVMA and APL explored the options of mutual recognition of MRLs with the United States, utilisation of Codex MRLs, the Japanese Positive List and import tolerances for addressing market access matters.

Japanese Positive List Project

The Japanese Positive List Project is a five-year project that will provide toxicology and residues data to the Japanese Ministry of Health, Labour and Welfare (MHLW) to enable it to set MRLs based on national data. Before the project commenced in 2006–07 a delegation from DAFF, including an APVMA officer, visited several Japanese government departments involved in the positive list process. In 2006–07 the APVMA provided data for 72 agricultural chemicals, 27 veterinary chemicals and 43 toxicology reports to the MHLW through DAFF, which provided funding for the first year of the project.

The APVMA continues to provide monthly updates on its website for ESIs for cattle and sheep products. ESIs are also routinely set for agricultural chemicals used on crops that are fed to livestock.

Active constituents

During 2006–07, 94 applications for active constituent approval were finalised within legislative timeframes. As part of the agricultural quality assurance scheme, the APVMA determined 11 new or amended standards for active constituents in 2006–07.

Maximum residue limits

During 2006–07 the APVMA evaluated residue data for 59 applications for product registration, 77 applications for permits and 5 chemical reviews, producing 377 amendments to the MRL standard.

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 programs for residues of pesticides and veterinary medicines are the DAFF's National Residue Survey and the FSANZ's Australian Total Diet Survey.

In 2006–07 the National Residue Survey conducted analyses of a total of 471 749 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 10). 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.

Table 10: Percentage compliance with MRLs for pesticides and veterinary medicines in the National Residue Survey

Commodity group	2002–03	2004–05	2005–06	2006–07
Meat products	99.99	99.99	99.99	99.08
Grain products	99.99	99.98	100.00	99.67
Horticultural products	100.00	99.99	100.00	98.78
Fisheries products	100.00	99.94	100.00	100.00
Honey	100.00	100.00	100.00	100.00

Alignment of MRL processes with FSANZ

In 2006–07 the APVMA worked with the DoHA, DAFF and FSANZ to develop legislation to implement a Food Regulation Standing Committee resolution on reducing the gap between the time the APVMA registers a product and gazettes an MRL, and for FSANZ to enter that MRL in the Food Standards Code.

The process is due to commence in October 2007 and will include a joint APVMA/FSANZ consultation process on applications for new products, review products and major extensions of use.

United Nations FAO/WHO Codex Committees on Pesticide Residues (CCPR) and Residues of Veterinary Drugs in Foods (CCRVDF)

The APVMA provides technical advice for the CCPR and the CCRVDF. These committees and the Food and Agriculture Organization (FAO)/World Health Organization (WHO) expert evaluation panels (the Joint FAO/WHO Meeting on Pesticide Residues [JMPR] and the Joint FAO/WHO Expert Committee on Food Additives [JECFA]) are responsible for determining the MRLs that underpin the trade in food commodities.

The APVMA contributed to the Australian delegation to the CCPR meeting in May 2007. Key issues for Australia were an amended JMPR prioritising procedure for the evaluation of new and review chemicals, the estimation and interpretation of measurement uncertainty of analytical results, the use of alternative Good Agricultural Practices (GAPs) where acute dietary risk concerns are raised in reviewed GAPs, regional

Meetings with Chinese Regulatory Authorities in Australia and China

Former CEO Dr Joe Smith and Mr Stephen McDonald (Manager Compliance) visited the People's Republic of China in March 2007 for a series of meetings with the APVMA's national regulatory counterpart for pesticides, the Institute for Control of Agrochemicals in the Ministry of Agriculture (ICAMA), and some provincial agencies (the Zhejiang and Jiangsu Institutes for Control of Agrochemicals [ICA]). Accompanied by officials from the ICAMA and the relevant ICAs, they also visited four pesticide-manufacturing plants, and attended the 8th International Agrochemical and Crop Protection Symposium and Exhibition in Shanghai.

The Director-General of the ICAMA and other government officials visited the APVMA in September 2006 to discuss areas of mutual interest and to learn more about the Australian regulatory system.

The visit of the APVMA's officials to China focused specifically on the regulation of pesticides and the assurance of their quality. Chinese manufacturers are a major source of pesticides imported into Australia. The key aims of the visit were to establish working relationships and a clear understanding of China's regulatory framework for pesticides, particularly China's requirements for approving the manufacture and supply of pesticides to overseas markets, and to raise awareness of the APVMA's regulatory role and requirements.

A brochure setting out the Australian system of management of agricultural and veterinary chemicals was produced in English and Chinese to assist communication with the Chinese authorities.

food consumption diets and a work plan and timetable for the revision of the Codex Classification of Foods and Animal Feeds.

Standards for listing and conditions for reservation from registration

In the 2005–06 Annual Report, the APVMA reported that it had finalised the text of two standards for listed registration and one set of conditions for reservation from registration. The standards for listed registration are for certain swimming pool chemicals and products that contain chondroitin and/or glucosamine to improve joint health in dogs and horses. The conditions for reservation are for a range of disinfectants.

The APVMA reported that the finalised text was being incorporated into the Regulations of the Agvet Code. The process of rendering the standards and conditions into regulations has proven to be extraordinarily difficult, with the result that the APVMA and the Office of Legislative Drafting in the Attorney General's Department have not been able to complete the task yet. The APVMA expects the process to be finished early in 2007–08.

In May 2007 the APVMA gained the support of the PSIC to request DAFF to prepare amendments to the regulations to the Agvet Code to allow the CEO of the APVMA to approve standards for the registration of certain products. Under this process, the APVMA would follow the current process of community and stakeholder consultation over draft standards, but the process of finalising the standards would be quicker and easier.

APVMA image

Dr Joe Smith and Mr Stephen McDonald at the 8th International Agrochemical and Pesticides Symposium and Exhibition in Shanghai, March 2007

An agreement was reached during discussions with the ICAMA to share information that would support compliance activities. An arrangement has now been formalised and Compliance staff in the APVMA can now obtain information about the registration of Chinese pesticides and the licensing of active constituent manufacturers.

Minor use reform

Over recent years the number and diversity of small or specialist crops grown in Australia has increased. This has led to demand for suitable pesticides and veterinary medicines, but not in volumes that have commercial benefit for manufacturers to register products in the usual way. This problem affects countries that have well developed regulations for pesticides and veterinary medicines. The minor use and permit system has been developed to meet this need.

In August 2006 DAFF and the APVMA announced a joint initiative to establish a Minor Use Liaison Office (MULO). Operating externally to the APVMA, two officers have been acting as a focal point to assist grower industries and to develop a long-term strategy for addressing minor use in Australia.

During 2006–07 the APVMA and the MULO have been undertaking a range of activities in accordance with five key strategies. The following is a brief summary of activities against each strategy.

1. Enhancing the approval of more minor uses on product labels

- holding discussions with key registrants to identify new product developments and encourage registration of minor uses in future submissions
- examining current minor use permits for transfer to product labels
- developing changes to data protection legislation to encourage the registration of minor uses
- reviewing the Guidelines for Determining Minor Uses, aiming to reclassify some major crops to minor use status
- developing guidance on efficacy and crop safety requirements for minor uses, to be circulated for public comment during 2007–08.

2. Increasing industry collaboration and coordination

- providing guidance on regulatory requirements and processes to a range of minor industries
- collaborating with existing minor use coordinators in Horticulture Australia Limited (HAL), the Rural Industries Research and Development Corporation (RIRDC) and the Grains Research and Development Corporation (GRDC)
- holding a forum, Minor Use 07, in June 2007 to discuss a permanent structure and funding for a Minor Use Program, with about 100 participants. The MULO is currently developing a new project proposal for consideration by DAFF in the next budget cycle.

3. Enhancing the availability of new and reduced-risk chemistry

- developing regulatory criteria and incentives to enhance the development and introduction of reduced risk chemistry
- holding discussions with registrants and other regulators internationally on ways in which new chemistry may be implemented.

4. Enhancing international collaboration

- holding discussions with other international minor use programs, and identifying pilot projects to conduct joint research with the United States and Canada, to be conducted in 2007–08
- Australia is Chair of a recently established OECD Expert Group on Minor Uses, to increase cooperation on technical and policy aspects of minor uses
- actively encouraging registrants to consider research conducted in other countries when developing regulatory submissions
- continuing active participation in the International Crop Grouping Consulting Committee convened by the United States Department of Agriculture (USDA) Interregional Research Project No. 4 (IR-4)
- the APVMA is represented on the Planning Committee for the Global Minor Use Summit to be held in Rome in December 2007.

5. Improving communication

- the APVMA and the MULO have attended several meetings with minor use industries and provided advice on regulatory requirements and processes
- a minor use site has been established on the DAFF website
- listings of approved crop protection products for individual commodities are being developed.

Labelling reform

The APVMA/stakeholder Labelling Code Working Group (LCWG) has embarked on a labelling reform project. In 2006–07 the work of the LCWG focused on:

- more clearly defining the regulatory 'box'
- defining restraint statements (wording, placement etc) in respect of control of use legislation
- clarifying requirements for content and format of labels, and 'best practice'
- having clearly established labelling requirements versus best practice, introducing reforms to allow changes to be made to labels using either permits such as 6868, 9284 and 9523 or via conditions of label approval.

Taking into account elements that are important in 'information design', a suite of concept labels has been developed that will be road-tested with user focus groups in the second half of 2007. The LCWG is also proposing to conduct a 'benchmarking study' on current labels and is working on developing a questionnaire for such a study.

The LCWG also continues to be involved in a number of ongoing initiatives to improve and reform the label approval process including:

- extending the provisions of Permit 6868 that allows certain administrative changes to product label without prior APVMA approval
- issuing Permit 9284 to allow additional promotional tags and stickers
- issuing Permit 9523 that allows the marketing of a range of pack sizes based on one label approval.

Electronic Labels (e-labels)

In January 2007 the APVMA announced that labels submitted for approval at the final stages of an application for product registration should be in electronic form. Applicants may send in the e-labels on CD or to a special email address.

Introducing e-labels has provided applicants with substantial cost and time saving. Applicants can send an e-label to the APVMA for approval without the time and expense of a small print run of paper labels. If the e-label has to be amended, the applicant can quickly and easily amend it at minimum cost. The label need only be printed when the APVMA has approved it and it is ready for production.

The APVMA is currently investigating how the use of e-labels can help the faster checking of labels to ensure they comply with labelling requirements. Any reduction in the time taken to check labels, which is an integral part of the overall evaluation process, will achieve further efficiency gains.

Quality of Regulatory Science

The objectives of the Principal Scientists Program are to:

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

The two Principal Scientists, Dr David Loschke and Dr Phil Reeves, made substantial progress in each of these areas during 2006–07.

Improve the quality of scientific work in the APVMA

The Principal Scientists audited a sample of evaluation reports prepared by staff and found them to be in the range 'good' to 'excellent'. The audit findings guided the scientific training needs of evaluators and the training was delivered through the Science Fellows Program. During 2006–07, external scientists delivered training in statistics, formulation chemistry, risk assessment methodologies particularly in relation to public health, international standards of risk and residues of veterinary drugs in foods (see box on next page). The materials were made accessible to staff online following the training sessions.

In 2007 Dr Dieter Arnold became the first overseas scientist to be appointed as an APVMA Science Fellow. He visited the APVMA from Germany for three weeks to share his international experience in residues of veterinary drugs in animal commodities and food safety programs.



Scientific training for staff

For the APVMA to operate effectively as an authoritative and credible science-based regulator of agvet chemicals, the scientific knowledge of its evaluation staff must be maintained and improved. During 2006–07, training topics were chosen based on the findings of audits of evaluation reports for regulatory science quality and in response to training requests from evaluation staff. The APVMA's Science Fellows and external scientists of high standing in regulatory science delivered the following training sessions:

Name	Training topic
Associate Professor Steven Stern	Statistics
Dr Margaret Doherty	Biopharmaceutics and formulation chemistry
Dr Margaret Hartley	The benefits of harmonisation of risk assessments within a global cooperation framework
Dr Jason Clay	Idiopathic environmental illnesses
Dr Robert Wells	Quantitative nuclear magnetic resonance
Dr David Loschke and Mr Chris Lee-Steere	Risk assessment issues for high-volatile esters of 2,4-D
Dr Mathew McCrone	Changes to the drugs and poisons scheduling process
Dr Nena Waight-Sharma	International approaches to cumulative and aggregate risk assessments
Dr Dieter Arnold	Residues of veterinary drugs in food

Evaluation staff are able to access online a repository of the training materials presented through the Science Fellows Program, which is maintained on an APVMA Intranet site.

A highlight of 2006–07 was the inaugural APVMA Science Fellows Symposium (see box on next page). The theme of the symposium was residues of veterinary drugs in animal-derived food products with a particular emphasis on trade, which was appropriate given the importance of Australia's trade in these products.

Increase domestic and international awareness and scientific credibility

The Principal Scientist for Residues and Veterinary Medicines, Dr Phil Reeves, participated in an APVMA workshop on developing methodology for setting export slaughter intervals (ESIs), served on the Board of Examiners of the Australian College of Veterinary Scientists and delivered invited university lectures.

Dr Reeves presented a paper at the 10th International Congress of the European Association for Veterinary Pharmacology and Toxicology, published a review in a peer-reviewed, international scientific journal, collaborated with another member of the VICH Expert Working Group on metabolism and residue kinetics to prepare a draft guideline on the harmonisation of scientific model assumptions and served on two editorial boards.

The Principal Scientist for Agricultural Chemicals, Dr David Loschke, made a presentation to an OECD conference in Vienna, Austria and another in Braunschweig, Germany as well as delivering invited presentations to 16 other national conferences in Australia.

Science Fellows Symposium

The inaugural Science Fellows Symposium was an important milestone for the APVMA as it marked the first major public expression of the APVMA's Science Fellows Program. The focus of the symposium was the science underpinning the safety and trade assessments of residues of veterinary drugs in animal-derived foods. The Hon Sussan Ley MP opened the symposium and the Chairperson of the APVMA's Board of Directors, Dr Kevin Sheridan AO, chaired the program. Speakers were APVMA Science Fellows Emeritus Professor Jock McLean, Dr Margaret Doherty, Dr Dieter Arnold, Professor Terry O'Neill, Dr Peter Miller and Dr Phil Reeves. The program addressed contemporary approaches, advances, issues and challenges to the assessment, mitigation and monitoring of potential risks from residues of veterinary drugs in food. The symposium demonstrated the APVMA's efforts to embrace advances in scientific understanding and to ensure that its regulatory decisions are based on the most up-to-date science. The symposium was the first in a series and will help build stakeholder and community understanding of the science that underpins the APVMA's regulatory decisions.

Effectively manage science-related issues and projects in the APVMA

The Principal Scientist for Residues and Veterinary Medicines, Dr Phil Reeves, completed two projects in 2006–07. One aimed to achieve greater alignment between substances listed in Appendix J of the Standard for the Uniform Scheduling of Drugs and Poisons and products declared as restricted chemical products. The project report has been released for public consultation. The second project involved the development of prototype software, demonstrated at an APVMA workshop, for setting ESIs for veterinary drugs used in food-producing animals. A third project to develop a risk management framework for regulatory science has progressed significantly during the year.

The Principal Scientist for Agricultural Chemicals, Dr David Loschke, completed a major revision of the *APVMA Guide for Demonstrating Efficacy of Pool and Spa Sanitisers* following a public comment period and an APVMA-hosted forum on the subject in Canberra. He also advanced the

Vacation Scholar Program

The Vacation Scholar Program is a regulatory science quality initiative that commenced in November 2006. The program aims to engage university students who are seeking short-term work in their fields of study during their vacations, to conduct targeted projects of importance to the APVMA. The program may also assist the APVMA with its future recruitment, either directly through the vacation scholar seeking employment with the APVMA, or indirectly through a vacation scholar helping the APVMA to identify suitable prospective employees. The inaugural vacation scholar completed a statistics degree with honours at the Australian National University in 2006 and was an outstanding student, winning the University Medal, a Monash Award and the Tillyard Prize. The scholar worked on APVMA projects with a strong biostatistical component.

APVMA's refinements of its spray drift risk assessment and risk management methods, travelling to many venues throughout Australia to present the latest developments to audiences and listen to their views. Dr Loschke also discussed these issues before a large audience at a national Spray Drift Forum that the APVMA hosted in Canberra in August 2006 (see box on page 42).

Science Fellows

The APVMA Science Fellows are eminent national and international scientists who have been appointed to assist with the training of APVMA staff and to provide high-level external scientific advice. In 2005–06 the APVMA appointed seven eminent scientists as inaugural Science Fellows, who continued their work in 2006–07 as follows:

- Dr Margaret Doherty: Pharmaceutical Sciences
- Dr Des Hennessy: Veterinary Parasitology and Residues of Veterinary Drugs in Foods. Dr Hennessy died tragically in a gliding accident in December 2006. As part of his appointment as an inaugural APVMA Science Fellow in 2006, Dr Hennessy provided training in drug residue analysis to APVMA scientific staff and wise counsel on complex regulatory issues. He also 'planted the seed' for the theme of the inaugural APVMA Science Fellows Symposium. The APVMA is indebted to Dr Hennessy.
- Emeritus Professor Jock McLean: Toxicology of Veterinary Drugs
- Professor Terry O'Neill: Statistics
- Dr Peter Young: Veterinary Vaccinology and Biotechnology
- Professor Brian Priestly: Toxicology of Pesticides
- Dr Andrew Hewitt: Spray Drift Risk Assessment
- In 2007 the APVMA appointed its first overseas Science Fellow, Dr Dieter Arnold. Dr Arnold was Acting Director of the former Federal Institute for Health Protection of Consumers and Veterinary Medicine in Germany before he retired in 2002. He served as rapporteur to the Codex Committee on Residues of Veterinary Drugs in Foods and was Chairman of the Residue Safety Working Group in the European Union (EU) for several years. Dr Arnold developed his laboratory in Germany into one of the first Community Reference Laboratories in the EU. Dr Arnold has also served on the Joint FAO/WHO Expert Committee on Food Additives (Veterinary Drugs) as an expert, Vice-Chairman and Chairman. Currently, he works as an international consultant on projects relating to food safety, particularly in Central Europe and the Near East, and as a member of FAO and WHO panels.

Provision of advice by external agencies

In making regulatory decisions such as product registrations and reviews, the APVMA receives advice from various Australian Government and state and territory government agencies on human toxicology, occupational health and safety, the environment, efficacy, target animal and crop safety, and genetically modified products and organisms. Formal Service Level Agreements (SLAs) or MOUs are in place between the APVMA and the agencies concerned to ensure that advice is provided in a framework that is cost-effective, accountable and has relevant performance measures.

Throughout 2006–07 the APVMA maintained and revised its SLAs with the Department of the Environment and Water Resources (DEW, formerly the Department of Environment and Heritage) and the Office of Chemical Safety (OCS) in DoHA. Services in the agreements include assessments for registration and permit applications, assessments of chemicals under review and other professional advice. The DEW delivered 84 per cent of application assessments within timeframe and the OCS 100 per cent.

This year the APVMA revised its MOU with the Office of the Gene Technology Regulator (OGTR). 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 provides comment on relevant draft risk assessments prepared by the OGTR.

During 2006–07, the APVMA and various state departments in NSW, Queensland, Tasmania and Western Australia, signed SLAs on the provision of advice on efficacy and crop/animal safety matters. The APVMA also advertised for further pesticide efficacy reviewers to add to our review panel.

The APVMA maintained and revised the *Efficacy and Target Animal/Crop Safety Reviewer's Manual* to assist reviewers and applicants in their understanding of the assessment of efficacy and target animal/crop safety.

Efficacy Reviewer Seminars

To coincide with the publication of edition three of the *Efficacy and Target Animal/Crop Safety Reviewer's Manual*, a series of half-day efficacy seminars were conducted in November 2006 in Brisbane, Sydney, Melbourne, Perth, Adelaide and Hobart. The manual is designed to assist reviewers and applicants understand the APVMA's needs in the assessment of efficacy and target animal/crop safety. The seminars were well attended with a total of 84 state and external reviewers in attendance.

The efficacy seminars contained specific topics that related to state and external reviewers. These topics included the assessment process, conflict of interest, confidentiality, report quality issues and technical issues.

Strategy 2: Engage stakeholders to improve awareness, inform policy development and to optimise the regulatory framework within which APVMA operates

Performance

Public Affairs Strategy

In 2005–06 the APVMA public affairs strategy was reviewed to seek better alignment between the public affairs function and the APVMA's corporate objectives. The review resulted in several strategic enhancements in 2006–07 to organisational performance, some of which are discussed below.

Visual Branding

One of the more graphic activities was the development of a visual branding scheme for the APVMA's new building at Symonston, Australian Capital Territory (ACT). The new branding scheme draws its inspiration from a colourful mural developed for the foyer of the building that depicts a range of Australian environments from the desert to the coast. Elements in the scheme include individual mural panels placed around the building, accent walls, patterned glass office fronts, an organisational timeline and the extensive use of contemporary Australian landscape art in public spaces. This visual branding and the adoption of a more formal brand statement by the APVMA are designed to create an identity for the organisation. The concepts in the graphic will be extended to include a range of corporate livery in 2007–08.

Communicating regulatory decisions

During 2006–07 the APVMA has taken a more proactive approach to communicating regulatory decisions. A key example was management of the outcome of the diazinon review. Data suggested that this chemical, widely used in Australia for dipping and jetting sheep, was dangerous to the health of rural workers. The APVMA actively engaged stakeholders at many different points in the regulatory process to explain the risks of the chemical and actions that were necessary to protect rural workers.

Improving the APVMA's website

During 2006–07 significant work was undertaken to improve the functionality and usability of the APVMA's website to meet growing user expectations. A fresh, new design was adopted as well as activity to enhance the structure of information presented. This activity is continuing and has three major projected outcomes: enhanced information architecture, better presentation of web-based information and the application of common style and conventions across all web-based applications. Achievements through the financial year have included the development of a public consultation page where all APVMA consultation activities have been brought together in one area, the development of a Hot Topics section that allows the APVMA to respond to issues of concern to stakeholders and self-registration facilities for events and consultation activities.

Better stakeholder interaction

This financial year the APVMA has also improved its event management capability to provide enhanced opportunities for stakeholder interaction. During the reporting period, for example, the APVMA organised and managed a Spray Drift Forum, a meeting for members of the pool and spa industry, chemistry seminars in three states and the flagship Science Fellows Symposium.

Stakeholder engagement

A key corporate goal of the APVMA is creating and maintaining stakeholder confidence. Stakeholder engagement is therefore vitally important.

APVMA stakeholder engagement is a multilevel activity. At the most basic level, we provide information on our activities to stakeholders through a wide range of tools. These include media releases, the *APVMA Gazette*, the fortnightly email bulletin *Regulatory Update*, reports, the APVMA website, seminars and a wide range of publications.

Seminars and meetings are particularly important means of information exchange and during the financial year the APVMA hosted a number of issues-based forums and seminars tailored to specific stakeholder groups, such as the forum on spray drift regulation (see box). Other forums held throughout the year related to pool and spa product regulation and the consultation needs of user groups.

Spray Drift Forum

The APVMA hosted a national public Spray Drift Forum in Canberra at the Telstra Theatre, Australian War Memorial on Wednesday 16 August 2006. Dr David Loschke and Dr Eva Bennet-Jenkins fielded questions and discussion throughout the day from concerned stakeholders including chemical and rural industry representatives, government regulators and community members.

The Spray Drift Forum was open to the public and provided an opportunity for all concerned stakeholders to discuss the APVMA's proposed refinements to its regulation of spray drift risk. The APVMA explained those spray drift related issues that fall under its legislative obligations and powers and the factors that the APVMA takes into account in assessing risk and making regulatory decisions.

The forum was very well attended and resulted in much lively discussion and comment from stakeholders.

APVMA staff also gave many presentations at stakeholder meetings, field days, conferences and seminars. These activities increase awareness of the APVMA and its requirements and improve stakeholder knowledge of the regulatory system. A summary of these activities is provided in Table 11.

Table 11: APVMA presentations 2006–07

Date	Title of event	Title of presentation
July 2006	Ecotoxicology Symposium, Melbourne, Vic.	Spray drift modelling outcomes
August 2006	*IUPAC/ICPC Congress of Pesticide Chemistry, Japan	Regulation of chemicals in Australia
August 2006	Invited lectures, University of Sydney, NSW	Chemical food hazards
September 2006	Australian Herb and Spice Industry Workshop, Adelaide, SA	Minor use reform
September 2006	*OECD Task Force for Biocides, Vienna, Austria	The APVMA's pool sanitiser guideline
September 2006	Interagency Meeting with NSW DPI, Sydney, NSW	Minor use reform
September 2006	*BBA/BVL, Braunschweig, Germany	The APVMA's spray drift risk management
September 2006	*10th International Congress of the European Association for Veterinary Pharmacology and Toxicology, Turin, Italy	Fat-soluble status of pesticide residues in animal commodities
September 2006	PIHC Peri Urban Biosecurity Workshop, Canberra, ACT	Risks posed by incorrect chemical use
September 2006	Visit to APVMA by ICAMA (the People's Republic of China's pesticides regulator)	Registration of pesticides in Australia
October 2006	Rice Industry, Griffith, NSW	Rapid screening tools for pesticides project
October 2006	Working Group Meeting, Brisbane, Qld	Pesticide use on sugar cane
October 2006	*European Plant Protection Organisation, Berlin, Germany	Efficacy and crop safety
November 2006	Pulse Australia/GRDC/DAFWA, Perth, WA	Use of pesticides for minor use in grains
November 2006	NSW Poisons Information Centre clinical meeting, Sydney, NSW	Adverse Experience Reporting Program for Agricultural and Veterinary Chemicals
November 2006	*4th Annual Pest Management Conference, Ontario, Canada	Minor use program
November 2006	*OECD Working Group on Pesticides, Bonn, Germany	Minor use
December 2006	PFIAA Technical Conference, Melbourne, Vic.	Regulatory updates on therapeutic pet foods

Date	Title of event	Title of presentation
December 2006	Growcom/Industry Forum on Post-harvest Dipping/Spray Drift, Gatton, Qld	Fenthion and dimethoate reviews
December 2006	Chemistry and Compliance Seminar, Perth, WA	Chemistry requirements, Ag QA Scheme and MLS
January 2007	CPAS Spray Drift Modelling, Brisbane, Qld	Spray drift modelling
January 2007	CPAS Aerial Spray Drift, Gatton, Qld	Spray drift aerial regulation
February 2007	ChemCert Professional Development Workshop, Dubbo, NSW	Spray drift
March 2007	User Industry Forum, APVMA, Canberra, ACT	Review of risks from 2,4-D high volatile esters
March 2007	Mango Growers Association, Cairns, Qld	Fenthion/dimethoate/carbaryl reviews
March 2007	CPAS Nozzle Workshop, Gatton, Qld	Spray drift risk assessment
March 2007	Dow Research Conference, Sydney, NSW	Spray drift risk assessment
March 2007	Invited lectures, Monash University, Melbourne, Vic.	Veterinary dosage forms
March 2007	ChemCert Qld Annual Conference, Townsville, Qld	Spray drift risk assessment
March 2007	Pool/Spa Industry Seminar, Canberra, ACT	Pool sanitiser efficacy guideline
March 2007	WA Farmers Federation Annual Conference, Perth, WA	The APVMA's review process, using diazinon as a case study
March 2007	Comcover Awards for Excellence in Risk Management Conference, Canberra, ACT	APVMA risk management
March 2007	CropLife Australasia Members' Forum, Canberra, ACT	APVMA compliance strategic reform
March 2007	*Chinese regulatory authorities, Beijing, China	Registration of pesticides in Australia The APVMA's Ag QA Scheme
March 2007	*OECD Risk Reduction Steering Group, Brno, Czech Republic	Minor use
March 2007	*OECD Registration Steering Group, Brno, Czech Republic	Minor use
April 2007	University of Sydney, Sydney NSW	Introduction to APVMA science
April 2007	University of Sydney, Sydney NSW	National Registration Scheme

Date	Title of event	Title of presentation
April 2007	User Forum, the APVMA, ACT	APVMA communication
May 2007	NSW Department of Environment and Climate Change (formerly the Department of Environment and Conservation) Conference	Spray drift
May 2007	FSANZ, Canberra, ACT	The APVMA's chemical review program
May 2007	Meeting Chief Plant Protection Officers, Melbourne, Vic.	Fenthion and dimethoate reviews
May 2007	PIRSA and SA Groundsprayers, Adelaide, SA	Spray drift risk management
May 2007	PSIC Workshop, Canberra, ACT	Issues of high risk chemicals
May 2007	Mango Growers Conference, Gold Coast, Qld	The APVMA's chemical review program
May 2007	Mango Growers Board, Cairns, Qld	The APVMA's chemical review program
May 2007	Fenthion and Dimethoate Reviews Forum, Canberra, ACT	Fenthion and dimethoate reviews
May 2007	AUSVEG Vegetable Industry Conference, Sydney, NSW	Presentation on chemicals
May 2007	Enterprise Risk Management for Government, Canberra, ACT	Application of balanced scorecard to risk management and risk monitoring
May 2007	QMAC Conference, Canberra, ACT	Risks and regulatory challenges
May 2007	Chemistry and Compliance Seminars, Melbourne, Brisbane, Sydney	Chemistry requirements, Ag QA Scheme and MLS
May 2007	Australian Veterinary Association Annual Conference, Melbourne	Adverse experience reporting in Australia
June 2007	Pesticides Use in Sugarcane Forum, Townsville, Qld	Update on diuron review
June 2007	AGCS meeting, Canberra, ACT	Bystander exposure modelling
June 2007	APVMA Science Fellows Symposium, Canberra ACT	Managing injection site residues: Is global harmonisation of the risk assessment achievable?
June 2007	AAAA 2007 Convention, Gold Coast, Qld	Update on spray drift regulation
June 2007	Atrazine Forum, APVMA, Canberra ACT	Chemical Review Program: atrazine
June 2007	Australian Technical Park, Sydney, NSW	Good clinical practice course guidelines

Date	Title of event	Title of presentation
June 2007	Australian Hydroponic Greenhouse Association Biennial Conference, Launceston, Tas.	The APVMA's reduced risk initiatives
June 2007	*OECD Working Group on Pesticides, Paris, France	Proposed establishment of an expert group on minor uses
June 2007	Minor Use Future Directions Forum, Canberra, ACT	Minor use
June 2007	Minor Use Future Directions Forum, Canberra, ACT	A regulatory perspective
June 2007	National Working Party on Grain Protection, Melbourne, Vic.	Adverse Experience Reporting Program

*Denotes attendance at meetings outside Australia

The APVMA's stakeholder engagement involves more than simply providing information. It includes seeking the opinions of stakeholders. The APVMA consulted widely with stakeholder groups throughout 2006–07 on an extensive range of issues. Stakeholder views were sought on topics that included changes to MORAG, chemical reviews, public release summaries, trade advice notices and policies and guidelines.

One innovation during the reporting year was the development of an enhanced consultation process for chemical reviews. Notices advising of the review were published in mainstream and industry media supported by targeted correspondence to relevant industry bodies. Interested individuals were asked to register online their interest in being consulted on the review. This process generated a significantly higher response rate than traditional methods and the APVMA is considering adopting it more widely.

The APVMA's consultation is not restricted to formal responses to documents or processes. Stakeholder functions were held in association with Board meetings in regional Australia and these provided opportunities for personnel from a range of organisations to meet with the Board and the APVMA's senior management. The CEO and senior staff also regularly met with stakeholders to hear their views on a range of subjects.

The APVMA also encouraged stakeholder participation in decision-making through its four major consultative groups: the Community Consultative Committee, the Registration Liaison Committee, the Industry Liaison Committee and the Industry Technical Committee. During the year a forum was held also with user groups to canvass opportunities for closer engagement between these groups and the APVMA. Working groups were actively used as well. During the year a number of such groups met on issues such as label reform, minor use and scope of regulation.

In some cases, the APVMA actively collaborates with stakeholders to achieve valued high-level outcomes. The APVMA works extensively at the international level, for example, to harmonise regulatory processes to improve outcomes for Australian registrants. Recently, the APVMA has participated in international work sharing arrangements where different international regulators cooperate to undertake different aspects of the evaluation process for a particular chemical product. The APVMA Science Fellows Program is another example of high-level collaboration. The APVMA's Science Fellows are distinguished Australian and international scientists appointed to provide specialised training to staff and to provide counsel on complex regulatory issues.

Informing policy

Throughout the financial year, the APVMA undertook significant policy work on legislative change to implement the recommendations of the Uhrig review, and prepared the organisation for efficient transition to new corporate governance arrangements from 1 July 2007. The APVMA contributed to the amended legislation to facilitate the alignment of the MRL process with FSANZ.

The APVMA also participated in a COAG project, led by the Department of Prime Minister and Cabinet, to develop a framework for the control of security sensitive chemicals.

During the year the APVMA engaged with stakeholders and policy makers in pursuing a number of proposals for both operational and legislative reforms. These relate to strengthening compliance, clarifying the scope of APVMA regulation, simplifying requirements of low regulatory risk and reforming label provisions. They also included policy reform that led to the creation of the Minor Use Liaison Office in DAFF.

Strategy 3: Review registered chemicals on the basis of their risk

Performance

Make effective regulatory decisions

The APVMA's chemical reviews reconsider the registration of pesticides and veterinary medicines when new information raises concerns about their continued use. Reviews may be based on one or more areas of concern including environmental safety, worker safety, public health, efficacy, residues or trade.

During a chemical review, the APVMA draws on the specialist expertise of its own staff and that of other advisory agencies and consults extensively with the chemical industry, users and the community. For an agvet chemical product to continue to be registered, the APVMA must be satisfied at the completion of a review that it remains safe and effective when used according to the label.

At 30 June 2007, the Chemical Review Program had 30 ongoing reviews, compared with 32 in 2005–06. Eleven of these are comprehensive reviews (see Table 12). The remaining reviews focus on more specific aspects of products and/or their labels.

Table 12: Chemicals under review 2006–07

1080 (Sodium fluoroacetate) (completed)	Dimetridazole (completed)	Methyl bromide (completed)
2,4-D	Diquat (c)	Molinate
Atrazine (c)	Diuron	Neomycin (new)
Azinphos-methyl (c)	Fenamiphos (c)	Omethoate
Carbaryl—part 1 completed	Fenitrothion	Paraquat (c)
Carbaryl—part 2	Fenthion (c)	Parathion methyl (c)
Carbendazim/thiophanate-methyl (new)	Fipronil	Polihexanide
Chlorfenvinphos (c)	Macrolides	Procymidone
Chlorpyrifos (c)	Maldison	Sheep ectoparaciticides
Diazinon (c)	Methamidophos	Temephos
Dichlorvos	Methidathion	
Dimethoate	Methiocarb (c)	

(c) covering all aspects of the active constituent, product and labels

During 2006–07 the APVMA finalised four reviews and commenced new reviews on carbendazim/thiophanate-methyl and neomycin. A review scope document was prepared for each, detailing the reasons for the review and the aspects of active constituent approval, product registration and/or labels to be examined. Two Preliminary Review Findings (PRF) reports were released for public consultation (azinphos-methyl and carbaryl —part 1), while a third (dichlorvos) was considered by the Board in June 2007 before being released for public comment in early 2007–08. The review of carbaryl (home garden, home veterinary, domestic and poultry uses) was completed in January 2007 and the reviews of methyl bromide, dimetridazole and 1080 were finalised in June 2007.

The APVMA also took regulatory action on label instructions for 2,4-D high volatile esters, diazinon and carbendazim products, suspending selected labels and issuing new instructions for use of the products.

1080 (Sodium fluoroacetate)

Sodium fluoroacetate, commonly known as ten-eighty (1080), is used to control feral animals including rabbits, foxes, wild dogs and pigs, and, in limited situations, native animals. Its use in controlling feral animals such as foxes plays an important role in biodiversity conservation. The review was undertaken to address concerns over the accidental poisoning of non-target animals. The review was finalised in June 2007, with label instructions and strengthened controls on use in order to minimise impacts on off-target species.

Azinphos-methyl

Azinphos-methyl is a broad spectrum, non-systemic organophosphorus insecticide used to control insect pests in pome fruit, stone fruit, citrus, macadamia nuts and grapes, with further minor uses in crops such as lychees, kiwifruit and blueberries. The PRF report was released for public consultation in October 2006. The report recommended no further use on apricots and kiwifruit because of residue concerns, and no use on citrus because of environmental concerns. In response to public comments, additional data is being considered which may result in changes to the preliminary recommendations.

Carbaryl

Carbaryl is a carbamate insecticide used to control insect pests in a broad range of agricultural and domestic situations, including stored grain, ornamentals, lawns, fruit and vegetables, around public buildings and to control insects on domestic animals. The review was undertaken in response to concerns about possible unacceptable residues in stored grain and fruit and vegetables, and exposure to residues when using products on produce grown in the home garden.

Part 1 of the review (home garden, home veterinary, domestic and poultry uses) found that risks to consumers from exposure to carbaryl residues in fruit, vegetables and poultry, to users from concentrated products in the home garden and carbaryl dust products in the home, home garden and domestic situations were unacceptable. These uses were cancelled in January 2007.

A PRF report for part 2 of the review (agricultural uses) was released in July 2006 for public consultation. This report found that there is a potential risk to users from exposure to carbaryl residues in some fruit and vegetables and there is a potential risk to human health from mixing, loading and applying some products. The assessment is continuing, taking into consideration information received during the consultation period.

Carbendazim and thiophanate-methyl

Carbendazim and thiophanate-methyl are benzimidazole fungicides with broad-spectrum systemic activity against a wide range of fungal diseases. They have been placed under review because of human exposure concerns. Laboratory studies have shown that carbendazim causes birth defects in laboratory animals at high oral doses administered as a bolus but not when administered in the diet. The relevance of these findings to human health needs to be investigated.

In May 2007 the APVMA suspended label approvals for carbendazim products. New instructions, specifically revised safety directions and a birth defects warning statement, are required to appear on all carbendazim product labels.

2,4-D (short chain esters)

The chemical 2,4-D is a phenoxy herbicide that acts by mimicking a major plant growth regulatory hormone. Products containing 2,4-D are used for post-emergent control of broadleaf weeds in an extensive range of crops and non-cropping situations. In 2003, 2,4-D was placed under review because of toxicological, occupational health and safety and environmental concerns.

- In 2005 label warnings about minimising chemical spray drift were strengthened for all 2,4-D products on the market.
- In April 2006 a PRF report for the environmental aspects of only the short chain ester forms of 2,4-D (2,4-D ethyl ester, 2,4-D butyl ester, and 2,4-D isobutyl ester) was released for public consultation, ahead of the completion of the other components of the review. It was determined that short chain ester forms of 2,4-D could pose an unacceptable risk to non-target terrestrial plants (including non-target crops) and non-target aquatic organisms due to their ability to volatilise and readily migrate from the site of application.
- In October 2006 the registrations and label approvals of 24 products containing high volatile forms of 2,4-D were suspended. New instructions were issued that limited use to between 1 May and 31 August each year and specified other controls to minimise effects on off-target vegetation (native vegetation and commercial crops) and the aquatic environment. Additional data on the physicochemical properties of high-volatile esters were requested and are being assessed.

Diazinon

Diazinon is a broad-spectrum organophosphorus insecticide that has been widely used in Australian wool production, to a lesser extent on other animals to control ectoparasite pests, and in agriculture and horticulture to control insects on crops, ornamentals, lawns, fruit and vegetables. Diazinon is currently available for use in and around domestic, agricultural and public buildings. The review of diazinon is examining all aspects of product registration and approval.

- In 2003 certain hydrocarbon-based formulations and dog flea treatment products containing diazinon were cancelled.
- In June 2006 the PRF report for part 2 of the review was released for public consultation. This report concluded that use of products containing diazinon could, in some situations, pose undue risks to workers, human health, trade and the environment but that these risks could be mitigated by cancelling some products, deleting some uses and changing instructions on labels.

- In May 2007 sheep dipping and jetting uses were suspended, based on evidence showing these practices may have unacceptable impacts on the health of rural workers. New data is currently being evaluated that may enable the use of diazinon to continue in remotely-controlled, automated cage dipping systems.

Dimethoate and fenthion

Dimethoate and fenthion are organophosphorus insecticides used in a wide variety of fruit and vegetable crops. They are valuable tools in the control of insect pests as a post-harvest treatment for quarantine purposes.

Dimethoate and fenthion are currently the only registered chemical products for treatment of fruit fly, particularly Queensland fruit fly (Q fly), with few commercially viable alternatives available.

The APVMA is working with industry to identify data gaps and HAL is coordinating all industries that are undertaking research trials, to support the current uses and provide data for the review. The Office of the Australian Chief Plant Protection Officer (OACPPO) in DAFF has established a national task force to consider non-chemical alternatives to dimethoate and fenthion, to reassess trade requirements, and to consider the potential outcomes of the review.

Dimetridazole

Dimetridazole is an antiprotozoal agent added to drinking water or feed of poultry, pigeons, caged birds, game birds and pigs to control blackhead, canker and swine dysentery. The APVMA published its Review Findings in May 2007, concluding that dimetridazole is a potential genotoxic carcinogen.

In June 2007 the APVMA cancelled the registrations and label approvals of products containing dimetridazole registered for use in food-producing animals (pigs, chickens and turkeys). The APVMA varied the labels of products used in pigeons, caged birds and game birds not intended for human consumption to include new safety directions, dosage and administration instructions, warnings and restraint statements. A two-year phase-out period has been granted to use remaining stock of the cancelled product, in accordance with specific instructions determined by the APVMA.

Methomyl

Methomyl is a carbamate insecticide registered for the control of a wide variety of insect pests in a large number of crops including pome fruit, vegetables, stone fruit, herbs, broad acre and forage crops.

In 2006 the APVMA was made aware of residue concerns associated with the use of products containing methomyl. Information from the NSW Department of Primary Industries' (DPI) 'Cleanfresh' residues monitoring program in 2005 detected methomyl residue violations in hydroponic lettuce. A study conducted by NSW DPI also showed that when hydroponic lettuces were treated according to label directions and harvested well after the prescribed withholding period of one day, the residues were found to be in excess of the current methomyl MRL.

The evaluation of acute dietary intake based on this data showed unacceptable exposures for children (aged 2 to 6 years) and the general population. This was considered relevant not only to hydroponically grown lettuce, but to all leafy vegetables or those grown in protected situations. Although not under review, the APVMA considered that, in the absence of relevant data, product labels needed to be changed to remove such uses.

Registrants voluntarily agreed to make the necessary changes to their product labels, specifically the removal of instructions for lettuce and leafy vegetables and inclusion of the statement *'Do not use in covered or protected situations such as glasshouses, greenhouses or plastic tunnels*'.

Methyl bromide

Methyl bromide is a gas with potent insecticidal, fungicidal and herbicidal properties and is a known potent ozone depleting substance. It is used as a soil fumigant in horticultural industries, a pest control treatment in dry commodities such as stored grain and dried fruit, and as a quarantine and pre-shipment fumigant for imports, exports and certain commodities transported interstate. The review of products containing methyl bromide and their labels was initiated in October 2005 to ensure that the use of the gas in Australia continues to meet Australia's obligations under the Montreal Protocol on Substances that Deplete the Ozone Layer.

The APVMA released the PRF report for methyl bromide for public consultation in April 2006 and the review was finalised in June 2007. Label approvals have been varied to limit the use of methyl bromide to only those situations allowable under the Montreal Protocol.

Neomycin

Neomycin is an antibiotic used in food-producing and non-food-producing animals. Two major uses of neomycin are for the control of scours in calves and the treatment of mastitis in dairy cattle. In February 2007 the APVMA began a review of oral, intramammary and injectable preparations of neomycin (including combination products with other antibiotics) and their associated approved labels. This was because of target animal safety and potential residue concerns for food-producing animals treated with these preparations of neomycin.

Other achievements

Pesticides in schools

On a number of occasions, the APVMA has been asked to respond to concerns about pesticide use in schools. The APVMA is developing a website publication to provide guidance and information on pest control in schools and the safe and effective use of pesticides.

This web publication, based on similar documents published by Australian and international bodies, is intended for managerial and teaching staff, students, parents, school councils, pest control operators, local government officers and the general public. It will provide information on integrated pest management (including non-chemical approaches), pests and their behaviour, chemicals used in pest management, and discussion on minimising the risks in controlling pests in the school environment. The APVMA is seeking input from state and territory departments of education before preparing a final draft.

Dip disposal

The dip disposal project was initiated in 2000 to address the concerns of state and territory environment authorities that the disposal of spent dip chemicals should not cause unintended environmental harm and that product labels should provide information to users on how this can be avoided.

In 2006 the DEW prepared a scoping report on this issue and developed criteria for determining the appropriateness of land-based disposal methods for certain dip chemicals. The APVMA has convened an APVMA/stakeholder Dip Disposal Working Group to advance the project.

Rationalisation and reprioritisation of review nominations list

In 2005–06 the APVMA continued to revise the Priority Candidate Review List (PCRL). This list resulted from the combination, in 2000, of chemicals previously nominated for review under the Existing Chemicals Review Program (ECRP) and the Special Review Program (SRP). The focus of the revised Chemical Review Program (CRP) is to respond to concerns about chemicals as they arise rather than reviewing them systematically as had been done in the past.

Chemicals which no longer have any registered products in Australia or which had been restricted by international treaties have been removed from the list. During 2006–07 the APVMA's advisory agencies, the OCS in DoHA, the DEW and APVMA's Residues Program were asked to review this list and update their priorities in a similar way to the initial prioritisation work done at the commencement of the APVMA review program in 1995. The APVMA will consider the agency responses before publishing a new PCRL.

Expanding and updating the APVMA's review website

In 2006–07 the Chemical Review Team continued a project to rationalise and expand the Review section of APVMA's website, to include more detailed information about chemicals which have been reviewed and the outcome of reviews. This work is designed to make the website more useful to stakeholders.

International engagement

OECD Task Force on Biocides (TFB)

In September 2006 the APVMA participated in the OECD Task Force on Biocides (TFB) in Vienna and delivered a presentation on the APVMA's guide for demonstrating the efficacy of pool and spa sanitisers. The aim of the presentation was to stimulate interest at the OECD for developing an international OECD Guidance Document based on the APVMA approach. The presentation was well received and Australia was made the lead country for advancing this project. A teleconference in December 2006 further advanced the project, and a draft document is scheduled for discussion at the next TFB meeting in September 2007.

OECD Working Group on Pesticides, Risk Reduction Steering Group and Registration Steering Group

Australia takes an active part in international work sharing of application submissions, work that has arisen from OECD activities.

In 2006–07 the APVMA participated at a number of meetings of the OECD Working Group on Pesticides (WGP) and associated steering groups (Risk Reduction Steering Group and Registration Steering Group). In November 2006 the APVMA participated in the OECD Working Group on Pesticides and Joint Chemicals Committee meetings in Bonn, Germany. In March 2007 the APVMA represented Australia at meetings in the Czech Republic and in June 2007 led the Australian delegation at meetings in Paris, France. The APVMA is actively participating in a number of topic areas including user compliance, product labelling, guidance documents on criteria for determining adversity of toxicological effects, guidance document development through the Expert Group on Residue Chemistry, addressing constraints to work sharing and coordination of minor

use activities. We are pleased that at its meeting in June 2007, the WGP agreed to establish an Expert Group for Minor Use that the APVMA is to chair.

APEC Chemical Dialogue

In June 2007 the APVMA participated in the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue meetings between government and industry leading up to APEC trade minister meetings.

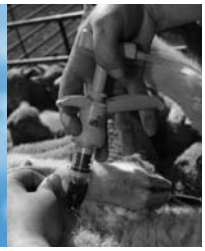
International engagement and minor use

During 2006–07 the APVMA continued to take a lead role in the OECD to examine issues facing minor uses, including presenting discussion papers to the Working Group on Pesticides (WGP), Registration Steering Group (RSG) and Risk Reduction Steering Group (RRSG). On 11 June 2007, the WGP agreed to the establishment of an Expert Group on Minor Uses appointing Australia as Chair. The Expert Group membership includes various member countries, FAO, IR-4, EPPO and CropLife International and will be advancing activities around three broad target areas of cooperation, technical and policy. Australia as Chair of the Expert Group will be presenting on the group's current and future activities at the upcoming Global Minor Use Summit to be held in Rome, Italy in December 2007.

OECD Joint Reviews and North American Work Share Activities

In 2006–07, the APVMA embarked on joint reviews of three new active constituents and their related products. Two of the joint review activities were trilateral reviews, undertaken with the United States Environment Protection Authority (USEPA) and the Pest Management Regulatory Agency (PMRA) in Canada. In these reviews, Australia took a role as lead reviewer for toxicology for one active constituent and for residues of another active constituent. The third project involved an OECD joint review with the US, Canada, the EU and Australia/New Zealand. For this active constituent, Australia was the lead reviewer for residues in food. Various other initiatives, including participation of all assessment agencies in a peer review capacity, have also commenced with another new active constituent.





Codex Committees

Joint Meeting on Pesticide Residues (JMPR)

The Joint Meeting on Pesticide Residues (JMPR) is an international scientific expert group administered by the FAO and the WHO. In October 2006, two APVMA officers attended the JMPR as invited experts. Dr Les Davies attended as a member of the WHO Toxicology Panel, while Dr Raj Bhula was on the FAO Residues Panel as an FAO consultant. The JMPR provides recommendations on maximum residue levels to the Codex Committee for Pesticide Residues (CCPR) for the establishment of Codex Maximum Residue Limits for trade.

Other international activities

Through visits of international officials to the APVMA and targeted visits by key staff, the APVMA has continued its international engagement in the interests of optimising regulatory quality, consistency and efficiency. During the financial year, meetings were held with representatives of the European Medicines Agency (EMEA), the United Kingdom Pesticides Safety Directorate, the UK Veterinary Medicines Directorate, the ICAMA, the German Federal Office for Consumer Protection and Food Safety, the German Federal Biological Research Centre for Agriculture and Forestry, the European Food Safety Authority, the USEPA, the USFDA, the Canadian Pest Management Regulatory Agency (PMRA) and the Veterinary Drugs Directorate (VDD), and the New Zealand Food Safety Authority (NZFSA).

Output 2: Chemical product quality

Responsive feedback mechanisms, and quality assurance and compliance programs that support ongoing chemical product quality and conformance with legislation

Overview

Pesticides and veterinary medicines may not be registered forever. The APVMA manages four programs that monitor the quality and safety of registered products to ensure that the high standards of registration are maintained. Through these programs the APVMA can take regulatory action if the registration standards are not maintained or if new information suggests that a product's registration should be reconsidered.

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: Consider stakeholder feedback including adverse experience reporting

Strategy 2: Ensure industry compliance with the legislation, including maintenance of quality assurance programs

Strategy 3: Respond to and manage emerging regulatory issues

Strategy 1: Consider stakeholder feedback including adverse experience reporting

Performance

Introduction

The Adverse Experience Reporting Programs for agricultural (AERP *Ag*) and veterinary chemicals (AERP *Vet*) are post-registration feedback loops that the APVMA has established to facilitate responsible management of agricultural and veterinary chemical products throughout their life.

The aims of AERP *Ag* and AERP *Vet* are 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 the APVMA makes continue to remain appropriate and promote and maintain public confidence in the NRS. Consideration of reports frequently involves consultation within the APVMA as well as with other relevant Australian Government, state and territory departments, monitoring agencies in other countries, recognised experts on advisory committees and the product registrants. Links have also been recently established with the Poisons Information Centre in Sydney as an alternative source of feedback about the safety of agricultural and veterinary chemicals.

In December 2006, the APVMA published a new guideline on the legal obligations of product registrants to report new information to the APVMA. This guideline sets out the types of information (including adverse experiences) that product registrants must submit to the APVMA, in compliance with section 161 of the Agvet Code, and the mechanisms by which registrants can submit that information.

AERP *Ag*

Activities undertaken to raise awareness of the AERP *Ag* program in the wider community included:

- publishing the *Annual Report of Adverse Experiences for Pesticides 2005* http://www.apvma.gov.au/qa/subpage_qa.shtml
- presenting a paper titled 'APVMA—Adverse Experience Reporting Program for Agricultural Chemicals' at the Annual Meeting of the National Working Party On Grain Protection
- encouraged reporting through the networks of members of our Community Consultative Committee
- discussed the AERP *Ag* at an APVMA User Forum in March.

During 2006–07 the APVMA assessed and classified 56 adverse experience reports related to agricultural chemicals. In addition, numerous enquiries were received from members of the public. Adverse experience reports involving effects on crops accounted for approximately 66 per cent of the reports, and human adverse experience reports 34 per cent. Corrective actions are under way after assessment of the information received.

AERP *Vet*

Activities undertaken to raise awareness of the AERP *Vet* program and to advise the community of the potential risks associated with the use of veterinary chemical products included:

- publishing the *Annual Report of Adverse Experiences for Veterinary Medicines 2005* (http://www.apvma.gov.au/qa/aerp.shtml)
- publishing an article titled 'APVMA veterinary pharmacovigilance program: suspected adverse experience reports for 2005' in the *Australian Veterinary Journal* (2006) 158: 418–420
- publishing an article titled 'Ensuring safety in animal products' in *Dogs Life* July/August 2006
- presenting a paper titled 'Reporting adverse events in Australia' at the Australian Veterinary Association's (AVA) Annual Conference.

During 2006–07 AERP *Vet* assessed and classified 1993 reports, involving suspected adverse reactions in animals, received from veterinary surgeons, owners, members of the public and product registrants. In addition, numerous enquiries were received from both veterinarians and members of the public. Of the adverse experience reports, 83 per cent involved animal safety, 12 per cent involved lack of efficacy and 6 per cent involved human health issues.

Corrective actions taken include:

- recommendations to include a warning statement on a vaccine label product advising against concurrent use of other selenium containing products
- recommendations to include a warning statement on a vaccine label warning the user to avoid self-injection as the product contains a mineral oil and is very irritant.

The quality of the information provided in the reports was generally of a high standard, which in part reflects the good interaction between the APVMA and the veterinary profession and registrants.

Reporting adverse experiences online

In June, the APVMA launched a new online reporting facility for both veterinary and agricultural adverse experiences. You can submit reports at https://services.apvma.gov.au/AerpWebApp/

Feedback received from users indicates that the new reporting form is user-friendly, easy to fill in, and straightforward. The APVMA encourages chemical users and people that may have been affected by agvet chemicals to use this online reporting facility.

Strategy 2: Ensure industry compliance with the legislation, including maintenance of quality assurance programs

Performance

Quality Assurance Scheme for Agricultural Actives and Products (Ag QA Scheme)

The Compliance Team has continued the development and effective operation of the Ag QA Scheme during 2006–07. The scheme was introduced in 2004 to help ensure that the quality of active constituents used in agricultural chemicals products is maintained. Conditions of product registration were imposed requiring registrants to supply only products containing active constituents that conform to APVMA standards, and to keep batch production and supply records relating to active constituent quality. Product testing was also introduced to cross check the accuracy of record keeping.

Record inspection by monitoring visits and data call-ins

The Compliance Team conducted 30 company-monitoring visits that resulted in the inspection of 234 batch records of 115 products. The team also called in records for a desk-based review of a further 54 products and inspected 72 batch records.

The APVMA has used two approaches to monitoring records to ensure efficiency and effectiveness. At company visits monitoring is interactive, in that companies have the opportunity to present records during the audit. Data call-ins are not interactive, and data submitted is assessed once as the onus is on the registrant to submit full records. In both cases, submitted records are comprehensively reviewed for compliance with the APVMA standard, compliance with the data required by the registration conditions and the continuity of the data.

Table 13: Results of batch inspections under the Ag QA Scheme 2006–07

		Batch compliance with conditions of registration		
Type of check conducted (No. of products)	No. of batches	Met the APVMA Standard	Adequate records	Continuity
Monitoring Visit (115)	234	233	42	53
Desk-based review (54)	72	72	23	24
Total (169)	306	305 (99.7%)	65 (21%)	77 (25%)

Compliance with the conditions of registrations was categorised according to:

1. whether the batch fully complied with the conditions (i.e. met the APVMA standard, had adequate records and records showed continuity)
2. whether the recorded particulars showed that the batch met the APVMA standard
3. whether records of the batch were adequate to demonstrate compliance
4. whether the records showed continuity, i.e. that the active constituent batch analysis records could be linked to a particular batch of product supplied into the Australian market.

Record inspections did not uncover any significant failures. Of a total of 306 batches, 33 (11 per cent) fully complied with conditions of registration. Companies that either failed to keep any records or failed to submit records will be targeted for inspection again in 2007–08. One nonconformity detected involved a possible breach of the APVMA standard and none warranted escalated compliance actions such as product recall. In keeping with the focus on maintaining active constituent quality and not pursuing minor record keeping errors (89 per cent), we issued formal warnings to registrants who failed to submit adequate records or failed to establish continuity between records. Such warnings can include increased record inspections during the next inspection cycles.

A risk criterion used to determine the registrants selected for inspection in 2006–07 was non-compliance found during inspections conducted in 2005–06. Of the 30 registrants who were subject to a company monitoring visit in 2006–07, 23 had been subject to a record review the previous financial year and had failed to meet the conditions of registration. Of these 23 registrants, two registrants continued significant non-compliance and stronger enforcement actions are being pursued.

Product testing

The APVMA conducted testing of products ready for supply into the marketplace, to check on the accuracy of batch records submitted. During 2006–07 the Compliance Team supervised sampling of 85 products containing mancozeb, chlorpyrifos, quintozene or oxyflurofen. Testing of samples continues and preliminary results show a high level of compliance with the APVMA's standards for levels of toxicologically significant impurities for both quintozene and mancozeb. Further, the results highlight a high level of compliance within allowable variation in active constituents in formulated products. Results for other chemicals are pending.

The records presented by the registrants, kept as part of the conditions of registration, are in general supported by the analytical results. However, the APVMA carries out increased monitoring of company records where there is a significant difference between the analytical result and the batch analysis results reported by the registrant.

As part of the 2005–06 sampling and testing program, 16 products containing the active constituent, trifluralin, were selected for analysis. Testing of products containing trifluralin was completed in 2006–07. The results indicated non-compliance with the APVMA's standards for active constituent concentration in three products and non-compliant concentrations of the impurity N-nitrosodiisopropylamine (NDPA) in seven products. Repeat NDPA analysis by a different laboratory was complicated by formulation interference and further research would be needed to develop a method that would allow accurate NDPA measurement in formulated product. The APMVA has contacted all registrants on the outcome of the trifluralin program for their product, but has decided not to take action on the NDPA results. The APVMA has advised registrants, where testing has indicated non-compliance of trifluralin concentrations of their products, of the continuing need for vigilance in the quality of these products released to the Australian marketplace.

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 2006–07, 205 new reports were received and of these 73 per cent were assessed as low risk. Of 216 reports finalised this year, 144 reports were finalised through warnings and negotiated compliance. No reports were escalated to a product recall, one resulted in a visit to the company to monitor compliance, and six reports were referred to another agency. Seventy per cent of all non-compliance reports were completed within three months of receipt.

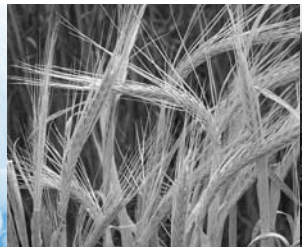
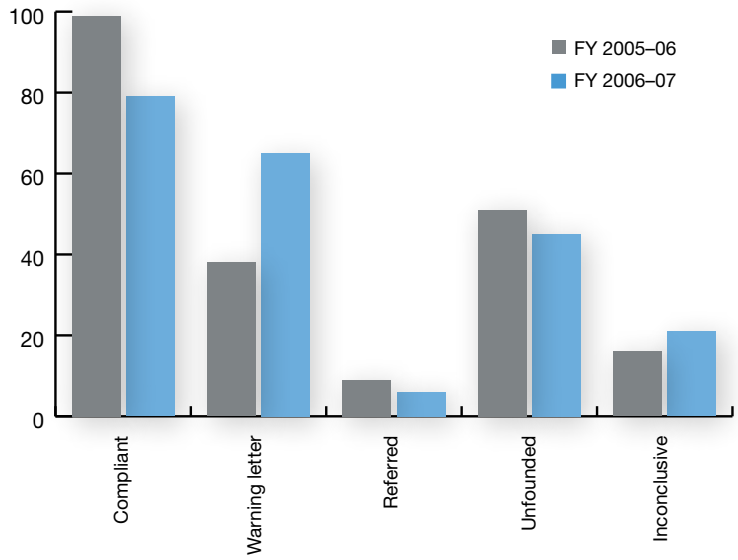
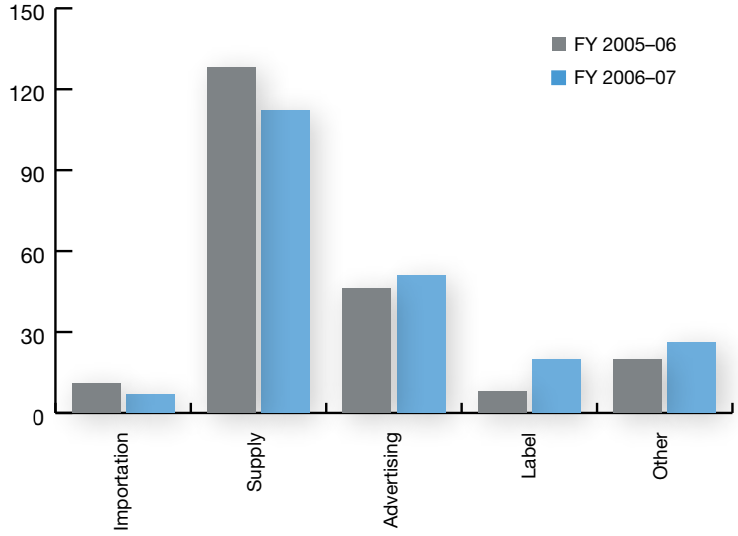




Figure 6: Outcome of inquiry into reports of non-compliance



- Unfounded: no offence committed
- Inconclusive: insufficient information presented
- Referred: to formal investigation, recall or another agency
- Negotiated compliance: 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

Figure 7: Offences recorded as a result of reports of non-compliance



Investigations and recalls

During 2006–07 the APVMA initiated one new investigation and continued with an investigation initiated in 2005–06. These investigations relate to alleged breaches of:

- section 69B of the Administration Act (Import an unregistered chemical product) and section 78 of the Agvet Code (Supply an unregistered chemical product)
- section 79 of the Agvet Code (Breach of a Condition of Registration), with respect to non-compliance with product conditions placed under the Ag QA Scheme. This investigation continues and is expected to be referred to the DPP in 2007–08.

As a result of an AQIS investigation into the use of an unapproved substance in fish farming, the DPP laid charges under the Administration Act for the importation of sodium nifurstyrenate. The defendant pleaded guilty at the Brisbane Magistrates' Court in May 2007 and was given a good behaviour bond without a recorded conviction.

The recall of five agricultural chemical products was in progress at the beginning of 2006–07. One recall was related to an unregistered pool ioniser product, and four due to manufacturing issues. During 2006–07, 12 more voluntary recalls were monitored. Five veterinary chemical products were recalled due to non-compliant formulation (three) and labelling errors (two). Seven agricultural chemical products were recalled due to non-compliant formulation (four), container issues (two) and a labelling error (one). By the end of the financial year, 14 recalls had been completed and three were in progress.

During the year, the Chemical Review Team reviewed the way in which 23 high volatile 2,4-D ester products and five methomyl products can be used. The 2,4-D product registrants accepted deed poll undertakings to meet their obligations to inform distributors and end users of the changes to the labels on these products, while the Compliance Team monitored the voluntary actions undertaken by methomyl product registrants, without needing to resort to more prescriptive measures.

Hormonal growth promotants

The EU requires continued assurance from Australia that beef and beef products imported by 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 2007 there were 271 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 that major corrective actions identified during the first visit have been carried out. During the year, the APVMA audited 62 HGP authorised suppliers (both retailers and wholesalers). Sixty per cent of the suppliers were found to be compliant on the first visit. Thirty-nine per cent were issued with a warning and subjected to more frequent audits. Eighty-seven per cent of suppliers were compliant when audited for a second time. One non-compliant audit has been referred for investigation and the remainder have been carried forward for completion in 2007–08.

Consent to import

The APVMA monitors the importation of agvet chemicals to limit the potential distribution of unregistered and unapproved chemicals in the Australian marketplace. In 2006–07 it conducted enquiries into six 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 382 applications and issued 332 Consents to Import. Of these, 133 were issued to allow importation for use under the APVMA general permit, 42 were issued with permit applications, 141 to veterinarians and 16 for other purposes. Fifty applications for consent were not approved or were found to be unnecessary.

Compliance Strategic Reform

This year the APVMA began reform of the tools available to take effective compliance action. An industry working group was formed to provide advice on proposals and the group met in February, March and April 2007. Following further working group consultation, a draft proposal will be made publicly available for wider consultation, before a policy proposal is provided to the Product Safety and Integrity Committee for consideration.

Publication of a new guideline on s161 obligations

In December 2006, the APVMA published a new guideline on the legal obligations of product registrants to report new information to the APVMA. This guideline sets out the types of information (including adverse experiences, chemical review data, changes to product details, recall information) that product registrants must submit to the APVMA and the mechanisms by which they can submit that information.

Manufacturers' Licensing Scheme (MLS)—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 Australian Code of Good Manufacturing Practice for Veterinary Chemical Products (GMP). Compliance is confirmed by regular audits by APVMA-authorised auditors or specified authorities recognised by the APVMA.

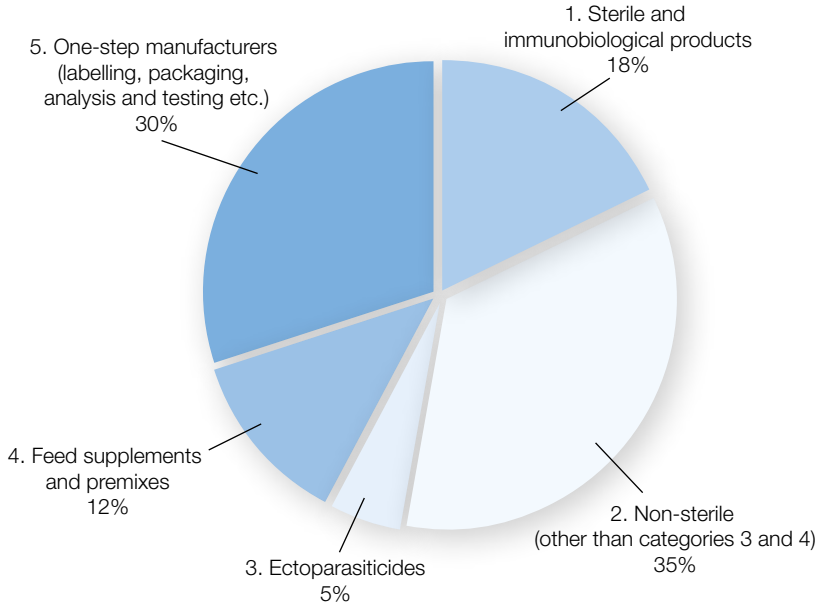
New manufacturing principles implemented

After consultation with industry over several years and a transition period of 12 months, the new Manufacturing Principles and the associated Australian Code of Good Manufacturing Practice for Veterinary Chemical Products took effect on 1 May 2007. They align the APVMA's requirements with contemporary international standards and provide greater transparency for both manufacturers and auditors. At the same time, the APVMA introduced revised audit reports and checklists to aid compliance with these manufacturing standards.

At 30 June 2007, 233 Australian-based manufacturers were licensed or being assessed for a licence. During the financial year, 28 new licences were issued and 49 variations to licences approved.

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 2007



The management of the MLS 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 at audit. In 2006–07 APVMA-authorised auditors conducted 66 audits and APVMA staff conducted one unannounced audit.

To ensure satisfactory audit closeout, the APVMA gave 27 notices of intent to suspend or cancel licences or to impose conditions. During the year, 31 licences were cancelled (24 voluntarily and seven imposed by the APVMA), and two were suspended. 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 March 2007 to explain the new manufacturing principles and the APVMA's desired approach to auditing. Feedback from licensed manufacturers concerning audits and auditors has continued to be very positive, with 96 per cent of manufacturers providing a rating of ≥7 (out of 10), based on a form completed at each audit.

The APVMA continued to provide assistance to manufacturers, primarily through feedback to enquiries and follow-up to audits. The operation of the scheme provides confidence that veterinary medicines are manufactured in Australia according to quality standards.

Imported veterinary products

The Overseas Good Manufacturing Practice Scheme assures the GMP compliance of overseas manufacturers of veterinary chemical products who supply veterinary medicines to the Australian marketplace.

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. Conditions of product registration are applied to ensure continuing compliance. During 2006–07, 151 overseas manufacturing sites were assessed for compliance with Australian manufacturing standards during the product application process. Of these, evidence from 40 sites was subjected to more detailed evaluation.

Post-registration compliance with conditions of product registration was monitored on 281 products and 86 per cent were found to be compliant on the first audit. Following further APVMA involvement, all were compliant after second audit, demonstrating confidence in the quality of veterinary products imported into Australia.

Australia has a mutual recognition agreement with the EU and the European Free Trade Association (EFTA), that both have a sectoral annex for medicinal products, GMP inspection and batch certification. These agreements continue to be monitored and maintained.

Export assistance

Many international 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 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 in the EU and the EFTA also accept certificates issued under the terms of two Mutual Recognition Agreements (MRAs).

During 2006–07, 115 export certificates were issued for compliance with Australian manufacturing standards. Of these, three were issued under the MRA with the EU.

Summary

APVMA activities throughout 2006–07 contributed to ensuring the continuing quality of pesticides and veterinary medicines available for sale in Australia. This has been achieved through 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.

Strategy 3: Respond to and manage emerging regulatory issues

APVMA audit by the ANAO

The ANAO conducted a performance audit of the APVMA in 2006. The audit was extensive and assessed whether the APVMA was delivering its key regulatory functions effectively. The ANAO examined APVMA arrangements for:

- planning and overseeing the delivery of regulatory functions
- registering pesticides and veterinary medicines in a timely manner
- obtaining external scientific advice to support the registration function
- monitoring the quality of pesticides and veterinary medicines approved for sale in Australia
- administering its cost recovery framework.

The ANAO audit report contained six recommendations dealing with:

- improved management of conflict of interest for advisory committees and service providers
- improving reporting and transparency of registration timeframe performance
- strategies for improving the quality of applications
- the arrangements for receiving scientific advice from government agencies
- improving the MLS
- optimising the management of throughput and transparency within the Chemical Review Program.

The report is available at
http://www.anao.gov.au/uploads/documents/2006-07_Audit_Report_14.pdf

The APVMA welcomed the report and agreed with all recommendations. The report acknowledges various initiatives that the APVMA has introduced in recent years to improve the effectiveness of its operations. However, the arena of chemicals regulation is constantly changing and the report provides valuable recommendations for further improvements.

The ANAO also conducts an annual financial audit of the APVMA (see Chapter 4 of this report).

The APVMA has developed a comprehensive plan to implement all the ANAO recommendations and its additional suggestions. Such an in-depth external audit provides confidence to stakeholders that the APVMA is effectively performing its responsibilities described in its governing legislation.

To date the APVMA has:

- strengthened conflict of interest arrangements for service providers
- formalised quality performance standards with its service providers through its contractual arrangements and service level agreements
- improved its arrangements for reporting on timeframes and began a schedule of audits to confirm and verify timeframe data
- designed mechanisms to monitor and record errors and omissions and budgeted resources for 2007–08 to facilitate systematic recording and analysis
- advanced contestability arrangements with Australian Government agencies and negotiated improved contractual arrangements
- improved the Manufacturers Licensing Scheme framework, by improving performance measurement. Mechanisms to improve the management of audits have been budgeted for 2007–08
- budgeted resources for 2007–08 to undertake an analysis of Chemical Review
- introduced new communications approaches for chemical reviews through the reviews of neomycin and carbendazim
- developed a memorandum of understanding with the States and Territories to strengthen operational arrangements.

Further detail on the APVMA's implementation activities is available on the APVMA website at www.apvma.gov.au/anao