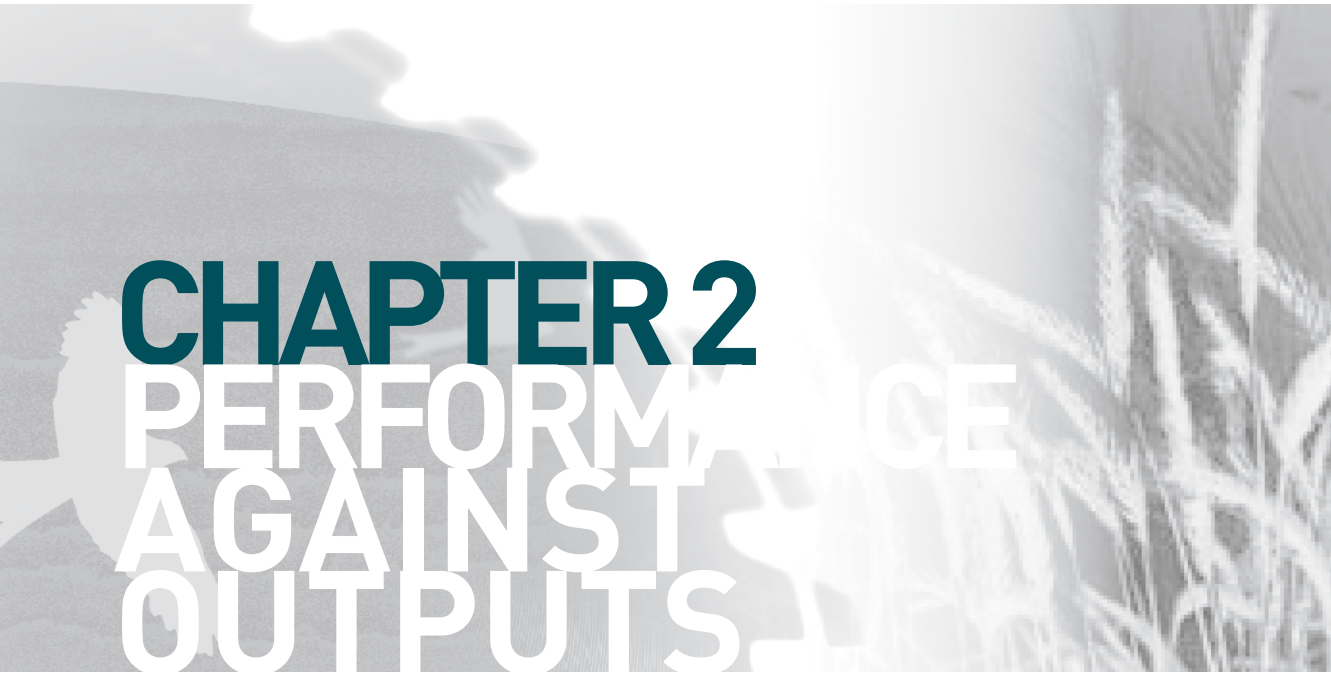


CHAPTER 2
PERFORMANCE AGAINST OUTPUTS

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 obtain approval for product container labels 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 it, 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 the evaluation of a product has shows that it is not likely to be harmful to target crops or animals, to users, consumers and the environment. The evaluation also has to demonstrate that the product is effective, suitably formulated and that its label contains adequate instructions. The APVMA must also assess whether using the product may unduly prejudice trade.

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

The APVMA uses 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*

The APVMA uses the highest quality standards of regulatory science to assess product applications. The authority also uses monitoring and reporting tools that allow it to identify classes of applications most likely to take a greater time to complete.

To maximise the efficiency of assessments, the APVMA also has a process reform program. During 2007–08 the APVMA continued the Elapsed Time Project which began in 2006–07. This project recognises that the APVMA needs to finalise applications in the minimum amount of elapsed time ('real time') so that applicants can have a degree of certainty about the projected date on which their applications will be finalised. It recognises the importance of the APVMA's procedures being efficient and an applicant's submission being complete and containing all the information that the APVMA needs to evaluate it.

During 2007–08 the APVMA began publishing a quarterly summary of statistics on timeframe performance on its website. These statistics show overall timeframe performance and show timeframe performance for five different groups of application categories, grouped by a common statutory timeframe. These statistics show that while a proportion of applications are finalised over the statutory timeframe, a much larger proportion of applications are finalised well under the timeframe.

Reducing elapsed time for applications

The statutory timeframe for evaluation of applications is set out in Schedules 6 and 7 of the Agvet Codes and depends on the nature of the application. The timeframe 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.

'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 elapsed time is usually longer than clock time because of 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.

In 2006–07 the APVMA began a project to reduce the elapsed time for applications. The APVMA discusses progress of the project at consultative meetings with the agvet chemicals industry.

Organisation restructure September 2007

During 2007–08 the APVMA made a number of changes to its structure and registration processes to reduce elapsed time for applications. The most important of these were:

- Chemistry and residues evaluators were relocated into the Pesticides and Veterinary Medicines registration programs to integrate them more closely into the overall evaluation of an application. The Good Manufacturing Practice Section was also moved for the same reason
- Three new positions were created for 'The Minors Team'—a team of three evaluators who handle applications made under Categories 6, 7, 8, 9, 12 and 13
- New Product Evaluator positions were created in Pesticides and Veterinary Medicines Programs.

Reforms and innovations to the registration process

- The APVMA introduced 'timeshift' for major applications. 'Timeshift' is a system of phased submission that allows applicants to submit an application for which not all the data are complete. This allows the APVMA to begin evaluation of the application much earlier than would otherwise be the case. As an example, the APVMA can start evaluating the chemistry and effectiveness of a new product before residues trials are complete.
- The APMVA started to manage major applications under a project management system, so that an applicant can have greater certainty of the projected time of registration and advance warning if the schedule is likely to be delayed.

Improvement in the quality of submissions

- In July 2007 the APVMA published a new edition of the *Manual of Requirements and Guidelines* (MORAG).
- In June 2008 the authority held a two-day registration seminar titled 'Back to Basics'. The seminar focused on helping applicants to improve the quality of submissions and so reduce elapsed time. One hundred and sixty people from the agvet chemicals industry attended the seminar.

Pesticide product applications approved

The Pesticides Program received approximately the same number of applications in 2007–08 as in 2006–07. The number of applications in progress carried over from the previous financial year was approximately 18 per cent higher in 2007–08 than in 2006–07 (1206 compared with 1019). However, by the end of 2007–08 the number of applications still in progress was approximately five per cent lower than in the previous financial year (1149 in 2007-08 compared with 1206 in 2006–07). (See Table 4 next page).

Finalisation against statutory timeframes has fallen since last financial year. Eighty-three per cent of applications were completed within the statutory timeframe during 2007–08 compared to 90 per cent during 2006–07.

Electronic Application Registration System (EARS)

This system offers industry and regulatory consultants the capability to electronically submit and monitor applications for the registration or variation of existing agricultural and veterinary medicines. In April 2008 the APVMA released the second version of EARS. This second release expands the number of application categories that can be submitted electronically (7, 8, 10, 12, 13 and 14). These categories account for 90 per cent of product applications that the APVMA receives.

This release also included several enhancements such as the access management module, which provides companies with the capability to give regulatory consultants access to view and/or submit applications on the companies' behalf.

This system streamlines the application process creating efficiencies for the APVMA and its applicants.

Table 4 Pesticide product applications for product registration or variation for 2007–08

APPLICATIONS	2007–08	2006–07	CHANGE FROM 2006–07 (%)
Commencing number of applications in progress	1206	1019	+18.4
Applications received	1543	1550	–0.5
Applications finalised	(284 (withdrawn) + 1265) 1549	1362	+13.7
Closing number of applications in progress	1149	1206	–4.7

During 2007–08, 284 applications received in screening during the year or previous years, were either withdrawn by the applicant or treated by the APVMA as having been withdrawn. This means that the APVMA did not accept these applications for evaluation. However, these applications are treated, for statistical purposes as having been finalised and so have been included in Table 5.

Table 5 Pesticide product finalisations for 2007–08

CLASS OF APPLICATION	TOTAL FINALISED	NUMBER IN TIMEFRAME	% IN TIMEFRAME	AVERAGE CLOCK TIME TO FINALISE	AVERAGE ELAPSED TIME TO FINALISE (MONTHS)
Received before 1 July 2005	0	0	-	-	-
2 to 3 months	1015	931	92	1.5	6.8
5 months	136	66	49	6.4	15.5
6 to 8 months	55	28	51	7.1	13.5
9 to 12 months	41	14	34	10.4	23.3
13 to 15 months	18	10	56	16.9	26.6
TOTALS	**1265**	**1049**	**82.9**		

The target for the APVMA is to complete all applications in timeframe. The initiatives within the elapsed timeframe project are also intended to address the shortfall in statutory timeframe. Applications that fall within the five- to nine-month timeframe, proportionally, have the longest elapsed times to finalisation. The causes of the long timeframes for finalising applications are being identified and solutions to reduce finalisation times are being sought.

Major pesticide assessments: New active constituents approved and major extensions of use

The APVMA considered and registered 12 new pesticides containing novel active constituents during 2007–2008. These new insecticides included products containing indoxacarb for the control of cotton bollworm and native budworm in azuki beans, cotton, chickpeas, faba beans, mungbeans and soybeans. Indoxicarb is also used for the control of green mirid in cotton, mirid complexes and soybean looper in azuki beans, mungbeans and soybeans. Other new actives approved were a methyl bromide replacement grain fumigant containing sulfuryl fluoride and a herbicide product, containing pyroxsulam combined with the established active constituent cloquintocet-mexyl, for the control of certain grass and broadleaf weeds in wheat. An acibenzolar-S-methyl cottonseed treatment product was also approved. This product has a novel mode of action to stimulate the plant's natural defence mechanisms against the diseases fusarium wilt and black root rot. Major crop extensions to currently approved label uses included registration of thiamethoxam for use in citrus and tomatoes, cyanamide in apples and metribuzin in sugarcane.

The APVMA must publish an advice summary as part of data protection requirements where, in making the decision to grant an application for registration of a new chemical product or approval of a label, it relied on advice received from external experts and other government specialist agencies that the authority consulted. In 2007–08, 99 advice summaries containing a detailed summary of expert advice received for pesticides applications were published on the APVMA's website.

During the financial year, the APVMA was actively involved in joint reviews or work sharing for assessments of new pesticide active constituents with several overseas regulatory agencies. Two new active constituents and associated products were completed as joint reviews with other international regulatory agencies. One joint pesticide review progressed to its final stages and another was begun. The APVMA has also been involved in the planning stages for five other proposed joint reviews, two of which are expected to start in 2008–09 (see 'International engagement' for more details).

Experience with joint reviews has led to the introduction of a pilot program to provide a planning approach to manage major applications with applicants over 12 to 15 months.

Veterinary medicine applications approved

The Veterinary Medicines Program received slightly less applications in 2007–08 than in 2006–07 and completed 22.5 per cent fewer, resulting in a greater number of applications in progress at the end of the year (see Table 6). Ninety-one per cent of the veterinary medicine product applications were completed within the statutory timeframes, compared with 94 per cent in 2006–07.

Table 6 Veterinary medicine product applications for product registration or variation 2007–08

APPLICATIONS	2007–08	2006–07	CHANGE FROM 2006–07 (%)
Commencing number of applications in progress	691	695	–0.6
Applications received	838	892	–6.1
Applications finalised	711	917	–22.5
Closing number of applications in progress	738	670	+10.1

During 2007–08, 77 applications screened during the year or previous years were either withdrawn by the applicant or treated by the APVMA as having been withdrawn. The APVMA rejected one application in screening. This means that the APVMA did not accept these applications for evaluation.

Table 7 Veterinary medicine finalisations for 2007–08

CLASS OF APPLICATION	TOTAL FINALISED	NUMBER IN TIMEFRAME	% IN TIMEFRAME	AVERAGE CLOCK TIME TO FINALISE	AVERAGE ELAPSED TIME TO FINALISE (MONTHS)
Received before 1 July 2005	1	1	100	0.5	66.4
2 to 3 month	513	507	99	1.0	5.8
5 month	137	93	68	5.3	12.8
6 to 8 month	32	27	84	6.1	17.8
9 to 12 month	20	14	70	7.6	26.5
13 to 15 month	8	5	63	12.0	35.7
TOTALS	**711**	**646**	**90.9**		

The target for the APVMA is to complete all applications in timeframe. The initiatives within the elapsed timeframe project are also intended to address the shortfall in statutory timeframe.

The 25 application categories are aggregated into statutory timeframe periods that are defined in Schedule 6 of the Agricultural and Veterinary Chemicals Code Regulations 1995.

Registration statistics can be found on the APVMA's website at http://www.apvma.gov.au/perfreporting/subpage_reporting.shtml.

Table 8 Description of product application categories

STATUTORY TIMEFRAME PERIOD	APPLICATION CATEGORY
2 to 3 months	Category 7, 8, 9, 12, 13, 14
5 months	Category 5, 6, 10, 14, 17, 18
6 to 8 months	Category 10,11, 14, 16
9 to 12 months	Category 10, 14, 15
13 to 15 months	Category 1, 10
Withdrawn	Treated as withdrawn by the APVMA, or voluntary withdrawal by the applicant
Cat 10	Cat 10 can be 5 to15 months, most commonly 6 to 8 months
Cat 14	Cat 14 can be 2 to 14 months, most commonly 5 to 7 months

Major veterinary medicine assessments: New active constituents approved

During 2007–08, the Veterinary Medicines Program registered a new antibiotic containing tulathromycin and vaccines containing avian influenza antigens and *Eimeria* spp. antigens. Halofuginone, an antiprotozoal agent, and the anthelmintic pyraclofos were both re-introduced into the pool of available veterinary medicines. The APVMA registered the first spinosad pour-on lousicide product for sheep.

Permits and minor uses

Pesticides

During 2007–08, 575 pesticide permits were finalised, of which 425 (74 per cent) were completed within the statutory timeframe. Approximately 70 per cent of finalised applications were for minor uses, 10 per cent for emergency uses and 30 per cent for research purposes.

During the year further progress was made in registering more minor uses, principally through enhancing proposals to move minor uses from current permits to product labels. Several active ingredients were examined during the year and current steps are being taken to have those considered for registration.

Veterinary medicines

During 2007–08 the Veterinary Medicines Program finalised 186 permit applications, of which 172 (93 per cent) were finalised within the statutory timeframe.

The majority of permits issued during 2007–08 were for extension of shelf life of a particular batch of products and for reissue or extension of previously issued permits.

Minor use permits were granted to producers in the aquaculture industry to administer antibiotics (oxytetracycline and florfenicol), adrenalin, hydrogen peroxide and formalin to finfish and salmonids. The APVMA also issued a minor use permit for use of calcium hypochlorite in abalone.

In September 2007 an outbreak of equine influenza occurred in New South Wales and subsequently spread to Queensland. Equine influenza is an exotic disease and no vaccine for the disease was registered in Australia. The APVMA was responsible for rapidly evaluating a number of applications from the DAFF for the issue of permits for the use of imported overseas-registered vaccines to combat the spread of the outbreak.

Chemistry and residues

When evaluating applications to either register products or grant permit approvals, 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 exposure assessment is conducted to establish if the use of a product on food crops and/or animals will be acceptable against relevant health standards, namely the Acceptable Daily Intake and the Acute Reference Dose. No product is registered unless the dietary exposures, assessed using internationally recognised methodologies, are found to be acceptable against the established health standards.

Communication of trade advice

Trade advice on labels is an essential part of the whole-of-food-chain quality assurance process. It enables the livestock producer to accurately complete the National Vendor Declaration under Meat and Livestock Australia's Livestock Production Assurance Scheme. The APVMA sets Export Slaughter Intervals (ESIs) with the registrant and the relevant producer industry. In 2007–08 the APVMA continued its initiatives to enhance communication of trade risk advice. 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. The APVMA has been a participant with DAFF in consultative meetings addressing the issue of mandatory display of trade advice on product labels.

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.

The APVMA held workshops in March 2006, March 2007 and November 2007 with stakeholders to gain their support for the new statistical approach, demonstrate the advantages of the prototype software, and to present APVMA policies for determining the target concentrations of residues that are used in setting ESIs.

Stakeholders included representatives from government authorities, animal production industries, the animal health industries, regulatory consultants, and academic and research institutions.

Stakeholders strongly supported further development of the software for a version that could be made available to help them prepare applications for ESIs.

Active constituents approved

During 2007–08, 101 approvals for active constituents (including new actives, variations and new sources) were granted of which 60 per cent were granted within statutory timeframes.

Maximum residue limits

The APVMA evaluated residue data for 51 applications for product registration, 92 for permits and 11 for emergency permits, producing 516 amendments to the MRL Standard.

Japanese Positive List Project

The Japanese Positive List is a five-year project that was started in 2006–07 through DAFF with support from relevant industry organisations. The aim of the project is to provide information to the Japanese Ministry of Health, Labour and Welfare (MHLW) to support the establishment of MRLs in Japan based on Australian use patterns and registrations.

Before the project began, a delegation from DAFF, including an APVMA officer, visited several Japanese government departments involved in the positive list process. In 2007–08 the APVMA provided information to support MRLs for 23 agricultural chemicals and three veterinary medicines as well as 43 toxicology reports.

Pesticides Residues Section hosts visitor from Taiwan

In November 2007 the Bureau of Food Safety, Department of Health, Taiwan requested that the Australian Government provide assistance with training in residues risk assessment principles. A training program was agreed through the International Division in DAFF and Dr Yi-Ting Kao joined the APVMA's pesticides residues section for eight weeks in April and May 2008. During that time, Dr Kao became familiar with internationally recognised methodologies for MRL setting, the assessment principles of JMPR and JECFA and dietary modelling methods used by FSANZ and the APVMA. Dr Kao also participated in a field trip and an audit organised by AQIS, gained knowledge of the APVMA's registration processes and the national registration scheme including links with state and territory governments.

Alignment of MRL processes with FSANZ

In 2007–08 the APVMA worked with FSANZ, to streamline the transfer of MRLs into the Food Standards Code. This occurred in association with legislative changes to the *Food Standards Australia New Zealand Act 1991* that took effect from 1 October 2007.

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 of the APVMA's scientific strength
- effectively manage science-related issues and projects in the APVMA.

Dr David Loschke, Principal Scientist for Agricultural Chemicals and Dr Phil Reeves, Principal Scientist for Residues and Veterinary Medicines, both made progress in each of these areas during 2007–08.

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 and new trends in risk assessment are used to guide special, ongoing training for scientific staff within the APVMA.

For the Pesticides Program during 2007–2008, spray drift risk assessment training was emphasised to coincide with the implementation of a number of improved risk assessment methods. Dr Loschke undertook most of this as in-depth, one-on-one training with residue specialists within the APVMA. Dr Loschke and Dr Andrew Hewitt, APVMA Science Fellow for spray drift risk assessment, also delivered special training to chemical risk assessment staff within the Department of the Environment, Water, Heritage and the Arts (DEWHA).

During 2007–08, Dr Phil Reeves collaborated with the Manager, Application Management and Enquiries, Mr David Dawson, to deliver scientific training relevant to all staff. Under the program, APVMA scientists presented a series of seminars on a range of topics (see box). The training addressed fundamental and applied sciences relevant to agvet chemicals to provide an appreciation of the science underpinning the APVMA's regulatory activities. As well as explaining the basis of data requirements and highlighting the complexity of many submissions, the training reinforced the importance of the role of each team member in ensuring that the APVMA meets the expectations of industry and the community.

Associate Professor Gordon Howarth also presented sessions to Veterinary Medicine Evaluators on probiotics and recombinant growth factors, subjects that are directly relevant to the work of the Veterinary Medicines Program.

Scientific Training for Staff

NAME	TRAINING TOPIC
Dr Phil Reeves	Interspecies differences between ruminants
Mr Alan Norden	Minor use and permit applications
Dr Jamie Nicholls	Adjuvants
Dr David Loschke	Application methods for agricultural chemical products
Dr Phil Reeves	Nanotechnology
Dr Robert Munro	Processes for setting maximum residue limits
Dr Joan Ashton	The atrazine review
Mrs Annelies McGaw	Plant anatomy
Dr Ken Young	Genetically modified organisms

Increase domestic and international awareness of the APVMA's scientific strength

In 2007–08 Dr Loschke made two overseas presentations, one to an OECD meeting on biocides and another to an international agricultural chemical forum. He was also invited to deliver presentations, mainly on the subject of spray drift, to other national conferences in Australia.

Dr Loschke also obtained agreement from the OECD (Working Group of National Coordinators of the Test Guidelines Program) that the APVMA's own guide for demonstrating efficacy of pool and spa sanitisers is suitable as the model for an international OECD guidance document. The APVMA guide, now revised into a draft OECD guidance document, will be reconsidered for final approval in the coming financial year.

Dr Reeves served on the Board of Examiners of the Australian College of Veterinary Scientists and was a guest lecturer at the University of Sydney, Charles Sturt University and Monash University. Dr Reeves had three book chapters accepted for publication and served on two editorial boards. As the Australia and New Zealand representative on the International Committee for Harmonisation of Veterinary Drug Registration Requirements (VICH) Expert Working Group on metabolism and residue kinetics, Dr Reeves participated in the drafting of four guidelines aimed at harmonising the data requirements for metabolism and residue studies for veterinary drugs.

Effectively manage science-related issues and projects in the APVMA

Dr Loschke submitted a final draft of the APVMA spray drift discussion paper as well as an accompanying Regulatory Impact Statement for a final round of public consultation. Written submissions received following the consultation period were considered and a final version of the document was prepared for publication in late June 2008 to mark the beginning of full implementation of the refinements described in the discussion paper.

Dr Reeves advised the Executive Management team about regulatory science considerations involving a number a number of complex and contentious matters during 2007–08. One of these matters was the regulation of agvet nanomaterials in Australia. Dr Reeves developed a roadmap of activities, which was adopted and substantially progressed during the year (see *Nanotechnology*, below). Dr Reeves, in collaboration with the Manager, Regulatory Reform, Dr John Paul, initiated a project aimed at further improving the quality of regulatory science at the APVMA. The six members of the APVMA Graduate Program are delivering the project and substantial progress was made in the first half of 2008 (see ***Graduate Program Project***, below). A risk management framework for regulatory science has also progressed during the financial year.

Nanotechnology

The APVMA is undertaking preparatory work on nanoscale technology and its applications that includes:

- reviewing the APVMA's existing regulatory framework for nanoscale agvet chemicals
- amending APVMA registration application forms to 'trigger' the inclusion of nanoscale agvet chemicals
- participating in multi-agency workshops on the risk assessment of nanoscale materials
- arranging nanoscale technology awareness training for APVMA scientific staff.

Up to 30 June 2008 the APVMA had not received any applications for agvet chemical products containing nanoscale materials, however, the agency continues to develop guidelines in preparation for the regulation of products of nanoscale technology.

The APVMA participates in the whole-of-government National Nanotechnology Strategy led by the Australian Office of Nanotechnology, within the Department of Innovation, Industry, Science and Research. One aspect of the APVMA's preparatory work is to collect information on the availability of nanoscale agvet chemical products in Australia.

A need has been identified for new data requirements to enable testing agencies to conduct appropriate risk assessments to ensure that nanoscale agvet chemical products coming on to the market are safe and effective.

The APVMA Science Fellows

An important component of the Regulatory Science Program is the appointment of eminent national and international scientists with the primary objective of enhancing regulatory science quality in the APVMA and to build public confidence in the APVMA. Science Fellows provide great value to the agency by offering their specialised knowledge and expertise in a wide range of scientific and professional fields that relate to areas of science to which the APVMA may not otherwise have access. The Science Fellows Program delivers scientific training to the authority and provides high-level independent scientific advice when required.

The APVMA's Science Fellows and their fields of expertise are listed in Table 9.

Graduate Program Project

Graduates within the APVMA are undertaking a project to enhance the quality of regulatory science. The project comprises three phases, the:

- appointment of new, and the reappointment of existing, Science Fellows and development of rules of engagement between the APVMA and the Science Fellows
- establishment of an expert advisory group, and
- convening of a second animal health science symposium.

The first phase of the project includes developing rules of engagement that will provide structure and enhance the performance of the existing APVMA Science Fellows Program. The second phase of the project will be to establish an expert advisory group that will provide the APVMA with access to high-level scientific experts. This initiative will enhance the accountability of regulatory science decisions the APVMA makes on complex and contentious issues. The third phase of the project will be to coordinate a second animal health science symposium that will continue to build stakeholder and community understanding of the complex scientific issues that underpin regulatory decisions that the APVMA makes.

The Graduate Program Project will enhance stakeholder confidence and community awareness of the APVMA regulatory scientific assessments.

Table 9 The APVMA's Science Fellows as at 30 June 2008

SCIENCE FELLOW	EXPERTISE
Emeritus Professor Jock McLean	Toxicology of Veterinary Drugs
Professor Brian Priestly	Toxicology of Pesticides
Professor Terry O'Neill	Statistics
Dr Andrew Hewitt	Spray Drift Risk Assessment
Dr Dieter Arnold	Residues of Veterinary Drugs in Foods
Dr Margaret Doherty	Pharmaceutical Sciences
Dr Peter Young	Veterinary Vaccinology and Biotechnology

Advice from external agencies

Through evaluating applications for registration, the APVMA receives advice from various Australian, state and territory government agencies on human toxicology, occupational health and safety, the environment, product effectiveness, target animal and crop safety and genetically modified products and organisms. Service Level Agreements (SLAs) or Memorandums of Understanding (MOUs) are in place between the APVMA and agencies to ensure that advice is cost-effective, accountable and has relevant performance measures.

Throughout 2007–08 the APVMA maintained and revised its SLAs with DEWHA and the Office of Chemical Safety (OCS) in the Department of Health and Ageing (DoHA) for scientific assessment services. Services include assessments for registration and permit applications, assessments of chemicals under review and other professional advice. The DEWHA delivered 88.3 per cent of application assessments within timeframe and the OCS 98.8 per cent.

The APVMA maintained its MOU with the Office of the Gene Technology Regulator (OGTR) in 2007–08. 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 medicines. The APVMA also provides comment on relevant draft risk assessments that the OGTR prepares.

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.

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

Performance

Initiatives

Since 2005–06 the APVMA has implemented a public affairs strategy that has three main elements:

- building recognition of the APVMA as an authoritative source of information on chemical issues
- strengthening brand values through higher standards of presentation and consistency
- building an enhanced stakeholder focus.

During 2007–08 this strategy continued to inform activities that were designed to engage stakeholders to improve awareness, inform policy development and optimise the regulatory framework within which the APVMA operates.

The agency's capacity to engage stakeholders was strengthened in 2007–08 through a restructure under which a new position to manage the APVMA website was created. The secretariat unit was also moved to the Public Affairs team as part of the restructure. The creation of the secretariat unit has allowed the APVMA to provide centralised, professional support to all the agency's external consultative bodies including the APVMA's Advisory Board, the Industry Liaison Committee (ILC), the Registration Liaison Committee (RLC), the Industry Technical Committee (ITC) and the Community Consultative Committee (CCC).

Stakeholder engagement strategy

In 2007–08 the APVMA began a stakeholder engagement strategy to refine existing engagement practices. A feature of the work to date has included stakeholder analysis and active consultation with stakeholder groups to confirm assumptions and proposals. A feature of this emerging strategy involves communication and engagement practices tailored to the specific

needs and requirements of different stakeholder groups. It is expected that the strategy will be completed in 2008–09.

Activity Based Costing (ABC) project

A comprehensive Activity Based Costing (ABC) project has been completed in preparation for the scheduled review of the Cost Recovery Framework. The objective of the ABC project was to establish the current cost of the APVMA's activities and to use the information to support the review of the cost recovery framework.

The current cost recovery framework was established in March 2005. The review of this framework will be concluded during 2008–09 with any changes in fees and levy (subject to the required legislation and regulation changes being in place) anticipated for 2009–10.

The review flows from the whole-of-government requirement that agencies review their cost recovery arrangements at least once every five years. The *Australian Government Cost Recovery Guidelines July 2005* provide the key principles for implementing the cost recovery policy.

Extension of visual branding

In 2006–07 the APVMA adopted a visual branding scheme for its new building at Symonston, ACT. This multifaceted scheme takes its inspiration from a colourful mural in the foyer. The mural depicts a range of Australian environments from the desert to the coast. In 2007–08 this branding was applied to corporate stationery and publications. One of the most distinctive features of this extension has been the development of covers for flagship, business and internal publications. The effect of this work and related initiatives such as the use of standard fonts, layouts and editing processes, will be to deliver stakeholder publications of a consistent quality and visual standard.

Enhancing electronic communication

The APVMA website is becoming increasingly important, not only as the authority's primary source of information for stakeholders, but also as a platform for various technological tools designed to provide services to registrants. Consistent with the strategy of ensuring that the website continues to meet stakeholder needs, a major project was implemented in 2007–08 to improve its structure. Significant research was undertaken with various stakeholder groups to identify the information each seeks, logical ways of grouping information and the search strategies they typically use in seeking information. This research project has generated a potential new structure for the APVMA website that will be considered for implementation in 2008–09.

Communicating regulatory decisions

The APVMA further enhanced its communication of regulatory decisions during 2007–08 particularly on the outcomes of chemical reviews. Recognising that these decisions impact on many stakeholders, particular effort was made to ensure that information was distributed through a number of information channels. Letters, media statements, direct contact, email newsletters and web postings are now part of the standard communication repertoire.

The media play a very important role in communicating the APVMA's regulatory decisions and other APVMA information. During 2007–08 significant effort was made to maintain relationships and develop media-friendly support materials available via the APVMA's website. Eight media statements with background information were released on the outcomes of the dimetridazole, 1080 and atrazine reviews and on compliance activities related to the Imtrade issue. These generated significant media interest. The APVMA also responded to general media enquiries and placed an open letter in the *Sydney Morning Herald* in response to factual inaccuracies in a special series on chemicals.

Registration seminar

From 12 to 13 June 2008, the APVMA held a *Registration: Back to Basics* seminar to update registrants on recent changes to registration requirements such as new application categories and fees, data protection, electronic labels and the introduction of EARS.

The program included four introductory presentations and 24 workshops divided into streams of pesticides, veterinary medicines, data requirements, and registration and communications. A selection of the most popular workshop topics was repeated throughout the two days of each workshop.

One hundred and sixty three people from 114 companies attended the registration seminar. Presenters included APVMA staff and representatives from DAFF, Office of Chemical Safety, DEWHA and members of the APVMA's ILC.

Stakeholder engagement

Stakeholder engagement is a significant activity for the APVMA and is crucial for maintaining the confidence and respect of the community, growers, the chemicals industry, our government colleagues and our fellow international regulators.

The APVMA engages its stakeholders through providing information, consultation designed to elicit particular views, involvement of stakeholders in decision making and, occasionally, through collaboration with regulatory peers.

The agency has actively provided information to stakeholders on the outcomes of regulatory decisions and processes through the monthly *APVMA Gazette*, the fortnightly *Regulatory Update*, media statements, its website, various special purpose publications, presentations and meetings.

Seminars and meetings are particularly important means of information exchange. During 2007–08 the APVMA not only hosted and organised a range of issue-based forums and seminars, but made a significant number of presentations at industry conferences and meetings.

Table 10 APVMA presentations

DATE	EVENT	TITLE
July 2007	Tramp Ant Strategic Management Committee	*APVMA Activities Related to Tramp Ants in the Past and in the Future*
July 2007	Gradlink Recruitment, Coffs Harbour, NSW	*About the APVMA*
August 2007	Gradlink Recruitment, Albury, NSW	*About the APVMA*
August 2007	Gradlink Recruitment, Perth, WA	*About the APVMA*
August 2007	Grains Industry Chemicals Training Workshop	*Training for High Risk Pesticides*
September 2007	Invited lectures, University of Sydney, Sydney, NSW	*Chemical Food Hazards*
September 2007	OECD Task Force on Biocides, Paris, France	*APVMA Pool/Spa Sanitiser Efficacy Guide for International Use*
September 2007	IIR Life Sciences AgChem Forum, Berlin, Germany	*The APVMA's International Activities*
October 2007	Food Safety Commission, Japan	*Pesticides and Veterinary Medicine Regulation in Australia*
October 2007	NVRQS Veterinary Drug and Biological Division, Korean Society of Veterinary Pharmaceutics	*Regulation of Veterinary Medicines*
October 2007	Biological Farmers of Australia Biological Inputters Meeting, Brisbane, Qld	*Minor Use Liaison Office*
October 2007	Hazelnut Growers of Australia Annual Conference, Mudgee, NSW	*Chemical Permits for Minor Crops*
October 2007	2,4-D stakeholder meeting, Perth, WA	*2,4-D Review*
November 2007	Comcover Awards for Excellence, Canberra, ACT	*Application of Balanced Scorecard to Risk Management and Monitoring*
November 2007	Comcover Awards for Excellence Presentation Ceremony, Canberra, ACT	*Application of Balanced Scorecard to Risk Management and Monitoring*
November 2007	Inaugural Meeting of the Network of Key Weed Scientists Researchers, Adelaide, SA	*Role and Function of the APVMA*
November 2007	1080 review stakeholder meeting, Melbourne, Vic.	*1080 Review*
November 2007	Atrazine review stakeholder meeting, Laverton, WA	*Atrazine Review*
November 2007	Global Animal Health Conference of the Drug Information Association, London, England	*Creating a Positive Environment for International Harmonisation*
December 2007	Global Minor Use Summit, Rome, Italy	*OECD Expert Group on Minor Use*
January 2008	6th International Fresenius Conference on Food Safety and Dietary Risk Assessment, Darmstadt, Germany	*Livestock MRLs and the International Situation*
February 2008	Meeting with Aquaculture Delegation from Vietnam at DAFF, Canberra, ACT	*The APVMA's Role in Regulating Chemical Use in Australia*
February 2008	Agribusiness Crop Updates Conference, Perth, WA	*Pathways to Registration*

February 2008	Atrazine review stakeholder meeting	*Atrazine Review*
February 2008	Invited lectures, Charles Sturt University, Wagga Wagga, NSW	*Residues of Ectoparasiticides in Sheep Tissues*
February 2008	Public Affairs in the Public Sector Conference, Sydney, NSW	*Managing the Regulator's Challenge: Putting Stakeholder Engagement and Reputation Management to Work in Government*
February 2008	CPA Public Sector Standards and Reporting Conference	*Minimising Adverse Impacts and Maximising Opportunities through Strategic Risk Management*
March 2008	Strategic Corporate Governance in the Public Sector, IIR Australia, Melbourne, Vic.	*Using Strategic Corporate Governance to Increase Operational Speediness and Accountability*
March 2008	CPA Public Sector Standards and Reporting Conference, Canberra, ACT	*Minimising Adverse Impacts and Maximising Opportunities through Strategic Risk Management*
March 2008	Strategic Corporate Governance in the Public Sector, IIR Australia, Melbourne, Vic.	*Using Strategic Corporate Governance to Increase Operational Speediness and Accountability*
March 2008	ChemCert Annual Conference, Dookie College, Vic.	*The APVMA's Spray Drift Control Framework*
April 2008	Turf Field Day, CanTurf, Fyshwick, ACT	*Minor Use*
April 2008	Invited lectures, Monash University, Melbourne, Vic.	*Veterinary Dosage Forms and Delivery Systems*
April 2008	Meat and Livestock Australia Commodity Vendor Declarations (CVDs) or By-Product Vendor Declarations (BVDs) Meeting, Sydney, NSW	*Revision of Commodity Vendor Declaration Forms*
April 2008	Public Relations Institute of Australia, Canberra, ACT	*Managing the Regulator's Challenge: Putting Stakeholder Engagement and Reputation Management to Work in Government*
May 2008	Joint Government Industry Meeting on Antifoulants in Aquaculture, Hobart, Tas.	*Permits for Copper Based Paints in the Tasmanian Aquaculture Industry*
May 2008	DAFWA, Canberra, ACT	*Adverse Experience Reporting Program for Agricultural and Veterinary Medicines*
June 2008	National Working Party on Grain Protection Meeting, Newcastle, NSW	*APVMA Regulatory Update*
June 2008	VMDA Board Meeting, Canberra, ACT	*The Regulatory Environment*
June 2008	Regulators Risk Assessment Workshop on Nanotechnology, FSANZ, Canberra, ACT	*Regulation of Agvet Nanomaterials—An APVMA Perspective*
June 2008	NSW Legislative Council Standing Committee on State Developments Inquiry into Nanotechnology in New South Wales	Expert Witness
June 2008	APVMA Registration Seminar, Canberra, ACT	Various
June 2008	OECD Expert Group on Minor Use, Paris, France	Australian Chair
June 2008	OECD Registration Steering Group Meeting and Risk Reduction Steering Group (RRSG) Meeting	*Spray Drift Risk Assessment at the APVMA*

The APVMA actively consulted with stakeholder groups on a wide range of issues throughout 2007–08. Views were routinely sought on registration matters through the use of Public Release Summaries and Trade Advice Notices, on policies and guidelines, on review issues and on program specific matters.

The APVMA also actively encouraged stakeholder participation in decision-making through its five formal consultative bodies: the Advisory Board, the Registration Liaison Committee, the Community Consultative Committee, the Industry Liaison Committee and the Industry Technical Committee. These committees considered a range of issues of issues during the year (see Appendix B).

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

Performance

At 30 June 2008, the Chemical Review Program had 32 ongoing reviews, compared with 30 in 2006–07. Eleven of these are comprehensive reviews, covering all aspects of the active constituent, product and labels (see Table 11). The remaining reviews focus on more specific aspects of products and/or their labels.

Chemical reviews

During 2007–08 the APVMA finalised reviews of atrazine and sodium fluoroacetate ('1080'). Both comprehensive reviews covered all aspects of the use of these chemicals, as pesticides in Australia and both were the focus of significant national and international attention. Although the target of five review decisions was not met, chemical review focused on resetting priorities and greater transparency as well as taking review activities forward through other channels.

Summary of the status of key chemical reviews

Details of activities related to key review chemicals are summarised below.

1080

Sodium fluoroacetate, commonly known as '1080' is an important chemical, not only for primary producers but also for state/territory government's management of pest animal populations. It 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 plays an important role in biodiversity conservation.

Table 11 Chemicals under review in 2007–08

2,4-D	Diuron	Neomycin
Atrazine (c)	Fenamiphos (c)	Omethoate
Azinphos-methyl (c)	Fenitrothion	Paraquat (c)
Carbaryl – part 2	Fenthion (c)	Parathion methyl (c)
Carbendazim/thiophanate-methyl	Fipronil	Polihexanide
Chlorfenvinphos (c)	Macrolide antibiotics	Procymidone
Chlorpyrifos (c)	Maldison (malathion)	Sheep ectoparaciticides
Diazinon (c)	Methamidophos	Sodium fluoroacetate
Dichlorvos	Methidathion	Temephos
Dimethoate	Methiocarb (c)	
Diquat (c)	Molinate	

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

The review was undertaken to address concerns over the accidental poisoning of non-target animals. The reviews confirmed the continued registration of use subject to tighter controls. This outcome enables state/territory governments, farmers, graziers and the forestry industry to continue to use the product to help restore and maintain biodiversity, while environmental and animal welfare groups can now be confident that, with the more extensive label instructions, the risk of poisoning of non-target animals has been significantly reduced. The final review report and regulatory decisions were released to the public in January 2008.

Atrazine

The atrazine review was completed in the context of a variety of views from different stakeholder groups. The final *Atrazine Review Findings and Regulatory Decision* report, dated March 2008, was published on 1 May 2008. The review affirmed the active constituent and required registrants to amend label instructions for newly manufactured stocks of products containing atrazine to reflect the outcomes of the review. Amended label instructions were introduced intended to further reduce the risk of atrazine entering waterways. Updated information on withholding periods, and additional information on how to report herbicide resistance was also introduced.

The APVMA also considered that the risk of atrazine entering waterways at harmful levels when used post-emergence on triazine-tolerant (TT) canola on raised beds may be unacceptable. This concern was based on limited information that became available after 2004. The APVMA has asked registrants to generate additional data so that it can further evaluate this concern. Registrants, who have a product with a label that continues to specify a claim for weed control on TT canola, are required to generate additional data. Products from other registrants must include a label restraint that specifies that atrazine must not be used post-emergence on TT canola grown on raised beds.

Bifenthrin

While a formal review of bifenthrin was not conducted, the Review Section took regulatory action to remove certain bifenthrin products from the market, because of health and safety concerns. Bifenthrin is an agricultural insecticide used for the control of borers and termites in timber, insect pests in agricultural crops and turf, as well as for general pest control. These concerns related to the availability of small pack sizes of bifenthrin products whose relative toxicity exceeded those of chemicals intended for domestic use. This regulatory action was completed in March 2008.

Other Reviews

Other review outcomes completed this financial year include publication of a Preliminary Review Findings (PRF) report on dichlorvos that was released for public consultation in June 2008 and progress with the review of temephos. Although OH&S concerns about the use of propetamphos for sheep dipping and jetting led to a formal nomination for review, the review has not begun because there are currently no products registered for this use on the Australian market.

Rationalisation and reprioritisation of review nominations list

Agricultural and veterinary medicines nominated for APVMA review have been given an order of priority according to the level of concern that led to the chemical being nominated. The priority given to chemicals is based on advice received from the APVMA's external advisory agencies—DEWHA and the OGTR, as well as from the APVMA's own residue chemists. The Priority Candidate Review List (PCRL) is located at http://www.apvma.gov.au/chemrev/Nominations.shtml.

Expanding and updating the APVMA's review website

In 2007–08 the Chemical Review Team continued 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.

Updating labels of grandfathered products

A project to update labels of grandfathered products was started in 2000 to cover all those products that were registered under the transitional arrangements between the Australian Government and the states and territories that existed at the time of the creation of the APVMA (then the NRA) in March 1995. It had been identified that these products did not have labels that complied with the current labelling requirements and/or may have changed formulation and product details without a formal application being made to the APVMA.

The majority of registrants updated their product labels and provided formulation details as the APVMA requested during 2000–03. In 2007 a group of 192 products were removed. More than 100 of the remaining products have been updated or voluntarily cancelled. Of the remaining products, the majority will be finalised in 2008–09, with only a small number requiring regulatory action to be undertaken to address outstanding issues.

Other projects

Pesticides management in schools

On a number of occasions the APVMA has been asked to respond to concerns about pesticide use in schools. The authority is developing a website publication to address community concerns and 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 provides 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 sought input from state and territory departments of education before preparing a final advisory document which can be accessed on the APVMA website (http://www.apvma.gov.au).

International engagement

Organisation of Economic Co-operation and Development

The APVMA has attended and participated in the Organisation of Economic Co-operation and Development (OECD) Working Group on Pesticides, the Task Force on Biocides and the Biopesticides Steering Group.

The authority has been the lead agency on several international workgroups dealing with minor use, efficacy guidelines for pool and spa sanitisers, and an international scientific advisory committee on residues and provision of pre-registration advice.

OECD Joint Reviews and Work-Share Activities

This financial year, the APVMA completed one joint pesticide review, progressed one to its final stages, and began another two joint reviews of new active constituents and their formulated products. Of the two joint review activities commenced, one is a trilateral review undertaken with the US Environmental Protection Agency and the Pest Management Regulatory Agency in Canada, while the second project involved the US, Canada, the European Union (EU) and New Zealand. The role of the APVMA and its advisory agencies in these joint reviews is in the capacity of primary reviewer

for some assessments and secondary reviewer for other assessments. The APVMA has also been involved in the planning stages for another five proposed joint reviews, two of which are expected to begin in 2008–09. The APVMA has continued to participate in the OECD Ad Hoc Exchange Program of review reports, by sharing and receiving assessment reports with chemical regulators from other OECD member countries.

International engagement and minor use

Many international activities focusing on finding solutions for minor uses were held during the financial year, within the OECD and the FAO.

The APVMA, as chair of the recently formed Expert Group on Minor Uses (EGMU), continued to work with member countries to develop the Terms of Reference and Programme of Work for EGMU. The group met via teleconferences and held a face-to-face meeting in June 2008. Key areas being addressed in the programme of work cover technical, policy and cooperation activities associated with minor uses including minor use definitions, minor use gaps and data availability, data requirements for efficacy and crop safety and regulatory incentives.

In December 2007 an Australian delegation attended the first Global Minor Use Summit, organised by FAO in Rome, Italy. Approximately 300 delegates from 60 countries attended the summit. Representatives from the APVMA were involved in the Summit Planning Committee. Australia, as chair of the OECD Expert Group on Minor Uses, presented activities of that group. Key action items arising from the summit focused on activities to help developing countries and enhancing the global regulatory approval of minor uses via data sharing and capacity building. Recommendations from the summit were presented at the 40th Session of the Codex Committee on Pesticide Residues held in China in April 2008. The committee agreed to the establishment of an electronic working group chaired by the United States and co-chaired by Australia and Kenya. The aim of the group is to provide guidance to facilitate the establishment of Codex MRLs for minor uses and specialty crops.

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) work progressing

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a trilateral (EU-Japan-USA) program aimed at harmonising technical requirements for registration of veterinary products. Australia and New Zealand have observer status at VICH meetings and an APVMA officer currently represents Australia and New Zealand.

The APVMA's Dr Phil Reeves attended a VICH meeting in Japan in October 2007. Dr Reeves represents Australia and New Zealand on a VICH expert working group that is developing new guidelines on assessment of drug residues in animal-derived foods.

Codex Committees

Joint Meeting on Pesticide Residues in Food (JMPR)

The JMPR is an international scientific expert group jointly administered by the FAO and WHO. In September 2007 an APVMA officer attended as an invited expert member of the WHO Toxicology Panel of the JMPR. Another officer was a peer reviewer for the FAO Residues Panel of the JMPR.

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. The CCPR met in April 2008. An APVMA officer attended as part of the Australian delegation and alternate delegation leader.

Codex Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance

This task force held its first meeting in Seoul in November 2007. An APVMA officer was part of the DAFF-led Australian delegation. The aim of the task force is to produce guidance documents on risk assessment and risk management, to minimise the emergence of food borne antimicrobial resistant micro-organisms, following the use of antimicrobial drugs in food-producing animals. The APVMA continues to contribute to drafts of working papers and guidance documents.

Other international activities

The APVMA has continued its international engagement through hosting international visits and targeted staff visits to other regulatory agencies. During the financial year meetings were held with representatives of the Japanese government (including the Ministry of Health Labour and Welfare, the Ministry of Agriculture Forestry and Fisheries, and the Food Safety Committee), the United States Environment Protection Agency, the United States Food and Drug Administration, Health Canada's Pest Management Regulatory Agency and the Canadian Veterinary Drugs Directorate.

The APVMA hosted a visit from a Taiwanese delegation interested in regulation and analysis of pesticide residues and contaminants in food. Dr Kao was also keen to understand linkages between Australian government agencies.

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

The APVMA manages four programs that monitor the quality and safety of registered pesticides and veterinary medicines 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 uses 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 pesticides (AERP *Ag*) and veterinary medicines (AERP *Vet*) are post-registration feedback loops that the APVMA has established to facilitate responsible management of agricultural and veterinary medicines throughout their life.

The aims of AERP *Ag* and AERP *Vet* are to provide the APVMA with feedback about the quality and performance of pesticides and veterinary medicines in the field. This information helps to ensure that registration decisions that the APVMA makes continue to remain appropriate and to promote and maintain public confidence in the National Registration Scheme. Consideration of adverse experience reports frequently involves consultation within the APVMA as well as with other relevant federal, state and territory government departments, monitoring agencies in other countries, recognised experts on advisory committees and product registrants.

The AERP considers reports relating to:

- animal health issues, including both domestic and native birds and animals
- damage to crops and plants
- human health issues, where people are exposed to veterinary medicines or pesticides
- lack of efficacy
- residue issues
- environmental damage.

Links have been established with the Poisons Information Centre in Sydney and Brisbane as alternative sources of feedback about the safety of pesticides and veterinary medicines.

AERP *Ag*

Activities undertaken in 2007–08 to raise awareness of the AERP *Ag* program in the community included:

- publishing the *Report of Adverse Experiences for Veterinary Medicines and Agricultural Chemicals 2006*
- encouraging reporting through the networks of members of our Community Consultative Committee (CCC)
- a presentation, promoting the AERP, by CCC member Neville Prowse-Brown at the ChemCert Conference at Bendigo, Victoria in May 2008
- promotion of the AERP to VFF and Latrobe Regional Hospital in the East Gippsland region
- promotion of AERP by banner display, pamphlets and provision of a short reporting form at the 16th Annual Weed Conference in Cairns, Qld in May 2008
- advertising the AERP at an APVMA registration forum in June 2008
- inclusion of an AERP article and banner advertising in *Farm Guide* magazine 2008.

During 2007–08 the APVMA assessed and classified 98 adverse experience reports related to agricultural chemicals. Numerous enquiries were also received from the public. Adverse experience reports involving effects on crops accounted for approximately 40 per cent of the reports, environmental or non-target effects for 23 per cent of reports, and human adverse experience reports for 20 per cent.

The environmental and off-target reports are being considered by the chemical review team as part of a project to consider regulatory controls of phenoxy-type herbicides.

AERP *Vet*

Activities undertaken in 2007–08 to raise awareness of the AERP *Vet* program and to advise the community of the potential risks associated with the use of veterinary medicines included:

- publishing the *Report of Adverse Experiences for Veterinary Medicines and Agricultural Chemicals 2006*
- promotion of the AERP by displaying the AERP banner at Australian Veterinary Association Conference in Perth in May 2008
- advertising the AERP at an APVMA registration forum in June 2008
- inclusion of AERP article and banner in advertising in the *Farm Guide* magazine 2008
- publication of an article titled 'Permethrin toxicosis in cats' by PJ Linnett, Kingston ACT, Australia. This article is available in the *Australian Veterinary Journal* (2008) January–February, 86(1–2):32–5
- a presentation to the Animal Health Alliance in Sydney in June 2008.

During 2007–08 AERP *Vet* assessed and classified 1718 reports, involving suspected adverse reactions in animals, received from veterinary surgeons, owners, members of the public and product registrants. Numerous enquiries were received from 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 five per cent involved human health issues.

Following the 2007 equine influenza (EI) outbreak, more than 40 reports about the (EI) vaccine were received. The most frequent reactions reported were typical vaccine reactions such as fever and local swelling. No deaths have been directly linked to exposure to the vaccine.

Corrective actions taken include:

- In 2007–08 the AERP recommended or supported seven label changes, including one label change relating to a group of products. These products were insect growth regulators with similar resistance issues to sheep lice.
- In October 2007 the AERP prompted an update of First Aid and Safety Directions for veterinary hormone products. Voluntary label changes are being undertaken.

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, the veterinary profession and registrants.

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 2007–08. 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 crosscheck the accuracy of record keeping.

Record inspection by monitoring visits and data call-ins

The Compliance Team conducted 16 company-monitoring visits that resulted in the inspection of 135 batch records of 34 products. The team also called in records for a desk-based review of a further 13 products and inspected 19 batch records. The APVMA uses two approaches to monitoring records to ensure efficiency and effectiveness. Company-monitoring visits are 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.

Compliance with the registration conditions was categorised according to whether:

- the batch fully complied with the conditions (that is, met the APVMA standard, had adequate records and records showed continuity)
- the recorded particulars showed that the batch met the APVMA standard
- records of the batch were adequate to demonstrate compliance
- the records showed continuity, such 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. Out of 154 batches, 100 per cent fully complied with registration conditions. In keeping with the focus on maintaining active constituent quality and not pursuing minor record keeping errors (64 per cent), the APMVA issued formal warnings to registrants who failed to submit adequate records or failed to establish continuity between records. Other corrective action can include increased record inspections during the next inspection cycles. A risk criterion used to determine the registrants selected for inspection in 2007–08 was non-compliance found during inspections conducted in 2006–07. Of the 16 registrants who were subject to a company-monitoring visit in 2007–08, 11 had been subject to a record review the previous financial year and had failed to meet the conditions of registration. All of these registrants were compliant in 2007–08 inspections.

Table 12 Results of batch inspections under the Ag QA Scheme 2007–08

BATCH COMPLIANCE WITH CONDITIONS OF REGISTRATION				
TYPE OF CHECK CONDUCTED (NO. OF PRODUCTS)	NO. OF BATCHES	MET THE APVMA STANDARD	ADEQUATE RECORDS	CONTINUITY
Monitoring Visits (34)	135	135	87	62
Desk-based reviews (13)	19	19	12	Total (58)
	154	154 (100%)	99 (64%)	62 (40%)

Product testing

The APVMA conducted testing of products ready for supply into the marketplace to check on the accuracy of batch records submitted.

The APVMA undertook eight programs as part of the 2007–08 testing regime. The active constituents selected were, triadimefon, triadimenol, chlorthal-dimethyl, diuron (agricultural products only), propineb, dicofol, pyrimethanil and metolachlor.

Sampling in all programs has been completed (no products containing dicofol were available). The APVMA is reviewing preliminary results for triadimefon and triadimenol. The reports for other programs are pending. Registrants with products in a program will be contacted regarding the results as soon as the APVMA has completed its scientific review.

Outcomes for 2006-07 product testing released

In 2006–07 the Compliance Team operated four product-testing programs. Products containing the active constituents mancozeb (21 products), chlorpyrifos (47 products), oxyfluorfen (10 products) and quintozene (seven products) were sampled and the analytical results for levels of toxicologically significant impurities relative to active content compared with records provided by registrants.

The results for the mancozeb and chlorpyrifos programs were finalised and published. Initial testing for mancozeb products found that three products had a mancozeb concentration below the allowable tolerance and that one of these was also non-compliant for the level of the nominated toxicological impurity. After consultation with the registrants of these products, two registrants undertook voluntary testing, while the third was able to satisfy the APVMA of the quality of mancozeb incorporated into the product.

Testing of chlorpyrifos products established that all products were compliant for levels of the nominated toxicological impurity. However six products, spanning four registrants, had chlorpyrifos levels outside the allowable tolerance. After discussion with the registrants of these products, all registrants entered into voluntary undertakings for testing of four products. The APVMA was satisfied by the response provided for two of the products and the Compliance Team took no further action in these cases.

The results for oxyfluorfen and quintozene have not yet been released due to ongoing dialogue between the APVMA and registrants with possible non-compliant results.

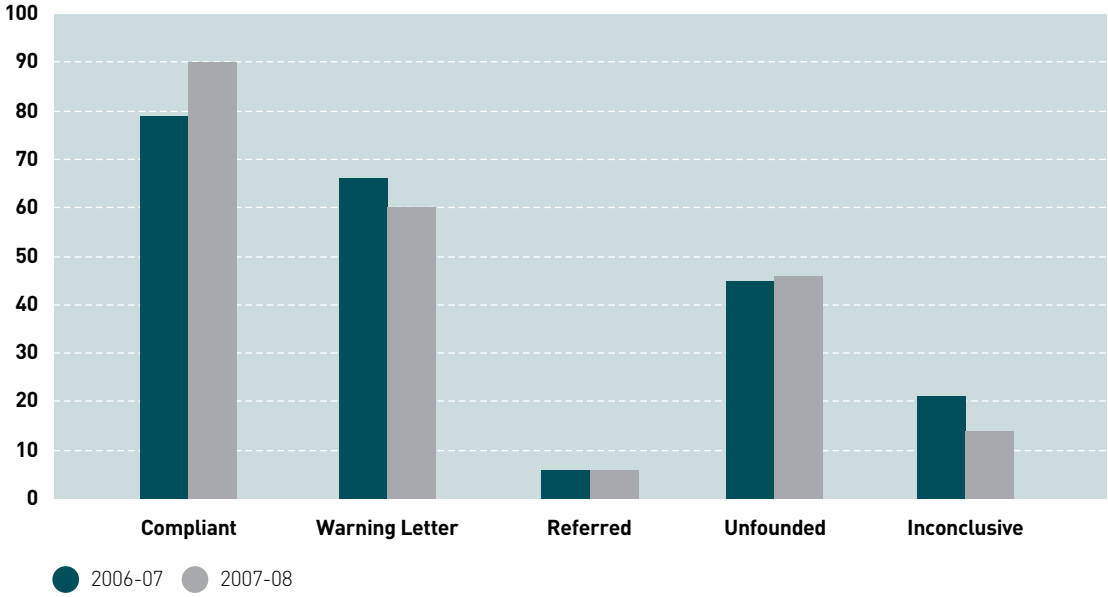
The results for all programs conducted in 2006–07 and released in 2007–08, show a high level of compliance with APVMA standards for the quality of the active constituent incorporated into product, and the level of active constituent within those products.

The records presented by the registrants, kept as part of the conditions of registration, in general support the analytical results found during APVMA testing. Where the APVMA finds significant difference between the records and the testing results, the registrant (and their activities) may be subject to increased levels of Compliance Team monitoring.

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. Current policy is that if all reports are acknowledged upon receipt and prioritised for action on the basis of ‘chemical risk’. Chemical risk is based on the potential or actual harm to the environment, human, plant or animal health, or trade with other countries.

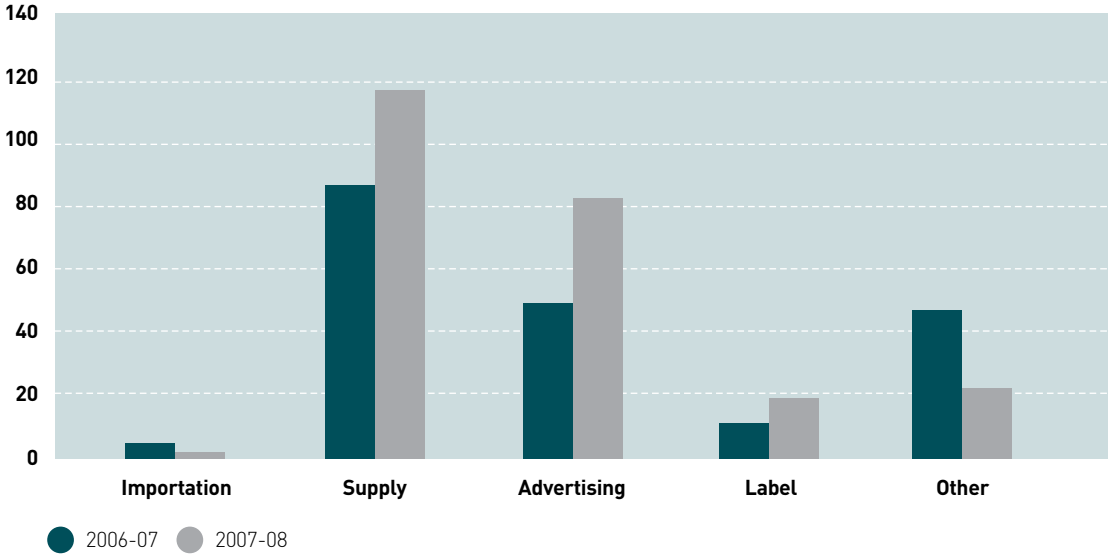
Figure 6 Outcome of inquiry into reports of non-compliance



Higher risk reports are pursued through 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 primarily dealt with through warnings and negotiation to achieve compliance. During 2007–08, 240 new reports were received and of these 74 per cent were assessed as low risk. Of 215 reports finalised this financial year, 150 reports were finalised through warnings and negotiated compliance. Three reports were escalated to a product recall, six resulted in a visit to the company to monitor compliance, and six reports were referred to another agency. Fifty two per cent of all non-compliance reports were completed within three months of receipt.

- 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 2007–08 the APVMA initiated five new investigations and continued with five investigations commenced in 2006–07. These investigations relate to alleged breaches of:

- section 69B of the Administration Act (Import an unregistered chemical product)
- 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.
- section 136 of the Commonwealth Criminal Code (supply false or misleading information)
- section 121(5) of the Agvet Code (contravene a condition of a licence to manufacture)

Two cases were closed in 2007–08. One case related to a possible incorrect formulation but subsequent investigation revealed that no offence had occurred. Another case relating to claims inconsistent with a label instruction was referred to the Commonwealth Director of Public Prosecutions (CDPP), but the CDPP chose not to proceed.

During 2007–08, two recalls initiated during 2006–07 were finalised. At 30 June 2008 there is one past recall still awaiting resolution. This remaining recall was initiated in 2003–04.

In 2007–08, 11 new compulsory and voluntary recalls were initiated. Of these eleven new recalls, three were fully resolved during 2007–08. The remaining eight recalls await resolution in 2008–09. These eight remaining recalls consist of four voluntary and four compulsory recalls.

Hormonal growth promotants

The EU requires continued assurance from Australia that beef and beef products that its member states import have not been treated with hormonal growth promotant (HGP) products. The National Hormone Growth Promotant Monitoring Control System provides this assurance by enabling 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 2008 there were 277 APVMA-authorised suppliers.

The APVMA continued to operate a compliance audit program of authorised HGP suppliers. The audit frequency 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 financial year, the APVMA audited 51 HGP-authorised suppliers (retailers and wholesalers). Fifty-six per cent of the suppliers were found to be compliant on the first visit. Forty-four per cent were issued with a warning and subjected to more frequent audits. Ninety-eight per cent of suppliers were compliant when audited for a second time.

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 2007–08 it conducted enquiries into two importation matters. 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 296 applications and issued 284 Consents to Import. Of these, 115 were issued to allow importation for use under the APVMA general permit, 36 were issued with permit applications and 123 to veterinarians. Twelve applications for consent were not approved or were found to be unnecessary.

Training program for Malaysian colleagues

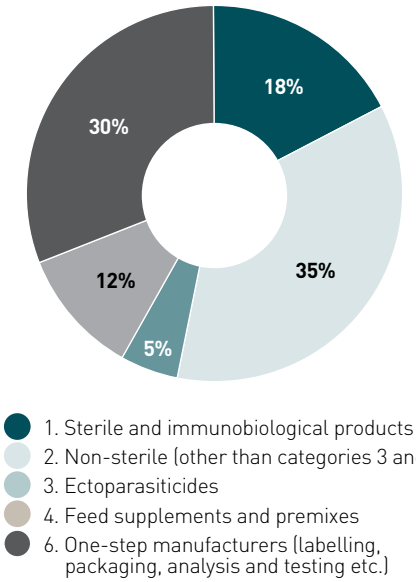
During June 2008 the APVMA provided a two-week training program in registration evaluation and good manufacturing practice for four officers from the National Pharmaceutical Control Bureau in the Malaysian Ministry of Health. The training included attendance at the registration seminar visits to a prominent manufacturer of veterinary products in Sydney and to a testing laboratory.

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 medicines. 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 medicines 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 associated 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.

At 30 June 2008, 222 Australian-based manufacturers were licensed or being assessed for a licence. During the financial year, 22 new licences were issued and 58 variations to licences approved.

Figure 8 Percentage of manufacturers licensed or being assessed for a licence, under the Manufacturers' Licensing Scheme, 30 June 2008.



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 2007–08 APVMA-authorised auditors conducted 82 audits and APVMA staff conducted two unannounced audits.

To align the APVMA's manufacturing requirements with contemporary international standards, the APVMA introduced new Manufacturing Principles and the associated Australian Code of Good Manufacturing Practice for Veterinary Chemical Products on the 1 May 2007. During the financial year, implementation of these updated manufacturing standards has continued to be relatively uneventful.

To ensure satisfactory audit closeout, the APVMA issued 30 notices of intent to suspend or cancel licences or to impose conditions. During the financial year, 39 licences were cancelled (30 voluntarily and nine imposed by the APVMA) and six were suspended. Conditions continued to be imposed on all new and existing licences to improve compliance and overcome delays in responding to audit findings. An Auditors' Workshop was held in May 2008 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 92.3 per cent of manufacturers providing a rating of greater than seven out of ten, 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 medicines that supply veterinary medicines to the Australian marketplace.

Applicants for product registration must demonstrate that the imported product is manufactured to quality standards comparable to those applying to veterinary medicines manufactured in Australia. During 2007–08, 197 overseas manufacturing sites were assessed for compliance with Australian manufacturing standards as part of the product application assessment process. Of these, evidence from 20 sites was subjected to more detailed evaluation.

As products are registered, conditions of product registration are applied to ensure continuing compliance with the APVMA's GMP requirements. Compliance with conditions of

product registration is monitored through the Post Registration Process. During 2007–08, GMP records were requested for 250 products. Satisfactory evidence was provided for 248 sites and the remaining cases are still being progressed. Although the overall objectives of the scheme are being met, nearly 29 per cent of registrants were not able to provide the necessary evidence within the required timeframe.

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.

The APVMA is conducting a Review of the Overseas GMP Scheme. A consultation paper was published on the APVMA's website on 5 June 2008, with a closing date for submissions on 29 August 2008. This paper initiates a review of the APVMA's Veterinary Post-Registration Overseas Good Manufacturing Practice (GMP) Compliance Scheme (Overseas GMP Scheme) which was introduced in October 2005.

The APVMA is undertaking the review to determine whether the Overseas GMP Scheme is effective in assuring that imported veterinary medicines are manufactured in GMP compliant facilities. The review also requests feedback about experiences with the Overseas GMP Scheme, whether it has affected GMP compliance generally and whether it is useful and fair.

The Review examines whether the Overseas GMP Scheme is meeting its original objectives, and could result in modifications to the scheme if these are necessary.

Export assistance

Many foreign governments require evidence of compliance with GMP to be provided before veterinary medicinal products can be imported. The APVMA has endeavoured to assist the export of Australian-made veterinary products by providing certificates of manufacture upon request. Such certificates confirming 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, 78 export certificates were issued for compliance with Australian manufacturing standards. Of these, two were issued under the MRA with the EU.

Summary

The APVMA's activities throughout 2007–08 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*

Australian National Audit Office (ANAO) audit of the APVMA

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

In 2007–08 the APVMA has continued activities to implement all the ANAO recommendations and its additional suggestions. By 30 June 2008 the APVMA had:

- 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
- reviewed its policies for the refusal and withdrawal of applications and improved its procedures for dealing with information submitted voluntarily during the course of an application.
- 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 (MLS) framework, by improving the management of audits and developing mechanisms to improve the follow-up of audits
- initiated an analysis of the Chemical Review process
- 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 ANAO audit, the ANAO's recommendations and the APVMA's implementation activities is available on the APVMA's website at http://www.apvma.gov.au/about_us/anao_report.shtml.

Productivity Commission reviews and studies

Following the work of the Regulation Taskforce and the publication of '*Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business*' (the Banks report) in January 2006, in early 2007 the former Australian Government asked the Productivity Commission to conduct ongoing annual reviews of the burdens on business arising from the existing stock of government regulation. The initial annual review, that began in April 2007, focused on regulatory burdens on business in the primary sector. The second annual review, that began in February 2008, focused on regulatory burdens on business in the manufacturing and distributive trades. Both annual reviews have touched on areas relevant to the regulation of agricultural and veterinary medicines.

In July 2007 the then Australian Government commissioned the Productivity Commission to conduct a study of chemicals and plastics regulation. This was in response to Recommendation 4.58 of the Regulation Taskforce that proposed the development of an integrated national chemicals policy for the information of the COAG Ministerial Taskforce. It is intended that the recommendations of the study will inform the COAG Ministerial Taskforce on chemicals and plastics regulatory reform to develop measures to streamline national chemicals and plastics regulation.

The APVMA has actively participated in both annual reviews and the chemicals and plastics study, consistent with its commitment to constantly improve its regulatory efficiency and assist the government's objective to minimise 'red tape' without compromising the overall policy objective of the National Registration Scheme.

The APVMA has been very active in developing and delivering operational reforms and has continued to work with policy makers to further improve and refine the National Registration Scheme to align it with contemporary needs and demands. The authority has also worked to develop and take advantage of international relationships to produce efficiencies in the delivery of its regulatory functions where possible. Despite these activities, the APVMA believes that there are opportunities to achieve further improvements in the efficiency and effectiveness of chemicals regulation. The Productivity Commission's reviews and study provide a vehicle for such opportunities to be explored and realised.

More information about the Productivity Commission's reviews and chemicals and plastics study can be found on the Commission's website at http://www.pc.gov.au. The APVMA's submissions to the Commission are also available from that site.