Australian Pesticides & Veterinary Medicines Authority

Performance Against Output

Principal goal 1. Product registration

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

Overview:

All manufacturers of pesticides and veterinary medicines must apply for registration of their products and approval of their labels with the APVMA before 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 made to the product, additional claims made about the product or other changes to its label.

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

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

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

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

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

Strategy 3. Support development of relevant Government policy.

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

Performance:

Pesticide applications

The Pesticides Program began the year with 833 applications for registration, variation to registration, or label approval being processed. An additional 1763 applications were received during the year. This year showed the same trend as the previous year in that 50 per cent of the applications were for variations to labels. This contrasts with previous years (2000–01 and 2001–02) where, on average, only 39 per cent of applications related to label variations.

During 2003–04 the Pesticides Program finalised 1478 applications. This number includes applications granted for product registrations and/or label approval, refusal of applications and withdrawals of applications. At 30 June 2004, 1118 applications remained unfinalised. of the applications finalised 87 per cent were completed within statutory timeframes compared with 97 per cent for the previous year. This figure is a yearly average of timeframe performance and reflects the added complexity of the new label approval requirements brought about by legislative amendments that came into force in October 2003.

Table 1. Agricultural product registrations

Class of application	Total no. registered or approved	No. finalised or approved vs statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		Within timeframe	Up to 20% above timeframe	More than 20% above timeframe		
15 month	6	4	2	0	15.0	23.3
13 month	5	3	2	0	13.1	23.4
8 month	43	16	16	11	8.9	14.1
6 month	2	0	1	1	7.3	9.9
5 month	60	30	13	17	5.2	11.8
3 month	1090	994	60	36	1.1	3.6
Total	1206	1047 (87%)	94	65		

Veterinary medicines applications

The Veterinary Medicines Program began the year with 689 applications in process for registration, variation to registration, or label approval. During the year the program received 1038 applications. of the applications, 50 per cent were for label amendments, compared with 57 per cent the previous year.

The Veterinary Medicines Program finalised 1148 applications so that 2004–05 will commence with 579 applications in process, a reduction of 16 per cent from the previous year. This number includes applications granted for product registrations and/or label approval, refusal of applications and withdrawals of applications.

Of the applications finalised during the year, 94 per cent were within statutory timeframes compared with 98 per cent the previous year. As for the Pesticides Program, the added complexity of new label approval requirements put pressure on timeframes for label approval.

Table 2. Veterinary product registrations

Class of application	Total no. registered or approved	No. finalised or approved vs statutory timeframe			Average clock time to finalise (months)	Average elapsed time to finalise (months)
		Within timeframe	Up to 20% above timeframe	More than 20% above timeframe		
15 month	7	7	0	0	6.5	30.1
12 month	2	2	0	0	8.4	33.2
8 month	52	45	4	3	6.4	16.0
5 month	179	168	10	1	3.3	7.7
3 month	720	685	17	18	0.9	4.0
Total	960	907 (94%)	31	22		

Efficient and effective risk assessment

During 2003–04 the APVMA continued to deliver an efficient and effective regulatory system for pesticides and veterinary medicines in Australia despite challenges brought about by increased complexity in approval of products and labels. The APVMA has improved processes to deal with such challenges.

Subsequent to amendments to the Agvet Code which came into force in October 2003, the APVMA was required to amend its label approval process by requiring applicants to submit the product label as marketed, or a printer's proof of the marketed label, before label approval could be granted.

This replaced the previous practice of granting label approval on the basis of a text version of the label. This requirement is an additional step in the product evaluation process, and must be completed within the existing timeframes.

During the year the APVMA implemented an action plan to achieve more efficient and effective processing of applications. As part of this action plan, the Veterinary Medicines and Pesticides programs made several process improvements resulting in significant productivity gains. The key elements were streamlining processing for purely administrative applications, developing and implementing new processes for approving variations to registrations and labels, and permitting certain minor administrative changes to labels without application to the APVMA. Productivity improvements were also implemented in processing the many queries that are received by the programs.

Chemistry and Residues Program

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

Residues and trade aspects of the product application are also evaluated to determine whether products can be used safely and properly in the market-place, without concern about potential residues in food. A key objective of trade evaluations is to ensure that Australian trade to other countries will not be prejudiced unduly as a result of product registration. Residues and chemistry data are also evaluated for active constituents and products under chemical review. The Chemistry and Residues Program maintains the Record of Approved Active Constituents for Chemical Products and publishes the Standard for Maximum Residue Limits (MRLs).

The action plan is part of an APVMA-wide ongoing productivity improvement plan that seeks to reform processes and procedures and to better match efficiency and effectiveness with the level of risk associated with a regulatory decision.

Trends indicate that the action plan is proving successful in managing the higher workloads and extra time and resource requirements resulting from the legislative changes and continuing high number of applications for label changes. The number of applications in process has stabilised and the monthly timeframe performance is again improving.

In 1998 approximately 1300 of the pesticides and veterinary medicines transferred to the APVMA (previously managed under State registration schemes) were identified as having never been assessed by the APVMA. This represented an unknown risk to the APVMA and a risk to the integrity

Communication of trade advice

During 2003–04 the APVMA prepared its operational policy document *Management of Trade Risks by Communication of Trade Advice* for stakeholder comment, and convened stakeholder meetings to discuss the best way to communicate trade risk advice to users and operators along the food production chain. Following these discussions the APVMA Board decided that Export Slaughter Intervals should be determined by the APVMA in consultation with the applicant and the relevant producer industry. The APVMA must be satisfied that the relevant trade advice is communicated effectively by the use of label statements, web sites, brochures or a combination of methods. As a result, Part 5B of the Agricultural and Veterinary Requirement Series *Overseas Trade Aspects of Residues in Food Commodities* has been amended taking into account stakeholder comments.

Stockfeed guidelines

Throughout the year, the APVMA continued a four-year project to prepare a series of stockfeed guidelines. To date, 28 guidelines have been completed and posted on the APVMA web site. A further eight guidelines are being developed. These guidelines determine acceptable feeding levels for animals consuming a commodity treated with chemicals. They enable farmers and stockfeed manufacturers to make informed decisions about the residue status of feed commodities and how the commodities should be incorporated into the livestock diet. Appropriate use of the guidelines will facilitate risk management of diets containing chemically treated commodities, and will reduce the risk of breaching MRLs for animal produce.

of the National Registration Scheme because of the possible existence of products and/or labels that did not meet contemporary standards. A project was set up to evaluate the products under current registration requirements. The project was completed by 30 June 2004. Nearly all of the products have either had their records and labels updated in line with current standards or been withdrawn from registration. A small number of products will require follow-up action via the review process.

Permits and minor uses

Pesticides

At 1 July 2003 the Pesticides Program had 352 permit applications in process. An additional 699 applications were received during the year.

The Pesticides Program finalised 611 permit applications of which 480 resulted in the issue of a permit, 32 did not require a permit, 96 were withdrawn and three were rejected because they did not satisfy the legislative criteria. At 30 June 2004 a total of 440 applications remained in process.

A total of 58 emergency use permit applications were finalised, including permits for the control of silverleaf whitefly in various broad-acre and horticultural crops, currant-lettuce aphid in lettuce and exotic ant eradication programs for red imported fire ants, Argentine ants and yellow crazy ants. Locust plagues occurred

in Queensland, New South Wales and Western Australia, requiring permits for a number of chemicals.

Approximately 84 per cent of applications (excluding emergencies) were finalised (permit issued or rejected) within the statutory timeframes. The average time taken to complete applications requiring minor technical assessment (which comprised 65 per cent of the applications finalised) was 55 days and applications requiring major technical assessment (29 per cent of the total finalised) 150 days.

Veterinary medicines

At 1 July 2003 the Veterinary Medicines Program had 66 permit applications in process. During the year 236 applications were received and a total of 225 applications were finalised. of the permit applications finalised, 192 permits were issued, 32 applications were withdrawn and a permit was not required in one case. Ninety per cent of permits were issued within statutory timeframes.

The majority (77 per cent) of permits issued were for off-label use of veterinary medicines and for the use of autogenous vaccines in a small number of livestock enterprises. of permits issued, 27 per cent were for the generation of safety and efficacy data to support applications for registration and 6 per cent were to allow export of unregistered veterinary chemicals.

Minor use reform

A key strategy for the APVMA in 2003–04 was to improve the management of minor use issues in Australia with a view to assisting the availability of safe and effective chemicals for minor use applications. To this end

Active constituents

During 2003–04 124 applications for active constituent approval were finalised, 94 per cent within legislative timeframes. The APVMA developed and implemented a new scheme for agricultural chemical active constituents. This scheme involves assessing the quality of the active constituent in a product at the time of product registration and keeping records verifying active constituent quality after registration. The new scheme emphasises the quality of the active constituent. The scheme aims to increase the robustness of the regulatory process for agricultural chemical products. As part of this process, the APVMA established 403 standards and updated the relevant requirements.

Maximum residue limits

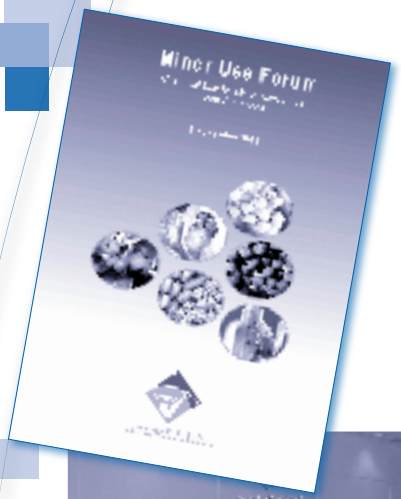
During 2003–04 the APVMA evaluated residue data for 74 applications for product registration and 185 applications for permits determining 346 MRLs. No product is registered unless both the short-term and long-term dietary intake evaluations are satisfactory for each chemical/commodity combination.

the APVMA has worked with chemical companies, grower industries and government stakeholders to reform the minor use framework and to streamline the approval of permits and registration of chemical products for minor crops.

The APVMA continued to work with peak research and development corporations including Horticulture Australia Ltd, Rural Industries Research and Development Corporation and Grains Research and Development Corporation. The APVMA also worked with industries and their associations including Queensland Fruit and Vegetable Growers and Crop Protection Approvals as well as State Departments of Agriculture/Primary Industries to enable access to safe and effective chemicals for minor crops. When Crop Protection Approvals went into liquidation in December 2003, the APVMA continued to process permit applications for the horticulture industry.

The APVMA convened a Minor Use forum in November 2003 with the aims of increasing understanding of APVMA requirements, improving communication between growers and the APVMA and within the industry groups, and developing a means of matching growers' needs with the available resources.

The forum established a Minor Use Taskforce with a steering group comprising representatives from the Australian Government Department of Agriculture, Fisheries and Forestry, agricultural research, the chemical industry, growers, State agriculture departments and the APVMA. Three working groups were also formed: a Policy Working Group to investigate matters relating to the policy framework affecting minor use; a Communications Working Group to improve communication between the various minor use stakeholders; and an Operational Issues Working Group to streamline APVMA requirements and processes for permits and registrations.



Participants at the 2003 Minor Use Forum

The Operational Issues Working Group, chaired by the APVMA, is working on reforms to consolidate and align permit renewals, streamline residues requirements, develop efficacy and crop safety guidelines, develop permits for crop groupings, facilitate access to overseas data and prioritise research for minor crops.

Following discussions between APVMA and representatives of the United States Minor Use Program (IR4), Australian delegates were

invited to the United States Food Use Workshop to be held in September 2004 with a view to collaborating on research trials for the use of chemicals on minor crops.

The APVMA has appointed a Minor Use Project Officer to coordinate minor use reform within the organisation including streamlining processes and liaising with peak grower groups and the chemical industry to prioritise research and to assist applicants for minor use permits and registrations. The Minor Use Project Officer will also be appointed the Australian contact for data access by OECD members.

Minor Use News is now published by the APVMA for the information of growers, peak associations, State departments, researchers, consultants, manufacturers and others with an interest in pesticides and veterinary medicines. It provides a monthly update on minor use issues, including notification of recently approved minor use permits and developments in regulatory activities. The newsletter also contains links to other topics of interest on the APVMA web site.

APVMA contribution to exotic disease preparedness

As part of Australia's foot and mouth disease preparedness campaign, the Veterinary Medicines Program cooperated with the Australian Government Department of Agriculture, Fisheries and Forestry to assess an application for a permit to allow a vaccine against foot and mouth disease to be issued to Animal Health Australia for the Australian Foot and Mouth Disease Vaccine Bank. The issue of a permit for emergency use, under the strict control of the Chief Veterinary Officer, will enable the vaccine to be used in a rapid response should an outbreak of the disease occur in Australia.

Regulatory science quality

The restructure of the APVMA's senior management in August 2002 resulted in the creation of three Principal Scientist positions (Principal Scientist, Veterinary Medicines; Principal Scientist, Pesticides; and Principal Scientist, Chemistry and Residues).

The objectives of the Principal Scientist Program are to:

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

Peer review

The APVMA bases its decisions on evaluation of scientific information, and it is therefore crucial that it verifies and enhances the quality of science within the organisation at every level. The strengthening of science within the APVMA has many facets. As one approach, the Principal Scientists

review each year the scientific quality of the APVMA's regulatory decisions. Principal Scientists review registration decisions to ensure that they are based on good science and regulatory practice. Based on the findings of the review, the APVMA has revised evaluation report formats and improved evaluators' training. In addition, training in scientific writing skills is improving the quality of technical reports.

Standard on Good Regulatory Science Practice

An APVMA Standard on Good Regulatory Science Practice is under development. This standard will form the basis of continued regulatory science quality assurance across the APVMA. The Principal Scientists have consulted with the APVMA's Community Consultative Committee and the chemical industry to explore stakeholders' perceptions of regulatory science quality and to develop principles for inclusion in the standard.

Improving regulatory science quality extends beyond the APVMA and applies also to scientific advice provided by external agencies and committees. In this regard, the APVMA has initiated and worked with the Australian Government Department of Health and Ageing to review the operation of the Advisory Committee on Pesticides and Health.

The work of the National Drugs and Poisons Schedule Committee directly impacts on the APVMA's administration of agvet chemicals regulation. To ensure the committee is well informed on agvet chemicals under consideration, additional measures have been implemented to strengthen the APVMA's input into the scheduling process. The Principal Scientists also represent the APVMA at science forums convened by the Australian Government Department of Health and Ageing where a key focus is to consider best practice approaches to health risk assessment.

Science Fellows Program

A Science Fellows Program is being established to address the APVMA's need for external technical expertise in specific areas. Priority areas for inclusion in the program have been identified and experts in those areas have been invited to become APVMA Science Fellows.

Service Level Agreements

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

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

Throughout 2003–04, the APVMA maintained and revised Service Level Agreements with the Department of the Environment and Heritage, the office of Chemical Safety (OCS) in the Department of Health and Ageing and the National Occupational Health and Safety Commission (NOHSC) for the provision of scientific assessment services. In April 2004 the agvet chemical assessment section of NOHSC was transferred to the OCS which therefore now provides the APVMA with assessment services in the areas of toxicology and occupational health and safety.

The APVMA also has a Memorandum of Understanding with the office of the Gene Technology Regulator (OGTR) that provides a framework for cooperation between the two organisations. The OGTR advises the APVMA on the impact of pesticides and veterinary medicines on genetically modified organisms and on genetically modified organisms that are part of pesticide and veterinary medicine products. In 2003–04 the APVMA sought OGTR advice on applications in relation to herbicides to be used on genetically modified canola. The APVMA also provided comment on relevant draft risk assessments prepared by the OGTR.

The APVMA continued negotiation on individual Service Level Agreements with State and Territory departments regarding the provision of efficacy and target safety advice for product registration or minor use applications. It is anticipated that these negotiations will be completed late in 2004.

Achievements in 2003–04 as a result of Service Level Agreements include:

- APVMA and agencies working closely to increase efficiencies in the delivery of scientific advice
- creation of a better framework for agency involvement in the chemical review process
- integration of AERP *Ag* advice
- improvements in timeframes
- improvements in evaluation efficiencies such as revisions to the First Aid and Safety Directions Handbook.

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

Performance:

APVMA communication strategy

In 2003–04 the APVMA Board approved a comprehensive communication plan designed to guide the organisation's communication activities through to 2005–06. The plan aims to build confidence in the APVMA and the regulatory system among the identified key audiences: the community, chemical industry, chemical users and government.

Broadly, under the communication plan the APVMA will:

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

The plan details communication initiatives to be conducted over the next two years. These include upgrading the APVMA web site, refining and updating the APVMA's publications, developing an electronic newsletter for registrants and conducting market research with the community and chemical industry.

Stakeholder interaction

The APVMA places great importance on establishing effective relationships with key stakeholder groups through both formal and informal means. The APVMA has a number of committees to help ensure effective two-way communication with stakeholders and has recently introduced the 'account manager' concept.

The concept involves the selection of senior officers to manage the ongoing relationship between the APVMA and nominated stakeholders. An account manager will help build awareness of the APVMA and its role with stakeholders and provide those stakeholders with a direct contact point in the organisation able to pursue issues of concern on their behalf.

The stakeholders for whom APVMA account managers have been selected to date include a range of rural producer organisations, specific commodity representative bodies and influential professional groups. The concept is expected to be fully operational in 2004–05.

Efforts are currently under way to build awareness of the APVMA with health professionals in rural Australia, specifically alerting them to the APVMA's Adverse Experience Reporting Program and encouraging their participation.

A program designed to strengthen relationships between the APVMA, industry and farmer organisations and relevant agencies in the Australian and State and Territory governments has been pursued over the year. The CEO, with the support of the organisation executive, met with senior personnel in relevant government agencies across Australia to increase understanding of the APVMA's role and foster closer working relations for the future.

Electronic media are becoming increasingly important for the APVMA in communicating effectively with its range of audiences. The APVMA web site has been extensively restructured to provide ease of navigation for the three key audiences: the community, the chemical industry and chemical users (see the case study *A more user-friendly APVMA web site* on page 36).

The APVMA's email subscription service was used increasingly over 2003–04 to direct information in a targeted way. The APVMA emails subscribers to a particular topic list alerting them, typically, to a policy change, procedural development or new information and usually referring to specific information on the web site.

Information materials are now routinely tailored to meet the needs of specific audiences on important issues. for example, following the APVMA's review of endosulfan an information sheet on the implications of the review was developed and distributed to members of the cotton industry, a major user of the chemical.

Throughout the year APVMA staff attended and gave presentations at stakeholder meetings, field days, conferences and seminars. These activities increase awareness of the APVMA and its requirements and improve stakeholder confidence in the regulatory system.

Media management

The APVMA's work attracted considerable media interest over the year—one sign of an active regulator. Most media attention was drawn by the APVMA's work in the chemical review area. The release for public comment of the draft review report on arsenic-treated timber drew particular attention as did the release of the final draft report on the future use of the pesticide endosulfan.

Typically the issue of an APVMA media release outlining proposed regulatory action was accompanied by publication of background material and a 'frequently asked questions' paper on the APVMA web site. There

A more user-friendly APVMA web site

In response to requests by web site users and in keeping with current thinking on web navigation, we have restructured our web site to introduce 'entry points' for each of the APVMA's key audiences—the community, chemical users and industry. The web site now provides three alternative entry points and users can choose whichever suits them best.

The new-look home page (**http://www.apvma.gov.au**) has been road-tested by staff and stakeholders. For example, the chemical users page has links to pages on chemical safety, disposal of containers, and buying and using chemicals. By contrast, the page for the chemical industry is more concerned with registration and regulatory issues.

The web site is constantly evolving, with additions and deletions. We will be adding new items as our services expand and in response to client demand.

After the client groups come links to the second type of entry point—the search options.

'Search the site' takes users to our site search engine, a powerful tool which, like most search engines, works best in the 'advanced search' mode. It is worth experimenting in this mode if your first search option does not yield useful results.

'Search for a product' takes users to the PubCris database, our one-stop shop for all currently registered products with options for searching by product, active constituent, host, pest and so on or combinations of these. PubCris links to copies of most product labels and other regulatory information.

'Search for a permit' takes users to our database of all issued permits, with links to the full text of the permit.

Next comes the third type of navigation or entry point—'drill down' menus.

First, APVMA core business activities are listed, such as product registration, active constituents and product recalls. These are followed by the generic links found on most government web sites, such as links to media releases, publications, recruitment, contacts and online payments.

Users tend to have a preferred method of web searching. Some like to follow links, drilling down menus and trusting their luck, while others prefer a tailored, structured search. Our new structure aims to cater for both preferences.

We are always looking to improve the quality of our web site. Users with suggestions for web content can email their comments to contact@apvma.gov.au.

were nine media releases issued during 2003–04, all of which prompted significant media interest.

The APVMA CEO, Program Managers and Principal Scientists acted as media spokespeople, depending on the issue. Generally, the Principal Scientists acted as spokespeople on scientific matters. An intensive media skills training program tailored to meet the needs of the group was conducted in 2003–04.

International engagement—building relationships with overseas regulatory agencies

The APVMA, under the umbrella of Australian Government participation, is involved in several international forums and expert working groups. These include the:

- OECD Working Group on Pesticides
- United Nations Food and Agriculture Organization/World Health Organization (FAO/WHO) Codex Committees on Pesticides Residues and Residues of Veterinary Drugs in Food
- International Cooperation for Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

The APVMA participates in these forums because it recognises the globalisation of the pesticides and veterinary medicines industries and the need for harmonised regulatory regimes. The forums also provide the opportunity for international cooperation in the development of harmonised registration requirements and the exchange of information. The benefits of increased international interaction include improved rigour and quality of regulatory decision-making through exchange of ideas, increased productivity and the protection of Australia's trade interests.

OECD

The APVMA engaged in the work of the OECD Working Group on Pesticides and its related committees. Through the OECD Working Group on Pesticides the APVMA focuses on achieving greater efficiency in registration processes, improving harmonisation of registration requirements and guidelines, promoting and participating in exchange of assessments, improving the scientific basis for decision-making and continuing to reduce risks to people and the environment.

The working group aims to facilitate common international approaches to pesticide regulation, through development of common evaluation and testing guidelines and promoting work-sharing among member countries. During the year a number of guidelines on testing and assessment were published. These included guidelines on statistical evaluation of data, validation of test methods, reproductive toxicity assessment, aquatic field

Members of the OECD Registration Steering Group and the Risk Reduction Steering Group that attended meetings hosted by the APVMA in November 2003

tests, pheromones and microbial pest control agents. Work on the development of test guidelines and guidance documents on residue chemistry began and the APVMA is taking a leading role in this project. The Agricultural Residues Manager represented the APVMA at two meetings of the OECD Residue Guidelines Expert Group in 2003–04. The Australian requirement for the provision of residues depletion data for livestock was accepted and will become part of an international guidance document.

The APVMA continued to work on OECD projects to address barriers to work-sharing and to harmonise requirements for electronic submission of registration applications including the development of harmonised templates. The APVMA is also participating in two pilot projects on work-sharing for agricultural pesticides.

Australia hosted the meetings of the OECD Registration Steering Group and the Risk Reduction Steering Group including a stakeholder seminar on minor use in November 2003. The Department of Agriculture, Fisheries and Forestry coordinated the arrangements with APVMA support.

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

Australia participates in the international forums on trade in food and food products known as the Codex Alimentarius (Food Code). The APVMA provides technical and regulatory advice for the Codex Committee on Pesticide Residues and Codex Committee on Residues of Veterinary Drugs in Food. These committees and the FAO/WHO expert evaluation panels, the Joint Meeting on Pesticide Residues and the Joint Expert Committee on Food Additives are responsible for determining the MRLs that underpin the trade in food commodities.

The APVMA contributed to the Australian delegation to the Codex Committee Meeting on Pesticide Residues in New Delhi in April 2004. Key issues for Australia include prioritisation of the evaluation of sulfuryl fluoride (a replacement chemical for methyl bromide), refining the variability factor in estimating acute dietary exposure, probabilistic modelling for Codex MRL setting, the classification of foods and animal feeds, work-sharing and the Pilot Project for National MRLs as Interim Codex MRLs for safer, replacement pesticides.

The Principal Scientist, Residues and Veterinary Medicines attended the 62nd Joint Expert Committee on Food Additives meeting in Rome in February 2004 where he was primarily responsible for evaluating

melengesterol acetate (MGA), a hormonal growth promotant for use in cattle, as well as peer reviewing other evaluations.

The Principal Scientist, Residues and Veterinary Medicines was also an invited contributor at the FAO/International Atomic Energy Agency Policy-makers Workshop in Vienna entitled Strengthening Capacities for Implementing Codex Standards, Guidelines and the Recommended International Codes of Practice for the Control of the Use of Veterinary Drugs. The workshop was designed for policy-makers in developing and developed countries and participants from 34 developing countries attended to promote awareness of the requirements for, and how to put in place, regulatory mechanisms for the use of veterinary drugs and the control of residues.

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

Throughout 2003–04 the APVMA retained its close involvement with VICH. The principal objective of VICH is to provide an international forum for regulators and the veterinary medicinal products industry to harmonise technical requirements for product registration. The members of VICH are drawn from the European Union, Japan and the United States. Australia and New Zealand have combined observer status at VICH. VICH working groups develop guidelines that are progressively adopted by the APVMA. During 2003–04 the APVMA adopted four evaluation guidelines on the safety of residues of veterinary drugs in food, carcinogenicity studies, repeat-dose toxicity testing, developmental toxicity testing, and general approaches to testing.

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

The Principal Scientist, Veterinary Medicines was invited to deliver a paper titled VICH—Global Progress in Animal Health Medicines Regulation at the Drug Information Association International Animal Health Conference, held in Nice, France in October 2003.

Other international activities

In October 2003, the Agricultural Residues Manager presented a paper entitled Data Requirements and Evaluation of Biopesticides in Australia at the International Union of Pure and Applied Chemistry Pesticides Workshop in Seoul, Korea. Following the workshop, two Korean regulators visited Australian regulators including the APVMA, the National Residues Survey and Food Standards Australia New Zealand.

The APVMA continued discussions with the New Zealand Food Safety Authority on possible areas for harmonisation of data requirements

for applications for registration of pesticides and veterinary medicines. Opportunities to harmonise the efficacy and safety requirements and guidelines for companion animals are being considered. In October/November 2003, the APVMA hosted an agricultural residues evaluator from the New Zealand Food Safety Authority for training purposes.

The APVMA has also been involved in deliberations on the implementation of the Globally Harmonized System of Classification and Labelling. The Globally Harmonised System is a United Nations sponsored international scheme to provide for harmonised criteria for classifying hazardous substances according to their health, environmental and physical hazards and for harmonised hazard communication elements, including labels and safety data sheets. Government policy on implementing the Globally Harmonised System is still being determined in relation to the extent that it would apply to pesticides and veterinary medicines.

The APVMA accepted an invitation to participate in a WHO/FAO/OIE expert workshop in March 2004 to consider international approaches to the regulation of antibiotics used in animals in order to limit the emergence of antibiotic resistance. The Principal Scientist, Veterinary Medicines also delivered a paper on risk analysis at the South African Medicines Control Council Antimicrobial Resistance Congress.

Strategy 3.
Support development of relevant Government policy

Performance:

Policy development

The APVMA does not have a primary role in the development of Government policy; rather it is responsible for the regulation of pesticides and veterinary medicines according to its governing legislation. However, given its unique and comprehensive knowledge in this area, the APVMA plays a vital role in informing development of policy impacting on the regulation of pesticides and veterinary medicines in Australia.

During the year, the APVMA contributed to policy development and reform in several areas, including:

- the policy and legislative programs of the Australian Government Department of Agriculture, Fisheries and Forestry related to the regulation of pesticides and veterinary medicines. of note have been the first tranche of amendments to the Agvet Code, development of proposed data protection legislation, revision of the APVMA's cost recovery framework and implementation of new international obligations for Persistent Organic Pollutants and Prior Informed Consent chemicals

- activities of the Product Safety and Integrity Committee of the Primary Industries Standing Committee. Key projects have focused on a policy framework underpinning chemical user awareness and training, development of national operating principles and outcome measures for Australia's overall agvet chemicals management system and developing a framework for collation of chemical use information
- efforts to streamline interaction between the APVMA and Food Standards Australia New Zealand in relation to setting MRLs
- the activities of the Environment Protection and Heritage Council Working Group on the Environmental Risk Management of Chemicals.

As discussed previously, the APVMA has engaged actively with international organisations such as the OECD Working Group on Pesticides, VICH, and the Codex Alimentarius Commission's Committee on Pesticide Residues and Committee on Residues of Veterinary Drugs in Foods. The APVMA has also interacted directly with counterpart regulators in other countries, in particular the United States, Canada, United Kingdom, Switzerland, China, Korea, Japan, New Zealand and the European Union. Substantial progress has been made in developing and adopting guidelines for various aspects of registration of pesticides and veterinary medicines, work-sharing with other regulators, developing harmonised residue requirements and developing common templates and formats for electronic submission of registration applications.

Summary:

Progress towards achieving the goal of stakeholder confidence that independent product assessment of pesticides and veterinary medicines protects public health, the environment and trade has been a major focus for the APVMA during 2003–04. Progress has been achieved through the APVMA's commitment to ensuring that registered products in the market-place meet legislative requirements for performance, safety and trade as a result of high quality and scientifically sound decision-making.

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

Principal goal 2.
Quality assurance and compliance

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

Overview:

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

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

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

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

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

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

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

Performance:

APVMA processes

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

Throughout the year, the APVMA conducted a complete review of core registration processes to ensure alignment with the legislation and optimise the effectiveness and efficiency of the procedures involved.

The revised key process for acceptance, evaluation and finalisation of applications was fully implemented by August 2003.

Documentation of APVMA processes is continually updated to reflect improvements in the processes and thereby maintain operational excellence. Major amendments were implemented in 2003–04 to reflect changes brought about by the legislative amendments that came into force in October 2003. Changes to the processes were communicated via the APVMA Gazette and web site and by a series of seminars conducted by the APVMA for registrants, their consultants and other stakeholders in capital cities around Australia.

During 2003–04, the APVMA conducted a comprehensive reassessment of the chemical review process and documentation. This led to refinements to existing procedures and development of new procedures. The revised processes also captured recent legislative amendments.

The documented key processes are available to all staff via the APVMA intranet, ensuring that staff always have the latest version of all documents and processes. APVMA management oversees the system through the Performance Review and Performance Improvement committees, both of which meet monthly.

Application categories

The APVMA is currently undertaking a comprehensive revision of the Agricultural and Veterinary Manuals (Ag and Vet Manuals) to ensure conformance to revised modules and categories which would be introduced as part of the proposed revised cost recovery framework for the APVMA. First drafts describing the requirements for 10 of the new categories were prepared and are undergoing internal review.

Meanwhile the existing manuals have been made available on the APVMA web site including revisions to specific categories to reflect current requirements and processes.

Data requirements

The APVMA has continued its program of reviewing and updating its advisory documentation. By providing this information, the APVMA aims to assist industry to satisfy legislative requirements for product registration and label approvals. This information is developed in consultation with APVMA stakeholders including industry, the States and the broader community. All guidelines are published on the APVMA web site.

During 2003–04, a number of new guidelines for specific data requirements were developed. The Pesticides Program progressed the development of guidelines for spray drift and work is progressing on dip disposal guidelines,

guidelines for trial protocol applications and guidelines for the registration and assessment of adjuvants.

During the year the APVMA adopted four VICH guidelines, as reported on page 39.

The APVMA finalised guidelines on data requirements for residues in poultry and assessment of the effect of antibiotic substances on the activity of dairy starter cultures. Work is progressing on guidelines on stability data for veterinary chemicals; validation of analytical methods; milk MRLs and withholding periods; residues at injection sites; blood products; autogenous

Spray drift

Spray drift is an issue of great interest to the community and one that the APVMA takes very seriously. Ideally, when a product is applied properly, it should be applied only to the intended target. However, spray drift can occur to some degree whenever a liquid is sprayed from a nozzle into the air. The APVMA keeps up with the latest international developments in methods to control and manage potential spray drift, and during the year the APVMA has trained staff in the latest spray drift science.

The new draft spray drift guidelines describe the approach the APVMA has developed in relation to the kinds of information it will require from registrants to enable it to be satisfied about spray drift risks. In brief, the APVMA examines each chemical separately to determine exposure thresholds of potential harm and then sets regulatory thresholds much lower to provide a large safety margin. It then determines, for each chemical, the likely exposure levels that might result from spray drift associated with agricultural practices.

For example, the APVMA determines likely exposure levels from spray drift for people in a field near an orchard where insecticide would be sprayed on trees. Similarly it determines whether spray drift could cause contamination of drinking water collected from roof collection systems. The APVMA also determines whether spray drift would be harmful to animals or plants in the environment and whether livestock feeding on pastures or forage near where spraying operations are being conducted would absorb residues of the chemical. Finally it compares those likely values with regulatory threshold values.

If the APVMA finds that a particular chemical would be likely to cause harm in any one of these areas and if there is no way to manage the application of the chemical to prevent that harm, then the APVMA does not allow the chemical to be used in that way.

The draft spray drift guidelines are being refined in consultation with the States and representatives of the community and industry organisations. The APVMA intends to finalise the spray drift guidelines and implement new data requirements during the coming year.

vaccines; cattle paralysis tickicides; and mineralised drenches. Existing guidelines on intramammary antibiotics are being revised.

Permits review

The permits review implementation project was completed. The aim of the project was to develop a permit system that continues to provide for the safe and effective use of pesticides and veterinary medicines for unapproved uses and research purposes. The revised permit system also complements the registration requirements and processes, operates with improved levels of efficiency by reducing the number of individual and unnecessary permit applications, introduces more efficient internal processes and allows for development of new data requirements and guidelines.

Initiatives implemented by the APVMA include an organisational restructure to facilitate better alignment of permit and registration processes and a re-engineering of processes and documentation.

The APVMA is revising the Permit Manual and is developing specific efficacy and crop safety guidelines for minor uses. These measures are expected to further enhance the assessment of permits.

Listed registration scheme

Amendments to the Agvet Code introduced in October 2003 now allow for a three-tiered regulatory framework for pesticides and veterinary medicines. Under this framework, products which require registration according to the criteria in the Agvet Code, but whose risk profile is low and well known, may be given listed registration if they conform to a pre-defined Standard. The existence of a Standard means this class of products does not need individualised evaluation of safety and efficacy as is applied to other products.

An extensive consultation process is an important part of developing a Standard. Once the final Standard has been published in the APVMA Gazette and the class of products has been included in a Schedule in the Agvet Code Regulations, applications may be made to the APVMA for listed registration of products that comply with the Standard.

A draft Standard for Listed Registration of Swimming Pool and Spa Products was gazetted in July 2004. This will cover swimming pool and spa products containing sodium, calcium or lithium hypochlorite, sodium dichloroisocyanurate and trichloroisocyanuric acid with a maximum pack size of 25kg or 25L. A draft Standard for nutraceuticals for companion animals will be released during 2004.

The third tier of the regulatory framework is reservation from registration. In this case, products which are not primarily intended for agvet use but

which are occasionally used for low-risk agvet uses, may be reserved from registration if they conform to pre-defined Conditions.

Benefits of the scheme will include lower costs of registration for these types of products, reduced timeframes for registration and more effective use of APVMA resources to focus on higher risk matters.

Label quality

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

The review has so far resulted in the development of key labelling principles including that labels must be clearer on what instructions are required to be followed by law and what statements on labels are warnings of possible adverse outcomes or advice to achieve best results. In order to illustrate the new proposals, example labels are being drafted for various product types. These will form the basis of wider consultation on the new proposals. A revised version of the Agricultural Chemicals Labelling Code is also being prepared based on these labelling principles.

Hormonal growth promotants

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

APVMA staff visited a commercial feedlot to increase understanding of HGP application technology

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 2004, there were 179 APVMA-authorised suppliers.

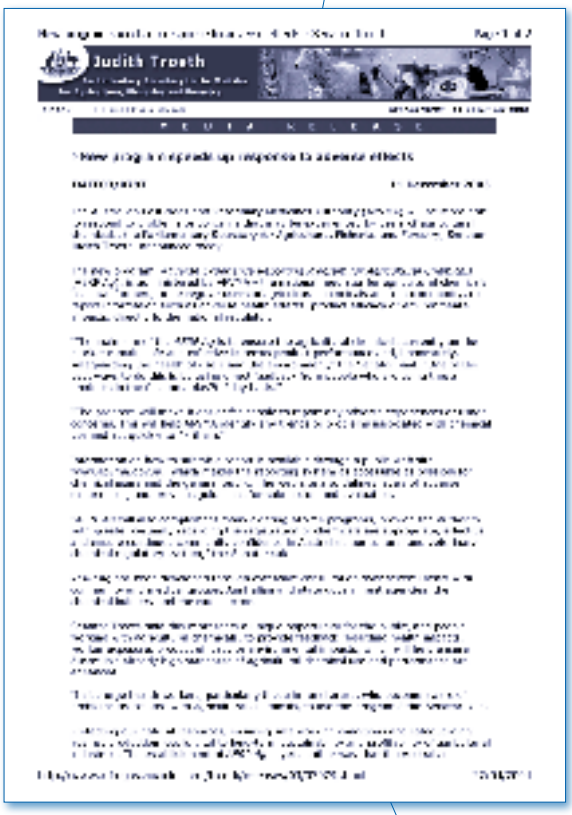
The APVMA continued to operate a compliance audit program of authorised HGP suppliers. The frequency of audit is determined on a risk basis and includes verification or a follow-up audit to confirm implementation of major corrective actions identified during the first visit. During the year, the APVMA audited 62 HGP authorised suppliers (both retailers and wholesalers). A total of 95 per cent of the suppliers were found to be compliant (either on the first or follow-up visit) with 45 per cent being issued with a warning and being subject to an increased audit frequency.

In 2003 the APVMA undertook to review the National Hormonal Growth Promotant Monitoring and Control System to identify reductions in the regulatory burden on the chemical industry resulting from the system. Early in 2004 the APVMA completed its assessment and has provided a report to the Department of Agriculture, Fisheries and Forestry for consideration.

AERP *Ag*

A new program for the APVMA

During 2003–04 the APVMA developed and implemented a new program to collect information on suspected adverse reactions (ie 'adverse experiences') that might occur with the use of agricultural chemical products or pesticides in Australia. This program is called the Adverse Experience Reporting Program for agricultural chemicals (AERP *Ag*).



Aim of the program

The aim of the AERP *Ag* is to provide the APVMA with feedback about the performance of agricultural chemical products in the field to ensure that registration decisions being made by the APVMA remain appropriate and effective, and to promote and maintain public confidence in the APVMA and the National Registration Scheme.

Structure of the program

There are three complementary components of the AERP *Ag*:

- the *'voluntary'* component encourages the general public (including farmers and other chemical users, agronomists and bystanders) and health workers (including doctors, nurses and alternative medicine practitioners) to

report any adverse experiences to both the APVMA and the product registrant.

- the *'State'* component encourages State agencies to pass on to the APVMA any adverse experience reports that they receive that are within APVMA jurisdiction. It also provides a mechanism for the APVMA to inform the relevant State authority of any information that it becomes aware of that falls within State jurisdiction (such as State control-of-use issues).
- the *'registrant'* component provides a mechanism for registrants of pesticides to report to the APVMA any adverse experiences that they become aware of for their products.

Development and implementation

The APVMA consulted widely during development of this program and discussions were held with community groups, industry, medical representatives and farming bodies. The *'voluntary'* and *'State'* components of the program were implemented in December 2003. The APVMA had been receiving ad hoc adverse experience reports involving agricultural chemicals prior to this.

In March 2004 the APVMA prepared and published a draft Regulation Impact Statement on the '*registrant'* component of the program for public consultation. A final Regulation Impact Statement was prepared after consideration of issues raised during the consultation phase and published in June 2004, prior to implementation.

Reports received

During 2003–04, the APVMA received a total of 83 adverse experience reports and inquiries. of these:

- 24 involved human health issues
- eight involved injury to native flora or fauna
- eight involved crop damage
- 12 involved injury to domestic animals (mostly snail bait poisonings due to incorrectly stored or applied product)
- two involved lack of efficacy
- 29 were seeking general information.

The quality of information provided in the reports to date has generally been of a very high standard. Registrants of implicated products have been involved in the investigations where possible. Based on assessments of information received, a number of corrective actions are being progressed.

Although the program is still in its infancy, there has been much positive feedback already from both members of the public and product registrants. It is important that the community, the medical profession, government departments and industry continue to support the AERP *Ag* by reporting suspected adverse experiences so that appropriate steps can be taken to maintain the high quality of agricultural chemicals in the Australian market.

AERP *Vet*

Aim of the program

The Adverse Experience Reporting Program for veterinary medicines (AERP *Vet*) is a post-registration quality assurance program established by the APVMA to facilitate responsible management of veterinary chemical products throughout their lifecycle. The program provides a means for identifying corrective actions necessary to assure continued safety, quality and effectiveness of registered veterinary medicines.

Recording and investigating reports of adverse experiences is an important step in detecting unusual or rare conditions that were not evident in clinical or field trials and therefore could not be assessed during the product registration process. The program helps to ensure that products on the market:

- remain safe, effective and of acceptable quality
- are used in the best possible way
- have appropriate instructions and warnings on the label.

Activities undertaken

Activities undertaken to raise awareness of the program with the veterinary profession included:

- two presentations at the Australian Veterinary Association Conference in Canberra in May 2004
- two scientific papers published in the Australian Veterinary Association Annual Conference Proceedings 2004
- articles prepared for publication in Australian Veterinary Surgeons Board's newsletters
- attendance at an international pharmacovigilance meeting for regulators in Ottawa, Canada.

Reports received

There were 1438 adverse experience reports processed and classified in 2003–04. Numerous inquiries were also received from both veterinarians and members of the public. Corrective action was taken as appropriate.

Adverse experience reports involving animals constituted approximately 80 per cent of the reports, followed by lack of efficacy. Human adverse experience reports comprised 3 per cent of all reports. The two most common groups of veterinary chemicals implicated in the reports were the parasiticides (65 per cent) and the vaccines (27 per cent). This is comparable with previous years.

Corrective actions taken included:

- additional warning, precautionary or restraint statements on 18 product labels, including changes to first aid instructions and safety directions for seven products
- additional instructions on four product labels
- one product recall.

The quality of the information provided in the reports was generally of a very high standard, which in part reflects the positive relationships the AERP *Vet* has established and maintained with product registrants. This year the program was consolidated after extensive redevelopment during 2002–03 and significant gains have continued to be made. for example, the increase in voluntary adverse experience reports during the first half of 2004 compared with the same time period last year is attributable to the promotional activities undertaken.

The AERP *Vet* is an essential part of the APVMA's quality assurance activities, providing veterinarians and other users of veterinary products with feedback about the performance of these products in the field. This is knowledge that would otherwise be lost if the program was not in operation.

It is important that the AERP *Vet* continues to meet the needs of the veterinary profession and the general community. To this end, more reports will be prepared and published, and the requirements of the veterinary profession and general public closely monitored. This dissemination of information is vital so that informed decisions can be made about the health and welfare of animals and their owners. The flow-on effects of the National Registration Scheme are many and include increased public and veterinary surgeons' confidence and awareness.

Performance monitoring

Australia's agricultural and veterinary chemicals management system provides vital and fundamental support to the success of Australian

Safety of Australia's food supply

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

The National Residue Survey monitors around 30 000 randomly selected samples for residues in raw food commodities each year. The incidence of residues in excess of MRLs reported in these surveys is very low (see Table 3). This reflects the success of the measures put in place by government and industry to mitigate trade risks, a key element of which is the chemical product registration scheme operated by the APVMA.

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

Table 3. Percentage compliance with MRLs for pesticides and veterinary medicines in the National Residue Survey

Commodity group	1999–00	2000–01	2001–02	2002–03
Meat products	99.98	99.98	99.87	99.99
Grain products	99.97	99..98	99.65	99.99
Horticultural products	99.98	99.96	98.83	100.00
Fisheries products	100.00	100.00	100.00	100.00

agriculture. It is essential that the system does this while also protecting the health and safety of people and animals, the environment and trade.

The APVMA is undertaking work to determine the scope of the monitoring that is currently undertaken and its adequacy in assessing the performance of the chemicals management system in relation to public health, worker exposure, the environment and trade. Feedback from such monitoring can provide an important basis for ongoing improvement of the management system. The findings of this work will form a basis for drawing conclusions regarding the impact of agvet chemicals, for proposing initiatives to improve performance outcomes of the overall agvet chemicals management system, and for guiding the future monitoring of the system's performance.

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

Performance:

Effective regulation through chemical review

The Chemical Review Program reconsiders the registration of pesticides and veterinary medicines in the market-place where potential risks to safety and performance have been identified. A review may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical or product.

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

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

At 30 June 2004, the Chemical Review Program had 33 (29 in 2002–03) ongoing reviews. Thirteen of these are comprehensive reviews (shown in Table 4 as (c)) covering all aspects of the respective active constituent, product and labels. The remaining 20 reviews focus on more specific aspects of products and/or their labels.

Table 4. Chemicals under review in 2003–04

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

(c) = comprehensive review

During 2003–04, four draft review reports were released for public consultation. These reports, for CCA (arsenic based timber treatments), carbaryl, endosulfan, and fenitrothion are available on the APVMA web site. Summaries of the reviews are presented below.

Chemical reviews were initiated in 2003–04 for benomyl, dimethoate, fipronil and omethoate. A comprehensive review scope document was prepared for each review and is available from the APVMA web site. The scope document details the background to a review including the reasons for review and the aspects of active constituent approval, product registration and/or labels that are to be examined.

Arsenic based timber treatments

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

There has been a high level of community, industry, media and public attention on this review. This is because of the concerns about possible health effects, particularly for children who may have a high level of contact from play equipment. Stakeholder concerns were also addressed through timely responses to enquiries, published information on the web site and meetings with industry groups.

A draft review report was released for public comment in December 2003. It recommended that CCA-treated timber products should not be used in future for children's play equipment, picnic tables, decking boards, handrails, or other structures with which people may have frequent and intimate contact. The report has also recommended a number of other measures to minimise health and environmental concerns from CCA or arsenic trioxide.

Public comments on the draft review report are being taken into consideration in finalising the regulatory outcomes of the review.

Fenitrothion

Fenitrothion is used to control a wide range of insect pests in fruits, vegetables, cereals and other crops. It is also used in stored grain facilities and for structural protection. The review was undertaken because of concerns relating to residues in food, worker exposure, and the potential harm that runoff and spray drift may have on birds and aquatic insects.

A draft review report was released for public comment in May 2004. The key findings were that use of fenitrothion might, in some situations, create unacceptably high risks to workers handling the chemical, to human health

through possible residues in food, and to animals in the environment. However, these risks can be eliminated by prohibiting a number of uses, and also by changes to instructions on how the chemical must be used.

It is proposed that the use of fenitrothion for controlling locust plagues will be retained. Farmers will also still be able to use it as a grain protectant in silos. However, most ground-based uses will no longer be allowed. This will have some implications for horticultural and broad-acre crops (including pastures).

Endosulfan

Endosulfan is used to control insect pests on a variety of horticultural and agricultural crops. The review was undertaken to assess a range of concerns relating to human health, environment, residues, and worker exposure. There were also some significant concerns for trade because of the potential for residues in meat that may result from cattle eating contaminated feed.

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

A draft review report was released for public comment in May 2004. It recommended that some uses of endosulfan be deleted, including for some horticulture and broad-acre crops. A key issue remaining for the review is the potential for by-products of cotton or legume vegetables, treated with endosulfan, to be fed to livestock and possibly lead to endosulfan residues contaminating meat.

The APVMA is seeking public comment on the options that have been proposed to address this issue before finalising the review.

Carbaryl

Carbaryl products control insect pests in a broad range of agricultural and domestic situations. The review of carbaryl was originally initiated to consider residues in cereal crops and in animal commodities. It was later extended to include possible human health concerns when carbaryl is used in home garden or domestic animal applications.

A draft review report was released for public comment in June 2004. It recommends a number of changes, including deletion of some uses and tightening of label instructions for other uses. The report recommends that many of the uses of carbaryl on fruit and vegetables be deleted. It recommends that registrations for dust products be cancelled. The report also recommends the continuation of uses on pastures, cropping and grain storage, in commercial or industrial areas and as domestic animal shampoos and eardrops.

Public comments on the draft review report are being assessed in finalising the regulatory outcomes of the review.

Virginiamycin

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

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

The draft review report on products which contain virginiamycin was released in April 2003. The draft report canvassed deletion of all registered uses for growth promotion, the retention of registered uses for prevention of necrotic enteritis and rumenal acidosis, but also the addition of label restraint statements which would restrict the length of time during which virginiamycin may be used.

The APVMA received more than 30 responses to the invitation for comment on the draft report. The responses fall into two broad groups: one group recommends that the use of virginiamycin in animals should be either deleted entirely or further curtailed. The other group recommends that there is no need for any label restraints additional to the use restraints associated with the Poisons Act scheduling of virginiamycin.

The APVMA is in the process of completing the final review report, which is scheduled to be released in the first quarter of 2004–05.

Other achievements

In 2003–04, new project management procedures and a comprehensive review of process documentation were implemented for the Chemical Review Program to improve efficiency and targeting of resources and to capture recent legislative change.

To better communicate review findings to the general community a simplified information sheet format has been developed for publication on the APVMA web site. This was developed from discussions with the APVMA Community Consultative Committee. Information sheets will be produced each time a draft review report is released for public consultation and a regular Chemical Review feature has been included in the *APVMA News*.

Following an evaluation of the potential implications of chemical reviews, greater attention is now given to the needs of chemical users in the review process. Reviews will identify potential impacts on user industries early in the process. This provides an opportunity for users to provide data or information to help address concerns with the chemical or to identify alternative pest control measures.

Strategy 3
Ensure product quality through risk-based compliance strategies

Performance:

Compliance

To further enhance the effectiveness of its enforcement actions the APVMA has put procedures in place to ensure clear distinction between accountability for compliance and technical decisions associated with particular products. The APVMA has also established a Regulatory Compliance Committee that includes senior management from different programs. This committee provides guidance to the Compliance Section in achieving effective, consistent and coordinated approaches to addressing issues of non-compliance.

Reports of non-compliance

The APVMA encourages industry and the public to report the advertising and supply of unregistered and unapproved chemicals or any promotion of products that is inconsistent with their approved label. 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 or animal health, or trade with other countries.

Reports assessed as representing a potential or actual high risk are dealt with by an inquiry that may escalate to an investigation, with a view to

prosecution or product recall. Those assessed as representing a low to medium or continuing risk are dealt with mainly by warnings and negotiation to achieve compliance. During the year 268 new reports were received. of these 75 per cent were assessed as low risk, 16 per cent as medium or continuing risk, and 9 per cent as high risk. A total of 248 reports were finalised during the year through warnings and negotiated compliance. Eight resulted in a product recall and three were considered for investigation.

During 2003–04, the APVMA developed a strategy to deal with situations where repeated non-compliance has occurred with the same product. As at 30 June 2004, three companies have been subjected to comprehensive audits of their entire product range and several products have been withdrawn from supply as a result of the strategy. To date companies have acted voluntarily to withdraw products from the market.

Investigations and recalls

During the year, the APVMA initiated two investigations with a view to prosecution. Seven investigations were completed: four were dealt with by a warning letter, two by negotiated compliance or were closed due to insufficient evidence to support any further action and one resulted in charges being withdrawn.

Two prosecutions were completed successfully during the year as follows:

- As a result of continued reports of non-compliance the APVMA conducted an investigation into the supply of unregistered veterinary products and their promotion by Group A Health Care and its Director. Proceedings were commenced by the Commonwealth Director of Public Prosecutions and after a contested hearing into the matters before Hobart Magistrates' Court in December 2003 the magistrate found a total of 161 charges proven against the company and its Director. Sentencing in this matter is still to be completed.
- In 1998 the APVMA received several complaints from veterinary surgeons about the promotion and supply of an unregistered veterinary medicine containing ranitidine hydrochloride and an investigation of the supplier Denlin Laboratories was launched. The company was subsequently wound up and upon advice from the Commonwealth Director of Public Prosecutions the APVMA agreed to have the charges under the Agvet Code withdrawn on 9 January 2004 as the individuals responsible for the breaches had been sentenced on other criminal matters.

The APVMA monitored 26 voluntary recalls during the year and managed 21 compulsory recalls as follows:

- After suspension of the APVMA manufacturing licence for Pan Pharmaceuticals Ltd the APVMA could not be satisfied that batches of product manufactured by Pan after May 2002 would not have an

unintended effect that could be harmful to animals treated with the products. The APVMA therefore recalled specific batches of Trisoprim Antibacterial Tablet, Illium Pyraquantel Allwormer Tablets for Dogs, Troy Wormex Allwormer Tablets for Dogs and Double Strength Cosequin DS Double Strength Sprinkle Capsules for Dogs. These recalls carried over into 2003–04.

- Batches of Allfire Triasulfuron Herbicide were recalled following the detection of the contaminant quinoline. The APVMA could not be satisfied that the presence of quinoline in the formulation would not be an undue hazard to people exposed to it during its handling or people using anything containing its residues. The contaminated product has been returned to the country of origin.
- The APVMA review of diazinon products resulted in the voluntary recall of several diazinon products that did not contain an adequate stabiliser and the compulsory recall of David Gray's Lawn and Insect Killer. The APVMA had determined that diazinon products based on hydrocarbon solvents formulated without an adequate concentration of stabiliser could degrade to toxic breakdown products over time, particularly if the contents of the container were mixed with a small amount of water. Such products were considered to be a risk to public health and animal safety.
- All batches of the product Keymix Keyquindox bearing an unapproved label were recalled following application of a sticker to the main label of the product, which stated that the product was a dustless formulation. The product contains olaquindox, which requires users to wear specific protective equipment and take precautions against exposure to the dust. The claim that the formulation was dustless had never been assessed by the APVMA. It was considered that placement of the dustless claim may lead users to believe that safety precautions to prevent exposure to the dust may not be required.
- Over the last two years the APVMA received complaints about the suspected use of unregistered plant hormones in the grape growing industry in the Mildura, Euston and Robinvale regions of Victoria. The chemicals are used to increase the size of grapes and contain the active constituents forchlorfenuron and gibberellic acid. The APVMA conducted an investigation into the suspected supply, which resulted in recall of an unregistered gibberellic acid product.
- The Compliance Program instigated a compulsory recall for the unregistered veterinary medicine Micro Bio Scoot, supplied by Micro Labs International in Queensland, after receiving an adverse experience report about the product and not receiving responses to two warning letters.
- In March 2003 the APVMA warned swimming pool and spa owners of the need for effective sanitation of pools and spas and advised that using silver and copper ion based pool and spa sanitising devices may result

in ineffective sanitation without also using a registered pool sanitiser. This warning followed analysis of available scientific evidence that was unable to show that these devices were effective for complete sanitation of pools and spas. The APVMA instigated compulsory recall action against a number of ionising products. Some suppliers of pool ioniser products have commenced legal proceedings challenging the APVMA's decisions to take recall action against them. Orders made by the Administrative Appeals Tribunal have temporarily affected the recall of some ionisers.

Advertising

Advertising that promotes unregistered products or makes unapproved claims about registered products is often referred to the APVMA for compliance action. In many instances the alleged non-compliance is concerned with commercial competition issues, rather than any significant threat to human or animal health, environmental harm or an adverse impact on trade. The APVMA clarified via a Gazette notice in June 2004 that it will not take action on complaints purely involving commercial competition issues. Such complaints can often be more appropriately considered by authorities responsible for fair trading in the States and Territories or the Australian Competition and Consumer Commission or through civil action. This clarification reflected the APVMA's focus on addressing non-compliance that poses risks of significance (to human and animal health, the environment, crop safety and trade) identified in the Agvet Code.

Quality Assurance Scheme for agricultural active constituents and products

In May 2004, the APVMA introduced a new scheme to help ensure the quality of active constituents used in agricultural chemical products.

The main elements of the scheme are the introduction of revised data requirements for chemistry and manufacturing and development of APVMA Standards for Agricultural Active Constituents in Chemical Products. The new scheme will require revised processes for considering applications for agricultural active constituents and related product registrations. The revised processes have been widely publicised among the agricultural chemical industry.

Under the new scheme the critical element in ensuring the quality of active constituents used in agricultural chemical products will be demonstrated compliance with the APVMA Standards.

The scheme will impose conditions for approval and registration. These conditions will be set for new active constituent approvals, for which there is a standard, and related product registrations. Products currently registered will have conditions set, where applicable, following a review. The conditions will require that active constituents can only be supplied if they

comply with a particular standard and registrants can only supply products where the active constituent contained in the product complies with the standard. The conditions will also require registrants to keep records of supply and evidence of compliance with the standards.

The transition to the new scheme began in April 2004 when the APVMA published the new requirements and the standards. In 2005 the APVMA will complete the implementation of a compliance program, which will monitor compliance through inspection of records and testing of products for compliance with standards.

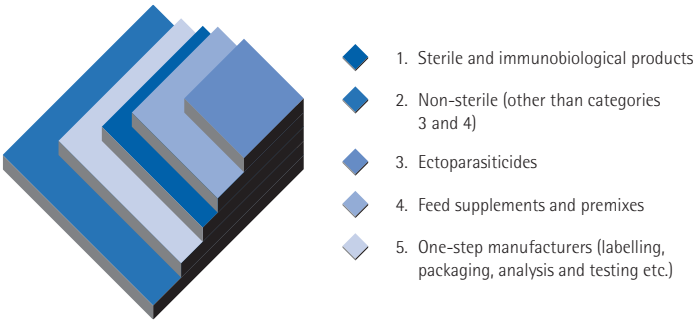
Manufacturers' Licensing Scheme—promoting good manufacturing practice

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

for veterinary chemical products manufactured overseas, the registrant must demonstrate that the product is manufactured to quality standards comparable to those applying to veterinary chemical products manufactured in Australia.

At 30 June 2004, the number of Australian–based manufacturers licensed or being assessed for a licence was 231. Figure 6 shows manufacturers distributed according to licence category.

Figure 6. Numbers of manufacturers licensed, or being assessed for a licence, under the Manufacturers' Licensing Scheme, by category, at 30 June 2004



MLS category of manufacturer	No. of manufacturers
1. Sterile and immunobiological products	40
2. Non-sterile (other than categories 3 and 4)	89
3. Ectoparasiticides	14
4. Feed supplements and premixes	29
5. One-step manufacturers (labelling, packaging, analysis and testing etc.)	59
	231

The management of the Manufacturers' Licensing Scheme was closely integrated with the APVMA's Recall, Adverse Experience and Compliance programs and a firm approach continues to be taken with manufacturers who fail to comply with required standards. More stringent conditions continued to be imposed on all new and existing licences to improve compliance and overcome delays in responding to audit findings. As a consequence of these and other initiatives, only one manufacturer still holds a conditional licence, issued at commencement of the scheme. At 30 June 2004, 11 per cent of licensed manufacturers were in the process of either applying for a new licence, changing site or changing ownership as a result of significant corporate activity within the veterinary chemical manufacturing industry.

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

Import facilitation

As part of the registration process for veterinary drugs, overseas-based manufacturers are assessed for their compliance with Australian GMP requirements. During 2003–04 181 such applications were assessed for compliance with Australian manufacturing standards.

The APVMA has been revising the Code of GMP as well as developing measures for ensuring the ongoing compliance of overseas manufacturers. When implemented in 2004–05, these changes will provide greater assurance of, and confidence in, the quality of veterinary products being supplied to Australian consumers.

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, Philippines, Saudi Arabia, Singapore, South Korea, Taiwan and Thailand. Countries within the European Community and the European Free Trade Association also accept certificates issued under the terms of two Mutual Recognition Agreements.

During the financial year, 65 export certificates were assessed for compliance with Australian manufacturing standards. of these, two were issued under the Mutual Recognition Agreement with the European Community. Officers from the APVMA attended liaison meetings in Europe and New Zealand.

Summary:

APVMA activities throughout 2003–04 contributed to ensuring the ongoing quality of pesticides and veterinary medicines available for sale in Australia. This has been achieved through a number of improvements to the regulatory framework as a result of new information, feedback and process enhancements. Product quality has also been supported through the timely review of a number of chemicals of possible concern when assessed against contemporary standards. Quality assurance programs along with risk-based compliance strategies have worked to ensure that registered products in the market-place continue to meet acceptable standards.

Delivery of output

The APVMA continued to provide a world-class registration scheme for pesticides and veterinary medicines in 2003–04.

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

The APVMA has maintained high standards in its provision of chemical registration services in an increasingly complex operational environment. At the same time it has implemented several initiatives to help enhance the quality of pesticides and veterinary medicines available in the Australian market-place.

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