

The Auditor-General  
Audit Report No.14 2006–07  
Performance Audit

## **Regulation of Pesticides and Veterinary Medicines**

**Australian Pesticides and Veterinary Medicines Authority**

Australian National Audit Office

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of Australia 2006

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Canberra ACT  
7 December 2006

Dear Mr President  
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in the Australian Pesticides and Veterinary Medicines Authority in accordance with the authority contained in the *Auditor-General Act 1997*. I present the report of this audit and the accompanying brochure to the Parliament. The report is titled *Regulation of Pesticides and Veterinary Medicines*.

Following its tabling in Parliament, the report will be placed on the Australian National Audit Office's Homepage—<http://www.anao.gov.au>.

Yours sincerely

A handwritten signature in black ink, which appears to read 'Steve Chapman', is positioned above the printed name.

Steve Chapman  
Acting/Auditor-General

The Honourable the President of the Senate  
The Honourable the Speaker of the House of Representatives  
Parliament House  
Canberra ACT

## AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office. The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits and financial statement audits of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

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# Abbreviations

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Agvet Code	<i>Agricultural and Veterinary Chemicals Code Act 1994</i>
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
CEO	Chief Executive Officer
DAFF	Department of Agriculture, Fisheries and Forestry
DEH	Department of the Environment and Heritage
DoHA	Department of Health and Ageing
GMP	Good Manufacturing Practice
KPI	Key Performance Indicator
MLS	Manufacturers' Licensing Scheme
OCS	Office of Chemical Safety
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration



# Glossary

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Active ingredient	The component of the pesticide or veterinary medicine responsible for its physiological or pharmacological action.
Cost Recovery	Fees and charges related to the provision of government goods and services (including regulation) to the private and other non-government sectors of the economy.
Elapsed time	The overall time taken for the APVMA to determine the outcome for an application for registration. It includes statutory time, and applicant time in addressing deficiencies with applications.
Label	Directions for the product's safe and effective use, which are attached to the container.
Licence	Authority to manufacture veterinary medicines, pursuant to s.123 of the Agvet Code.
Minor Use	A use that would not produce sufficient economic return to an applicant to meet the cost of registering the product for that use.
Pesticides	Also known as agricultural chemical products.
Registrant	A person or company that registers a pesticide or veterinary medicine for use in Australia.
Statutory time	The legislatively prescribed timeframe in which the APVMA must process applications for registration.



## **Summary and Recommendations**



# Summary

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## Background

1. Pesticides and veterinary medicines are used widely in Australia to protect crops, livestock, and plants from pests and diseases, and to treat animals, including household pets, for illnesses and conditions.<sup>1</sup> In 2004–05, sales of pesticides and veterinary medicines in Australia totalled in excess of \$2.3 billion.
2. Although pesticides and veterinary medicines provide benefits to users, they can also be hazardous if manufactured or used incorrectly—potentially causing illness or death to humans or animals, or damage to crops and the environment. Also, high levels of chemical residues in food or livestock can jeopardise trade to export markets.
3. The National Registration Scheme sets out the regulatory framework for the management of pesticides and veterinary medicines in Australia. It is a partnership between the Australian, State and Territory governments. Under the Scheme, the Australian Pesticides and Veterinary Medicines Authority (APVMA) is responsible, on behalf of the Australian Government, for:
  - registering pesticides and veterinary medicines for use in Australia, having satisfied itself that such products are safe and effective for humans, animals, crops and the environment, and are not a trade risk; and
  - assessing the ongoing quality of products following registration, and monitoring compliance with regulations on the importation, manufacture, supply and advertising of pesticides and veterinary medicines, up to the point of retail sale.
4. State and Territory governments are responsible for controlling the use of registered products, following retail sale. Policy on the management of pesticides and veterinary medicines is formally determined by the Primary Industries Ministerial Council.
5. The APVMA is a statutory body, governed by a Board of Directors, which operates within the Agriculture, Fisheries and Forestry portfolio. It

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<sup>1</sup> The term 'pesticides and veterinary medicines' is used to refer to agricultural and veterinary chemical products, as defined in ss. 4-5 of the *Agricultural and Veterinary Chemicals Code Act 1994*.

commenced operations in June 1993, but did not receive full regulatory powers until March 1995.

6. The APVMA's principal activity is the evaluation of applications to register pesticides and veterinary medicines for use in Australia. These are required to be processed within statutory timeframes. The APVMA also conducts various activities to monitor product quality and compliance. These include a licensing scheme for manufacturers of veterinary medicines, and a program to review whether products registered in previous years meet contemporary standards of safety and efficacy. In delivering its regulatory functions, the APVMA obtains scientific advice and services from external providers, mainly Australian and State government departments.

7. The APVMA operates on a cost recovery basis. Its principal source of revenue is a levy on the sale of pesticides and veterinary medicines, which it collects annually from registrants. In 2005–06, the APVMA collected revenue of \$24.3 million, and incurred expenses of \$21.2 million.

8. Prior to this audit, the Australian National Audit Office (ANAO) completed a performance audit of the APVMA in 1997–98 (then called the National Registration Authority for Agricultural and Veterinary Chemicals).<sup>2</sup>

## Audit objective and scope

9. The objective of the audit was to assess whether the APVMA is performing its key regulatory functions effectively. In particular, the audit examined the APVMA's arrangements for:

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

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<sup>2</sup> ANAO Audit Report No. 26 1997–98, *Strategic and Operational Management*, National Registration Authority for Agricultural and Veterinary Chemicals.

## Key findings

### Governance arrangements (Chapter 2)

10. The APVMA has met legislative requirements for developing its Corporate and Operational Plans, and seeks input from stakeholders in developing these plans. Legislative requirements, corporate objectives and risk management strategies are aligned in the APVMA's current planning documents. The APVMA monitors its performance against the objectives set out in the Corporate and Operational Plans.

11. In 2003, the Department of Agriculture, Fisheries and Forestry (DAFF) and the Department of Health and Ageing (DoHA) developed an outsourcing framework for the APVMA. The framework was designed to address recommendations in the previous ANAO report<sup>3</sup> and in a National Competition Policy Review<sup>4</sup> to introduce more contestability into the provision of scientific advice to the APVMA. Under the governance arrangements for the National Registration Scheme, policy affecting the operations of the APVMA is set by either being formally approved by the Primary Industries Ministerial Council, or through a Ministerial direction. The framework was not established under these arrangements. Also, it was not apparent from the available documentation that the framework has been formally endorsed by the APVMA Board.

12. To underpin the integrity of its decision-making processes, and to provide confidence to stakeholders, the APVMA needs to better manage the risk of actual or perceived conflict of interest. The APVMA's arrangements for managing potential conflict of interest for some external service providers have, until recently, been inadequate. Aspects of the current arrangements also require strengthening. This includes requesting conflict of interest declarations from providers before work commences, and developing appropriate procedures to cover members of consultative committees.

### Timeliness of the registration process (Chapter 3)

13. In processing applications to register pesticides and veterinary medicines, the APVMA is required to meet statutory timeframes for conducting preliminary assessments and finalising formal evaluations. The ANAO found that the APVMA does not have adequate systems and processes

<sup>3</sup> ANAO Audit Report No. 26 1997–98, op. cit., paragraph 4.21, p. 37.

<sup>4</sup> *National Legislation Review: Agricultural and Veterinary Chemicals*, Final Report, 13 January 1999, p. ix.

to provide assurance that the time recorded to measure its performance is reliable, and reflects actual performance.

14. The APVMA did not meet its legislative obligation of finalising all applications within statutory timeframes in the period examined by the ANAO (2001–02 to 2005–06). The overall time taken by the APVMA to make registration decisions, which includes applicant time in addressing deficiencies with applications, has increased over this period. Schemes designed to reduce the level of regulatory intervention for lower risk products have not been effective. No products have yet been registered under these schemes.

15. Although the APVMA has put in place a range of measures to assist applicants in registering products, there is still a high number of deficiencies (errors or omissions) in applications. The APVMA does not have systematic processes for analysing the type and cause of these deficiencies.

#### **Managing external scientific advice (Chapter 4)**

16. The APVMA obtains expert advice to assist it in evaluating applications to register pesticides and veterinary medicines, and to support other regulatory functions. This advice is provided mainly by the Office of Chemical Safety (OCS), the Department of the Environment and Heritage (DEH), State government departments and private consultants.

17. The APVMA has established adequate formal arrangements with external service providers, with the exception of some State government departments.

18. OCS and the DEH have generally met the assessment timeframes set by the APVMA. However, almost half of all efficacy and safety assessments finalised in 2004–05 by State government departments or private consultants exceeded the timeframe specified by the APVMA. The ANAO considers the APVMA's arrangements for managing the timeliness of safety and efficacy assessments could be improved by systematically monitoring reviewer's performance, and analysing the causes of delays, to identify opportunities for improvement.

19. Since 2001–02, the APVMA has committed in its Service Level Agreements with OCS and DEH to paying a minimum of 80 per cent of the annual budget for estimated services agreed with each agency. This is regardless of whether services of an equivalent value are provided during the financial year. The current arrangement of providing guaranteed minimum funding to OCS and DEH for provision of scientific advice is different from the



APVMA's arrangements for engaging other services providers, and stems from its reliance on these agencies for advice. In this context, the APVMA has recently sought to identify other sources of advice, but only for some of the services provided by OCS. No action has been taken to identify alternative providers for the advice currently provided by DEH. It would be timely for the APVMA to assess whether a more contestable approach to the provision of scientific advice would be beneficial and lead to greater efficiencies in the allocation of resources, and thus benefit fee and levy payers.

## **Monitoring product quality (Chapter 5)**

20. All veterinary medicines must be manufactured to quality standards, and the APVMA has two schemes to confirm that manufacturers comply with these standards—the Manufacturers' Licensing Scheme, and the Overseas Good Manufacturing Practice Scheme.

### ***Manufacturers' Licensing Scheme***

21. A licence is issued to manufacturers by the APVMA under Part 8 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). Under the current licence conditions, the APVMA has not established appropriate access arrangements for staff to undertake regulatory activities. In practice, the APVMA relies on the licence holder granting access when and if requested. The APVMA uses third-party auditors to assess manufacturers' initial and ongoing compliance with quality standards. However, third-party auditors have only been authorised to conduct audits prior to a licence being issued to a domestic manufacturer of veterinary medicines. In practice, third-party auditors also undertake audits after the licence has been issued, and appropriate authorisations should be in place.

22. The APVMA relies on the results of the compliance audits to determine whether licenced manufacturers of veterinary medicines are meeting quality standards. The ANAO found that audits were regularly undertaken after the due date and key documents, such as the audit report, were either overdue or had not been provided to the APVMA. Without these reports, the APVMA has limited assurance that veterinary medicine manufacturers are complying with the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products.

23. The APVMA was unable to provide documentation (including the audit report) for the audits undertaken by the Therapeutic Goods

Administration (TGA) on its behalf. This is contrary to the arrangements in the Memorandum of Understanding between the APVMA and the TGA.

### *Overseas Good Manufacturing Practice Scheme*

24. Prior to October 2005, the APVMA did not have systems to confirm that overseas manufacturers of veterinary medicines complied with manufacturing requirements following registration. Conditions of product registration are now in place that require the registrant to hold appropriate certifications of compliance for all relevant overseas-based manufacturers. The APVMA undertook an initial assessment of evidence of overseas manufacturer compliance in October 2005, and found that its data set was incomplete because registrants did not identify all overseas manufacturers to be used when completing the product application; and/or had not advised the APVMA of changes to the manufacturers they use, after the product was registered.

### *Quality of pesticides*

25. In September 2005, the APVMA established a program to assess the quality of active ingredients used in the manufacture of pesticides. Records must be held by registrants to prove the quality of the active ingredients used. In February 2006, the APVMA commenced checking these records. The checks found that more than 90 per cent of the records were missing, incomplete or contained errors. Without reliable records, the APVMA can not gain assurance on the quality of pesticides available for sale in Australia.

### *Reviewing registration decisions*

26. Under the Agvet Code<sup>5</sup>, the APVMA determines whether chemicals approved or registered in previous years meet contemporary standards of safety and efficacy, and do not pose unacceptable risks to people, animals, crops, the environment or to trade. The APVMA established the Chemical Review Program (CR Program) in October 1994 to identify and review chemicals of concern. The APVMA has reasonable arrangements in place to identify chemicals that require review and to prioritise the reviews according to the risks they represent. However, the time taken to progress through the list of chemicals to be reviewed is slow despite efforts being made to improve the timeliness of reviews. Of particular concern is that the risks associated with the use of these chemicals remain. Up-to-date information on the review program has not been made available to the general public, including users of the affected products.

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<sup>5</sup> Part 2, Division 4.

## Cost recovery arrangements (Chapter 6)

27. The APVMA has taken practical measures to collect the required amount of levy and annual fee revenue. Although there is some misstatement by companies of sales on which the APVMA's levy payments are calculated, the amounts are relatively minor, and the APVMA has taken steps to address these.

28. The APVMA has established processes to identify the costs of its regulatory activities, to inform the setting of appropriate charges. The cost recovery model is due to be reviewed in 2007–08, as part of a broader review occurring within the Agriculture, Fisheries and Forestry portfolio. This review is timely given some major legislative and organisational changes to the APVMA since its current costing model was last revised in 2003.

29. The APVMA has generally taken appropriate measures to manage the under or over recovery of revenue. This includes proposing reductions to levy rates when excess revenue has accumulated, and setting funds aside (in a Risk Reserve) to off-set an unexpected fall in revenue.

## Overall audit conclusion

30. The APVMA plays a vital role in the regulation of pesticides and veterinary medicines. Since the ANAO's previous audit in 1997–98, and particularly in recent years, the APVMA has introduced various initiatives to improve the effectiveness of its operations. However, key programs to monitor the quality of pesticides and veterinary medicines, such as the Manufacturers' Licensing Scheme and the Chemical Review Program, could be better administered. Greater emphasis needs to be given to compliance programs and to completing chemical reviews in order for the APVMA to provide assurance that manufacturers of pesticides and veterinary medicines are meeting the required standards, and that products approved for sale in Australia are safe and effective. The APVMA is also not meeting its obligation to finalise all applications within statutory timeframes. This increases the cost of regulation, for both the APVMA and applicants, and impacts on users' access to pesticides and veterinary medicines.

31. The ANAO considers that, to deliver its regulatory functions more effectively, the APVMA needs to address some key issues relating to the broader management of the National Registration Scheme. These include reviewing the current arrangements for sourcing expert scientific advice to inform its registration decisions, and the role of State and Territory

government agencies in conducting compliance monitoring activities on its behalf. In addition, the APVMA should examine options for establishing more effective arrangements for regulating pesticides and veterinary medicines deemed to be lower risk. Such arrangements should allow the APVMA to utilise its resources better, potentially resulting in improved timeframe performance for determining applications.

32. The ANAO has made six recommendations aimed at improving the APVMA's regulation of pesticides and veterinary medicines.

## **APVMA response**

33. The APVMA welcomes the ANAO report and accepts the six recommendations of the report. The recommendations will assist our efforts to continue to strengthen performance as an efficient and effective regulator. Actions to implement the recommendations are underway.

34. With respect to Recommendation 1, the APVMA will strengthen existing arrangements for managing potential conflicts-of-interest in the identified areas. The APVMA will implement Recommendations 2 and 3 by building on current initiatives to manage and report on timeliness of processing registration applications and by more systematic analysis and communication to the chemical industry of types of deficiencies in their applications. Current arrangements for procuring external scientific advice will be reviewed to implement Recommendation 4. The operation of the APVMA's Manufacturers' Licensing Scheme will be strengthened through implementation of Recommendation 5. With respect to Recommendation 6, the APVMA will assess current approaches to chemical review and disseminate more comprehensive information on reviews to stakeholders.

35. The APVMA's full response is at Appendix 1.

# Recommendations

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## Recommendation No. 1

### Para 2.26

The ANAO recommends that the APVMA strengthen arrangements for managing potential conflict of interest by:

- (a) requesting external service providers to provide positive assurance on the absence of a conflict of interest, prior to undertaking any work; and
- (b) documenting appropriate procedures for members of consultative committees, consistent with legislative requirements.

*APVMA response: Agreed.*

## Recommendation No. 2

### Para 3.8

To improve arrangements for monitoring and reporting on statutory timeframes for processing applications to register pesticides and veterinary medicines, the ANAO recommends that the APVMA:

- (a) systematically monitor timeframes for conducting preliminary assessments;
- (b) report timeframe performance for applications that are refused or deemed to be withdrawn; and
- (c) establish processes to verify the accuracy of time entries.

*APVMA response: Agreed.*

## Recommendation No. 3

### Para 3.32

The ANAO recommends that the APVMA improve its registration processes by systematically analysing the type and cause of errors or omissions in applications, to better target its initiatives to improve the quality of applications.

*APVMA response: Agreed.*

**Recommendation  
No. 4**

**Para 4.30**

The ANAO recommends that the APVMA review its current arrangements for obtaining scientific advice from Australian government agencies to assess whether a more contestable approach would be beneficial and lead to greater efficiencies in the allocation of resources.

*APVMA response: Agreed.*

**Recommendation  
No. 5**

**Para 5.19**

To improve the Manufacturers' Licensing Scheme compliance framework, the ANAO recommends that the APVMA:

- (a) include appropriate access provisions for relevant APVMA staff and third-party auditors in licence conditions and Deeds of Authorisation; and
- (b) develop and implement processes for third-party auditors to undertake audits by the required date and institute follow-up mechanisms if the relevant audit report is not received within stated timeframes.

*APVMA response: Agreed.*

**Recommendation  
No. 6**

**Para 5.43**

To improve the effectiveness of the Chemical Review Program, the ANAO recommends that the APVMA:

- (a) assess whether the current approach and time taken to complete reviews adequately addresses the risks presented by the chemicals not yet under review; and
- (b) communicate the status of reviews currently underway, emerging issues and updates on planned activities.

*APVMA response: Agreed.*

## **Audit Findings and Conclusions**





# 1. Background and Context

*This chapter describes the Australian Pesticides and Veterinary Medicines Authority’s (APVMA) role in regulating pesticides and veterinary medicines in Australia. It also sets out the objectives, scope and methodology for the audit.*

## Introduction

**1.1** Pesticides and veterinary medicines are used to protect crops, livestock, and plants from pests and disease. They are also used to treat animals, including household pets, for illnesses and conditions.<sup>6</sup>

**1.2** Primary industries, such as agriculture and horticulture, use pesticides and veterinary medicines to enhance produce quality, and to increase productivity and competitiveness. Other users include: pest controllers; veterinarians; home gardeners; and pet owners. In 2004–05, sales of registered pesticides and veterinary medicines in Australia totalled in excess of \$2.3 billion.<sup>7</sup> Table 1.1 provides some examples of pesticides and veterinary medicines.

**Table 1.1**

**Examples of pesticides and veterinary medicines**

Pesticides	Veterinary medicines
<b>Herbicides:</b> such as sprays used to control annual and perennial weeds found in crops.	<b>Anti-inflammatory drugs:</b> such as tablets and injections to relieve arthritis in dogs.
<b>Insecticides:</b> including household fly sprays and garden dusts to control aphids.	<b>Vaccines:</b> such as injectable products to immunise sheep against footrot.
<b>Fungicides:</b> such as sprays used to eradicate the fungal disease, Black Sigatoka, in banana crops.	<b>Antibiotics:</b> such as injections for the treatment of pneumonia.
<b>Vertebrate pest baits:</b> such as 1080 for fox control.	<b>Parasite treatments:</b> such as drenches used to control or prevent blow fly or louse infestations in sheep.

Source: ANAO analysis of APVMA data.

<sup>6</sup> The term ‘pesticides and veterinary medicines’ is used to refer to agricultural and veterinary chemical products, as defined in ss. 4-5 of the *Agricultural and Veterinary Chemicals Code Act 1994*.

<sup>7</sup> Pesticides and veterinary medicines are required to be registered by the APVMA before they can be supplied for sale in Australia.

**1.3** Although pesticides and veterinary medicines provide benefits to users, they can also be hazardous if manufactured or used incorrectly—potentially causing illness or death to humans or animals, or damage to crops and the environment. Also, high levels of chemical residues in food or livestock can jeopardise trade to export markets.

## The National Registration Scheme

**1.4** The National Registration Scheme sets out the regulatory framework for the management of pesticides and veterinary medicines in Australia. It is a partnership between the Australian, State and Territory governments. Under the Scheme, the APVMA is responsible, on behalf of the Australian Government, for:

- registering pesticides and veterinary medicines for use in Australia, having satisfied itself that such products are safe and effective for humans, animals, crops and the environment, and are not a trade risk; and
- assessing the ongoing quality of products following registration, and monitoring compliance with regulations on the importation, manufacture, supply and advertising of pesticides and veterinary medicines, up to the point of retail sale.

**1.5** State and Territory governments are responsible for controlling the use of registered pesticides and veterinary medicines, following retail sale.<sup>8</sup> In general, this involves monitoring whether products are being used in accordance with the directions for use on the label. Policy on the management of pesticides and veterinary medicines is formally determined by the Primary Industries Ministerial Council<sup>9</sup>, based on advice from its sub-committees, in particular the Product Safety and Integrity Committee. Figure 1.1 illustrates the regulatory framework for the National Registration Scheme.

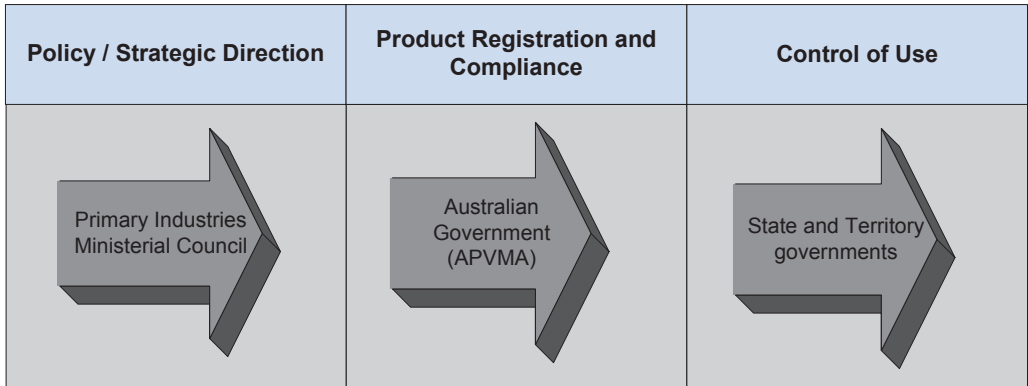
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<sup>8</sup> Prior to the introduction of the National Registration Scheme, each State and Territory government exercised full responsibility for regulating pesticides and veterinary medicines within their jurisdiction, including product registration.

<sup>9</sup> Comprised of Ministers from the Australian, State and Territory governments.

Figure 1.1

Regulatory framework for the National Registration Scheme



Source: ANAO analysis of APVMA data.

About the APVMA

1.6 The APVMA is a statutory body, governed by a Board of Directors, which operates on a cost recovery basis within the Agriculture, Fisheries and Forestry portfolio. It was established in June 1993 to administer the registration function of the National Registration Scheme.<sup>10</sup> It received full regulatory powers in March 1995, following the passing of complementary legislation by the Australian, State and Territory governments.

Legislation and governance

1.7 The APVMA operates under the *Commonwealth Authorities and Companies Act 1997*. Its regulatory function is underpinned by the:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992*, which established the APVMA; and
- *Agricultural and Veterinary Chemicals Code Act 1994*, together with its Schedule, which provides detailed operational procedures on the registration and management of pesticides and veterinary medicines.<sup>11</sup>

<sup>10</sup> The APVMA was originally called the National Registration Authority for Agricultural and Veterinary Chemicals.

<sup>11</sup> The *Agricultural and Veterinary Chemicals Code Act 1994* is a law of the Commonwealth that only applies in the Australian Capital Territory. To enable the Code to have national coverage each of the States and the Northern Territory enacted complementary legislation that has the effect that the *Agricultural and Veterinary Chemicals Code Act 1994* is applied as a law of each State and the Northern Territory.

**1.8** The APVMA is managed by a Chief Executive Officer (CEO), who is required to follow any policies determined, and any directions given, by the Board of Directors. Directors are appointed by the Minister for Agriculture, Fisheries and Forestry.

## **Regulatory functions**

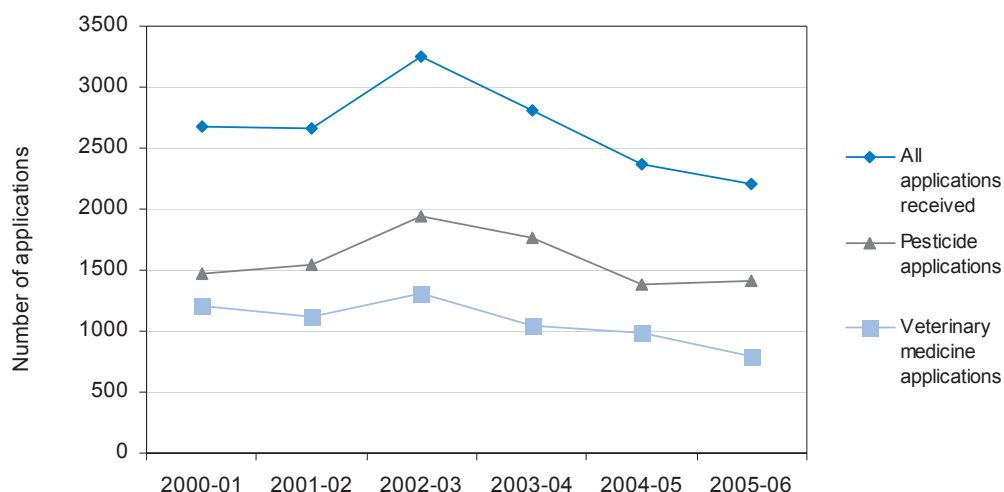
**1.9** The APVMA's principal activity is the evaluation of applications to register, or obtain a permit to supply and use<sup>12</sup>, pesticides and veterinary medicines in Australia. These applications include:

- approval of a new active constituent for a pesticide or veterinary medicine;
- registration of a new pesticide or veterinary medicine containing an approved active constituent; and
- variations to a registered pesticide or veterinary medicine (for example, changing the formulation, or amending the label).

**1.10** Figure 1.2 illustrates the number of applications received by the APVMA in the period 2000–01 to 2005–06.

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<sup>12</sup> Permits allow the use of registered products in ways not covered by the label, or the limited use of unregistered products. They are generally issued for: emergencies; research purposes; or 'minor use' situations.

**Figure 1.2****Applications received by the APVMA, for the period 2000–01 to 2005–06**

Source: ANAO analysis of APVMA data.

**1.11** The APVMA obtains expert advice to assist it in evaluating applications to register pesticides and veterinary medicines, and to support other regulatory functions. This advice is provided mainly by the Office of Chemical Safety (OCS) within the Department of Health and Ageing (DoHA), the Department of the Environment and Heritage (DEH), State government departments and private consultants. An overview of the APVMA's registration process is provided at Appendix 2.

**1.12** A key output from the APVMA's registration process is a label specifying directions for use of the registered product. The label reflects the APVMA's assessment of how potential risks to humans, animals, crops, the environment and trade can, if the directions are followed correctly, be managed appropriately.

### *Quality assurance and compliance*

**1.13** The APVMA undertakes a number of activities to monitor the quality of pesticides and veterinary medicines, following registration, and to assess compliance with regulations. These include:

- assessing whether local and overseas manufacturers of veterinary medicines comply with quality requirements;
- assessing the quality of ingredients used to manufacture pesticides;

- reviewing whether products registered in previous years meet contemporary standards of safety and efficacy; and
- identifying and investigating reports of non-compliance relating to the import, supply and advertising of pesticides and veterinary medicines.

## **Funding and resourcing**

**1.14** The APVMA's principal source of revenue is a levy on the sale of pesticides and veterinary medicines, which it collects annually from registrants. Revenue is also obtained through: application fees to register products; annual fees to re-register products; and other charges, such as licensing fees for manufacturers of veterinary medicines. In 2005–06, the APVMA collected revenue of \$24.3 million, and incurred expenses of \$21.2 million. In recent years, the APVMA has spent around 85 per cent of its annual budget on activities relating to the registration of products, with the balance spent on quality assurance and compliance activities.

## **Stakeholders**

**1.15** The APVMA has a broad and diverse stakeholder base, which includes: Australian, State and Territory governments; the pesticides and veterinary medicines industries; chemical users, including the farming sector and the general public; and other national and international regulators of chemicals. The APVMA employs a range of mechanisms to engage stakeholders, including separate consultative committees with industry representatives, community and user groups, and government agencies.

## **Audit objective, scope and methodology**

**1.16** The objective of the audit was to assess whether the APVMA is performing its key regulatory functions effectively. In particular, the audit examined the APVMA's arrangements for:

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

**1.17** The Australian National Audit Office (ANAO) completed a performance audit of the APVMA in 1997–98 (then called the National Registration Authority for Agricultural and Veterinary Chemicals).<sup>13</sup> In undertaking this audit, the ANAO has, where relevant, taken into consideration the findings and recommendations of the earlier audit.

## **Audit methodology**

**1.18** The ANAO audit methodology included quantitative and qualitative analysis, file and documentation reviews, and interviews with agency officers. Industry stakeholders were also consulted and site visits carried out.

**1.19** The audit was undertaken in accordance with ANAO auditing standards, at a cost of \$450 000.

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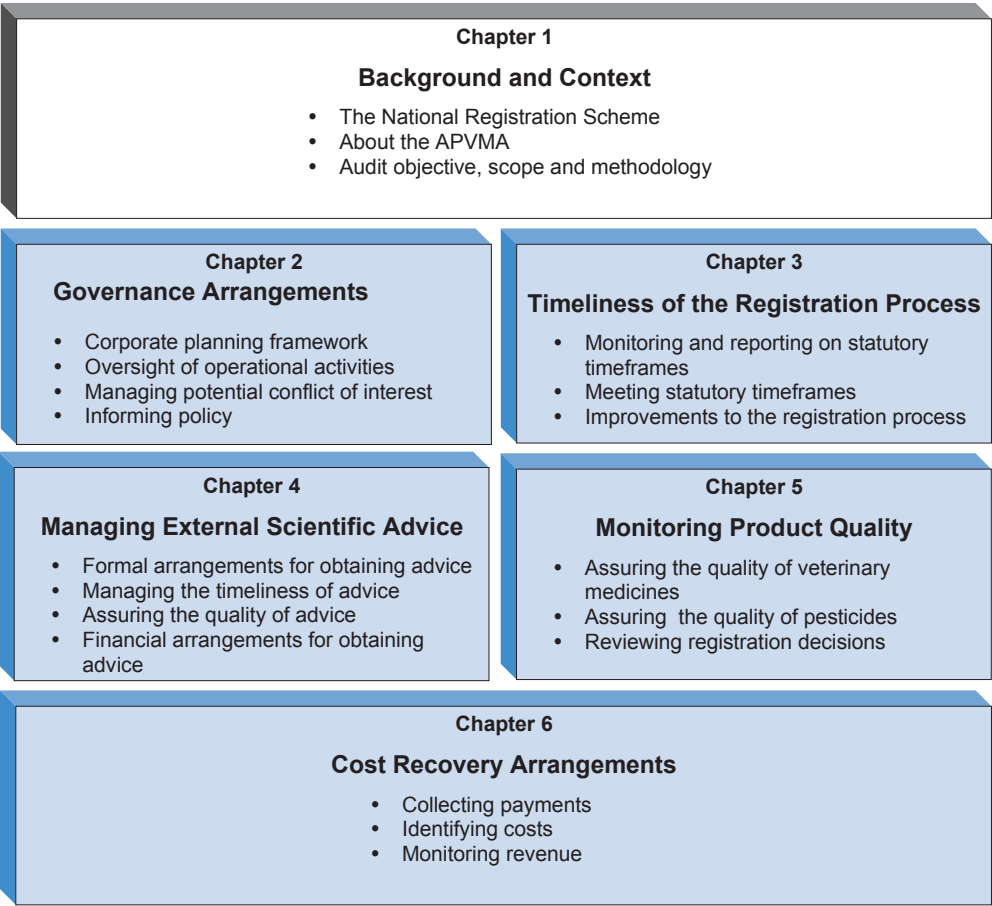
<sup>13</sup> ANAO Audit Report No. 26 1997–98, *Strategic and Operational Management*, The National Registration Authority for Agricultural and Veterinary Chemicals.

# Structure of this report

1.20 The structure of this report is outlined in Figure 1.3.

Figure 1.3

## Report structure





## 2. Governance Arrangements

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*This chapter examines aspects of the APVMA's arrangements for planning and overseeing the delivery of its regulatory functions.*

### Introduction

**2.1** Under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, the CEO is responsible for managing the APVMA in accordance with the policies determined by, and the directions given by, the Board of Directors. In turn, the Board must comply with the policies for the National Registration Scheme, agreed by the Australian, State and Territory governments.

**2.2** In this context, the ANAO has assessed whether the APVMA has established an effective framework to: plan and oversight the delivery of its regulatory functions; and inform the development of policy, to improve its operational effectiveness.

### Corporate planning framework

**2.3** The key elements of the APVMA's planning framework are:

- a Corporate Plan, which sets the strategic direction for the APVMA for a three-year period;
- an annual Operational Plan, which underpins the Corporate Plan and outlines the actions necessary to achieve the goals and outcomes set out in the Corporate Plan; and
- a Risk Management Plan, which identifies strategic and business risks and corresponding treatment strategies.

**2.4** These documents are supported by business plans for program areas, project plans for major initiatives, and individual performance plans for staff.

## Development of, and linkages between, planning documents

2.5 In developing its Corporate and Operational Plans, the APVMA is required to cover matters prescribed in the Administration Act.<sup>14</sup> The ANAO found that the APVMA has met legislative requirements, and seeks input from stakeholders in developing these plans. However, future Corporate Plans could be improved by more explicitly addressing the requirement in the Administration Act to set out the APVMA's assessment of factors that will affect its operations during the period of the plan. In the APVMA's current planning documents, legislative requirements, corporate objectives and risk management strategies are aligned.<sup>15</sup>

## Performance monitoring and reporting

2.6 The APVMA monitors its performance against objectives set out in the Corporate and (especially) Operational Plans, through Key Performance Indicators (KPIs) and targets. Performance is reported quarterly to the Board, and monitored more regularly by management.

2.7 The ANAO found that some KPIs in the 2005–06 Operational Plan were difficult to measure or inconsistent with legislative requirements. For example:

- there was a KPI that 'chemicals of concern [be] assessed and decisions made in a timely manner'. The APVMA has not defined 'timely', reducing its ability to assess performance in finalising chemical reviews; and
- the APVMA set an internal target of finalising 95 per cent of applications within statutory timeframes. However, this target is inconsistent with its legislative obligation to finalise all applications within statutory timeframes. The APVMA has revised this target in the 2006–07 Operational Plan to 'Statutory timeframes met'.

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<sup>14</sup> See ss. 50 and 55 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

<sup>15</sup> In contrast, the APVMA's 2003 Risk Management Plan was not explicitly linked to its legislative responsibilities, or to strategies in the corresponding Corporate Plan.

## Oversight of operational activities

**2.8** The Board of Directors has ultimate responsibility for the operational performance of the APVMA, and so has a duty to exercise appropriate oversight of management and staff in the delivery of regulatory functions. This includes being assured that any decision-making powers delegated to management and staff are being used as intended.

### Management of delegations

**2.9** Pursuant to its powers under the Administration Act, the Board has delegated most of its powers and functions to the CEO and other APVMA staff, through a formal instrument of delegation.<sup>16</sup>

**2.10** The APVMA has implemented various measures to provide assurance that delegations are being used in accordance with the instrument of delegation. This includes: making the instrument of delegation accessible to staff; providing training on the use of delegated powers; and, conducting checks, including external audits, on the exercise of delegations.

**2.11** An external audit, conducted in May 2005, reviewed 99 organisational files and found that ‘in most files the delegate’s name and position were not stated in the instrument evidencing the exercise of a delegated power’. In reviewing a sample of 15 applications to register pesticides or veterinary medicines, the ANAO also found that delegates had not properly identified their name and position. The ANAO considers that better documentation surrounding the identity of delegates would strengthen arrangements for providing assurance to the Board that delegated powers are being exercised appropriately.

### Outsourcing framework for scientific advice

**2.12** In 2003, DAFF and DoHA established an outsourcing framework for the APVMA. The Health Assessment Services Framework (‘the Framework’) was designed to address recommendations made in the previous ANAO report<sup>17</sup> and in a National Competition Policy Review of Agricultural and Veterinary Chemicals Legislation<sup>18</sup> to introduce more contestability into the

<sup>16</sup> A key exception is that the Board has retained responsibility for determining chemical reviews under Part 2, Division 4 of the Agvet Code.

<sup>17</sup> ANAO Audit Report No. 26 1997–98, op. cit., paragraph 4.21, p. 37.

<sup>18</sup> *National Legislation Review: Agricultural and Veterinary Chemicals*, Final Report, 13 January 1999, p. ix.

provision of scientific advice and services to the APVMA. It outlines the protocols to be followed by the APVMA in using alternative providers for some of the services currently provided by the OCS.

**2.13** Under the governance arrangements for the National Registration Scheme, policy affecting the operations of the APVMA is set by either being formally approved by the Primary Industries Ministerial Council, or through a Ministerial Direction. The Framework was not established under these arrangements. Also, it was not apparent from the available documentation that the Framework has been formally endorsed by the APVMA Board.

**2.14** In reviewing the Framework, the ANAO found that there are tensions between some of the protocols and the APVMA's role as an independent statutory body. For example, the Framework allows OCS the right to veto the APVMA's appointment of other service providers. It also states that some scientific services are inherently Government/OCS business<sup>19</sup>, and can not be outsourced to other providers. However, the APVMA's legislation does not require it to seek advice specifically from OCS.

**2.15** The APVMA is in the process of implementing this policy framework, and has identified other service providers, but has yet to outsource any application evaluation work. Therefore, to date, there have been no tangible benefits to the APVMA in terms of cost savings or more timely advice.

**2.16** The ANAO considers that the APVMA should seek formal consideration of the Framework by the Primary Industries Ministerial Council, including reviewing the nature of existing arrangements for obtaining external scientific advice.

## **Compliance planning with the States and Territories**

**2.17** Under an Agreement signed in 1995 between the Australian, State and Northern Territory governments<sup>20</sup>, the APVMA is required to prepare an annual Compliance Program Plan with each of the States and the Northern Territory. Among other things, the Plan is to set out funding and reporting requirements for compliance activities to be undertaken by each party on behalf of the APVMA.<sup>21</sup>

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<sup>19</sup> This advice includes: risk assessment framework, management, setting policies and human health standards—including advice to the APVMA on acceptability of proposed uses from a human health viewpoint.

<sup>20</sup> The Australian Capital Territory is covered under Commonwealth legislation.

<sup>21</sup> The APVMA provided around \$250 000 to the States and the Northern Territory in 2004–05.

**2.18** The ANAO found that, although the APVMA prepared compliance plans in the initial years after the 1995 Agreement was signed, these plans have not been revised since 1997–98. In place of annual compliance plans, the APVMA established Service Level Agreements with each State and the Northern Territory. However, these Agreements have not been updated since 2000–01.

**2.19** The APVMA advised that in recent years the States and Territories progressively handed back responsibility for some compliance monitoring in their jurisdiction. During the same period the APVMA increased its compliance resources and moved to a risk-based program to better target these resources. The APVMA considers that adopting this approach has improved the effectiveness of its compliance activities and its ability to deliver an effective national compliance program. However, as the APVMA is not undertaking formal compliance planning as required by the 1995 Agreement, it should inform the Primary Industries Ministerial Council of its current compliance programs, including its ongoing interactions with the States and Northern Territory; and seek revision of the 1995 Agreement to recognise more recent developments.

## Managing potential conflict of interest

**2.20** To underpin the integrity of its decision-making processes, and to provide confidence to stakeholders, the APVMA needs to manage the risk of actual or perceived conflict of interest. The Administration Act places an obligation on Board Members, the CEO and members of any committees to disclose any financial interests.<sup>22</sup> In this regard, the ANAO found that:

- the APVMA’s arrangements for managing potential conflict of interest for Board Members comply with the legislative requirements, and are being administered effectively;
- the CEO’s requirement to disclose financial interests to the Chair of the Board was met in January 2006—two years after the CEO was appointed; and
- members of the APVMA’s consultative committees have not disclosed financial interests to the APVMA; nor has the APVMA developed procedures to give effect to this requirement.

<sup>22</sup> See ss. 23, 29, and 42 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

**2.21** The ANAO acknowledges that the consultative committees are advisory in nature, and do not make regulatory decisions. However, members are required to disclose financial interests. The ANAO considers the APVMA should promulgate a formal policy for disclosing financial interests and develop appropriate procedures to manage any potential conflict of interest.

## **External service providers**

### *State government departments*

**2.22** State government departments that provide advice to the APVMA on the safety and efficacy of pesticides and veterinary medicines may have commercial dealings with parties that lodge applications with the APVMA.<sup>23</sup> Prior to October 2005, these departments were not required to declare any conflict of interest to the APVMA. The APVMA advised that some State government departments considered that the existing conflict of interest provisions within their departments were sufficient for the purposes of undertaking work for the APVMA.

**2.23** Under current arrangements, State government departments are not required to declare any conflict of interest until their work has been completed and their final report submitted to the APVMA. In contrast, private consultants engaged to provide advice to the APVMA must declare any conflict before the APVMA permits any work to be undertaken. The ANAO considers that the provision of positive assurance on the absence of a conflict before work is undertaken is an important safeguard for the APVMA, and avoids any difficulties that may arise if a conflict is declared after the advice has been provided.<sup>24</sup>

### *Third-party auditors*

**2.24** The ANAO found that the APVMA's current framework for managing potential conflict of interest for third-party auditors, whom it uses to assess whether manufacturers of veterinary medicines comply with quality standards, is adequate.<sup>25</sup> However, prior to October 2005, the APVMA did not require third-party auditors to provide positive assurance on the absence of a

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<sup>23</sup> For example, some State government departments may undertake research and compile efficacy data for companies seeking to register pesticides and veterinary medicines for use in Australia.

<sup>24</sup> For example, the work may have to be re-allocated to another provider, potentially impacting on the cost and timeliness of the advice.

<sup>25</sup> The auditors operate under a Deed of Authorisation requiring conflicts to be declared; no auditor is permitted to do more than two consecutive audits at the same manufacturer; and there is a stand-down period of three years if the auditor has previously worked for the manufacturer to be audited.

conflict of interest, prior to conducting an audit. This was some 10 years after third-party auditing was introduced.

## Conclusion

**2.25** The ANAO considers that the APVMA's arrangements for managing conflict of interest for some external service providers have, until recently, been inadequate. There are also aspects of the current arrangements that require strengthening. This includes requesting conflict of interest declarations from providers before work commences, and developing appropriate conflict of interest procedures to cover members of consultative committees, consistent with legislative requirements.

## Recommendation No.1

**2.26** The ANAO recommends that the APVMA strengthen arrangements for managing potential conflict of interest by:

- (a) requesting external service providers to provide positive assurance on the absence of a conflict of interest, prior to undertaking any work; and
- (b) documenting appropriate procedures for members of consultative committees, consistent with legislative requirements.

### *APVMA response*

**2.27** The APVMA agrees with this recommendation, noting that it will add to the well-established conflict of interest protocols already in place for the Board and staff of the APVMA and many service providers. Formal arrangements for consultative committees will be articulated, noting that they are not regulatory decision-making forums and that members will often represent particular constituents. The APVMA will also seek to strengthen its existing arrangements for external service providers by requiring them to declare known conflicts of interest prior to undertaking work.

## Informing policy

**2.28** The Product Safety and Integrity Committee is responsible for advising the Primary Industries Ministerial Council on policy direction for the National Registration Scheme. The Committee comprises members from Australian,

State and Territory government departments, other public sector bodies<sup>26</sup>, and the APVMA. It meets twice a year, and is chaired by DAFF.

**2.29** The ANAO found that the APVMA has made various representations to the Product Safety and Integrity Committee, typically through DAFF, to propose changes to aspects of its legislative framework. These have been in the context of improving the efficiency and effectiveness of its regulatory functions. For example, the APVMA has proposed changes to the type of chemicals to be covered by its regulation. The intent behind this proposal is to more closely align regulatory processes and resources with the inherent risks posed by different types of chemicals. This proposal has been endorsed by the Committee and has been included in its Work Plan for 2005–06 to 2007–08.

**2.30** The APVMA has also sought to bring its operational experience to bear to inform policy on other matters, including:

- the design of the *Listed Registration* scheme and the *Reserved from Registration* scheme (discussed in Chapter 3); and
- the new cost recovery framework introduced on 1 July 2005 (discussed in Chapter 6).

**2.31** The ANAO concluded that the APVMA has taken an active role to inform the development of policy for the National Registration Scheme, to improve its operational effectiveness.

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<sup>26</sup> Namely: CSIRO; New Zealand Food Safety Authority; Environment Protection and Heritage Council; Workplace Relations Ministerial Council and the Australian Health Ministers' Advisory Council.



## 3. Timeliness of the Registration Process

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*This chapter discusses the adequacy of the APVMA's processes to support timely decision-making when registering pesticides and veterinary medicines for use in Australia.*

### Introduction

**3.1** Before pesticides or veterinary medicines can legally be supplied, sold or used in Australia, they must be registered by the APVMA. The majority of applications received by the APVMA are to 'image' an existing pesticide or veterinary medicine (that is, to produce a similar product, but with a different name), or to vary an existing product.

**3.2** In processing applications, the APVMA is required to meet statutory timeframes for:

- *conducting preliminary assessments*—once an application has been lodged, the APVMA must, within one month, make a preliminary assessment as to whether the application complies with requirements; and
- *finalising formal evaluations*—if an application passes preliminary assessment, and undergoes formal evaluation, the APVMA is required to make a decision on whether to register the product within three to fifteen months, depending on the type of application.<sup>27</sup>

**3.3** These timeframes account only for the time taken by the APVMA to process applications. They do not include the time taken by applicants to respond to any deficiencies in their applications.

**3.4** The ANAO examined whether the APVMA has robust systems to monitor and report reliably on its performance in meeting statutory timeframes, and adequate processes to support timely decision-making.

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<sup>27</sup> Types of applications are outlined in paragraph 1.9. Of the 1 954 applications finalised by the APVMA in 2004–05, some 82 per cent had a formal evaluation timeframe of three months. Less than one per cent of applications finalised in this period had a timeframe of 15 months.

## Monitoring and reporting on statutory timeframes

3.5 The APVMA uses a software application, called the Application Tracking System, to record and monitor its performance in meeting statutory timeframes for processing applications. The basic rules of time recording are that the statutory 'clock' is:

- turned 'on' when the APVMA is evaluating the application;
- turned 'off' when the applicant is responding to a request from the APVMA; and
- turned back on when the applicant's response is received.

3.6 The ANAO found a number of limitations with the APVMA's arrangements for monitoring and reporting reliably on statutory timeframes. These included:

- the APVMA did not systematically monitor whether it has met the one-month timeframe for conducting preliminary assessments;
- until March 2006 (when the APVMA issued a *Clock Management Manual*) there was no detailed guidance for staff on how to manage the rules for time recording;
- errors in time recording were found in the 15 applications examined by the ANAO. For example, dates recorded in the Application Tracking System were inconsistent with the dates of relevant correspondence provided by applicants;
- the APVMA had no formal processes in place to verify the reliability of times recorded in the Application Tracking System;
- timeframe performance data was incomplete: it did not include applications that were 'refused' or 'deemed to be withdrawn' by the APVMA; and
- applicants are not formally advised of whether statutory timeframes are met.<sup>28</sup> However, the APVMA is in the process of implementing an Electronic Application Registration System which, among other things, is intended to provide applicants with on-line access to monitor the status of their applications.

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<sup>28</sup> The Agvet Code provides applicants with the right to make an application to the Administrative Appeals Tribunal for a review of the decision if an application made to the APVMA is not determined within the statutory timeframe the APVMA has to determine the application.

**3.7** Some of these limitations do not adversely impact on actual timeframe performance. For example, some of the errors in time recording identified by the ANAO favoured the applicant (that is, time was assigned incorrectly to the APVMA). However, the current arrangements do not provide assurance to applicants or stakeholders that the APVMA has adequate systems in place to monitor and report reliably on meeting statutory timeframes—one of its key obligations in processing applications.

## Recommendation No.2

**3.8** To improve arrangements for monitoring and reporting on statutory timeframes for processing applications to register pesticides and veterinary medicines, the ANAO recommends that the APVMA:

- (a) systematically monitor timeframes for conducting preliminary assessments;
- (b) report timeframe performance for applications that are refused or deemed to be withdrawn; and
- (c) establish processes to verify the accuracy of time entries.

### *APVMA response*

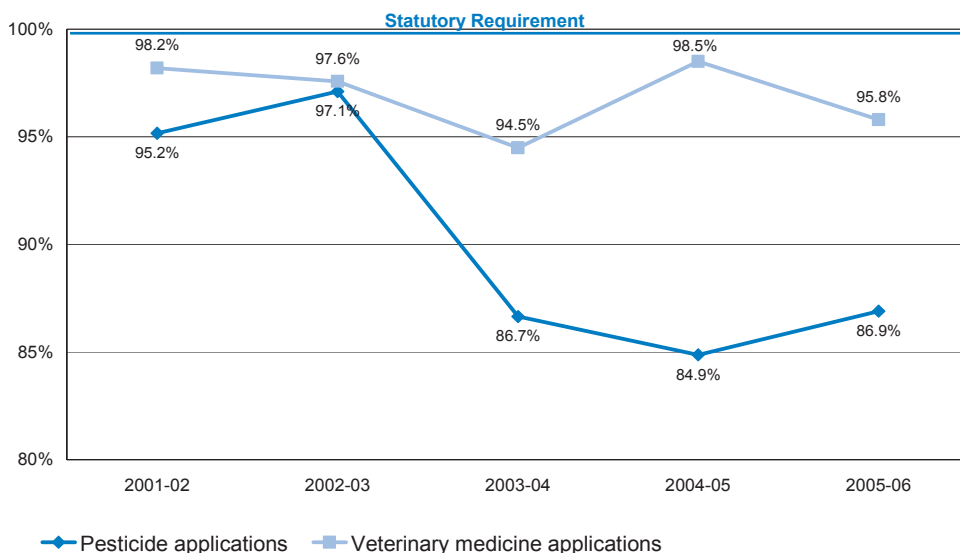
**3.9** The APVMA agrees with this recommendation. The APVMA has, through initiatives such as its Timeframes and Productivity Project, demonstrated a strong commitment to optimising timeframe performance and addressing the challenges presented by additional demands associated with legislative changes implementing new label approval requirements and introducing data protection. Over 98 per cent of all applications received since 1 July 2005 have been completed within statutory timeframes, and the three actions in this recommendation will further improve the rigour and transparency of the overall timeframe monitoring process.

## Meeting statutory timeframes

**3.10** Over the five-year period examined by the ANAO (2001–02 to 2005–06), the APVMA did not meet its legislative obligation to formally evaluate all applications for registration within prescribed timeframes. As illustrated in Figure 3.1, the number of pesticide applications finalised within statutory timeframes declined from 97 per cent in 2002–03 to 85 per cent in 2004–05.

**Figure 3.1**

**Formal evaluations finalised by the APVMA within statutory timeframes, for the period 2001–02 to 2005–06**



Source: ANAO analysis of APVMA data.

**3.11** The APVMA advised that timeframe performance since 2002–03 has been impacted by various factors, including legislative changes to:

- *the label approval process*—since October 2003, the APVMA has been required to approve the final version of the label to be affixed to the product container. Previously, the APVMA approved a text version only; and
- *data protection requirements*—since 1 January 2005, the APVMA has been required to comply with new requirements for protecting data supplied by applicants.

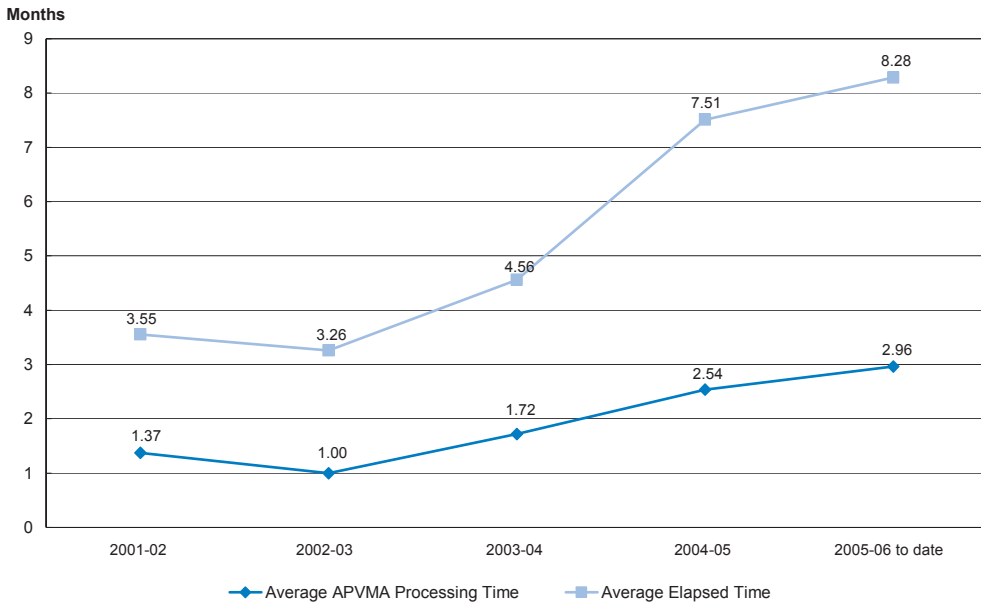
**3.12** The APVMA estimates that these tasks have increased its workload by up to 30 per cent, with consequent pressure on resources and timeframes. However, this estimate was not able to be substantiated by the APVMA.

## Elapsed time

**3.13** In addition to statutory timeframes not being met in all cases, average elapsed time has increased over the period 2001–02 to February 2006, especially for pesticide applications.<sup>29</sup> Figure 3.2 illustrates this increase.

**Figure 3.2**

**Average APVMA processing time, and average elapsed time, for finalised pesticide applications, for the period 2001–02 to 2005–06**



Note: 2005–06 to date figure based on data extracted on 17 February 2006.

Source: ANAO analysis of APVMA data.

**3.14** For some pesticide applications finalised in 2004–05, the average elapsed time was double or triple the average APVMA processing time. For example, it took over nine months, on average, to finalise some 252 pesticide applications that had a statutory timeframe of three months, taking account of both APVMA and applicant timelines.

**3.15** The ANAO recognises that the APVMA cannot directly control the time taken by applicants to properly complete applications. However, unnecessarily long timeframes add to the cost of regulation, for both the APVMA and applicants, and impact on users' access to pesticides and veterinary medicines.

<sup>29</sup> Elapsed time is the sum of APVMA processing time (for conducting preliminary assessments and formal evaluations) and applicant time in addressing deficiencies with applications.

## Improvements to the registration process

**3.16** The APVMA has introduced various initiatives in recent years to improve the timeliness of application processing, and, more broadly, to use resources more efficiently and effectively in administering its registration function. Key initiatives include:

- *consolidating application categories and increasing the use of modular assessment*—since 1 July 2005, application categories have been consolidated from 50 into 25, and a new modular structure introduced.<sup>30</sup> This framework enables the APVMA to tailor its assessment and data requirements to better suit the type of application being made;
- *reducing the need for applications on some minor matters*—in August 2003, the APVMA issued a special permit (Permit No. 6868) which allows certain variations to labels on pesticides and veterinary medicines without requiring an application; and
- *finalising applications during the preliminary assessment*—since 2004, the APVMA has introduced a process to finalise some minor applications during the preliminary assessment, rather than requiring a separate process to evaluate and finalise such applications.

**3.17** In addition, the APVMA has focussed attention on improving performance for applications received since 1 July 2005 (which coincided with the introduction of a new cost recovery regime and the new application categories).

**3.18** The ANAO found that these, and other measures, have contributed to 99 per cent of pesticide, and 98 per cent of veterinary medicine applications, received after 1 July 2005, being finalised within statutory timeframes. This contrasts with the timeliness of applications received before 1 July 2005. Table 3.1 shows that almost 25 per cent of pesticide applications received before this date were not finalised within statutory timeframes.

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<sup>30</sup> Modules allow the APVMA to assess specific aspects of applications. For example, toxicology or residues.

**Table 3.1****Applications finalised within statutory timeframes, 2005–06**

Program	Received before 1 July 2005	Received after 1 July 2005
Pesticides	75.6%	99.0%
Veterinary medicines	94.1%	98.2%

Source: ANAO analysis of APVMA data.

**3.19** Despite some recent improvements, there was a backlog of some 121 pesticide applications received before 1 July 2005. Further improvement in timeframe performance will be dependant on the prompt resolution of these, and other outstanding cases.

**3.20** The remainder of this chapter discusses three areas where the APVMA could further enhance its registration processes, to improve timeframe performance and facilitate more effective use of resources.

## Regulating lower risk products

**3.21** Under the new regulatory framework introduced in October 2003, as part of amendments to the Agvet Code, the APVMA has three options for regulating products:

- **Normal Registration**—products are assessed against one of the current (25) application categories; or
- **Listed Registration**—products deemed to pose a lower regulatory risk can be assessed against a pre-determined Standard, reducing the level of assessment required; or
- **Reserved from Registration**—products deemed to pose a very low regulatory risk can be assessed against pre-determined Conditions, effectively removing these products from normal regulatory controls.

**3.22** This framework provides a means of aligning the level of regulatory intervention with the level of risk the products present. It has the potential to benefit applicants through simpler and more streamlined processes, while also providing the APVMA with a means of targeting resources in a more effective, risk-based manner.

**3.23** The ANAO found that this framework has not delivered the expected benefits to the APVMA or to applicants. As of July 2006, no products had been registered under the *Listed Registration* or *Reserved from Registration* categories.

Since 2003, the APVMA has developed two Standards for the *Listed Registration* category and Conditions for the *Reserved from Registration* category for a range of disinfectants.<sup>31</sup> However, while the Standards and Conditions have been approved by the relevant Minister, they have not been incorporated into regulations. As a result, products eligible for registration under these arrangements have been required to undergo the normal registration process, intended for higher risk products.

**3.24** The APVMA advised that the timely development and implementation of Standards and Conditions has been influenced by several factors, including:

- the length of time required to consult widely with industry;
- a lack of support by some sections of industry on the format or content of draft Standards; and
- the need to involve or have the support of other government bodies, including relevant State government departments.<sup>32</sup>

**3.25** Some industry stakeholders consulted by the ANAO indicated that the new processes are impractical and have not provided an effective mechanism to promote the registration of lower risk products. In this context, the APVMA advised that it is currently working with the Product Safety and Integrity Committee (which has a policy role for the National Registration Scheme) to address perceived deficiencies in the design and implementation of the framework.

## Quality of applications

**3.26** The assessment and registration of pesticides and veterinary medicines can be a complex undertaking, often requiring applicants to supply extensive scientific data and evidence to demonstrate that products are safe and efficacious.

**3.27** The APVMA has a range of measures in place to assist applicants to provide the information that it requires to evaluate applications. In 2005, the APVMA comprehensively revised and published manuals for pesticide and veterinary medicine applications.<sup>33</sup> These manuals provide information on the

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<sup>31</sup> One for swimming pool products; the other for chondroitin and glucosamine products to assist in maintenance of joint health in dogs and horses.

<sup>32</sup> For example, the National Drugs and Poison Scheduling Committee is responsible for setting poison classifications, and may need to review the active constituents in certain products.

<sup>33</sup> Known as the Manual of Requirements and Guidelines—one for pesticides, and one for veterinary medicines.



application process, and on the type of data required to support applications. Other measures include: an enquiries facility on the APVMA's website; a number that registrants or members of the public can call to make enquiries; and advice provided by APVMA staff.

**3.28** Notwithstanding these measures, the ANAO found a high number of deficiencies (that is, errors or omissions) in applications. These included relatively minor administrative errors, such as applicants not completing part of the required application form, to more serious technical deficiencies, such as incomplete formulation details, or inadequate data to substantiate the claims being made for products. Of the 2 236 applications finalised in 2004–05<sup>34</sup>:

- 74 per cent of pesticide, and 76 per cent of veterinary medicine, applications had one or more deficiencies;
- the number of deficiencies generally increased with the length of the formal evaluation timeframe<sup>35</sup>; and
- some seven per cent of pesticide applications, and nine per cent of veterinary medicine applications, had five or more deficiencies (with a few applications having 15 deficiencies).

**3.29** Deficient applications can reduce the administrative efficiency of the application process by requiring the APVMA to check and re-check the validity of the information supplied by applicants. They also impact on the timeliness of the registration process, consuming both statutory and applicant response time.

**3.30** The APVMA is taking measures to reduce the number of deficiencies in applications. For example, it conducts seminars with industry to explain registration requirements and legislative changes. At the time of the audit, it was analysing deficiencies with chemistry aspects of applications, and plans to hold further workshops with industry to correct common problems. However, the APVMA does not have systematic processes for analysing the type and cause of discrepancies in applications.

**3.31** The ANAO also found that some of the guidance material relating to data requirements has not been revised for many years (although some material was being revised during the audit). For example, the specific

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<sup>34</sup> This figure includes applications that were refused or withdrawn.

<sup>35</sup> The average number of deficiencies for pesticide applications with a three-month timeframe was two; with an average of four deficiencies for applications with an eight-month timeframe.

requirements relating to the environment have not been updated since 1997. The systematic analysis of deficiencies would enable the APVMA to identify aspects of its processes, including the currency and completeness of guidance material, which could improve the quality of applications. This would also allow the APVMA to more effectively target initiatives aimed at improving applicants' understanding of registration processes and data requirements.

## **Recommendation No.3**

**3.32** The ANAO recommends that the APVMA improve its registration processes by systematically analysing the type and cause of errors or omissions in applications, to better target its initiatives to improve the quality of applications.

### ***APVMA response***

**3.33** The APVMA agrees with this recommendation. Following analysis of common deficiencies in applications the APVMA has, from time to time, conducted workshops with industry to assist their understanding of published requirements with a view to improving the overall quality of applications. Currently, an analysis of common chemistry deficiencies in applications is being used to provide feedback to registrants and focus to planned industry workshops. Companies also receive direct feedback on their individual applications. Further systematic analysis of errors and omissions, as recommended, will be used to refine the targeting of future initiatives with companies to improve the quality of their applications.

## **Applications that do not meet requirements**

**3.34** The APVMA has documented procedures for refusing an application, or deeming it to be withdrawn, and has formally communicated its policies to applicants. The ANAO found that where applicants failed to meet the APVMA's stated requirements, or failed to provide information by due dates, they were (repeatedly) given additional time to respond to requests rather than their application being withdrawn in line with documented procedures. This can result in excessive administrative processes, and lead to substantial increases in elapsed time. There are also cost-recovery implications: the more staff time spent on an application, the higher the costs.<sup>36</sup> Figure 3.3 outlines an example of this practice.

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<sup>36</sup> The APVMA's cost recovery arrangements are discussed in Chapter 6.

### Figure 3.3

#### Example of an application, where extensions of time were granted to the applicant

- An application to register a pesticide product was lodged on 7 May 2004. The application had a statutory timeframe, for the formal evaluation, of 91 days.
- The preliminary assessment of the application took nearly 15 months to complete. During the preliminary assessment, the applicant requested, and was granted, four separate extensions of time, of three months each, to address deficiencies identified by the APVMA.
- The applicant failed to meet the APVMA's deadline for the second extension. However, the APVMA did not send a letter notifying its intention to deem the application to be withdrawn until nearly two months after the deadline was missed.
- The applicant subsequently responded by the due date in the APVMA's letter, avoiding the application being withdrawn.
- The product was registered on 6 December 2005. The APVMA met the statutory timeframe in evaluating this application (91 days). However, the application took 487 days in total to finalise, of which 396 days were attributed to the applicant in addressing the APVMA's requirements.

Source: ANAO analysis of APVMA data.

**3.35** The APVMA advised that it only refuses or deems an application to be withdrawn in the most serious circumstances. This approach reflects a culture of working with applicants to facilitate successful outcomes. It also reflects more pragmatic concerns relating to applicants' legislative rights to challenge the APVMA's decisions, and the additional costs such challenges can impose. In addition, under the Agvet Code, applicants are permitted when submitting applications to register new products to provide additional or varying information to the APVMA at any stage until the application is formally determined.<sup>37</sup>

**3.36** Notwithstanding these points, current practice is not consistent with documented operational procedures, or with the policy communicated to applicants. To provide more consistency and certainty in its application of legislative provisions, the APVMA should:

- review the appropriateness of its policies and procedures for refusing or deeming applications to be withdrawn;
- align operational practices with any changes to policies or procedures; and
- formally communicate any changes to applicants, to manage expectations and facilitate compliance.

<sup>37</sup> s.11(3)(a) of the *Agricultural and Veterinary Chemicals Code Act 1994*.

## 4. Managing External Scientific Advice

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*This chapter examines the APVMA's arrangements for obtaining external scientific advice, to assist it in delivering some regulatory functions.*

### Introduction

**4.1** The APVMA obtains expert advice to assist it in evaluating applications for registration, and to support other regulatory functions.<sup>38</sup> Currently, this advice mainly relates to:

- human toxicology and occupational health and safety, provided by the Office of Chemical Safety (OCS), which is part of the DoHA;
- risks to the environment, provided by the Department of the Environment and Heritage (DEH); and
- the efficacy and safety of pesticides and veterinary medicines, provided by State government departments and private consultants.<sup>39</sup>

**4.2** The ANAO examined whether the APVMA's current arrangements for obtaining advice adequately support its statutory obligations, particularly the timeliness and quality of registration decisions.

### Formal arrangements for obtaining advice

**4.3** The APVMA's formal arrangements for obtaining scientific advice from current service providers are summarised in Table 4.1.

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<sup>38</sup> This includes the Chemical Review Program, and the assessment of adverse experience reports.

<sup>39</sup> Efficacy and safety assessments determine whether products work as claimed (for instance, by eliminating a particular pest) and avoid causing damage or ill-health to the target crop or animal.

**Table 4.1****Formal arrangements with service providers**

Service Provider	Type of arrangement
Office of Chemical Safety, and the Department of the Environment and Heritage	Service Level Agreements and Work Orders
State government departments (New South Wales <sup>40</sup> Western Australia and Tasmania)	Service Level Agreements and Work Orders
State government departments (Victoria, Queensland and South Australia)	Purchase orders
Other providers (mainly private consultants)	Short-term contracts

Source: ANAO analysis of APVMA data.

**4.4** The ANAO considers that the Service Level Agreements (SLAs) and Work Orders provide a sound framework for managing the provision of advice. The SLAs are subject to annual review, and set out the agencies' obligations including:

- the work to be performed for each type of service being requested; and
- associated performance standards, fee and timeframe for completion.

**4.5** Work Orders, which are issued under each SLA, detail the specific service to be provided, and state the timeframe and fee to be paid. Agencies are required to sign and return Work Orders to the APVMA to confirm these requirements.

**4.6** The short-term contract used to engage private consultants is based on a standard template used by Australian government agencies. It specifies requirements, including timeframe and confidentiality obligations. The APVMA advised that it intends to introduce a more comprehensive three-year contract for those private consultants it uses more frequently. This is expected to improve administrative efficiency.

## **Arrangements with State government departments**

**4.7** The APVMA has traditionally relied on State government departments to provide advice on the safety and efficacy of products. However, in some States the relevant government departments<sup>41</sup> have never signed a SLA or

<sup>40</sup> New South Wales has not signed the 2005–06 SLA. It continues to operate under the 2004–05 SLA.

<sup>41</sup> The Department of Primary Industries and Fisheries in Queensland, and the Department of Primary Industries and Resources in South Australia.

other formal agreement with the APVMA, although these departments have provided advice – albeit infrequently in recent years.

**4.8** State government departments that do not have formal agreements with the APVMA are engaged through a purchase order. Unlike SLAs or contracts, purchase orders do not detail the APVMA’s requirements, which include protecting the confidentiality of registrants’ data and the need to declare any potential conflict of interest. They provide only brief information on the product to be assessed and the fee to be paid. The APVMA advised that, when purchase orders are used, the provider is expected to obtain information on the APVMA’s service requirements from its *Efficacy & Target Animal/Crop Reviewer’s Manual*. However, the Manual, which was not issued until October 2005, contains guidance material only.

**4.9** The APVMA advised that its pool of suitably qualified efficacy and safety reviewers has diminished in recent years. The APVMA plans to seek Expressions of Interest from appropriately qualified providers by the end of 2006, to increase the number of available reviewers. In the meantime, the ANAO considers that the APVMA should assess whether there are alternative approaches to gaining assurance that its performance standards are met by those providers that have not signed formal agreements. For example, by requesting providers to acknowledge that service requirements will be met, or engaging their services through a Work Order.

## Managing the timeliness of advice

**4.10** As previously noted, the APVMA is required to meet statutory timeframes for finalising applications. In evaluating the more complex applications, the APVMA may obtain advice from various external sources.

### Australian government agencies

**4.11** Agencies are allocated part of the APVMA’s statutory timeframes for evaluating applications. For OCS the timeframes range from 91 to 335 days, while for DEH they range from 91 to 360 days. Under SLAs, these agencies are required, on an annual basis, to meet specified timeframes in 95 per cent or more of cases.<sup>42</sup> The ANAO found that, in 2004–05<sup>43</sup>, both OCS and DEH generally met the APVMA’s timeframes, sometimes providing advice well

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<sup>42</sup> This standard reflects the APVMA’s now obsolete internal performance target of finalising 95 per cent of applications within statutory timeframes. See paragraph 2.7.

<sup>43</sup> Based on Work Orders completed from 1 July 2004 to 31 March 2005 only.

within the required time. Further, where agency timeframes were not met, the additional time taken did not usually impact on the APVMA's ability to finalise applications within statutory timeframes.

**4.12** The APVMA advised that it negotiated an overall reduction in agency timeframes of 6.5 per cent from the 2004–05 SLAs to the 2005–06 SLAs. Consistent with the APVMA's goal of meeting its statutory requirements, the ANAO considers improvements could be made by requiring agencies to meet specified timeframes in all cases where advice is provided. The APVMA could also request OCS and DEH to provide data on the actual time taken to complete assigned tasks. Discussions with the agencies would suggest that the time taken may be less than required by the SLA. This would allow the APVMA to determine whether current timeframes are appropriate.

**4.13** The ANAO found that, in setting timeframes, the APVMA takes account of agencies' capacity to provide advice within available resources. The ANAO considers that, while this approach is not unreasonable, it also reflects the APVMA's reliance on OCS and DEH for advice, rather than seeking advice from other providers. The ANAO found that although a framework has been established to use alternative providers (discussed in paragraphs 2.12 to 2.16), the APVMA has rarely used service providers other than OCS or DEH.

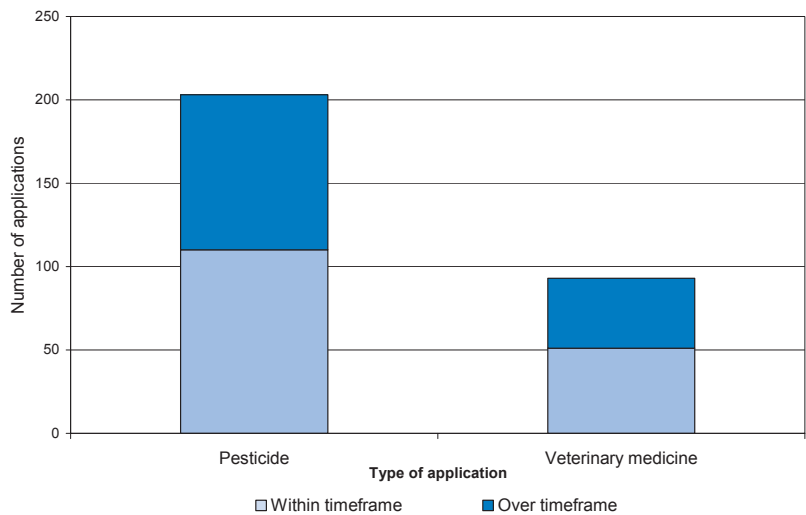
**4.14** The ANAO considers that in the short-term, the APVMA should review existing arrangements to improve agency timeframes. In the longer-term, further and more substantial reductions in timeframes—which would provide the APVMA with a means of reducing the overall time taken to finalise applications—may require the APVMA to identify and use additional providers.

## **State government departments and private consultants**

**4.15** The timeframe assigned to State government departments and private consultants for conducting efficacy and safety assessments currently ranges from nine to 21 weeks, depending on the level of assessment required. The ANAO found, as shown in Figure 4.1, that almost half of all safety and efficacy assessments finalised in 2004–05, relating to pesticide and veterinary medicine applications, exceeded the timeframe specified by the APVMA. In 11 cases, the actual timeframe was double or triple the specified timeframe.

**Figure 4.1**

**Timeliness of efficacy and safety assessments provided to the APVMA, for the period 2004–05**



Source: ANAO analysis of APVMA data.

**4.16** The APVMA has acknowledged that the failure of reviewers to meet specified timeframes has impacted on its ability to meet statutory timeframes. However, the ANAO found that while the APVMA has the facility to monitor timeframes, it has not done this in a systematic manner, or analysed the common causes of delays, to identify ways of improving performance. Applications examined by the ANAO indicated that timeframes were exceeded because:

- reviewers failed to complete the work on time;
- there were delays in obtaining input from State government departments (that are invited to provide feedback on draft and final reports); or
- APVMA staff did not take appropriate follow-up action when reports were overdue.

**4.17** In addition, the APVMA’s ability to meet statutory timeframes for finalising applications has been impacted by difficulties in identifying suitable reviewers to conduct efficacy and safety assessments. As previously discussed, the APVMA is taking steps to increase the number of appropriately qualified reviewers. However, the ANAO considers the APVMA’s arrangements for



managing the timeliness of safety and efficacy assessments could be improved by regularly monitoring reviewers' performance, and analysing the causes of delays, to identify improvement opportunities.

## Assuring the quality of advice

**4.18** The APVMA remains accountable for any regulatory decisions for which it obtains advice. As such, it requires a means of gaining assurance that the advice is sound, and addresses the risks posed by pesticides or veterinary medicines. The ANAO has not assessed the validity of the advice provided to the APVMA. However, it has assessed whether the APVMA's processes for gaining this assurance are adequate, while recognising the inherent limitations in assessing the quality of advice provided by external subject matter experts.

### Formal arrangements

**4.19** The APVMA has a range of formal measures in place for managing and monitoring the quality of advice provided by external parties. These include:

- setting performance standards against which the quality of advice can be assessed, and evaluating the quality of advice in draft reports, prior to the finalisation of advice;
- APVMA delegate sign-off of regulatory decisions, and an internal peer review of the quality of advice for regulatory decisions considered to be high-risk or sensitive; and
- periodic audits by the APVMA's Principal Scientists of regulatory decisions, as part of their role to promote regulatory science quality.

**4.20** In addition, some reliance is placed on the internal quality assurance processes within the agencies that provide advice, and other avenues of scrutiny. For example, when obtaining safety and efficacy advice from a State government department, the APVMA invites other State government departments to provide input and feedback on the draft and final report prepared by the primary State reviewer.

**4.21** The ANAO found that the APVMA does not supplement its internal expertise by using independent experts to review the advice provided by OCS and DEH. However, the APVMA advised that it is in the process of appointing scientists with expertise in key areas to provide independent advice on contentious issues.

## Improving administration

**4.22** Other measures the APVMA could take to improve its arrangements for assuring the quality of advice by external providers include:

- *maintaining a formal record of any issues identified through its quality checks of advice provided by OCS and DEH.* This would assist with management of SLAs, and allow the APVMA to identify and apply appropriate corrective measures for improving the quality of the advice. The ANAO found that quality concerns tend to be identified and resolved through informal channels, rather than being formally documented.
- *obtaining the credentials of all persons used to provide advice.* This would assist the APVMA to select the most appropriate reviewer to provide advice. The ANAO found that, for some officers from State government departments, the APVMA had limited, or in some cases, no information on the person undertaking the review.<sup>44</sup>
- *having direct access to reviewers who prepared the advice.* This would facilitate discussion and feedback. Unless special arrangements are made, the APVMA is not given direct access to the actual reviewer from State government departments. Instead, communication is channelled through the relevant State Coordinator.

## Financial arrangements for obtaining advice

**4.23** External scientific advice constitutes a significant annual expense for the APVMA. In 2004–05, it spent \$4.1 million on advice from OCS and DEH, around 20 per cent of annual expenditure. Over the same period, advice from State government departments and private consultants cost \$330 338.

## Guaranteed funding

**4.24** Since 2001–02, the APVMA has committed in its SLAs with OCS and DEH to paying a minimum of 80 per cent of the annual budget for estimated services agreed with each agency. This is regardless of whether services of an equivalent value are provided during the financial year. This arrangement is to allow each agency to maintain an appropriate level of expertise and resources to provide the required services to the APVMA.

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<sup>44</sup> Under current practices, efficacy and safety reviewers from State government departments are selected by a State Coordinator, rather than by the APVMA.

**4.25** The APVMA's records indicate, as outlined in Table 4.2, that actual annual expenditure on services provided by OCS and DEH has exceeded the minimum amount required to be paid, and therefore no payments have been made to OCS or DEH for services that were not provided.

**Table 4.2**

**Funding arrangements under the APVMA's SLAs with OCS<sup>45</sup> and DEH, for the period 2001–02 to 2004–05**

Financial year	Annual budget	Minimum amount required to be paid by the APVMA	Actual expenditure
2001–02	\$4 530 479	\$3 624 383	\$4 382 367
2002–03	\$4 436 852	\$3 549 481	\$4 685 630
2003–04	\$4 932 900	\$3 946 329	\$4 975 156
2004–05	\$5 090 861	\$4 072 688	\$4 354 090

Source: ANAO analysis of APVMA data.

**4.26** The APVMA's commitment to provide guaranteed funding to OCS and DEH is different from its arrangements for engaging other service providers (who are paid on a more straightforward fee-for-service basis) and with established practices in public sector agencies. This arrangement also places additional pressure on the APVMA in managing its budget for scientific advice across the financial year. For example, in 2004–05, when the number of applications requiring advice from OCS and DEH dropped unexpectedly, the APVMA brought 'project-type' work forward, to help ensure that actual expenditure for that year exceeded the minimum amount required to be paid.

**4.27** The ANAO recognises the important role that OCS and DEH play in assisting the APVMA to meet some key regulatory responsibilities. However, the risks that arise under the current guaranteed funding arrangement would not arise under a more straightforward fee-for-service arrangement, where payments are made only where services are provided. Nevertheless, it is appreciated that when negotiating a fee-for-service arrangement, consideration will have to be given, at least in the short-term, to the APVMA's ability to access alternative sources of scientific advice.

<sup>45</sup> Prior to 2004, OH&S assessments were provided by the National Occupational Health and Safety Commission. Since then, OH&S assessments have been provided by OCS.

## Contestability of services

**4.28** One means of providing value for money is to establish a contestable service environment in which a range of parties can tender to provide advice, creating competitive pressures on costs and timeframes. The ANAO's previous audit of the APVMA recommended that the APVMA assess the possibility of using alternative sources of advice, to provide a more informed and contestable framework for the delivery of services.<sup>46</sup> The APVMA has made limited progress in establishing a more contestable environment for obtaining scientific advice. Table 4.3 summarises current arrangements.

**Table 4.3**

### Contestability arrangements for obtaining scientific advice

Type of advice	Current arrangements	ANAO comment
Human toxicology & occupational health and safety	This advice is obtained from the OCS. In 2003, an outsourcing framework was established to identify alternative providers for some of the advice provided by OCS.	The outsourcing framework has no formal standing under the National Registration Scheme, and has yet to be implemented.
Risks to the environment	This advice is obtained solely from DEH.	No arrangements have been put in place to identify other providers for advice on risks to the environment, although preliminary discussions have commenced.
Safety and efficacy assessments	These assessments are obtained from State government departments and private consultants. However, State government departments are given the first choice of conducting the assessments.	The APVMA's practice of giving State government departments first choice is not required under its legislation, and potentially disadvantages other providers.

Source: ANAO analysis of APVMA data.

**4.29** The ANAO recognises that much of the advice required by the APVMA is of a specialist nature and, as a result, the pool of appropriately qualified persons may be limited. However, the APVMA has only recently sought to identify other sources of scientific advice, and only for some of the services provided by OCS. These measures have yet to deliver any tangible benefits to the APVMA (see paragraphs 2.12 to 2.16). No action has been taken to identify alternative providers for the advice currently provided by DEH. It would be timely for the APVMA to assess whether a more contestable approach to the

<sup>46</sup> ANAO Audit Report No. 26 1997–98, op. cit., p. 37.

provision of scientific advice would be beneficial and lead to greater efficiencies in the allocation of resources, and thus benefit fee and levy payers.

## Recommendation No.4

**4.30** The ANAO recommends that the APVMA review its current arrangements for obtaining scientific advice from Australian government agencies to assess whether a more contestable approach would be beneficial and lead to greater efficiencies in the allocation of resources.

### *APVMA response*

**4.31** The APVMA agrees with this recommendation. Notwithstanding the complexities involved, the APVMA has made some progress in pursuing a degree of contestability for the scientific advisory services provided to it by Australian government agencies, and has obtained limited public health and environmental project work from alternative sources. Through the introduction and refinement of service level agreements with clearly defined fees for services and performance expectations, the framework for managing provision of these services has been significantly strengthened in recent years. The recommended review will be progressed to assess whether greater contestability will deliver further benefits and cost-efficiencies.

## 5. Monitoring Product Quality

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*This chapter discusses the APVMA's activities for assuring the safety and efficacy of pesticides and veterinary medicines approved for sale in Australia.*

### Introduction

**5.1** Once registered, pesticides and veterinary medicines can be manufactured and marketed for sale in Australia. The APVMA conducts various activities to gain assurance that products approved for sale are fit for their intended use.<sup>47</sup> This includes:

- assessing whether local and overseas manufacturers of veterinary medicines comply with quality requirements;
- assessing the quality of ingredients used to manufacture pesticides; and
- reviewing whether products registered in previous years meet contemporary standards of safety and efficacy.

**5.2** The ANAO examined whether the APVMA's implementation and management of these key activities provides adequate assurance on the safety and efficacy of pesticides and veterinary medicines approved for sale.

### Assuring the quality of veterinary medicines

**5.3** All registered veterinary medicines must be manufactured according to required quality standards.<sup>48</sup> The APVMA has two schemes in place to confirm that manufacturers' practices comply with these standards:

- the Manufacturers' Licensing Scheme (MLS)—established in 1996 to assess whether Australian veterinary medicine manufacturers comply with the standards; and
- the Overseas Good Manufacturing Practice Scheme—established in 2005 to obtain certificates of compliance from acceptable regulators for veterinary medicine manufacturers based overseas.

**5.4** Separate schemes are necessary as the APVMA has no jurisdiction to license overseas-based manufacturers.

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<sup>47</sup> The APVMA is not responsible for monitoring whether products are used correctly, once sold. This is the responsibility of State and Territory governments.

<sup>48</sup> The standards are designed to build quality into veterinary medicines during the manufacturing process.

## Manufacturers' Licensing Scheme

5.5 Section 121 of the Agvet Code requires Australian manufacturers of veterinary medicines to be licensed by the APVMA. A licence is issued when the APVMA has confirmed the manufacturer complies with the *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products* (Code of GMP).

### Framework for the Manufacturers' Licensing Scheme

5.6 Sub-section 122(2) of the Agvet Code allows the APVMA to assess a manufacturer's compliance with the Code of GMP before a licence is issued. Once issued, the licence will remain in force until suspended or cancelled. At 30 April 2006, 214 manufacturers held licences to manufacture veterinary medicines in Australia.

5.7 The licence includes a condition that requires licence holders to provide access to their premises for compliance audits. These audits are to be conducted every 6-24 months to confirm ongoing compliance with the Code of GMP. The audits are undertaken on the APVMA's behalf by GMP auditors from the chemical manufacturing industry and the Therapeutic Goods Administration (TGA).<sup>49</sup> The use of third-party auditors (as opposed to in-house staff) was endorsed by the APVMA Board in 2001 as the most cost-effective arrangement for the APVMA to manage its licensing scheme.

#### *Access to licence holders' premises*

5.8 Section 126 of the Agvet Code allows the APVMA to include conditions on a licence that assist in regulating veterinary medicine manufacturers. This includes gaining access to licence holders' premises. However, the current licence conditions only provide for third-party auditors to access manufacturers' premises to conduct audits after the licence has been issued.

5.9 The condition does not allow APVMA staff access to conduct audits or perform other regulatory activities. In practice, the APVMA relies upon the licence holder granting access, when and if requested. The ANAO is aware that the APVMA has been refused access on at least one occasion. The APVMA sought to address this issue by appointing two of its GMP staff as inspectors (in January 2006).<sup>50</sup> Inspectors have powers to enter licence holders' premises

<sup>49</sup> The TGA is part of the Department of Health and Ageing. It already conducts audits of therapeutic goods manufacturers against the TGA's Code of GMP, which the APVMA has deemed to be equivalent to the Code of GMP. For this reason, the APVMA has determined it is appropriate for the TGA to audit the approximately one-third of veterinary medicine manufacturers who also make therapeutic goods.

<sup>50</sup> Under s.69F of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.



to assess compliance with the Agvet Code. This includes assessing whether manufacturing standards are being met. As of June 2006, these inspectors had conducted four unannounced audits and one short notice audit to assess manufacturer compliance.

**5.10** Notwithstanding the appointment of two APVMA staff as inspectors, the ANAO notes that other APVMA staff, who have not been appointed as inspectors, could be provided with access to licence holders' premises by including an appropriate access condition in licences. This approach would provide the APVMA with more flexibility to monitor compliance with the Code of GMP.

#### *Authorisation of third-party auditors*

**5.11** For third-party auditors to conduct audits on its behalf, the APVMA has established a Memorandum of Understanding with the TGA, and executes Deeds of Authorisation with industry-based auditors. The ANAO found these authorisations only provide for third-party auditors to conduct audits for manufacturers seeking a licence. The third-party auditors have not been authorised to conduct audits once the licence has been issued. In practice, third-party auditors do undertake audits after the licence is issued, because licence holders are required to use these auditors to undertake ongoing compliance audits. Good practice suggests that it is better to have the proper authorisation in place. The APVMA agrees that the auditors' authorisations should be reviewed.

#### *Administration arrangements*

**5.12** For audits conducted by the TGA, all administrative decisions are made by the TGA, including the frequency of the audit. The APVMA requires licence holders and auditors to notify the APVMA in writing that these arrangements have been carried out appropriately. For example, the TGA is to provide the APVMA with the audit report and checklist to show the coverage and findings from the audit.

**5.13** For audits not undertaken by the TGA, the licence holder is responsible for arranging the compliance audit in the timeframe determined by the APVMA. For example, the licence holder:

- selects the APVMA-approved auditor; and
- negotiates the amount to be paid for the audit and the date(s) when the audit will be undertaken.



**5.14** The APVMA advised that in 2004–05, some 82 compliance audits were undertaken by industry-based auditors. However, the APVMA was unable to provide details of the audits undertaken by the TGA on its behalf.

### **APVMA oversight of the Manufacturers' Licensing Scheme**

**5.15** The APVMA relies on the results of the compliance audits being provided by the licence holder and third-party auditor to determine whether manufacturers of veterinary medicines are meeting quality standards. In addition to its audit program, the APVMA has established the MLS Industry Liaison Committee to discuss issues arising from the MLS arrangements; and it may observe or jointly conduct an audit.<sup>51</sup>

**5.16** The ANAO reviewed 19 audits conducted by industry-based auditors and found that these audits were regularly undertaken after the due date. Key documents, such as the audit report, were either overdue or had not been provided to the APVMA. Without these reports, the APVMA has limited assurance that veterinary medicine manufacturers are complying with the Code of GMP.

**5.17** The APVMA was unable to provide documentation (including the audit report) for audits undertaken on its behalf by the TGA. This is contrary to the arrangements in the Memorandum of Understanding between the two parties. The APVMA advised that it was currently reviewing the adequacy of its existing Memorandum of Understanding with the TGA. In addition, it has recently included a condition in the licence that the licence holder is to provide the APVMA with copies of reports from the TGA's audit.

### **Conclusion**

**5.18** The ANAO considers that the APVMA's current arrangements for monitoring veterinary medicine manufacturers' compliance with the Code of GMP are inadequate. Relevant APVMA staff, who have not been appointed as inspectors, need to have access to licence holder's premises to check compliance with the Code of GMP. Third-party auditors also need to be properly authorised to conduct ongoing audits. In addition, protocols should

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<sup>51</sup> For a joint audit, the APVMA's GMP staff will conduct the audit with the third-party auditor. The APVMA conducts, on average, four observed or joint audits each year.

be put in place to ensure audits are undertaken when they are due and that the relevant audit report is provided within the timeframe stated on the licence.<sup>52</sup>

## Recommendation No.5

**5.19** To improve the Manufacturers' Licensing Scheme compliance framework, the ANAO recommends that the APVMA:

- (a) include appropriate access provisions for relevant APVMA staff and third-party auditors in licence conditions and Deeds of Authorisation; and
- (b) develop and implement processes for third-party auditors to undertake audits by the required date and institute follow-up mechanisms if the relevant audit report is not received within stated timeframes.

### *APVMA response*

**5.20** The APVMA agrees with this recommendation. The report notes some of the more recent initiatives that the APVMA has instituted, in consultation with industry, to develop the Manufacturers' Licensing Scheme since it was introduced. Implementing this recommendation will further improve the rigour of the MLS framework. In doing so, the APVMA will consider various options to include appropriate access conditions for relevant staff and third-party auditors, and develop processes to facilitate improved timeliness of conduct and follow-up of audits.

## Overseas Good Manufacturing Practice Scheme

**5.21** The APVMA estimates that one-third of the veterinary medicines for sale in Australia are manufactured overseas. Unlike for Australian manufacturers of veterinary medicines, the APVMA cannot subject overseas-based manufacturers to licensing requirements. Instead, the APVMA confirms these manufacturers have been certified by another regulator as compliant against a quality standard equivalent to the Code of GMP before registering a veterinary medicine. The Overseas Good Manufacturing Practice Scheme was introduced by the APVMA in October 2005 to assess the ongoing compliance of these manufacturers. This is some ten years after the APVMA commenced operations.

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<sup>52</sup> The licence holder must forward the original audit report to the APVMA within 25 working days of the audit.

**5.22** To implement the Overseas GMP Scheme, the APVMA imposed a condition on veterinary medicine registrations that required the registrant to hold appropriate certifications of compliance for all relevant overseas-based manufacturers. The condition was applied only where APVMA data identified overseas-based manufacturers were involved. Of the 3 185 veterinary medicines registered by the APVMA as at 13 January 2006, the registration condition was applied to 1 093 registrations.

**5.23** The APVMA undertook an initial assessment of evidence of overseas manufacturer compliance in October 2005 and found its data set was incomplete, because registrants:

- did not identify all overseas manufacturers to be used when completing the product application; and/or
- had not advised the APVMA of changes to the manufacturers they use, after the product has been registered.

**5.24** The ANAO considers that this incomplete data set limits the APVMA's assurance that veterinary medicines supplied to the Australian market are manufactured to the required quality standards. The APVMA advised that consideration is being given to proposing a legislative amendment that would make all veterinary product registrants responsible for ensuring all veterinary medicines are manufactured in a GMP compliant site, whether in Australia or overseas. However, until such a legislative amendment is introduced and compliance with this requirement enforced, there is a risk that some veterinary medicines available for sale in Australia are not manufactured to required quality standards.

**5.25** Practical options available to the APVMA to help identify overseas-based veterinary medicine manufacturers missing from the APVMA's data set include:

- promulgating the APVMA's position on the Overseas GMP Scheme and its requirements through an Operational Notice<sup>53</sup>; and
- advising its relevant Committees, particularly the MLS Industry Liaison Committee, of the risks associated with overseas products and encourage reporting of information about undetected overseas manufacturers.

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<sup>53</sup> Operational Notices provide stakeholders with formal advice on the APVMA's position on a matter. They are published on the APVMA website and in the APVMA Gazette.

## Assuring the quality of pesticides

**5.26** Manufacturers of pesticides<sup>54</sup> are exempt from the APVMA's licensing requirement under Regulation 59 of the *Agricultural and Veterinary Chemicals Code Regulations 1995*. The APVMA advised that in place of a licensing scheme, it had conducted testing on the ingredients used in pesticides. Testing of ingredients was discontinued soon after the APVMA was established in 1995 as it was not considered to be a cost-effective means of monitoring compliance. The APVMA has relied upon other activities, such as the Adverse Experience Reporting Scheme, which received reports of any unexpected results from the use of pesticides, to identify issues relating to the quality of pesticides.

**5.27** In response to stakeholder concerns about the purity of imported ingredients, the APVMA implemented a quality assurance scheme for agricultural active constituents and agricultural chemical products (known as the AgQA Scheme) in September 2005. The scheme assesses the quality of ingredients used to manufacture pesticides against standards for the purity of active ingredients.<sup>55</sup> This includes the checking of records and product testing.

**5.28** Registrants of pesticides are responsible for manufacturing pesticides from ingredients which meet these standards and records must be held to prove the quality of the active ingredients used. In February 2006, the APVMA commenced checking these records. It found that more than 90 per cent of the records providing assurance of the quality of pesticides were missing, incomplete or contained errors. Without these records, the APVMA can not gain assurance on the quality of pesticides available for sale in Australia. The APVMA advised that it intends reviewing the effectiveness of the AgQA Scheme in late 2006 to identify areas for improvement. However, the ANAO considers that it would also be useful for the APVMA to:

- communicate its findings to stakeholders;
- develop strategies to raise awareness of the need to comply with registration conditions; and
- develop and impose sanctions for (repeat) non-compliance.

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<sup>54</sup> The term 'pesticides' refers to all agricultural products within the APVMA's scope of regulation.

<sup>55</sup> The APVMA has established a standard that specifies the maximum amount of impurity that may be present in each approved active ingredient.

## Reviewing registration decisions

**5.29** Under the *Agricultural and Veterinary Chemicals Code Act 1994*<sup>56</sup>, the APVMA has powers to review:

- the approval of an active constituent for a proposed or existing chemical product; or
- the registration of a chemical product; or
- the approval of a label for containers of a chemical product.

**5.30** These powers allow the APVMA to determine whether chemicals approved or registered in previous years meet contemporary standards of safety and efficacy, and do not pose unacceptable risks to people, animals, crops, the environment or to trade.

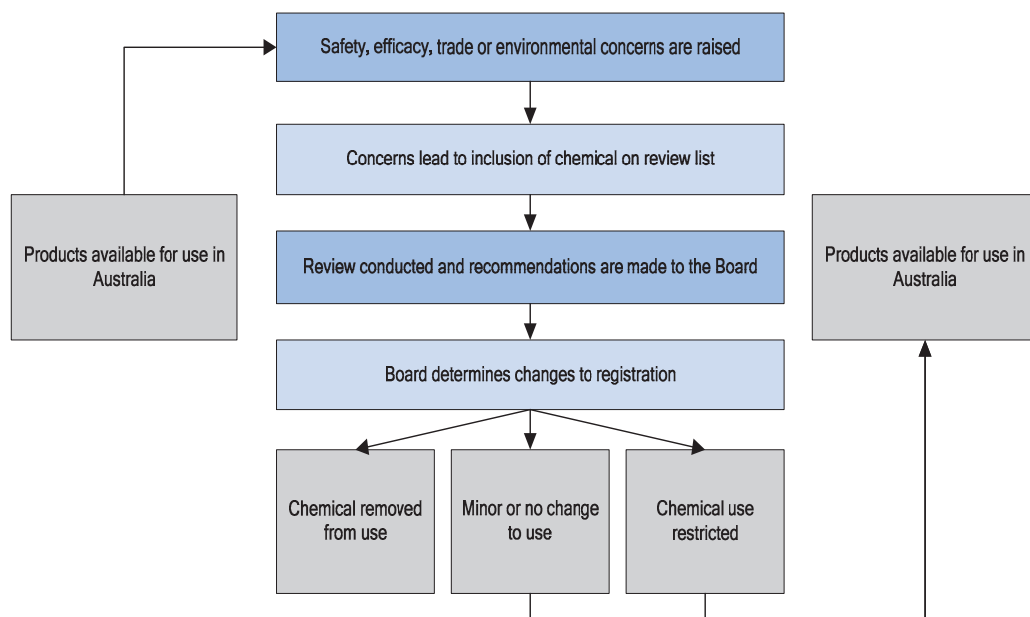
**5.31** The APVMA established the Chemical Review Program (CR Program) in October 1994 to identify and review chemicals of concern. As part of the CR Program, reviews are conducted by the APVMA, with input from stakeholders, and can result in products being removed from use in Australia, or restrictions placed on their use. The review process is summarised in Figure 5.1.

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<sup>56</sup> Part 2, Division 4.

**Figure 5.1**

**The process to identify and review chemicals of concern**



Source: ANAO analysis of APVMA data.

**Identifying chemicals for review**

**5.32** The processes to identify the chemicals to be reviewed have been in place since the CR Program was established and involve collecting nominations for chemicals of concern from:

- stakeholders, principally Government agencies, and input from the public; and
- APVMA programs, such as the Adverse Experience Reporting Program.

**5.33** Nominated chemicals are assessed against criteria to confirm there is a need for a review and to determine the priority of the review. The criteria address, amongst other things, the current use of the chemical, international regulatory information and the source(s) of the concern.

**5.34** In May 1995, 79 chemicals were listed for review from 208 nominated chemicals. As of April 2006, the CR Program had identified 142 chemicals to be reviewed. Chemicals on the list are prioritised according to the level of risk they represent, with the highest risk being given priority. The order of priority

was reviewed in 2000 and 2003, and is again currently under review. Between these reviews, the APVMA will evaluate any new data available and re-prioritise, suspend or cancel the product if necessary.

## Progress through the list of chemicals to be reviewed

**5.35** Of the 142 chemicals identified by the CR Program, 34 reviews have been completed. Almost 50 per cent of these reviews have resulted in the removal of the chemical and its associated product(s) from the Australian market. In addition, the APVMA revised the list in 2005 and removed 15 chemicals from the list as there were no longer any registered products available for sale in Australia or the chemical had been restricted by international treaties. Of the remaining 93 reviews on the list, the APVMA has started 45 reviews.

**5.36** The total number of reviews underway at any point in time is dependent on the resources available to conduct these reviews. To better utilise available resources, the APVMA has re-evaluated some of its processes to enable the reviews to be completed in a shorter timeframe. The revised processes are summarised in Table 5.1.

**Table 5.1**

### Changes made to chemical review practices

Previous practice	Current practice
A full reassessment against the registration requirements in s.14 of the Agvet Code was conducted.	A partial reassessment is conducted to reassess the parts of the s.14 decision affected by the concern. The scope may be expanded to accommodate any new findings.
To conduct a review, independent of other regulators.	To utilise relevant review findings from other regulators to reduce the time required to conduct the review.
Reviewing each chemical separately.	Consolidating chemicals into a single review if similar concerns are held about chemicals used for the same purpose. For example, 12 chemicals used to treat ectoparasites in sheep were consolidated into one review.

Source: ANAO analysis of APVMA information.

**5.37** There is no legislative requirement for reviews to be completed within a set timeframe. The ANAO analysed the time taken by the APVMA to complete reviews and found that on average, each review took almost three

years to finalise. The ANAO also analysed the elapsed time since the 45 reviews in progress commenced. The ANAO found that the average time taken to complete a review is increasing as a number of these reviews have already taken, on average, five years and eight months. Fifteen reviews have taken significantly longer. For example, the review of carbaryl commenced in 1993, and is still underway.<sup>57</sup>

## Informing stakeholders

**5.38** It is the APVMA's stakeholders, such as the users and manufacturers of pesticides and veterinary medicines, who are most affected by the lengthening timeframes of the chemical review process. The APVMA has an obligation to keep stakeholders informed about the status of reviews in progress and reviews yet to commence. The review may restrict or remove the registrant's rights to supply pesticides and veterinary medicines and as a consequence, user access to those products is affected.

**5.39** The ANAO reviewed the information provided to stakeholders about the CR Program. The APVMA provides:

- regular updates about the findings, potential changes to use and upcoming opportunities for discussion with groups directly affected by the review, for example, peak industry bodies or grower organisations;
- documents published during the review on its website, including:
  - the preliminary findings and the proposed regulatory decisions on which stakeholders may submit comments; and
  - the final report advising of the Board's decision; and
- information about reviews in progress and decisions made by the Board in its Annual Report.

**5.40** The ANAO found reviews where significant time had elapsed since previous documents has been released and no regular updates had been provided on the website about the APVMA's progress. For example, for the review of Malathion, only the scope document appears on the website. This was released in February 2003 and no further updates have been provided.<sup>58</sup> The ANAO also found the APVMA does not advise stakeholders of its overall

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<sup>57</sup> This review was originally started by a State government department. It was added to the APVMA's list of priority chemical reviews in 1995, following the APVMA's establishment in June 1993.

<sup>58</sup> As of July 2006.



progress through the CR Program list or of the names of chemicals on the list for which reviews have not yet commenced. The entire CR Program list was not publicly available during the course of the audit, although the list was published in the APVMA's Gazette in 1995 and 2001.<sup>59</sup> On the occasions when the list was published, the concerns leading to the chemical's inclusion were not communicated to the public.

**5.41** Placing the complete CR Program list on the website would allow stakeholders ready access to the list of chemicals to be reviewed. The list could be updated by the APVMA to provide information about the APVMA's progress or intended review start dates for each chemical. In addition, the CR Program webpage could include contact details for stakeholders to obtain further advice about chemicals in use that have been identified for review.

**5.42** The ANAO concluded that the APVMA has reasonable arrangements in place to identify chemicals that require review and to prioritise the reviews according to the risks they represent. However, the time taken to progress through the list of chemicals to be reviewed is slow despite efforts being made by the APVMA to improve the timeliness of reviews. Of particular concern is that the risks associated with the use of these chemicals remain. Given that the time taken to complete these reviews is increasing, the ANAO considers there would be benefit in the APVMA re-evaluating its current approach and processes for undertaking these reviews. This would provide assurance that the program is adequately addressing the risks presented by the chemicals. The information made available to stakeholders on the CR Program would also be more useful if the APVMA provided regular updates on its planned reviews and the status of reviews currently underway.

## Recommendation No.6

**5.43** To improve the effectiveness of the Chemical Review Program, the ANAO recommends that the APVMA:

- (a) assess whether the current approach and time taken to complete reviews adequately addresses the risks presented by the chemicals not yet under review; and
- (b) communicate the status of reviews currently underway, emerging issues and updates on planned activities.

<sup>59</sup> The APVMA Gazette is issued monthly and promulgates formal notices from the APVMA to the agricultural and veterinary chemicals industry.

### *APVMA response*

**5.44** The APVMA agrees with this recommendation. The review of existing chemical products is invariably complex and contentious and the APVMA works actively to strengthen the management and effectiveness of the review program. Advances in recent years have included enhancing publicly available review scope documents, improving project management, conducting reviews on a more targeted risk basis and greater collaboration with international counterparts. A review of the current approach to assess whether it adequately addresses risk is, however, timely. The APVMA will also strengthen communication of the status of reviews as recommended. This will build on existing communication strategies, which include advising consultative committees of the status of all reviews, communicating directly with stakeholders affected by particular reviews, seeking public input to reviews and comment on preliminary findings, awareness raising through the media and publishing review reports and related material on the APVMA website.

# 6. Cost Recovery Arrangements

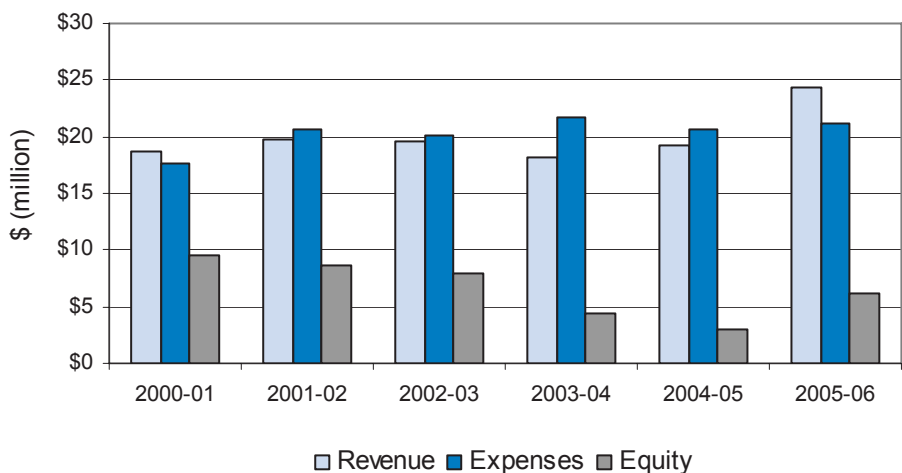
*This chapter examines whether the APVMA has administered its cost recovery arrangements effectively, to support the delivery of its regulatory functions.*

## Introduction

**6.1** The APVMA operates on an almost full cost recovery basis.<sup>60</sup> Its principal source of revenue is a levy on the sale of pesticides and veterinary medicines, which it collects annually from registrants. Revenue is also obtained through: application fees to register products; annual fees to re-register products; and other charges, such as licensing fees for manufacturers of veterinary medicines. The APVMA’s revenue, expenses and equity levels for the period 2000–01 to 2005–06 are shown in Figure 6.1.

**Figure 6.1**

**APVMA revenue, expenses and equity, for the period 2000–01 to 2005–06**



Source: ANAO analysis of APVMA data.

**6.2** From 1 July 2005, a number of changes were made to the APVMA’s fee structure, including the introduction of tiered levy rates, and a flat annual fee to re-register products (outlined at Appendix 3). These changes were determined by the Australian, State and Territory governments, which set cost recovery (and other) policy for the National Registration Scheme. The

<sup>60</sup> In 2004–05, the APVMA received an appropriation of \$123 000 to fund ‘minor use’ activities.

APVMA's role is to administer the cost recovery arrangements effectively to support the delivery of its regulatory functions. In this context, the ANAO examined whether the APVMA has adequate processes to:

- collect the required levy and annual fee payments;
- identify the cost of regulatory activities; and
- monitor the under or over recovery of revenue.

## Collecting payments

### Levy payments

**6.3** In 2004–05, the APVMA collected \$10.7 million in levy payments, some 55 per cent of total revenue for that year. Levy payments were calculated by the APVMA, based on pesticides and veterinary medicines with annual sales of \$100 000 or more, as declared by registrants. From 1 July 2005, the levy applies to all products regardless of sales, with the first payments due on 15 January 2007.

**6.4** The APVMA verifies the accuracy of sales declarations by auditing the financial records of a sample of registrants on an annual basis.<sup>61</sup> Criteria for selecting registrants include whether:

- the registrant is new, and is declaring sales for the first time;
- sales have been approximated for the purpose of reporting to the APVMA; and
- reported sales are in the range immediately below \$100 000.

**6.5** The APVMA's past three levy audits (2001 to 2003)<sup>62</sup> found that more than half the registrants audited had misstated sales, by either understating or overstating sales. In 2003, these errors resulted in net additional levy revenue of \$21 565 being recovered. Table 6.1 outlines the results of the APVMA's levy audit for the period 2001 to 2003.

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<sup>61</sup> Because sales are required to be declared on a product-by-product basis, there is no obvious other source of sales data the APVMA could use to assess the veracity or reasonableness of declarations.

<sup>62</sup> The audit of levy payments received in 2004 (calendar year) commenced during the ANAO's audit of the APVMA.

**Table 6.1****Results of the APVMA's levy audits, for the period 2001 to 2003**

Audit results	2001	2002	2003
No. of registrants audited	20	20	18
No. of registrants with misstated sales data <sup>1</sup>	10	11	9
Net additional levy revenue collected	\$74 940	\$13 690	\$21 565

Note 1: Misstatements were recorded only when sales data was found to be \$5 000 higher or lower than the amount reported to the APVMA.

Source: ANAO analysis of APVMA data.

**6.6** The APVMA advised that most errors made by registrants were due to poor accounting procedures and record keeping. This was confirmed by the ANAO. Key measures the APVMA has taken to address the level of misstatement, and to improve its targeting of audits, include:

- advising registrants of the common errors found by annual audits, with a view to reducing errors in future declarations;
- publishing audit results in the APVMA Gazette, including the names of companies that misstated sales or had inadequate records<sup>63</sup>; and
- periodically reviewing its criteria for selecting registrants, and conducting follow-up audits.

**6.7** The APVMA has considered increasing the number of registrants audited each year. However, it found that this may not be an effective use of resources, as audit costs usually exceed the net additional levy collected.<sup>64</sup>

**6.8** The ANAO considers the APVMA has implemented practical and feasible measures to manage the collection of levy revenue. However, given that the levy is now applied to sales of all products (rather than only those with sales over \$100 000) it may be timely for the APVMA to review its criteria for targeting registrants for audit, and to implement specific measures to raise awareness among registrants who have not previously been required to declare sales data.

<sup>63</sup> The APVMA Gazette is issued monthly and promulgates formal notices from the APVMA to the agricultural and veterinary chemicals industry.

<sup>64</sup> In 2003, the levy audits cost the APVMA approximately \$65 000 and recovered an additional \$21 565 (net) in levy revenue.

## Annual fee

6.9 Registrants must pay an annual fee for each product they wish to re-register for use in the following year (currently \$390). If the annual fee is not paid, the APVMA is required to remove the product from its register, thereby making it an offence for the product to be advertised or supplied for sale in Australia.

6.10 The ANAO reviewed a small sample of annual fee payments due on 1 July 2005, and found that:

- the correct annual fee had been paid for all products examined;
- where registrants did not wish to re-register products, the relevant products were removed from the APVMA's register; and
- the annual fee was not collected for products that were removed from the register.

6.11 The APVMA confirms the accuracy of its records on annual fee payments by publishing in the APVMA Gazette a list of products that were not re-registered, and notifying the registrants in writing that their registration has not been renewed.<sup>65</sup>

## Identifying costs

6.12 Although the APVMA does not set cost recovery policy, it is responsible for identifying the costs of its regulatory activities, to inform the setting of appropriate charges. In 1999, the APVMA developed an activity-based costing model, to identify the cost of its regulatory and corporate activities. This involved:

- *determining activities that consumed expenditure*—the APVMA's activities were costed into four groups: registration; compliance; chemistry and residues; and other services;
- *defining processes and activities*—workshops were held with staff to document key processes;
- *identifying resources and costs*—it was determined that APVMA staff were the key resource, followed by external parties that provided scientific advice; and

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<sup>65</sup> Registrants can apply to have products re-registered after the cut-off date for paying the annual fee has passed. However, a late fee may apply.

- *identifying cost drivers*—it was determined that the time taken by staff or external parties to perform activities was the principal cost driver.

**6.13** The costing model was revised, in part, in 2003 to provide updated data to inform the development of the APVMA's new fee structure introduced on 1 July 2005. The APVMA advised that the fee structure is due to be reviewed again in 2007–08, as part of a broader review of cost recovery arrangements in the Agriculture, Fisheries and Forestry portfolio. This timeframe is consistent with a key principle in the *Australian Government Cost Recovery Guidelines* that cost recovery arrangements be reviewed periodically, but no less frequently than every five years.<sup>66</sup>

### Upcoming review of fee structure

**6.14** The ANAO did not examine in depth the basis on which costs were determined for the APVMA's recently-changed fee structure. However, the ANAO has identified certain aspects of the APVMA's cost model which may warrant some consideration in the upcoming review. These include:

- assessing the impact of legislative changes to registration processes on the time required by staff to process applications;
- considering the costs and benefits of collecting data on the time taken by staff to process individual applications, to provide assurance that the amount charged for each application reflects its true costs; and
- obtaining information from providers of scientific advice (notably OCS and DEH) on the actual time taken to provide advice to the APVMA, to assess the appropriateness of the fees paid for such advice.

**6.15** As staff time is the APVMA's key cost driver, any improvements in the timeliness of processing applications for registration also has the potential to reduce the cost of regulation.<sup>67</sup>

<sup>66</sup> Available from <[http://www.finance.gov.au/finframework/docs/Cost\\_Recovery\\_Guidelines.rtf](http://www.finance.gov.au/finframework/docs/Cost_Recovery_Guidelines.rtf)>[accessed on 24 February 2006].

<sup>67</sup> The timeliness of the APVMA's registration process is discussed in Chapter 3.

## Monitoring revenue

**6.16** The amount of revenue collected through the APVMA's cost recovery arrangements is influenced by factors beyond its control. In particular, levy revenue, from the sale of pesticides and veterinary medicines, is susceptible to market forces and climate conditions, and fluctuates from year to year.<sup>68</sup> Nevertheless, the APVMA needs to monitor and address the under or over recovery of revenue. This includes identifying the need for charges to be adjusted to obtain sufficient funds to deliver its regulatory functions, and to avoid collecting excess revenue from fee and levy payers.

### Risk Reserve

**6.17** The APVMA has established a fund, known as a Risk Reserve, to provide protection in the event of an unexpected fall in revenue. In 2004–05, the Risk Reserve was set at \$4.5 million (some 22 per cent of the APVMA's operating expenditure in that year), and was comprised of a:

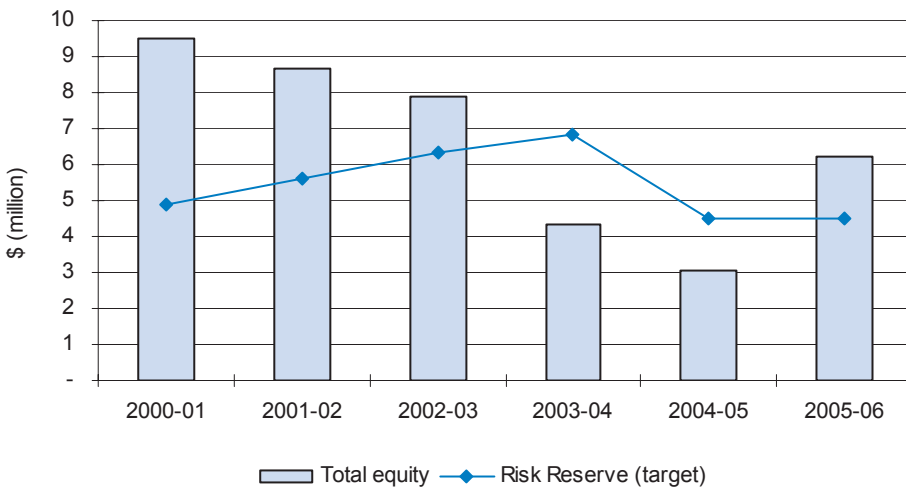
- \$3.5 million general reserve to provide protection against major downturns in sales (approximately three months operating costs);
- \$500 000 legal reserve, in the event of litigation; and
- \$500 000 capital expenditure provision.

**6.18** The Risk Reserve is set by the APVMA Board. It is funded from either cash surpluses (equity), or through an increase in the levy rate, which occurred when the APVMA's fee structure was introduced on 1 July 2005. In most years, the Risk Reserve has constituted only part of the APVMA's total equity. For example, in 2005–06, the APVMA had equity of approximately \$6.2 million, some \$1.7 million above its Risk Reserve of \$4.5 million. Figure 6.2 outlines the APVMA's equity and Risk Reserve for the period 2000–01 to 2005–06.

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<sup>68</sup> For example, in 2003–04, revenue fell by nearly \$1.5 million from the previous year. The APVMA has attributed this fall mainly to the effect of the drought on the sale of pesticides and veterinary medicines.



**Figure 6.2****The APVMA's equity and Risk Reserve, for the period 2000–01 to 2005–06**

Note: Balances as at 30 June each financial year.

Source: ANAO analysis of APVMA data.

**6.19** The ANAO acknowledges that the APVMA has a legitimate need to set funds aside to off-set an unexpected fall in revenue. However, both the Risk Reserve, and other equity, effectively represent an over-recovery of revenue from fee and levy payers. In this context, the APVMA has taken steps to minimise the collection of surplus revenue and to provide transparency to stakeholders on its cost recovery arrangements. These include:

- proposing reductions to levy rates in 2000 and 2006 when excess revenue (and equity) had built up<sup>69</sup>;
- seeking to improve its ability to forecast revenue, to inform its budgeting process, including the setting of the Risk Reserve<sup>70</sup>; and
- briefing key stakeholders on its financial position, including providing details on its Risk Reserve.

**6.20** The APVMA also proposed to DAFF, during the development of its current cost recovery arrangements, that the APVMA Board be given authority

<sup>69</sup> For example, in June 2000, levy rates were reduced from 0.75 per cent to 0.65 per cent.

<sup>70</sup> For example, in mid-2004, the APVMA approached the Australian Bureau of Agricultural and Resource Economics (ABARE) to develop a forecasting model. ABARE was unable to assist as the data available from the APVMA at the time did not support the development of such a model.

to adjust levy rates within set parameters. However, this proposal was not supported by some stakeholders.

**6.21** Notwithstanding these measures, the ANAO considers that the APVMA could improve the transparency of its cost recovery arrangements by more widely articulating its policy for the management of equity, including the amount, and components of, its Risk Reserve. This may include providing further, and more detailed, information on its website, or in its Annual Report.

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Steve Chapman  
Acting/Auditor-General

Canberra ACT  
7 December 2006

# Appendices



## Appendix 1: APVMA's response to this audit



Australian Pesticides &  
Veterinary Medicines Authority

13 November 2006

Mr Ian McPhee  
Auditor General  
Australian National Audit Office  
19 National Circuit  
BARTON ACT 2600

Dear Mr McPhee

Thank you for your letter of 18 October and the opportunity to provide comments on the proposed performance audit report of the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The APVMA accepts the six recommendations made by the ANAO, aimed at improving the APVMA's regulation of pesticides and veterinary medicines. The full text of the APVMA's responses to the report recommendations is at Attachment A. We have commenced planning and implementing actions to address the recommendations.

We believe that the recommendations will build on improvements and reforms introduced in recent years. The APVMA welcomes the acknowledgement from the ANAO that, since the ANAO's previous audit in 1997-1998, the APVMA has introduced various initiatives to improve the effectiveness of its operations.

The APVMA will need to give appropriate consideration to the resource implications of implementing the ANAO's recommendations in parallel with our commitment to meet our full range of regulatory responsibilities.

Thank you for the constructive approach to this performance audit, particularly the audit team, who interacted professionally with APVMA representatives during its conduct.

Yours sincerely

Dr Joe Smith  
Chief Executive Officer

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## ATTACHMENT A

### Summary

The Australian Pesticides and Veterinary Medicines Authority (APVMA) welcomes the ANAO report and accepts the six recommendations of the report. The recommendations will assist our efforts to continue to strengthen performance as an efficient and effective regulator. Actions to implement the recommendations are underway.

With respect to Recommendation 1, the APVMA will strengthen existing arrangements for managing potential conflicts-of-interest in the identified areas. The APVMA will implement Recommendations 2 and 3 by building on current initiatives to manage and report on timeliness of processing registration applications and by more systematic analysis and communication to the chemical industry of types of deficiencies in their applications. Current arrangements for procuring external scientific advice will be reviewed to implement Recommendation 4. The operation of the APVMA's Manufacturing Licensing Scheme will be strengthened through implementation of Recommendation 5. With respect to Recommendation 6, the APVMA will assess current approaches to chemical review and disseminate more comprehensive information on reviews to stakeholders.

### Recommendation No. 1

*The ANAO recommends that the APVMA strengthen arrangements for managing potential conflict of interest by:*

- (a) *requesting external service providers to provide positive assurance on the absence of a conflict of interest, prior to undertaking any work; and*
- (b) *documenting appropriate procedures for members of consultative committees, consistent with legislative requirements.*

### APVMA Response

The APVMA agrees with this recommendation, noting that it will add to the well-established conflict of interest protocols already in place for the Board and staff of the APVMA and many service providers. Formal arrangements for consultative committees will be articulated, noting that they are not regulatory decision-making forums and that members will often represent particular constituents. The APVMA will also seek to strengthen its existing arrangements for external service providers by requiring them to declare known conflicts of interest prior to undertaking work.

### Recommendation No. 2

*To improve arrangements for monitoring and reporting on statutory timeframes for processing applications to register pesticides and veterinary medicines, the ANAO recommends that the APVMA:*

- (a) *systematically monitor timeframes for conducting preliminary assessments;*

- (b) *report timeframe performance for applications that are refused or deemed to be withdrawn; and*
- (c) *establish processes to verify the accuracy of time entries.*

#### **APVMA Response**

The APVMA agrees with this recommendation. The APVMA has, through initiatives such as its Timeframes and Productivity Project, demonstrated a strong commitment to optimising timeframe performance and addressing the challenges presented by additional demands associated with legislative changes implementing new label approval requirements and introducing data protection. Over 98% of all applications received since 1 July 2005 have been completed within statutory timeframes, and the three actions in this recommendation will further improve the rigour and transparency of the overall timeframe monitoring process.

#### **Recommendation No. 3**

*The ANAO recommends that the APVMA improve its registration processes by systematically analysing the type and cause of errors or omissions in applications, to better target its initiatives to improve the quality of applications*

#### **APVMA Response**

The APVMA agrees with this recommendation. Following analysis of common deficiencies in applications the APVMA has, from time to time, conducted workshops with industry to assist their understanding of published requirements with a view to improving the overall quality of applications. Currently, an analysis of common chemistry deficiencies in applications is being used to provide feedback to registrants and focus to planned industry workshops. Companies also receive direct feedback on their individual applications. Further systematic analysis of errors and omissions, as recommended, will be used to refine the targeting of future initiatives with companies to improve the quality of their applications.

#### **Recommendation No. 4**

*The ANAO recommends that the APVMA review its current arrangements for obtaining scientific advice from Australian government agencies to assess whether a more contestable approach would be beneficial and lead to greater efficiencies in the allocation of resources.*

#### **APVMA Response**

The APVMA agrees with this recommendation. Notwithstanding the complexities involved, the APVMA has made some progress in pursuing a degree of contestability for the scientific advisory services provided to it by Australian Government agencies, and has obtained limited public health and environmental project work from alternative sources. Through the introduction and refinement of service level agreements with clearly defined fees for services and performance expectations, the framework for managing provision of these services has been significantly

strengthened in recent years. The recommended review will be progressed to assess whether greater contestability will deliver further benefits and cost-efficiencies.

#### **Recommendation No. 5**

*To improve the Manufacturers' Licensing Scheme compliance framework, the ANAO recommends that the APVMA:*

- (a) *include appropriate access provisions for relevant APVMA staff and third-party auditors in licence conditions and Deeds of Authorisation; and*
- (b) *develop and implement processes for third-party auditors to undertake audits by the required date and institute follow-up mechanisms if the relevant audit report is not received within stated timeframes.*

#### **APVMA Response**

The APVMA agrees with this recommendation. The report notes some of the more recent initiatives that the APVMA has instituted, in consultation with industry, to develop the Manufacturers' Licensing Scheme since it was introduced. Implementing this recommendation will further improve the rigour of the MLS framework. In doing so, the APVMA will consider various options to include appropriate access conditions for relevant staff and third-party auditors, and develop processes to facilitate improved timeliness of conduct and follow-up of audits.

#### **Recommendation No. 6**

*To improve the effectiveness of the Chemical Review Program, the ANAO recommends that the APVMA:*

- (a) *assess whether the current approach and time taken to complete reviews adequately addresses the risks presented by the chemicals not yet under review; and*
- (b) *communicate the status of reviews currently underway, emerging issues and updates on planned activities.*

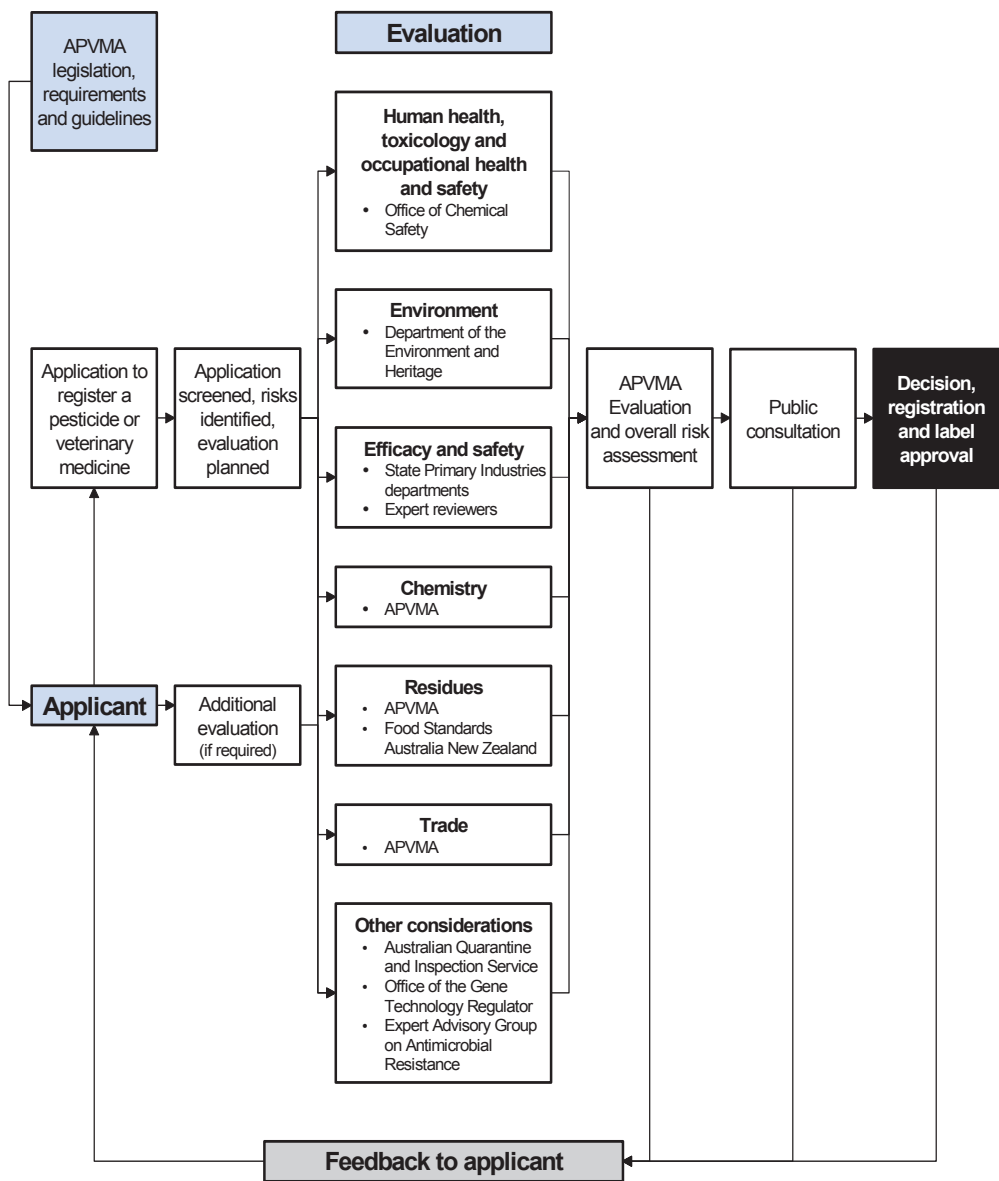
#### **APVMA Response**

The APVMA agrees with this recommendation. The review of existing chemical products is invariably complex and contentious and the APVMA works actively to strengthen the management and effectiveness of the review program. Advances in recent years have included enhancing publicly available review scope documents, improving project management, conducting reviews on a more targeted risk basis and greater collaboration with international counterparts. A review of the current approach to assess whether it adequately addresses risk is however, timely. The APVMA will also strengthen communication of the status of reviews as recommended. This will build on existing communication strategies, which include advising consultative committees of the status of all reviews, communicating directly with stakeholders affected by particular reviews, seeking public input to reviews and comment on preliminary findings, awareness raising through the media and publishing review reports and related material on the APVMA website.





# Appendix 2: Overview of the APVMA’s registration process



Source: ANAO analysis of APVMA data.

### Appendix 3: Key changes to the APVMA's fee structure, introduced on 1 July 2005

Charge	Pre-1 July 2005	Post-1 July 2005
<b>Application Fee</b>	Varied according to the type of assessment required for the particular application (50 application categories)	Varies according to the type of assessment required for the particular application (25 application categories)
<b>Annual Fee</b>	Varied, based on annual sales for the product	A flat fee of \$390 per annum per product
<b>Levy</b>	Flat rate of 0.65 per cent charged on products with sales over \$100 000 Levy payments capped at \$25 000 per product	Tiered rate based on sales: – 0.9 per cent up to \$1 000 000; – 0.55 per cent from \$1 000 001 up to \$5 000 000; and – 0.4 per cent above \$5 000 000 Levy payments uncapped

Source: ANAO analysis of APVMA data.

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