

CHAPTER 3

OVERVIEW OF OPERATIONS

THE APVMA'S CORPORATE OBJECTIVES AND THE PERFORMANCE FRAMEWORK

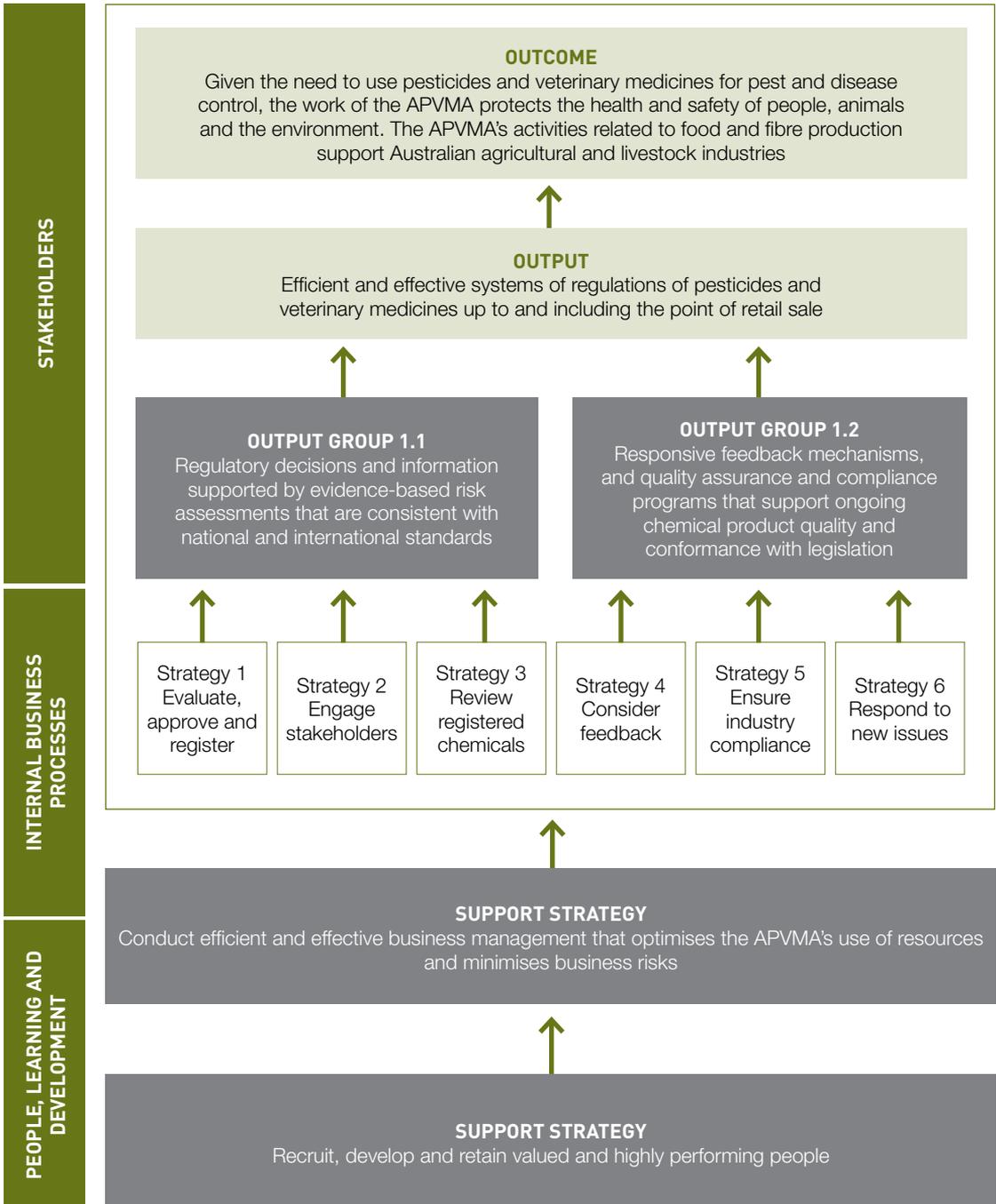
The work of the APVMA protects the health and safety of people, animals and the environment through its role in regulating pesticides and veterinary medicines. The APVMA's activities relate to food and fibre production and to support Australian agriculture and livestock industries.

The APVMA has developed a performance framework that links its legislative objectives to an outcome–outputs model. This framework involves a detailed planning and reporting process that incorporates portfolio budget statements, corporate plans, annual operational plans and annual reports.

The outcome, outputs and related performance indicators in the APVMA's component of Australian Government Department of Agriculture, Fisheries and Forestry's (DAFF) *Portfolio Budget Statements 2008–09* are reflected in the APVMA's *Operational Plan 2008–2009*.

Figure 3 below outlines the APVMA's strategic framework structure for 2008–09. From 2009–10, all General Government Sector entities will be reporting on a program basis following the outcomes of Operation Sunlight. For the APVMA this means only the minor change of replacing its outputs and sub-outputs by a single program.

Figure 3: Strategic framework structure





Summary of performance against outputs

The APVMA has met most of its projected targets for the year in relation to its two output groups:

- Output Group 1.1—Regulatory decisions and information supported by evidence-based risk assessments that are consistent with national and international standards
- Output Group 1.2—Responsive feedback mechanisms, and quality assurance and compliance programs that support ongoing chemical product quality and conformance with legislation.

Tables 1 and 2 report against the key performance indicators and targets set out in the *Portfolio Budget Statements 2008–09* for the Agriculture, Fisheries and Forestry Portfolio. Detailed performance information against each of the strategies in the *Operational Plan 2008–2009* is on pages 24–63.

Output Group 1.1 Regulatory decisions and information

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

- Evaluate and consider applications to approve active constituents, register chemicals, approve labels, and provide regulatory consents such as permits following scientific evaluation (Strategy 1—page 25)
- Engage stakeholders to improve awareness and inform policy development and to optimise the regulatory framework within which APVMA operates (Strategy 2—page 40)
- Review registered chemicals on the basis of their risk (Strategy 3—page 45)

The *Corporate Plan 2006–2009*:

- outlines the APVMA's corporate objectives and sets its strategic direction
- defines the APVMA's strategic framework (Figure 3), which helps focus the agency's activity and enables staff to understand its purpose and to deliver best-practice accountability to the APVMA's stakeholders
- presents the single high-level outcome and key output, as outlined in the *Portfolio Budget Statements 2008–09*, supported by two operational outputs and two support outputs
- provides the framework for reporting on the APVMA's performance for 2008–09. Progress is reported on the basis of performance indicators as well as other major achievements.

The *Corporate Plan 2006–2009* was approved in June 2006, and the *Operational Plan 2008–2009* was approved in June 2008.

Table 1: Performance against targets for Output Group 1.1 Regulatory decisions and information

KEY PERFORMANCE INDICATORS	2008–09 TARGET
Timeframe performance and evaluation standards maintained	Regulatory decisions made within statutory timeframes Appropriate standards of scientific evaluation maintained
Appropriate regulation provided to meet minor and emergency use needs and to encourage reduced risk chemicals	Reduction in the regulatory process burden consistent with the risk posed by introducing reforms to decrease process Existing chemicals reviewed in a timely manner on the basis of risk
Increased use of contemporary science and international collaboration in risk assessments	Efficiencies gained and international consistency strengthened through increased international collaboration
A more harmonised and integrated approach to agvet chemical regulation and risk management throughout Australia through policies that have APVMA input	National regulatory policy framework informed by relevant APVMA input

PERFORMANCE AGAINST TARGETS

- Finalised 1513 applications for registration, variation to registration, or label approval for pesticide products (85% within the statutory timeframe)
- Finalised 512 permit applications for pesticide products (75% within the statutory timeframe)
- Finalised 807 applications for registration, variation to registration, or label approval for veterinary medicines (88% within the statutory timeframe)
- Finalised 168 permit applications for veterinary medicines (93% within the statutory timeframe)
- Continued strengthening the quality of the APVMA's regulatory science through the Standard of Good Regulatory Science Practice and the Science Fellows program
- Issued 46 emergency permits
- Continued progress on a major reform agenda for Minor Use, including increased international engagement
- Completed one joint review and commenced three new joint reviews with other international regulators
- Participated in key international forums, including the OECD, the United Nations Codex Alimentarius Commission, Food and Agriculture Organization, and the International Committee for Harmonisation of Veterinary Drug Registration Requirements
- Provided information to Japanese and Taiwanese agencies to assist in setting maximum residue limits
- Hosted regular meetings of the APVMA Community Consultative Committee, the Registration Liaison Committee, the Industry Liaison Committee and the Industry Technical Committee
- Conducted or continued reviews of 32 chemicals
- Dealt with issues relating to existing chemicals through chemical review actions or voluntary compliance involving five chemicals
- Finalised operating principles for spray drift risk assessment and commenced targetted spray drift reviews
- Expanded the information about review chemicals on the APVMA website
- Updated labels or cancelled registration of several products grandfathered at the time the APVMA started



Output Group 1.2: Responsive feedback mechanisms

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

- Consider stakeholder feedback including adverse experience reporting (Strategy 4—page 52)
- Ensure industry compliance with the legislation, including maintenance of quality assurance programs (Strategy 5—page 54)
- Respond to and manage emerging regulatory issues (Strategy 6—page 61).

Table 2: Performance against targets for Output Group 1.2 Responsive feedback mechanisms

KEY PERFORMANCE INDICATORS	2008-09 TARGET
Effective management of emerging regulatory issues	Regulation of new technologies developed and adopted as needed Improved adverse experience feedback received
Effective industry compliance with legislation	Industry compliance with legislation strengthened Improved stakeholder awareness of, and confidence in APVMA regulatory actions
PERFORMANCE AGAINST TARGETS	
<ul style="list-style-type: none"> • Assessed 1718 veterinary product adverse experience reports and 98 pesticide product adverse experience reports • Continued to test products and review data on the quality of marketed agricultural chemicals • Increased compliance field operations in response to reports of non-compliance • Increased communication of recall activity by the APVMA website and other means • Continued to enforce compliance with the updated Manufacturing Principles and Australian Code of Good Manufacturing Practice for Veterinary Chemical Products • Took part in developing a whole-of-government strategy for regulation of nanoscale technology • Provided significant input to external reviews and studies and COAG reform agenda 	

In addition, there are two support strategies in the *Operational Plan 2008–2009*:

- Conduct efficient and effective business management that optimises our use of resources and minimises business risks (Strategy 7—page 18)
- Recruit, develop and retain valued and highly performing people (Strategy 8—page 20)

Tables 3 and 4 report against the key performance indicators and targets for these two support strategies.

Table 3: Performance against targets for support strategy to conduct and effective efficient business

KEY PERFORMANCE INDICATORS	TARGET
Responsible management of resources	No significant audit findings Business risks identified and resources appropriately allocated Successful implementation of new policy and regulatory reform initiatives
Compliance with legislation	No successful challenges as a result of non-compliance with legislation
PERFORMANCE AGAINST TARGETS	
<ul style="list-style-type: none"> Continued International Organization for Standardization (ISO) accreditation of the APVMA's quality management system Achieved an unqualified audit result on the 2008–09 financial statements Internal and external audits of financial operations with no adverse findings No successful challenges as a result of non-compliance with legislation Development of the cost recovery impact statement 25% increase in number of registered users of EARS 35% increase in number of EARS accesses Successful implementation of new policy and regulatory reform initiatives 	

Table 4: Performance against targets for support strategy to recruit, develop and retain valued and highly performing people

KEY PERFORMANCE INDICATOR	TARGET
Recruit, retain and develop high performing staff	Staff satisfaction Trained staff
PERFORMANCE AGAINST TARGETS	
<ul style="list-style-type: none"> Implemented a new collective agreement in July 2008 Surveys indicate high levels of overall staff satisfaction Enhanced partnership with Charles Sturt University Implemented a strategic learning and development program using the integrated leadership system Maintained and enhanced a graduate program Staff achieved their training point targets 	



Summary of financial performance

The APVMA's financial management framework continues to provide sound support. The Auditor General gave an unqualified audit opinion of the 2008–09 financial statements.

An overview of the APVMA's financial performance for 2008–09 is included in this section. Full details are contained in the audited financial statements and accompanying notes included in this report (pages 79–127).

Operational income

In 2008–09, 96 per cent of total revenue was derived from industry contributions (94 per cent in 2007–08). This indicates the majority of APVMA's operations continue to be cost recovered.

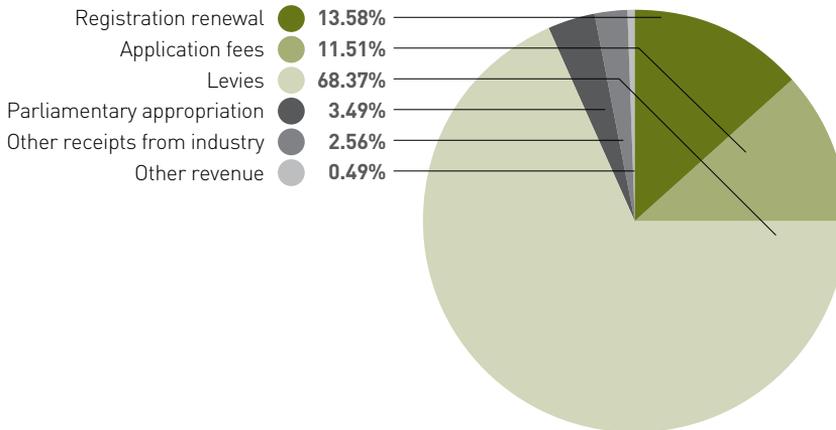
Registrants pay fees to register products and an annual fee to maintain a product registration. Levies are also paid annually, and the amount is based on the value of sales (and other disposals) of registered products.

The APVMA's total income for 2008–09 was \$24.83 million, an increase of \$2.37 million (10.65 per cent) from 2007–08 (see Table 5 and Figure 4). This increase is primarily due to higher levy income.

Table 5: APVMA income 2008–09

RECEIPTS FROM INDUSTRY	\$	% OF INCOME
Application fees	2 858 724	11.51
Levies	16 974 652	68.37
Annual fees (renewal fees)	3 370 390	13.58
Other receipts from industry	635 393	2.56
Parliamentary appropriation	866 000	3.49
Other revenue	122 241	0.49
TOTAL INCOME	24 827 400	100.00

Figure 4: APVMA income 2008–09



Operational expenditure

Total operating expenses for 2008–09 were \$25.86 million (see Table 6 and Figure 5), an increase \$1.01 million (4.06 per cent) from 2007–08.

The net operating deficit of \$1.04 million for 2008–09 resulted in equity decreasing to \$4.87 million. The levy rate is adjusted periodically to ensure that the APVMA’s equity remains at appropriate levels (three months’ operating costs).

As stated earlier, the outcome–output structure above applies to 2008–09. The reporting structure will change to an outcome–program structure on 1 July 2009 because of the outcomes from Operation Sunlight.



Table 6: APVMA expenditure 2008–09

EXPENDITURE	\$	% OF EXPENDITURE
Employee expenses	15 950 806	64.15
Scientific assessment services other government agencies	3 419 571	13.75
Asset depreciation, write down and impairment	666 093	2.68
Rent	975 018	3.92
State compliance services	247 445	1.00
Other expenses	4 605 417	14.50
TOTAL EXPENDITURE	25 864 350	100.00

Table 7: APVMA expenditure by output 2008–09

	2008–09 ACTUAL	2008–09 BUDGET (PER PBS)	2007–08 ACTUAL
OUTPUT 1.1: REGULATORY DECISIONS AND INFORMATION			
Administered Items	19,558,719	12,039,000	17,871,062
Departmental outputs	523,444	542,000	525,013
Departmental Special Appropriation	20,409,480	20,074,000	19,860,636
Other revenue	287,353	287,000	323,875
SUBTOTAL FOR OUTPUT GROUP 1.1	21,220,277	20,903,000	20,709,524
OUTPUT 1.2: CHEMICAL PRODUCT QUALITY			
Administered Items	4,280,440	1,736,000	3,573,673
Departmental Outputs	114,556	88,000	104,987
Departmental Special Appropriation	4,466,629	3,268,000	3,971,528
Other revenue	62,888	47,000	64,765
SUBTOTAL FOR OUTPUT GROUP 1.2	4,644,073	3,403,000	4,141,280
TOTAL RESOURCES FOR OUTCOME 1	25,864,350	24,306,000	24,850,804

Purchasing

In 2008–09, the APVMA spent \$1 002 212 (GST inclusive) on consultants, awarding 45 consultancy contracts during that period. Each program within the APVMA is responsible for its own purchasing, but programs are subject to Chief Executive Instruction 12 'Procurement' and Finance Procedure 4 'Purchasing'. Chief Executive Instructions and finance procedures complement the *Commonwealth Procurement Guidelines* and purchasing policies.

Finance Procedure 4 details the process for the purchasing of goods and services. It outlines the key principles of purchasing: value for money, efficient and effective use of monies, accountability and transparency, and ethics. Appendix E lists the number of quotes required in relation to the value of the good or service. It also lists individual consultancies with a value of more than \$10 000.

The APVMA publishes its annual procurement plan on Austender by 1 July each year to advertise potential opportunities.

The APVMA's financial reserve

As the APVMA's revenue can vary significantly from year-to-year due to variability in the sales of pesticides and veterinary medicines, the APVMA maintains a financial reserve (forming part of its equity) that allows it to manage revenue variations. Without this financial reserve, the APVMA would risk having periods of time during which its liabilities would exceed its assets (negative equity).

The financial reserve provides a responsible and prudent form of protection against fluctuations in sales and variations in revenue.

The financial reserve is currently set at three months of operating expenses (about \$6.0 million). At 30 June 2009, the APVMA's equity was \$4.87 million, which is approximately \$1.13 million below its target reserve. As a result of the anticipated fee increases following the approval of the *Final Cost Recovery Impact Statement (2009)*, the APVMA's equity is expected to be rebuilt to the three-month operating cost target during the next three financial years.