Australian Government

Australian Pesticides and Veterinary Medicines Authority

OPERATIONAL PLAN 2013–14

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Comments and enquiries can be made to:

The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Australia

Telephone: +61 2 6210 4812
Email: communications@apvma.gov.au

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Kareena Arthy,
Chief Executive Officer

CEO'S INTRODUCTION

Australia has an enviable global reputation for its food and fibre production. Underpinning this reputation are many inter-woven policy and regulatory arrangements to ensure the safety and integrity of these economically important industries.

The APVMA's role—as articulated in our mission—is a significant regulatory one that helps maintain national and global confidence in the quality and safety of the agricultural chemicals and veterinary medicines (agvet chemicals) used in Australia.

In my first year as APVMA chief executive officer, I am committed to building on the legacy of the past 20 years and leading the organisation to fulfil our goal of being a world-class agvet chemical regulator.

Since commencing in January 2013, I have met many of our stakeholders: registrants, industry representative organisations, our regulatory partners, chemical users and non-government organisations–and particularly members of our new advisory board who we welcomed to the APVMA following their appointment in November 2012. Equally important have been the conversations I've had with our staff.

These conversations have helped me to understand the APVMA's operating environment and identify opportunities for improvement in our timeliness, transparency, predictability and consistency.

This year, we will be focusing on improving APVMA's operations—those that are directly related to our agvet chemical regulatory services as well as our supporting business systems and technologies.

A critical element of this work will be support for high quality risk-based scientific assessment and decision making through the development of our new Regulatory Guidelines (known as the Risk Compendium).

Through our rebuilding efforts, clients and stakeholders will be at the centre of our business processes—and we will hold ourselves accountable in delivering on the commitments we make.

While a significant component of this work will relate to the implementation of new legislation, the APVMA is committed to ensuring its processes are as efficient and effective as possible.

In addition to rebuilding our agency into a much more modern and efficient chemical regulator, we will continue our work to generate community confidence in the system. We will continue to manage applications for registration of thousands of new products and hundreds of minor-use permits in the coming year. We will continue to deliver effective post-market authorisation services especially in compliance and adverse experience reporting. This year will see a renewed commitment to our chemical review work program and continued work on significant longer-term issues such as the implications for regulating agvet chemicals of antimicrobial resistance, nanotechnology, bee and pollinator health and endocrine-disrupting chemicals.

I look forward to working with APVMA staff and stakeholders through a strong and constructive partnership approach as we tackle the challenges and opportunities in the year ahead.

2013 MARKS 20 YEARS OF THE APVMA (PREVIOUSLY KNOWN AS THE NRA)

ABOUT THIS PLAN

This operational plan has been developed by the APVMA and approved by the Minister for Agriculture, Fisheries and Forestry as required by sections 55 and 56 of the *Agricultural and Veterinary Chemicals Administration Act 1992*.

The plan details how we will give effect to our 2012–15 corporate plan during its second year of operation. The key strategies outlined in the corporate plan are further developed in the eight strategy tables in this document.

It also takes account of amending legislation that is currently before the Australian Parliament and which sets a commencement date of 1 July 2014 for the majority of the changes that are required under this legislation.

EVALUATING OUR PERFORMANCE

The APVMA is committed to transparency and providing feedback on how well we perform against our vision and mission as well as the outcomes in the government's 2013–14 budget statements for the agriculture, fisheries and forestry portfolio (PBS).

The key performance indicators (KPIs) in the 2013–14 PBS relate to improvements to timeframe performance:

- 90% of product applications determined within the statutory timeframe
- 60% of active constituent applications determined within the statutory timeframe
- 85% of permits determined within the statutory timeframe.

There are two 'end-use' measures that indicate the quality of our risk-based scientific assessments and evaluations:

- less than 1 per cent of adverse experience reports lead to significant regulatory action
- at least 99 per cent compliance with maximum residue limits for pesticides and veterinary medicines in food commodities.

The final KPI is an indicator of awareness of the agvet chemical regulatory requirements in Australia as well as a community perception that noncompliance will be effectively dealt with:

- no more than six instances of significant regulatory action arise from non-compliance with registration requirements.

These KPIs are incorporated with the relevant strategy tables in this operational plan, together with a range of more specific performance indicators for each activity or initiative.

While reform and business transformation will mean significant changes to the APVMA operations, we will remain focused on building community confidence in industry and the regulatory system we oversee.

THE APVMA IS AN INDEPENDENT STATUTORY AUTHORITY RESPONSIBLE FOR THE ASSESSMENT AND REGISTRATION OF AGRICULTURAL CHEMICALS AND VETERINARY MEDICINES AND FOR THEIR REGULATION UP TO AND INCLUDING THE POINT OF RETAIL SALE

FINANCIAL SUMMARY

OVERVIEW

The APVMA is one of a number of Australian Government regulators funded by fees, charges and levies imposed on the industry it regulates. In the APVMA's case, chemical companies are charged application fees for the APVMA to evaluate registration and approval proposals, an annual fee to maintain a chemical product's registration and levies based on the wholesale sales of chemical products. These funds are collected by the APVMA, remitted to the Australian Government and returned to the APVMA to pay salaries and to purchase goods and services.

The APVMA is in a sound financial position. In 2013–14 we will continue providing strong expenditure control over our operating budget to ensure our regulatory activities are undertaken in the most cost effective and efficient manner.

FINANCIAL RESERVE

The APVMA's revenue can vary significantly from year to year as a result of fluctuations in sales of agvet chemicals. This is largely the result of prevailing environmental conditions. To manage financial risks arising from this situation, the APVMA aims to hold a financial reserve (part of our equity) that allows revenue fluctuations to be managed. Without this financial reserve we risk a situation where our liabilities could exceed our assets over a period of time (negative equity). The financial reserve is based on three months of operating expenses and is currently set at $7 million.

COST RECOVERY

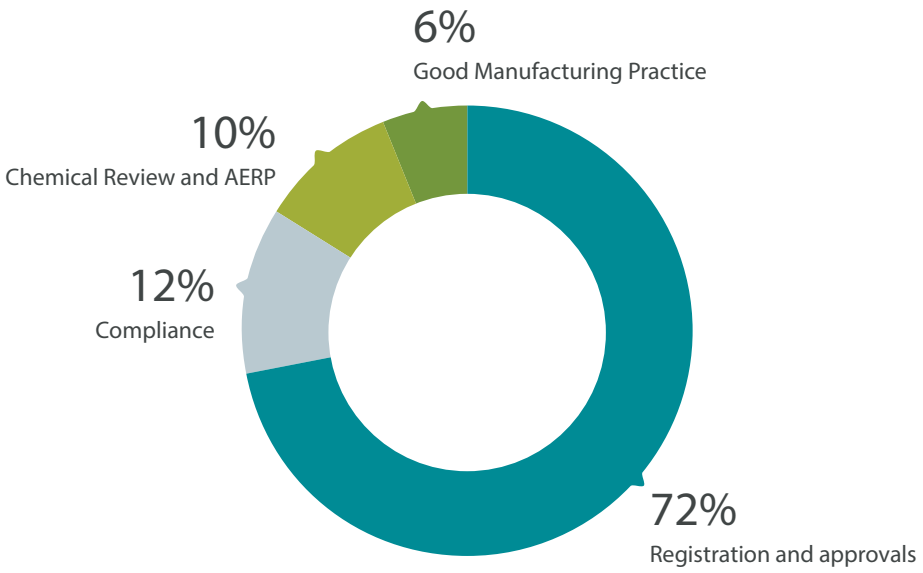
From 1 July 2013, the APVMA will implement the new cost recovery arrangements outlined in the cost recovery impact statement originally published on 29 November 2012 and updated in June 2013 to incorporate changes required as a result of passage of the Agricultural and Veterinary Chemicals Amendment Bill 2012.

FOR CURRENT INFORMATION ABOUT THE APVMA, OUR ORGANISATION STRUCTURE AND OUR BUSINESS OPERATIONS, SEE WWW.APVMA.GOV.AU/ABOUT

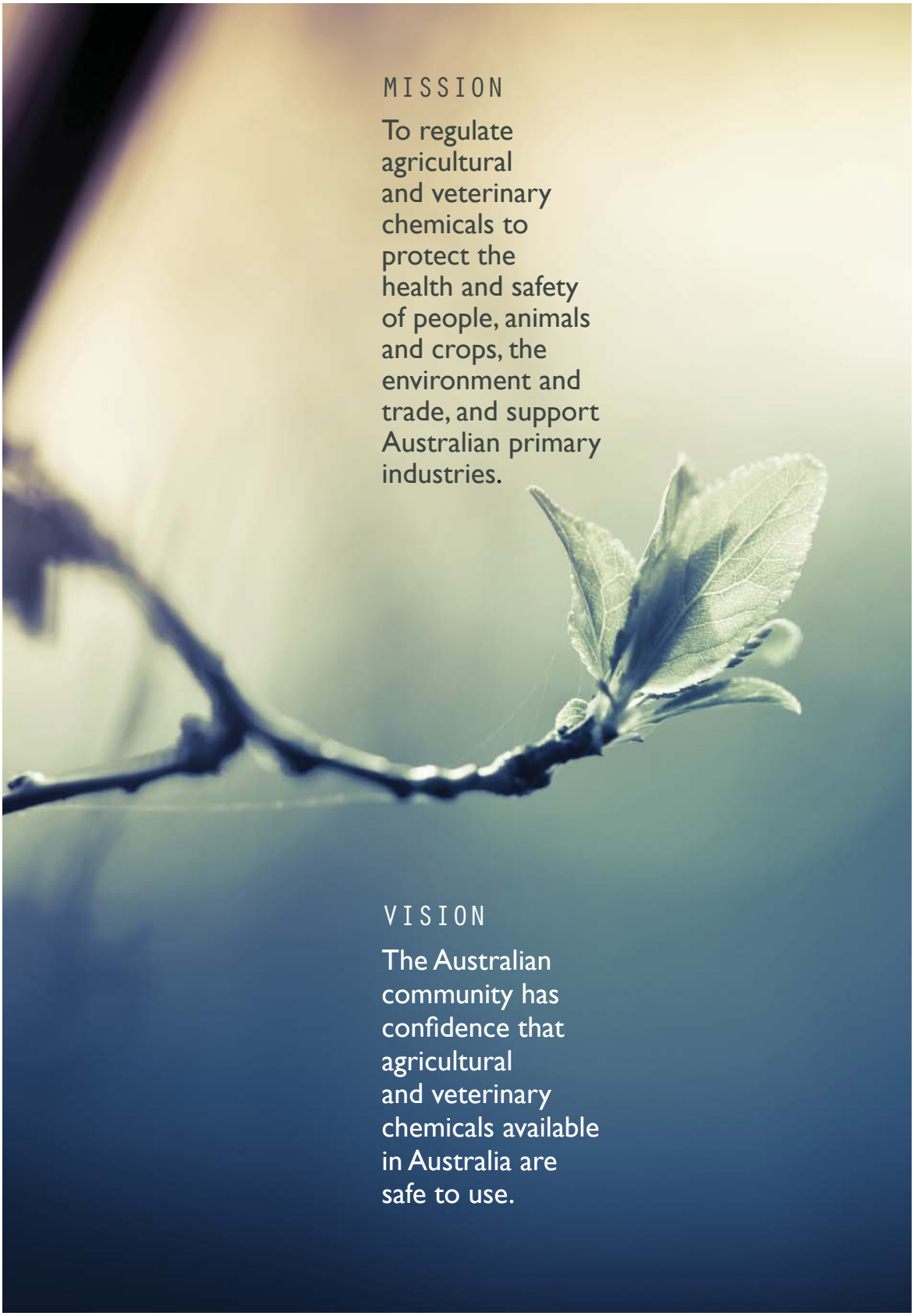
APVMA FINANCIAL PROJECTIONS 2013–15

	2013–14 ($)	2014–15 ($)
Expenditure (ongoing)	30,163,000	30,812,000
Reform implementation	2,344,000	–
Compliance and enforcement	–	814,000
Re-registration and re-approval scheme	–	593,000
TOTAL	32,507,000	32,219,000

ANTICIPATED EXPENDITURE ACROSS CORE ACTIVITIES



Note: all corporate activities have been allocated across the core business activities



MISSION

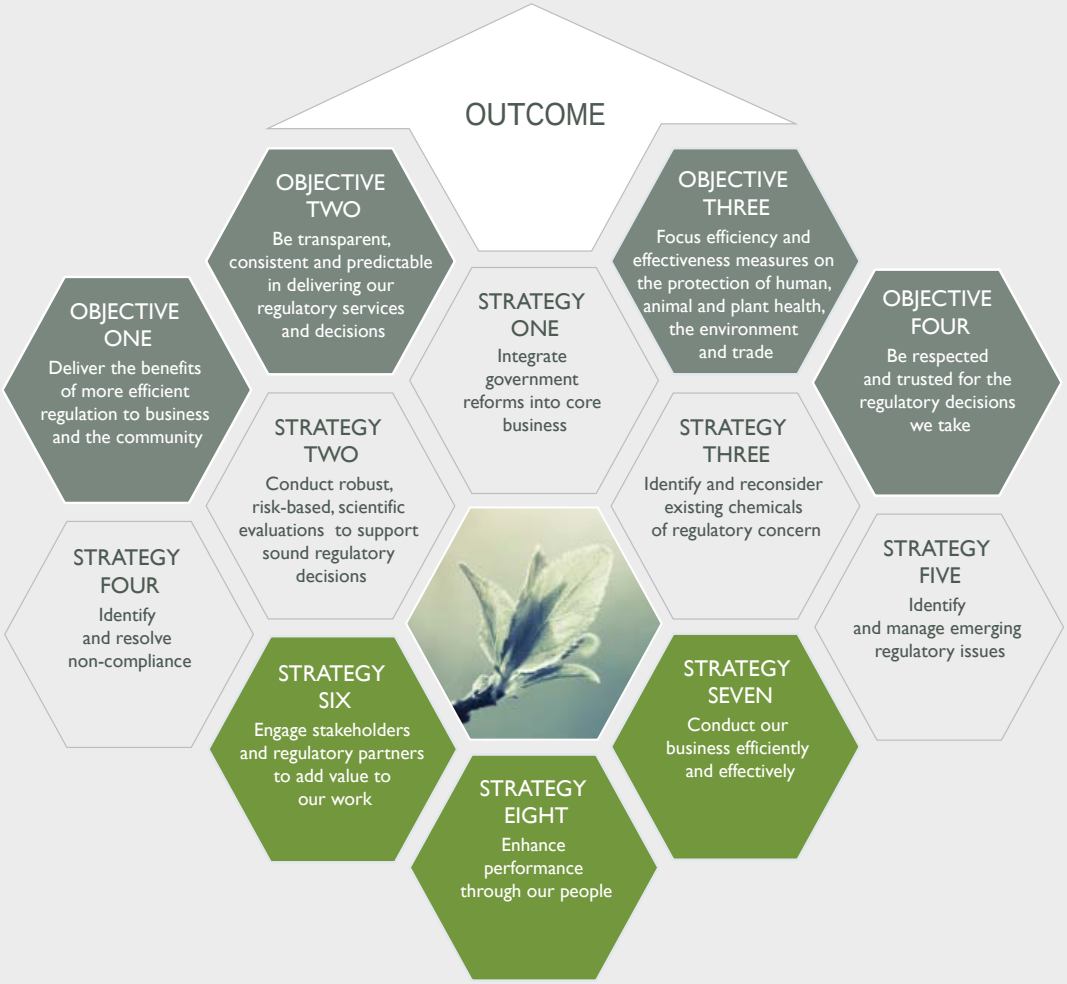
To regulate agricultural and veterinary chemicals to protect the health and safety of people, animals and crops, the environment and trade, and support Australian primary industries.

VISION

The Australian community has confidence that agricultural and veterinary chemicals available in Australia are safe to use.

STRATEGIC FRAMEWORK

'Protection of the health and safety of people, animals, the environment, and agricultural and livestock industries through regulation of pesticides and veterinary medicines.'



The APVMA's Corporate Plan identifies four objectives. The diagram above shows the relationship between these objectives, the eight strategies to achieve the objectives and the APVMA's outcome.

STRATEGY ONE

Integrate government reforms into core business

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Embed revised APVMA regulatory guidelines (Risk Compendium) into APVMA systems and processes	• Draft compendium in place by January 2014, for stakeholder consultation, awareness raising and education • Compendium content finalised by April 2014 for further communication and training
Enhance transparency of APVMA operational practices, policies and guidelines	• All relevant operational information published under the Information Publication Scheme according to the APVMA agency plan • Relevant guidelines (including Risk Compendium) published online to improve transparency of APVMA policies and procedures for stakeholders
Support industry readiness to comply with new regulatory frameworks	• Reform communication strategy developed by end July 2013 and activities undertaken in accordance with strategy • Detailed industry support material in place and seminars conducted with relevant stakeholders prior to commencement of new legislation • New case management system developed and piloted, ready for full implementation by 1 July 2014
Implement changes arising from the 2013 amendments to the APVMA's governing legislation in preparation for commencement on 1 July 2014	• Reforms implemented in accordance with time frames
Ensure staff are aware of changes and are capable of delivering the reform objectives	• All staff undertake training before commencement of new legislation

STRATEGY TWO

Conduct robust, risk-based scientific evaluations to support sound regulatory decisions

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)

Make quality and timely decisions on registration, active approval and permit applications	• Timeframe performance met for applications received before commencement of new legislation
	  • 90% product registrations
	  • 60% active approvals
	  • 85% permits
	• Work practices reviewed to ensure alignment with legislative requirements and staff trained appropriately
	• Enhanced peer review processes implemented

Support provision of high quality applications	• Tools developed to promote online submission of applications and data • Current electronic application and registration system replaced with a web-based system • Examination undertaken of new models to better support minor use • Implement processes to provide formalised pre-application assistance to applicants • Two courses run for applicants and consultants on application preparation
Adopt enhanced regulatory standards and frameworks for evaluations	• Analysis of VICH international guidelines undertaken to determine suitability for adoption in Australia and at least two guidelines adopted • Expert panels established and used for at least two science quality issues • New arrangements in place to register biological products independently of biosecurity requirements • Ensure changes to regulatory frameworks and standards are applied across the APVMA and advisory agencies
Develop regulatory framework to support spray drift policy	• Draft consultation framework published by January 2014 • Consultation completed by June 2014

STRATEGY TWO (CONTINUED)

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Finalise arrangements for control of labels in the marketplace	• Revised arrangements for control of market labels in place by June 2014
Review application of Joint Expert Committee on Food Additives methodology for setting maximum residue levels for veterinary medicines	• Review undertaken by March 2014
Continuous improvement of risk management frameworks underpinning decision making	• Research undertaken into best practice risk management approaches in science-based regulators • Risk assessment practices and procedures reviewed to ensure best practice

STRATEGY THREE

Identify and reconsider existing chemicals of regulatory concern

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Monitor regulatory and scientific developments and adverse experiences, and initiate reviews when warranted	• Issues identified and considered; responses developed and reported as needed • Annual summary of adverse experience reports published
Select and take action on registered chemicals when concerns are identified and validated by the APVMA	• At least six chemical review decisions completed • Number of adverse experience reporting program reports requiring significant regulatory action is less than 1% • 99% compliance with maximum residue limits of agvet chemicals in food commodities (as reported in the National Residue Survey)
Inform stakeholders of regulatory activity on registered chemicals	• Participation in, or delivery of, review-related stakeholder forums
More proactive planning of chemical reviews	• Work plans are developed and published for chemicals under review, from January 2014

STRATEGY FOUR

Identify and resolve non-compliance

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Implement a risk-based strategy for compliance	• Strategy developed by June 2014 • New powers from reforms ready to implement • Intelligence-led approach integrated into compliance activities by December 2013
Manage our systems, practices and procedures to support a proactive compliance and enforcement regime	• 90% of consents to import are processed within 14 days of receipt • Upgrade of compliance systems completed by December 2013 • Permit audit strategy developed and implemented by June 2014
Target communication activities to significant emerging non-compliance issues	• Finalise a new communications strategy by September 2013 and deliver activities according to the strategy • Increased stakeholder awareness of identified issues
Improve voluntary compliance and deter non-compliance	• Establish baseline level of awareness of compliance responsibilities by December 2013 as the basis of future surveys
Undertake effective risk based enforcement	• 100% of allegations of non-compliance risk assessed and prioritised • 100% of identified high priority allegations investigated • Field investigations validate accuracy of risk assessment and prioritisation process • Six significant regulatory actions undertaken due to non-compliance with registration requirements
Undertake effective inspection, auditing and enforcement activities for the Good Manufacturing Practice (GMP) and Manufacturers' Licensing Scheme	• 100% of GMP non-compliances assessed and prioritised
Improve decision making on the application of coercive powers through a new enforcement committee	• Committee established and operating effectively • Level of enforcement action considered appropriate during after action reviews

STRATEGY FIVE

Identify and manage emerging regulatory issues

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Assess and manage significant emerging regulatory issues	• Regulatory Strategy Group meets quarterly to identify emerging issues and oversee work to address issues • Effective relationships with national and international regulatory counterparts and relevant agreements in place with national and international counterparts • Stakeholder satisfaction for issues management initiatives
Contribute to high level forums relating to regulation of agricultural and veterinary chemicals	• Contributions made to the Regulators' Forum, the Regulatory Science Network, the Agvet Chemical Regulation Committee and other relevant forums
Support DAFF initiatives on quality assurance of imported chemicals	• Substandard agrochemical intelligence project completed
Lead work on implications of nanotechnology on the regulation of agricultural and veterinary chemicals	• Inter-agency symposium held by March 2014 • Report on regulatory considerations for agvet nanotechnology by June 2014
Investigate the regulation of endocrine disrupting chemicals by other regulators	• Symposium held by October 2013 • Outcomes and APVMA response published by December 2013
Investigate what regulatory action may be required to protect pollinator health from use of agricultural chemicals	• Workshops for regulatory stakeholders and broader stakeholder consultation held by September 2013 • Report outcomes by December 2013

STRATEGY SIX

Engage stakeholders and
regulatory partners to add value to our work

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Develop and implement new communications strategy including stakeholder engagement model and implementation of reforms	• Strategy developed by September 2013 and activities undertaken in accordance with strategy
Develop and deploy suitable tools and resources to allow staff to communicate more consistently and efficiently with stakeholders	• Web based content management system implemented • New intranet in place • Visual identity and language style guides updated
Develop new case management system and client service charter	• New system and charter in place by June 2014
Redevelop website with an online presence for the Risk Compendium	• New website launched in early 2014 • Website meets relevant government online and accessibility standards
Seek input on strategic issues from the APVMA's Advisory Board	• Four advisory board meetings held by June 2014
Implement new industry consultative committee arrangements including the use of special-purpose working groups	• At least two industry forums undertaken • Stakeholder satisfaction with consultative arrangements
Engage effectively with the states and territories on the management of the National Registration Scheme, including increase involvement of states and territories in chemical review processes	• Two Registration Liaison Committee meetings held by June 2014 • Update on suspension and reconsideration activities provided to the Agvet Chemical Regulation Committee twice a year • Risk Compendium is provided to states and territories for discussion
Establish revised arrangements for the provision of advice from advising agencies	• New arrangements in place by June 2014
Work effectively with DAFF on agvet chemical issues of mutual interest	• Satisfaction with level and quality of engagement

STRATEGY SEVEN

Conduct our business efficiently and effectively

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Enhance information technology systems to improve service delivery	• New payment module launched • PUBCRIS relaunched to cater for mobile device users • An online annual returns submission facility developed by 30 June 2014 • An online electronic registered label particulars facility launched by June 2014
Develop or modify IT systems to support changes required from the legislative and business reforms	• Legacy IT systems redeveloped to incorporate changes arising from reform legislation
Finalise the rollout of the electronic document and records management system	• APVMA-wide implementation by February 2014
Commence redevelopment of the APVMA's core agvet chemical database	• Migration of data to new database underway by June 2014
Protect and manage information resources	• Maintain IT system up time of 97% or greater • No significant security incidents • Cyber intrusions defeated before damage occurs • Virus attacks defeated before damage occurs • Penetration testing of IT systems undertaken and sound report achieved
Implement IT, physical, personnel and governance security policies to align to the Protective Security Policy Framework	• Compliance with Protective Security Policy Framework • Data loss prevention strategy implemented and the APVMA's physical and information security environment hardened
Maintain and enhance efficient quality system	• No significant ISO audit findings • Procedure amendment requests resolved within six months • Quality management procedures revised to reflect changes arising from reforms • New document governance framework implemented by December 2013

STRATEGY SEVEN (CONTINUED)

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Comply with government reporting requirements, legislation and standards	• Audited financial statements cleared by due date • Input to Portfolio Budget Statement submitted by due date • Responses to government surveys, questions on notice, ministerial correspondence and related material delivered on time and to a high quality • No significant findings from internal and external audits
Enhance access to information	• Adhere to Information Publication Scheme requirements according to the APVMA agency plan • Comply with statutory timeframes for freedom of information requests
Launch a secure extranet for registrants to lodge their documentation online	• Secure extranet developed and lodgements available to registered users by June 2014
Ensure cost recovery arrangements reflect APVMA operating requirements	• Implement a new cost recovery impact statement • Support provided to the First-principles review of the APVMA's cost-recovery arrangements being conducted by DAFF

STRATEGY EIGHT

Enhance performance through our people

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Provide a safe, supportive and fair workplace	• Average reportable worker health and safety incidents at or below Australian Public Service (APS) average • Accurate and timely remuneration service (100%)
Align people policies with legislation and best practice	• All people policies and legislative requirements reviewed annually • Implement changes arising from 2013 amendments to the *Public Service Act 1999*.
Enhance the effectiveness and performance of our people	• 100% participation in performance management • 80% of recruitment processes completed within 45 days • A tailored executive leadership program implemented by December 2013 • Participate in relevant training offered by other regulatory agencies

Ensure our people have the skills they need to do their job	• A range of online training modules delivered, including:
	  • science risk
	  • accountable and ethical decision-making
	  • procurement
	  • security
	• New learning and development framework developed by September 2013

Foster values and behaviours that support a robust accountable Public Sector agency	• Absenteeism rate at or below APS average • Staff at or below 40 day annual leave cap by 31 December 2013 • Adherence to the Code of Conduct
Develop a new enterprise agreement	• New enterprise agreement developed consistent with the APS bargaining framework

GLOSSARY

Advisory agencies	Australian Government agencies, state and territory departments of agriculture and other specialist external organisations that provide advice to the APVMA in relation to the evaluation of product registration or provide specialised input to chemical reviews
Advisory Board	As a requirement of the *Agricultural and Veterinary Chemicals Administration Act 1992*, and appointed by the Minister for Agriculture, Fisheries and Forestry, the board provides advice and makes recommendations to the CEO in regards to APVMA business
Agvet Chemical Regulation Committee	A committee consisting of members from all states, territories and the Australian and New Zealand government, responsible for developing over-arching policy for the National Registration Scheme.
APS	Australian Public Service
Code of Conduct	Mandatory principles of professional conduct by which all Australian public servants must abide
Commencement of (amending) legislation	The date on which changes to the Agvet Code come into force
extranet	A secure computer network allowing access by registered external stakeholders for business interaction
GMP	Good Manufacturing Practice
Information Publishing Scheme (agency plan)	An outline of the practices and procedures that the APVMA has in place in order to facilitate, and to achieve, the publication and proactive disclosure of its information holdings in accordance with its obligations under section 8(1) of the *Freedom of Information Act 1982*
ISO	International Organization for Standardization
Joint Expert Committee on Food Additives	An international expert scientific committee administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO)
Manufacturers' Licensing Scheme	An APVMA quality assurance program whose primary objective is to assure, and give confidence in, the quality of veterinary medicines manufactured and supplied in Australia
minor use	A use of a registered chemical that would not produce sufficient economic return to an applicant to meet the cost of registering the product for that use

National Residue Survey	An industry-funded activity whose core work is to facilitate the testing of animal and plant products for pesticides and veterinary medicine residues and environmental contaminants. The NRS is administered by the Department of Agriculture, Fisheries and Forestry
Portfolio Budget Statement	Information provided to senators and members of parliament of the proposed allocation of resources to government outcomes by agencies within the portfolio
Protective Security Policy Framework	The Protective Security Policy Framework is an Australian Government framework to protect its people, information and assets, at home and overseas
PUBCRIS	Public Chemicals Registration Information System—the APVMA database of registered chemical products
Registration Liaison Committee	The main consultative forum between the APVMA, the states, territories and agencies relating to operational management of the National Registration Scheme
Regulators' Forum	A forum for the coordination and exchange of information, ideas and expertise between the Australian government agencies that regulate therapeutic goods, pesticides and veterinary medicines, food safety, biosecurity, gene technology, industrial chemicals and radiation protection
Regulatory Strategy Group	A high-level internal forum which considers and provides advice on the resolution of strategic regulatory issues. The RSG promotes cooperation, collaboration and communication between the different program areas within the APVMA
Regulatory Science Network	A network of Australian government agencies responsible for regulating chemicals (including radio-isotopes) and biological agents. Its aim is to forge closer linkages between these agencies on common science-related issues
Risk Compendium	A collection of documents that will provide the APVMA, its regulatory partners and the agvet industry a common understanding of APVMA regulatory processes. The Risk Compendium will replace the current Manual of Requirements and Guidelines (MORAG)
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products—a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration
Web content management system	An application that can be readily used by multiple authors to create, maintain, manage and publish content on web pages

CONTACT US

More information about the APVMA and how it discharges its important national role can be found in the government's Portfolio Budget Statement, our annual report and corporate plan. The latter documents can be found on the APVMA website at www.apvma.gov.au and the portfolio budget statement on www.daff.gov.au.

Australian Pesticides and Veterinary Medicines Authority
18 Wormald St
Symonston ACT 2609

PO Box 6182
Kingston ACT 2604 Australia
www.apvma.gov.au

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