Australian Government

Australian Pesticides and Veterinary Medicines Authority

OPERATIONAL PLAN 2014–15

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2014–15

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‘Our focus this year will be on further reducing regulatory burden through a range of initiatives, including fundamental changes to our business processes.’

Kareena Arthy,
Chief Executive Officer

CEO'S INTRODUCTION

Last year we achieved so much, this year we go further.

The APVMA is already recognised globally for our work with agricultural and veterinary chemicals. This plan is another step on our path to being a more contemporary world-class regulator.

There is still much to be done.

We are committed to regulatory excellence while continuously improving our business outcomes for industry and government.

In 2014–15, as well as embedding changes in the legislation that take effect from 1 July 2014, we will embark on a major program to improve our decision making skills and enhance our scientific capability. We will also ensure our business processes and systems work better—for us and those that interact with us.

This year will see many new things—a case management system, better IT tools and a revamped web site. These innovations will make it easier for applicants to work with the APVMA.

We are also reinventing the way we handle risk. We're doing this by embarking on an exciting new project that will enable us to better match regulatory effort to regulatory risk. Over time, we expect to implement 'lighter touch' approaches to those applications assessed as being of lower regulatory risk. This work is ground-breaking and promises to reduce the regulatory burden on a significant section of the agricultural and veterinary chemical industry.

Last year we also began our new focus on staff training and systems development. This year we will build on this great work to better deliver more timely, consistent, transparent and predictable decisions for applicants.

All this effort is to further our mission: regulating agricultural and veterinary chemicals to protect the health and safety of people, animals, crops, the environment and trade, and to support Australian primary industries.

We take a lot of pride in what we do at the APVMA. The strategies outlined in this operational plan are a map to us becoming a more contemporary world class regulator delivering safe chemicals for use by Australian farmers and the broader community.

THIS PLAN IS ANOTHER STEP ON OUR PATH TO BEING A MORE CONTEMPORARY WORLD CLASS REGULATOR

ABOUT THIS PLAN

This operational plan has been developed by the APVMA and approved by the Minister for Agriculture 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 third and final year of operation. The key strategies outlined in the corporate plan are further developed in the eight strategy tables in this document.

The corporate plan will be reviewed and updated in 2014-15.

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 2014–15 budget statements for the agriculture portfolio (PBS).

The key performance indicators (KPIs) in the 2014–15 PBS relate to improvements to timeframe performance:

- 90% of product applications determined within the statutory timeframe for applications lodged on or before 30 June 2014
- 60% of active constituent applications determined within the statutory timeframe for applications lodged on or before 30 June 2014
- 85% of permits determined within the statutory timeframe for applications lodged on or before 30 June 2014
- 100% of product applications determined within the statutory timeframe for applications lodged on or after 1 July 2014
- 100% of active constituent applications determined within the statutory timeframe for applications lodged on or after 1 July 2014
- 100% of permits determined within the statutory timeframe for applications lodged on or after 1 July 2014.

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.

The KPIs will be reviewed in conjunction with the development of the new corporate plan.

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 funded by fees, charges and levies imposed on the regulated industry. 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 2014–15 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.

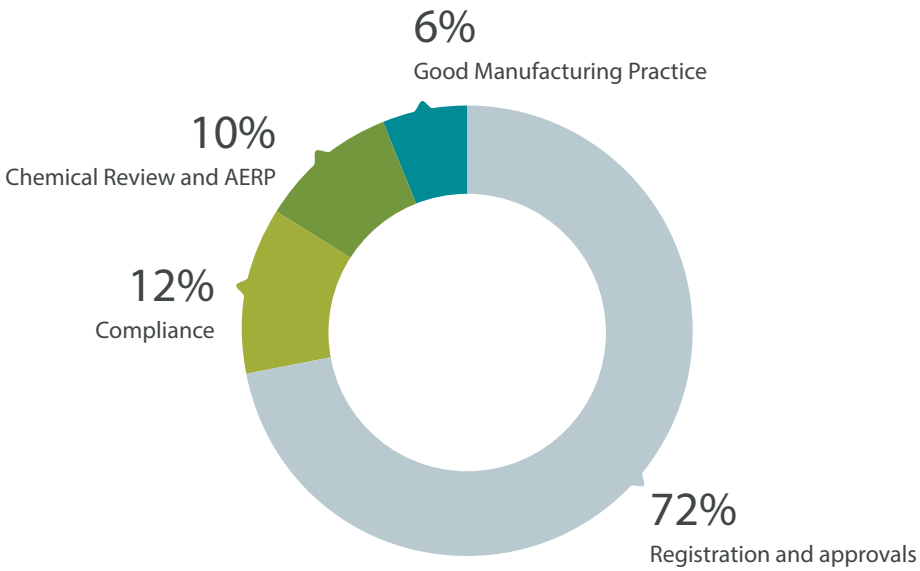
FOR CURRENT INFORMATION ABOUT THE APVMA, OUR ORGANISATION STRUCTURE AND OUR BUSINESS OPERATIONS, SEE WWW.APVMA.GOV.AU/ABOUT

APVMA FINANCIAL PROJECTIONS 2014–15

	2014–15 ($)	2015–16 ($)
Expenditure (ongoing)	30,155,000	30,617,000
Compliance and enforcement	814,000	840,000
Re-registration and re-approval scheme	1,213,000*	1,951,000*
TOTAL	32,182,000	33,408,000

*subject to the commencement of the scheme in FY 2014–15

ANTICIPATED EXPENDITURE ACROSS CORE ACTIVITIES

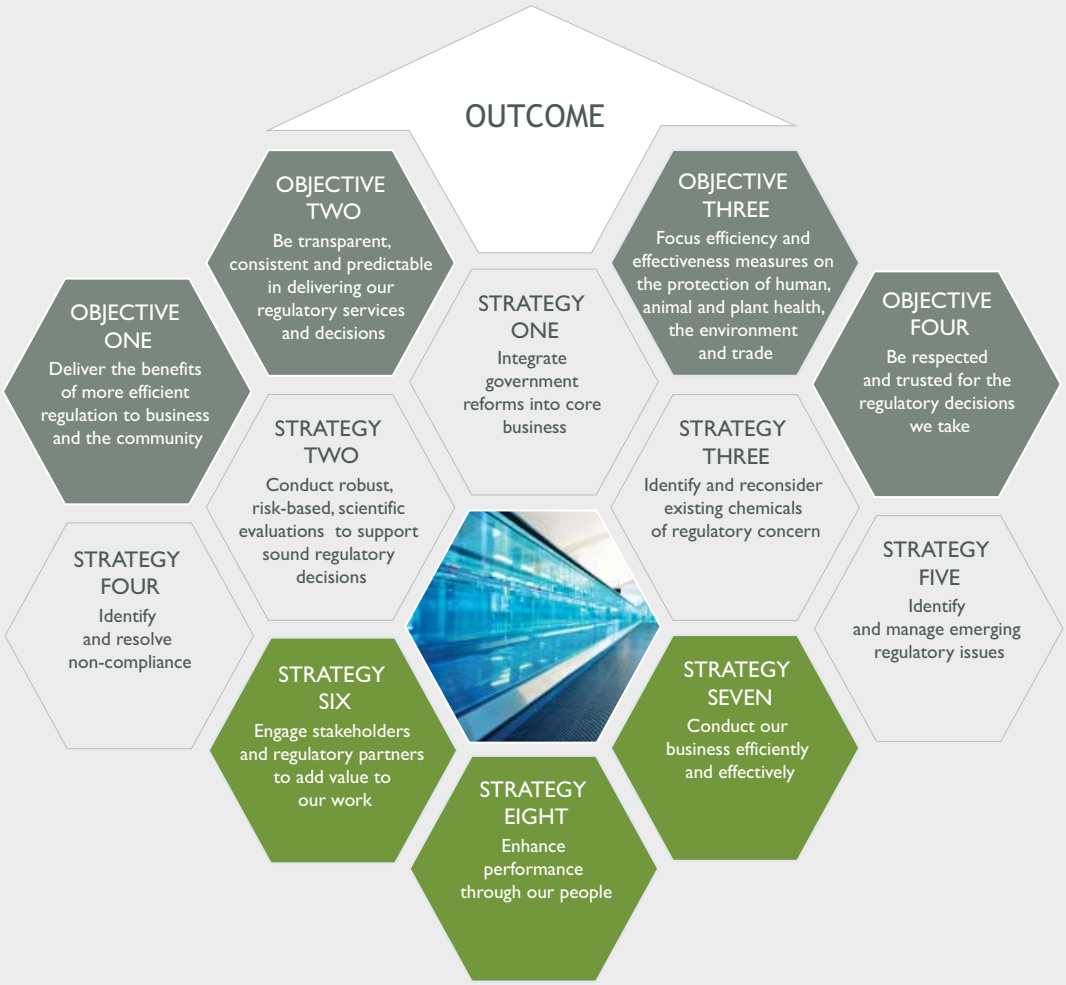


Note: all corporate activities have been allocated across the core business activities


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)

Reduce the administrative and regulatory burden on industry	• The APVMA will pursue a range of activities to reduce the administrative and regulatory burden on industry including:
	  • the development of a new Risk-based Assessment Framework that will allow the development of lighter touches on chemicals of lower regulatory concern
	  • streamlining registration processes
	  • the recognition of overseas data and studies and opportunities to participate in Global Joint Reviews (for both agricultural chemicals and veterinary medicines)
	  • an automated system for industry to report adverse experiences
	  • a range of new IT tools to make it easier to transact with the APVMA

Support the Commonwealth Government's minor use project to improve access to minor use permits by the agricultural industry	• Engage and participate in the planning, development and implementation of the initiative
Continue to enhance transparency of APVMA operational practices, policies and guidelines	• All relevant regulatory guidance and operational information published in user friendly formats and in a timely manner
Support industry readiness to comply with the new regulatory framework	• Implement case management system from 1 July 2014 • Refresher training conducted for industry on new requirements

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
	• Timeframe performance met for applications received after commencement of new legislation
	  • 100% product registrations
	  • 100% active approvals
	  • 100% permits
	• Further enhance Regulatory Guidelines including the provision of new technical manuals
	• Develop criteria to be used to determine if efficacy is a relevant consideration in assessing an application

Support provision of high quality applications	• New IT tools launched to allow online submission of applications and data • Two courses run for applicants and consultants on application preparation • Implement pre submission meetings from 1 July 2014
Enhance quality assurance	• Develop new internal quality assurance systems to provide confidence that individual decisions are sound and consistent with statutory obligations • Develop processes to give assurance of the quality of external advice provided as part of the registration process
Implement streamlined application assessment processes	• Design and implement a single, integrated end-to-end process for registration and compliance to ensure better alignment, visibility and coordination • Implement a case management system to manage the case load of applications through the registration process and provide proactive communication and defined points of contact for applicants/registrants

STRATEGY TWO (CONTINUED)

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Enhance the use of overseas data, assessment and decisions to reduce regulatory burden	• Design and implement a framework for increasing the use of data, assessments and decisions from comparable regulators and for when data generated overseas can be used to support an Australian application • Analysis of relevant international guidelines undertaken to determine suitability for adoption in Australia • Model developed to enable international expertise to be used to assist in the resolution of scientific issues • Harmonise data requirements with international regulatory partners for chemistry to reduce regulatory burden on applicants
Develop regulatory framework to support spray drift policy	• Public consultation commenced by 30 January 2015 • Public consultation and review of proposal completed by 30 June 2015
Enhance International Engagement	• Develop a new International Engagement Strategy that enables the APVMA to share information, identify emerging trends, and solve common regulatory issues with our international regulatory partners
Build and maintain a quality scientific assessment capability	• New MOU in place with advising agencies to provide expert advice to support APVMA decision making • Finalise a tender process for additional providers of external scientific assessment services
Implement outcomes from the Joint Expert Committee on Food Additives methodology for setting maximum residue levels for veterinary medicines	• Outcomes implemented by 1 January 2015

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)
Implement new chemical review work-plans and enhanced stakeholder engagement with review activities	• Work-plans in place by 30 June 2015 • Review the existing Priority List by December 2014 • Conduct a feasibility study into the development of a dynamic (near real time) online publication system for AERP reports • Implement improved web site for chemical reviews
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)
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 2015 • Update on suspension and reconsideration activities provided to the Agvet Chemical Regulation Committee twice a year • Implementation of review into State and Territory involvement in chemical reviews completed by January 2015
Inform and engage with stakeholders about regulatory activity on registered chemicals	• Participation in, or delivery of, review-related stakeholder forums

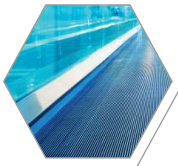
STRATEGY FOUR

Identify and resolve non-compliance

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Develop a 2015–17 Compliance and Enforcement Strategy	• Strategy developed by June 2015 • Communications strategy implemented to support the Compliance and Enforcement Strategy by 30 June 2015
Manage our systems, practices and procedures to support a proactive risk based, compliance and enforcement regime	• 90% of consents to import are processed within 14 days of receipt • Review of approved analysts and laboratories undertaken by December 2014 • Establish procurement processes for analytical testing services by 30 June 2015 • Review standard conditions of approval for all authorisations by 30 June 2015 • Undertake at least two 'intelligence led' operations
Undertake effective risk based enforcement	• 100% of allegations of non-compliance risk assessed and prioritised within 5 days • 100% of identified high priority allegations investigated in accordance with APVMA compliance and enforcement policy • Implementation of new enforcement powers flowing from reform legislation • 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	• GMP Audit program conducted to schedule • Trial in-house capacity to support domestic GMP audits • Implement more transparent risk-based audit schedule • Develop guidelines for the release of toll manufactured and imported products • Develop new IT systems to better support GMP work practices • Undertake necessary actions for the APVMA to be recognised by the European Union to audit export manufacturers • Review mutual recognition with national and international agencies to build confidence in collaborative arrangements

STRATEGY FOUR (CONTINUED)

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Enhance compliance and enforcement governance	• At least ten Enforcement Committee meetings held annually to integrate compliance and enforcement into APVMA business processes • Level of enforcement action considered appropriate following 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	• Participate in the Regulatory Science Network to promote consistent approaches to the management of emerging issues • Effective relationships with national and international regulatory counterparts and relevant agreements in place with national and international counterparts • Strategic issues are effectively managed and input to ministerials, briefs and other government processes are coordinated and represent a whole of APVMA position
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 Department of Agriculture initiatives on quality assurance of imported chemicals	• Stage 2 of the Agrochemical Intelligence Project completed by December 2014
Lead work on implications of nanotechnology on the regulation of agricultural and veterinary chemicals	• Inter-agency symposium held by December 2014 • Report on regulatory considerations for agvet nanotechnology by December 2014
Implement regulatory action that may be required to protect pollinator health from the use of agricultural chemicals	• Work with partner agencies to update technical assessment manuals • Additional label advice developed and applied as necessary

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)
Implement communications activities to support the strategic direction of the APVMA	• Publish Chief Regulatory Scientists 'Our Science' page on website • Develop regulatory science news items of public interest for website publication • Development and implement a refreshed visible identity • Undertake a review of APVMA channels to ensure consistency in external facing products such as letters, notices, information, web content, and align with the service charter
Develop a new client service charter	• Develop a new service charter that provides guidance to staff and stakeholders on the experience to be expected from engagement with the APVMA by December 2014
Redevelop APVMA website	• New website launched on 1 July 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 2015
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
Work effectively with the Department of Agriculture on agvet chemical issues of mutual interest	• Satisfaction with level and quality of engagement
Enhance staff capability in science communication	• Staff trained in communication skills for scientists

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	• Implement 'iPos' electronic procurement system • PUBCRIS search interface redesigned to improve useability and launched by 30 August 2014 • Implement automated workflow that is integrated with the electronic records management system for all critical business processes • Extend Agency e-Portal to include existing work tracking systems • Implement new IT systems to support the Manufacturing Licencing Scheme by October 2014 • Implement AERP Phase 2 (near real time online reporting and improved internal systems) by 30 June 2015 • Replace the import consents access system with a portal interface by June 2015 • Implement a new Business Intelligence system • Develop and implement a system to collect data on antibiotic sales
Develop a new Corporate Plan with new key performance measures	• Develop a new Corporate Plan for 2015–18 to support the APVMA in its goal of being a contemporary world class regulator • Develop new key performance measures to provide an accurate reflection of overall performance
Enhance the APVMA's mobile device capability to improve access to APVMA systems for mobile users	• Implement a secure, platform independent system to facilitate BYOD for mobile devices by December 2014
Complete redevelopment of the APVMA's core agvet chemical database	• Migration of data to new database completed by 30 June 2015

STRATEGY SEVEN (CONTINUED)

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
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 • Migrate from hard-copy to digital data for application data by July 2014 • Transition from hard-copy to digital library by 30 June 2015 • Implement a real time corporate data backup solution by February 2015 • Develop IT risk management plans for all critical business systems by June 2015
Implement IT, physical, personnel and governance security policies to align to the Protective Security Policy Framework	• Continued compliance with Protective Security Policy Framework • Review the APVMA's physical and information security environment • Implement online IT security training module
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
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 • Complete transition from FMA Act to PGPA Act

STRATEGY SEVEN (CONTINUED)

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
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
Implement new accountability framework for business processes	• Specific accountability for business processes is built into the organisational structure to ensure decision making is supported by efficient and effective business systems
Ensure cost recovery arrangements reflect APVMA operating requirements	• Support provided to the First-principles review of the APVMA's cost-recovery arrangements being conducted by the Department of Agriculture • Facilitate partner agency input into cost recovery arrangements

STRATEGY EIGHT

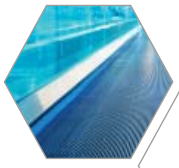
Enhance performance through our people

HOW WE WILL ACHIEVE THIS (INITIATIVES/ACTIVITIES)	HOW WE WILL MEASURE OUR SUCCESS (PERFORMANCE MEASURES)
Provide a safe, supportive and fair workplace	• Review Work Health and Safety Management Arrangements to ensure compliance with relevant Codes of Practice and best practice incident reporting procedures • No preventable health and safety incidents requiring notification to the regulator, Comcare • 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 the finalised enterprise agreement
Enhance the effectiveness and performance of our people	• Implement a foundation leadership skills program to develop emerging leaders for APS level staff • Continue implementation of a leadership program for executive level staff • 100% participation in performance management • 80% of recruitment processes completed within 45 days • Implement new online recruitment portal
Ensure our people have the skills they need to do their job	• Undertake a capability review to identify current and future staff capability requirements by June 2015 • Continue implementation of Learning and Development Strategy
Foster values and behaviours that support a robust accountable Public Sector agency	• Absenteeism rate at or below APS average • 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
BYOD	Bring Your Own (mobile) Device
Code of Conduct	Mandatory principles of professional conduct by which all Australian public servants must abide
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*
iPos	iPos is a role based, end-to-end, browser procure-to-pay solution that integrates with the Sun Systems financial management system that the APVMA utilises
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

PBS	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
PSPF	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
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 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
Regulatory Guidelines	A collection of documents that will provide the APVMA, its regulatory partners and the agvet industry with a common understanding of APVMA regulatory processes. The Regulatory Guidelines replace the Manual of Requirements and Guidelines (MORAG)



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.

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