Australian Government

Australian Pesticides and Veterinary Medicines Authority

OPERATIONAL PLAN 2015–16

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ABOUT THIS PLAN

An annual operational plan is a requirement under Section 55 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

The operational plan outlines:

- activities to be undertaken by the APVMA to deliver the objectives of the corporate plan
- performance indicators to monitor progress.

This is the first operational plan for the new APVMA Corporate Plan 2015–19.

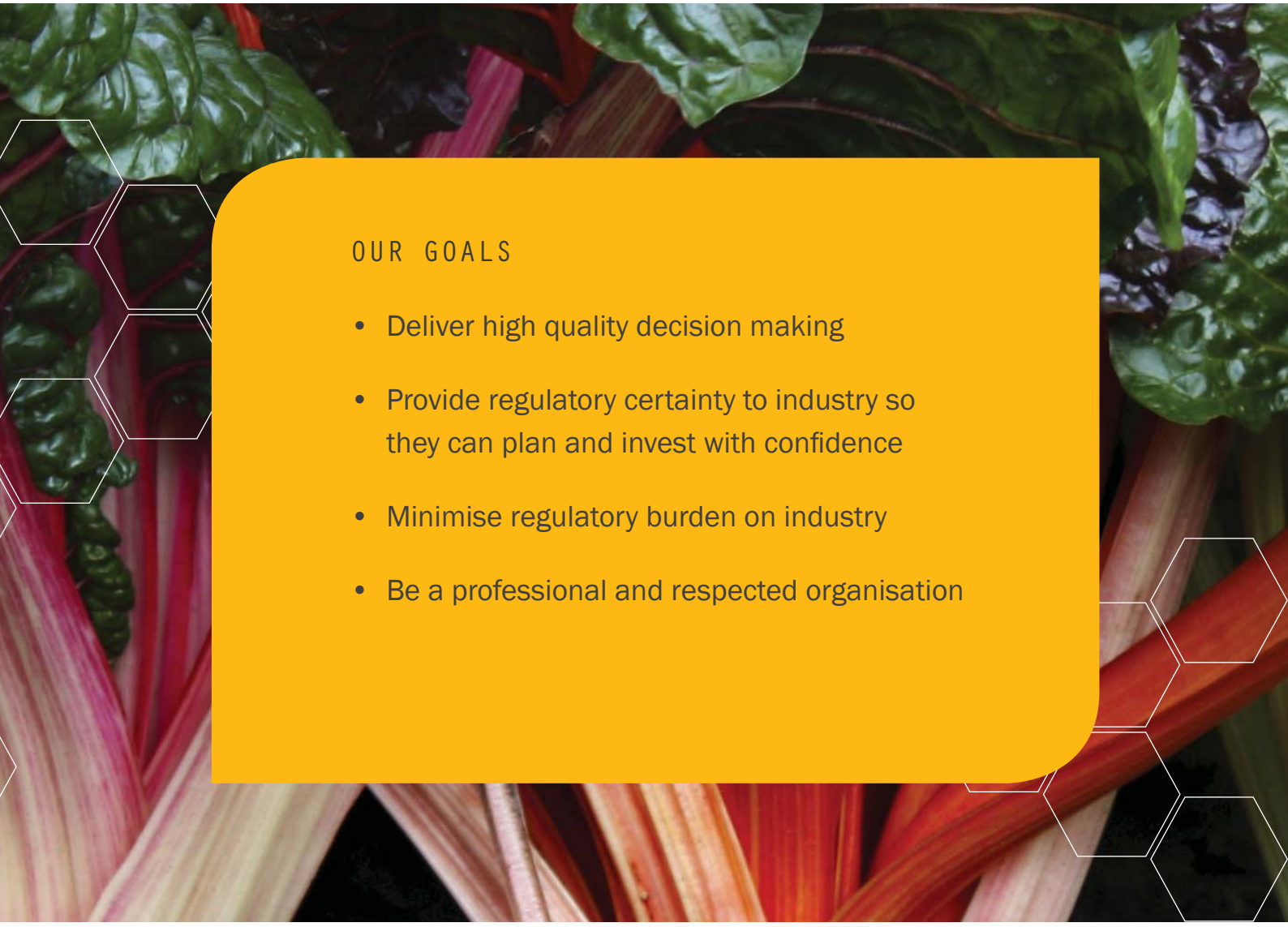
Progress and outcomes will be provided in the annual report.

OUR VISION

Australians have confidence that agricultural and veterinary chemicals are safe to use.

OUR MISSION

To protect the health and safety of Australia—its people, animals and environment—and support Australian agriculture by taking a science- and risk-based approach to regulating agricultural and veterinary chemicals.



OUR GOALS

- Deliver high quality decision making
- Provide regulatory certainty to industry so they can plan and invest with confidence
- Minimise regulatory burden on industry
- Be a professional and respected organisation

STRATEGIC FRAMEWORK

STRATEGY 1

Deliver regulatory decisions that are timely, science-based and proportionate to the risks being managed.

STRATEGY 2

Reduce the burden on industry in complying with regulatory requirements.

STRATEGY 3

Build a client focussed approach to service delivery, committed to continuous improvement.

STRATEGY 4

Operate as a contemporary, high performing and efficient organisation.

STRATEGY 1

DELIVER REGULATORY DECISIONS THAT ARE TIMELY, SCIENCE-BASED AND PROPORTIONATE TO THE RISKS BEING MANAGED

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
Regulatory decisions are completed within statutory timeframes	• Percentage of applications completed within timeframes • Percentage of compliance and enforcement activities completed within timeframes	1. Timeframe performance met for applications • 100% product registrations • 100% active approvals • 100% permits. 2. 90% of consents to import are processed within 14 days. 3. 100% of internal review requests addressed within the 90 day timeframe. 4. 100% of pre-application assistance timeframes are met. 5. Timeframes for chemical reviews are met. 6. GMP audit program implemented as per APVMA approved schedule. 7. 100% of statutory notices issued by compliance are gazetted in accordance with legislative requirements.	1. Assess applications for pre-application assistance, registration of products and permits and approval of active ingredients. 2. Implement new legislative requirements for chemical review.
Actions undertaken are proportionate to the regulatory risk being managed	Risk management frameworks and policies are in place and regularly reassessed	1. Documented compliance and enforcement strategy, including options for graduated compliance. 2. Risk framework reviewed every three years.	1. New Risk Assessment Framework finalised by June 2016. 2. Compliance and Enforcement Strategy finalised by December 2015 and implemented from January 2016. 3. Framework for regulating spray drift finalised by December 2015. 4. Framework in place to provide assurance about the quality of APVMA decision making.

STRATEGY 1 (CONTINUED)

DELIVER REGULATORY DECISIONS THAT ARE TIMELY, SCIENCE-BASED AND PROPORTIONATE TO THE RISKS BEING MANAGED

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
	Lower regulatory effort is applied to activities of lower regulatory risk	1. 100% of applications assessed as low regulatory risk processed according to risk assessment framework tools and mechanisms (n/a for 2015–16). 2. Documented approaches in place to review level of regulatory effort applied to agvet chemical registration and approval. 3. Risk framework applied to registration decision making accessible to regulated entities.	1. Design and implement a contestable efficacy pilot. 2. Streamline approach to veterinary residues by publishing and implementing the JECFA review findings by February 2016. 3. Revise criteria for when efficacy is a relevant consideration in assessing an application for implementation from 1 July 2016. 4. Complete a review of the approach to licensing and auditing of veterinary manufacturers by December 2015, with implementation from 1 July 2016 (if applicable). 5. Complete project to group like crop types for minor use consideration. 6. Review all permits to identify candidates that can be moved to registered product labels.
	Compliance and enforcement regulatory activities and responses to non-compliance are proportionate to risk	1. Compliance and enforcement strategy accessible to regulated entities. 2. 100% of compliance allegations are risk assessed prior to enquiries commencing. 3. Documented policy for determining GMP audit schedules accessible by regulated entities in place.	1. Publish 2015–17 Compliance and Enforcement Strategy by 31 December 2015. 2. Review GMP Audit Schedule and implement from 1 January 2016. 3. Refined compliance and enforcement risk model is applied to new allegations received from 1 July 2015. Responses employ graduated tools and responses are proportionate to risk.

STRATEGY 1 (CONTINUED)

DELIVER REGULATORY DECISIONS THAT ARE TIMELY, SCIENCE-BASED AND PROPORTIONATE TO THE RISKS BEING MANAGED.

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
Regulatory science underpins quality regulatory decision making	Improvements in regulatory science capability are consistent with agreed priorities and strategies.	1. Documented science strategy. 2. Regulatory science activities are aligned with relevant activities of similar regulators. 3. Regulatory science communication to external stakeholders improved by provision of targeted web-based information. 4. Three staff seminars completed on regulatory science issues, including risk assessment methodologies and new technologies. 5. Regulatory science projects undertaken according to agreed timeframes.	1. Develop APVMA regulatory science strategy. 2. Identify opportunities for aligning APVMA's regulatory practices for veterinary medicines with those of overseas authorities by June 2016. 3. Expand the content of the 'Our Science' webpage. 4. Develop staff capability by providing training in regulatory science and new chemical and biological technologies. 5. Progress projects on: • Pharmaceutical equivalence • Develop and test a model framework for the regulation of products of emerging technologies • Risk profiling of imported live microorganisms for use in veterinary vaccines • Suitability of new US and EU worker exposure methods for adoption in Australia • Tier–3 aquatic exposure modelling—dryland cropping component • Develop regulatory framework to support spray drift policy • Scoping the development of a fumigant risk assessment framework. 6. Develop and implement a framework for obtaining external expert scientific advice.

STRATEGY 2

REDUCE THE BURDEN ON INDUSTRY IN COMPLYING WITH REGULATORY REQUIREMENTS

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
Unnecessary impediments to the efficient operation of regulated entities are removed	Demonstrated understanding of the operating environment for the regulated entities	1. Four stakeholder forums held each year to discuss issues affecting regulated entities. 2. Three industry information and training seminars delivered each year. 3. Four industry awareness workshops conducted for APVMA staff each year. 4. Environmental scan published annually.	1. Hold two CEO-only forums with key industry stakeholder groups to discuss APVMA performance and key issues. 2. Conduct series of industry information sessions. 3. Hold quarterly briefings for APVMA staff about industry specific issues/trends/practices. 4. Undertake an environmental scan with stakeholders each year for publishing in the following year's operational plan.

(CONTINUED)

STRATEGY 2 (CONTINUED)

REDUCE THE BURDEN ON INDUSTRY IN COMPLYING WITH REGULATORY REQUIREMENTS

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
	International data guidelines, standards, assessments adopted to reduce effort to register agvet chemicals	1. Demonstrated application of the policy for use of international standards, guidelines, assessments and decisions. 2. Participation in Global Joint Reviews. 3. 100% of relevant international standards are accepted for new chemical products and chemical review decisions. 4. Documented justification for when international standards and guidelines are not adopted.	1. Develop and implement a plan for review and adoption of international guidelines and standards, including a web site to communicate decisions to stakeholders. 2. Identify opportunities to improve data sharing and access to assessment with international regulators. 3. Develop and implement an International Engagement Strategy. 4. Partner in at least three Global Joint Reviews (GJR). 5. As part of the OECD network and with GJR partners participate in a review of the conduct of GJRs to streamline processes and ensure it meets the needs of industry and regulators. 6. Participate in relevant OECD and VICH activities designed at harmonising assessment, data requirements and/or registration systems across international regulators.

STRATEGY 2 (CONTINUED)

REDUCE THE BURDEN ON INDUSTRY IN COMPLYING WITH REGULATORY REQUIREMENTS

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
	Efficient and effective APVMA business processes	1. Satisfaction with APVMA on-line systems for submitting and managing applications. 2. Regulatory decisions are completed in timeframes. 3. Average decision time for applications by item.	1. Complete a useability review of the external portal and implement enhancements. 2. Enhance on-line automatic validation of applications to facilitate complete applications. 3. Streamline application process through end to end project management (by end 2015). 4. Continuously improve access to external scientific reviewers. 5. Identify opportunities for the further expansion of Objective Workflow. 6. Collect annual returns on actives information for DoA. 7. Review GMP business processes and implement administrative enhancements.
Compliance and monitoring approaches are streamlined and coordinated	Monitoring and enforcement strategies allow for a range of regulatory responses	1. 100% of allegations of non-compliance are risk-assessed and prioritised within five working days. 2. Usage of compliance tools.	1. System developed to capture and report on data on assessment of non-compliance allegations and how compliance tools are used. 2. Undertake compliance assessments and relevant compliance activities.

STRATEGY 2 (CONTINUED)

REDUCE THE BURDEN ON INDUSTRY IN COMPLYING WITH REGULATORY REQUIREMENTS

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
	Compliance activities are responsive to business needs of regulated entities, where relevant	1. 100% of audit and inspection schedules designed to minimise overlap with audits from other government regulators. 2. Evidence of compliance activities conducted jointly with other regulators.	1. Review existing MOU with TGA and identify opportunities to minimise duplication of audits for manufacturers of mutual interest. 2. Progress EC recognition of APVMA GMP audits to facilitate export to the EC. 3. Explore options for conducting additional joint audits.
	Information requested from regulated entities is necessary and acted upon	1. Average number of formal requests for information (including notices) provided for each registration application. 2. Evidence demonstrates consideration of alternate means of information gathering before coercive information gathering powers are exercised during investigations into compliance of regulated entities.	1. Develop MOUs with partner regulators for exchange of compliance and enforcement information. 2. Conduct an audit of refusals and s159 notices to demonstrate 100% are within policy parameters. 3. Develop system to capture and report average number of requests for information. 4. Identify options to improve AER through process automation and integration of AER intelligence.

STRATEGY 3

BUILD A CLIENT FOCUSSED APPROACH TO SERVICE DELIVERY, COMMITTED TO CONTINUOUS IMPROVEMENT

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
The APVMA is open and transparent in its dealings with regulated entities	Performance information is published	1. Timeframe performance statistics published quarterly. 2. Performance against customer service standards published quarterly. 3. Performance against regulator performance framework published annually. 4. 100% of decisions to approve or register published within 14 days of decision. 5. 100% of enforceable undertakings accepted by the APVMA are published within 30 days.	1. Design and implement a system to publish performance information and decisions. 2. Implement a survey to benchmark and track client experience across a range of criteria for APVMA service delivery. 3. Communication of compliance and enforcement outcomes is consistent with the compliance and enforcement strategy 4. Publish new chemical review work plans.
	Feedback mechanisms are in place and used to improve service to regulated entities	1. Demonstrated processes to collect stakeholder feedback. 2. 100% of feedback received through the on-line feedback system is assessed within five working days.	1. Review existing online feedback system to inform the design and implementation of service delivery.

STRATEGY 3 (CONTINUED)

BUILD A CLIENT FOCUSSED APPROACH TO SERVICE DELIVERY COMMITTED TO CONTINUOUS IMPROVEMENT

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
Communication with regulated entities is clear, targeted and effective	Level of satisfaction with the quality and timeliness of advice on decisions	1. Feedback about the quality of pre-application assistance. 2. Customer service standards are met. 3. 100% of correspondence provided to applicants and registrants assessed as comprehensive and easily understood.	1. Design and implement a new model for pre-application assistance. 2. Design and implement a system to capture and report data relevant to customer service standards. 3. Implement a stakeholder perceptions survey to establish baseline metrics on satisfaction.
	Level of satisfaction with information and guidance materials	1. Feedback from stakeholders about the quality of guidance material. 2. 100% of website content is reviewed by the nominated review date. 3. Use of the APVMA website. 4. Number of subscribers to the APVMA Regulatory Update. 5. Website meets relevant Government online and accessibility standards.	1. Refresh the design of the APVMA's Regulatory Updates and seek quarterly user feedback on content relevance. 2. Design and implement a system to regularly check stakeholder views and experiences with the APVMA website. 3. Develop and implement a program of content review for guidance material on the website. 4. Develop and implement a communication strategy aimed at farmers. 5. Develop and implement a program for technical guidance material.

STRATEGY 3 (CONTINUED)

BUILD A CLIENT FOCUSSED APPROACH TO SERVICE DELIVERY COMMITTED TO CONTINUOUS IMPROVEMENT

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
	Extent and satisfaction with APVMA consultative processes	1. 100% of new or major changes to operational policies or guidelines provided to relevant stakeholders for consultation prior to finalisation. 2. Feedback from key industry stakeholders about the quality of APMVA consultation.	1. Develop and implement system to capture and report stakeholder satisfaction with APVMA consultation processes.
The APVMA actively contributes to the continuous improvement of regulatory frameworks	Level of stakeholder engagement in implementing regulatory frameworks	1. Documented stakeholder consultation procedures in place. 2. 100% of significant changes to APVMA regulatory frameworks involve stakeholder consultation.	1. Design and implement new stakeholder consultation framework.
	Feedback is provided to inform the development or amendment of regulatory frameworks	1. Documented procedures in place to facilitate engagement with the Department of Agriculture and relevant states and territories.	1. Engage with states and territories on initiatives as required. 2. Offer hosting of twice yearly forums for states and territories. 3. Hold monthly meetings with Department of Agriculture about legislative frameworks and implementation. 4. Provide input as requested to government documents, including ministerials, policy documents and legislative proposals.

STRATEGY 4

OPERATE AS A CONTEMPORARY, HIGH PERFORMING AND EFFICIENT ORGANISATION.

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
Organisational health and financial viability	Efficient and effective business processes and financial management systems	1. No significant findings from internal and external audits. 2. Audited financial statements cleared by due date. 3. Sound budget management. 4. No preventable health and safety incidents requiring notification to the regulator, Comcare. 5. Equity reserve targets managed. 6. Comply with government reporting requirements, legislation and standards.	1. Implement a new quality system by 30 June 2016 including the development of a business model and definition of key APVMA business processes. 2. Complete a new Cost Recovery Impact Statement based on current fee structure for implementation from 1 July 2016. 3. Ensure governance arrangements underpin quality decision making and efficient business process.
	Protect and manage information and enhance information technology to improve service delivery and staff capability	1. Maintain IT system up time of 97% or greater. 2. No significant security incidents. 3. Cyber intrusions defeated before damage occurs. 4. Virus attacks defeated before damage occurs.	1. Complete a refresh of desktop PCs by December 2015. 2. Conduct a pilot of secure cloud infrastructure for public facing IT systems. 3 Comply with the PSPF and review APVMA compliance against ASD Top 35 Mitigation Strategies for cyber security. 4. Undertake a project to cleanse the agvet database. 5. Improvements to APVMA's external and internal applications completed to agreed timeframes.

STRATEGY 4 (CONTINUED)

OPERATE AS A CONTEMPORARY, HIGH PERFORMING AND EFFICIENT ORGANISATION.

KEY RESULT AREA	PERFORMANCE MEASURES	PERFORMANCE TARGETS	2015–16 INITIATIVES
	Motivated and trained workforce	1. Absenteeism rate at or below APS average. 2. Adherence to the Code of Conduct. 3. Number of corporate training days per full time equivalent. 4. 80% of recruitment processes completed within 45 days. 5. Ensure our people have the skills to do their job.	1. Develop and implement a new Enterprise Agreement. 2. Develop and implement a learning and development strategy flowing from the identified needs in the Capability Review by 30 June 2016. 3. Implement a learning network to better tailor and target learning requirements. 4. Implement a corporate training calendar focussed on personal efficiency and management by 30 June 2016.

SPECIAL PROJECTS

PROJECT	2015–16 INITIATIVES
APVMA relocation	1. Advise government on matters relating to a potential relocation of APVMA. 2. Implement measures to support staff.

GLOSSARY

AER	Adverse experience report
agvet	Agricultural and veterinary (chemicals)
APS	Australian Public Service
ASD	Australian Signals Directorate
Code of Conduct	Mandatory principles of professional conduct by which all Australian public servants must abide
C&E	Compliance and enforcement
DoA	Department of Agriculture
EC	European Community
GJR	Global Joint Review
GMP	Good Manufacturing Practice
JECFA	Joint FAO/WHO Expert Committee on Food Additives (FAO: Food and Agriculture Organzation of the United Nations, WHO: World Health Organization)
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
MOU	Memorandum of understanding
OECD	Organisation for Economic Co-operation and Development
PC	Personal computer
PSPF	Protective Security Policy Framework
Risk Assessment Framework	A framework for determining the appropriate regulatory effort to be used in assessing applications for product registration or active approval
s159 notices	In the context of applications under the *Agricultural and Veterinary Chemicals Code Act 1994*
TGA	Therapeutic Goods Administration
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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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