Australian Government

Australian Pesticides and Veterinary Medicines Authority

APVMA Regulator Performance Framework 2018–19

Self-assessment

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CONTENTS

LIST OF TABLES

1 INTRODUCTION

1.1 About the APVMA

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority responsible for the assessment and registration of agricultural chemicals and veterinary medicines (agvet chemicals) and for their regulation up to, and including, the point of retail sale. The APVMA evaluates the safety and performance of agvet chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected and that Australia's international trade is not jeopardised through the use of agvet chemicals.

The APVMA is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992.*

1.2 The Australian Government Regulator Performance Framework

The Australian Government Regulator Performance Framework (RPF) was developed to 'encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives and to effect positive ongoing and lasting cultural change within regulators'[1].

The RPF contains six indicators against which regulators are to measure their performance:

1. regulators do not unnecessarily impede the efficient operation of regulated entities
2. communication with regulated entities is clear, targeted and effective
3. actions undertaken by regulators are proportionate to the regulatory risk being managed
4. compliance and monitoring approaches are streamlined and coordinated
5. regulators are open and transparent in dealing with regulated entities
6. regulators actively contribute to the continuous improvement of regulatory frameworks.

1.3 The APVMA Regulator Performance Framework

The APVMA Regulator Performance Framework (APVMA RPF) sets out how the APVMA intends to measure and report its performance against the RPF. It contains performance measures against each key indicator as well as the evidence that will be collected to demonstrate performance.

1.4 Self-assessment method

Assessment of, and reporting against, the APVMA RPF performance measures and indicators was undertaken by relevant business areas in preparation of the self-assessment and the Annual Performance Statement.

[1] Australian Government Regulator Performance Framework (2014), p4

Achievement against each performance measure was monitored by APVMA management, with oversight through the Executive Leadership Team.

In preparing the self-assessment the APVMA:

- drew from internal processes, procedures and systems
- considered results of independent audits and reviews
- sourced key material from the *Australian Pesticides and Veterinary Medicines Annual Report 2018–19*.

The information supporting each RPF measure was analysed and allocated an appropriate rating using a three point scale to indicate the level of regulatory performance achieved. The report is considered by the APVMA Chief Executive Officer and made available for comment with clients and stakeholders through public consultation.

Table 1: Rating scale

Rating key	Performance explanation
Needs improvement	Performance and progress criteria are partially met with some deficiencies evident
Satisfactory	Most performance and progress criteria are met and any deficiencies are of minor concern
Achieving	Performance and process criteria are met

1.5 Stakeholder consultation

Stakeholder consultation will occur during the period 4 November to 2 December 2019. The draft RPF Self-assessment will be made available on the Public Consultations page of the APVMA website, with a survey made available through Survey Monkey for respondents to provide feedback. Following the conclusion of the consultation period, responses will be compiled, analysed, and feedback incorporated into the final RPF Self-assessment where appropriate.

2 SELF-ASSESSMENT SUMMARY

Table 2: APVMA self-assessment against the Regulator Performance Framework

Performance indicator	Self-assessment rating
Regulators do not unnecessarily impede the efficient operation of regulated entities	Satisfactory
Communication with regulated entities is clear, targeted and effective	Satisfactory
Actions undertaken by regulators are proportionate to the regulatory risk being managed	Achieving
Compliance and monitoring approaches are streamlined and coordinated	Achieving
Regulators are open and transparent in dealing with regulated entities	Achieving
Regulators actively contribute to the continuous improvement of regulatory frameworks	Achieving
Overall	Achieving

In 2018–19, the APVMA completed our relocation activities to Armidale, delivering on our commitment to implement the Government Policy Order issued in November 2016. We did this while continuing to focus on improving registration processes and procedures, and improving the overall experience of applicants in interacting and transacting with us.

Improvements in our registration processes and procedures have continued to deliver strong improvements in our regulatory timeframe performance, resulting in the finalisation of 2992 applications. On-time assessment of agvet products, permit and active applications increased from 73 per cent in 2017–18 to 85 per cent in 2018–19.

We released Risk Assessment Manuals for Chemistry and Manufacture, Residues and Trade, Health, and Environment, providing applicants with greater visibility of our assessment standards and approach. We continued to encourage applicants to submit assessment data from comparable international regulators as part of their application, reducing the assessment timeframes for many that did so. In 2018–19, 17 per cent of the applications finalised had received formal requests for additional information under section 159 of the *Agricultural and Veterinary Chemicals Code Act 1994*. This is up from 13 per cent in 2016–17.

We continued to apply and strengthen our strategic risk-based approach to compliance and good manufacturing practice, and every allegation of non-compliance was risk-assessed before any action was taken. 100 per cent of non-compliance allegations were investigated on time. Most allegations (80 per cent) were assessed as low risk and were resolved through education and negotiated compliance.

Our commitment to scientific excellence, combined with our ongoing drive for business and process improvement, will continue to support our long-term goals of being a world leader in agvet chemical regulation that uses the best science and attracts strong investment to register safe products that advance Australia's agricultural productivity and animal health.

3 RESULTS

3.1 Performance indicator 1—Unnecessary impediments to the efficient operation of regulated entities are removed

Table 3: PM 1.1—Demonstrated understanding of the operating environment for the regulated entities

Ref	Evidence	Results
1.1.A	4 stakeholder forums held each year to discuss issues affecting regulated entities	The APVMA held 4 meetings of the APVMA Relocation Advisory Committee through 2018–19, which had representation from major industry bodies.
1.1.B	3 industry information and training seminars delivered each year	The annual industry information sessions did not proceed in 2018 because the APVMA was revising its approach to engagement and exploring new ways of engaging clients and stakeholders, however 11 industry engagement sessions were conducted in 2018–19.
1.1.C	4 industry awareness workshops conducted by APVMA staff each year	The APVMA has conducted and participated in 10 industry awareness activities throughout 2018–19.
1.1.D	Environmental scan published annually	The environmental scan was published as part of the APVMA Corporate Plan 2018–19.

Table 4: PM 1.2—International data guidelines, standards and assessments adopted to reduce effort to register agvet chemicals

Ref	Evidence	Results
1.2.A	Demonstrated application of the policy for use of international standards, guidelines, assessments and decisions	During 2018–19: • international assessments contributed to the assessment of 16 products, and supported the residues assessment on a further 24 applications for minor use or emergency permit • the APVMA has adopted and published 12 international guidelines for use by stakeholders. These are available at 'Adopted international technical guidance material—agricultural' and 'Adopted international technical guidance—veterinary'. Additionally, the APVMA has provided guidance on the use of international assessments for applications.
1.2.B	Participation in Global Joint Reviews (GJRs)	The APVMA attended and participated in meetings with other regulators and industry for the conduct of Global Joint Reviews.

Ref	Evidence	Results
1.2.C	100% of relevant international standards adopted for new chemical products and chemical review decisions	The APVMA applies international standards in risk assessments undertaken for product applications and chemical reviews as appropriate for the Australian product and use pattern as standard procedure.
1.2.D	Documented justification for when international standards and guidelines are not adopted	The APVMA continues to harmonise its guidance materials with international guidance and apply them as appropriate for products and uses as proposed for Australia. There were no instances of non-adoption of international guidance documents in 2018–19.

Table 5: PM 1.3—Efficient and effective APVMA business procedures

Ref	Evidence	Results
1.3.A	Satisfaction with APVMA online systems for submitting and managing applications	The APVMA provides a feedback form for applicants as part of our online services portal. In 2018–19, 4%of responses received were positive, 42% were negative, and 54% were neutral.

1.3.B	Regulatory decisions are completed within timeframes (all targets are 100%, except import consents which are a 90% target)	The APVMA publishes quarterly performance statistics on regulatory decisions on its website. See 'Performance statistics'.
		
		The APVMA did not achieve 100% on-time assessment. However, performance process criteria was achieved.
		
		In 2018–19, the APVMA:
		• finalised 2 992 applications.
		• achieved overall performance rates of 85 per cent within timeframe, including
		  • 83% for product registration
		  • 92% for active approvals
		  • 84% for permits
		  • 99% for preliminary assessments
		  • 76% of import consents.

1.3.C	Average decision time for applications by item	In the last two years (2017–19), the APVMA has reduced the average time taken to process an application to 5.7 months; a reduction of approximately 2 months compared with assessments completed in 2016–17. Further detail on application type by item is on the APVMA website at 'Performance statistics'.

3.2 Performance indicator 2—Communication with regulated entities is clear, targeted and effective

Table 6: PM 2.1—Level of satisfaction with information and guidance materials

Ref	Evidence	Results
2.1.A	Feedback from stakeholders about the quality of guidance material	The APVMA provides an online feedback system on each page of the website. Across all published webpages in 2018–19, we received and addressed where the feedback was required. Overall feedback was: • 277 (59%) positive • 189 (40%) negative • 5 (1%) neutral ratings.
2.1.B	100% of website content is reviewed by the nominated review date	We have reviewed the APVMA website content however 100% was not updated by the nominated date. Content review systems were maintained and feedback from the website was monitored and acted on to improve online information.
2.1.C	Usage of the APVMA website	There were 1 006 906 unique visits to pages on the APVMA website in 2018–19, an increase of 73 084 from the previous year.
2.1.D	Number of subscribers to the APVMA Regulatory Update	At 30 June 2019 the APVMA had 3 174 subscriptions to the APVMA Regulatory Update and 2 661 subscriptions to the APVMA Gazette.
2.1.E	Website meets relevant government online and accessibility standards	Content published to the APVMA website was continuously quality checked to ensure compliance with the Australian Digital Service Standard.

Table 7: PM 2.2—Level of satisfaction with the quality and timeliness of advice on decisions

Ref	Evidence	Results
2.2.A	Feedback about the quality of Pre-Application Assistance (PAA)	The APVMA conducted 135 pre-application assistance requests, over 50 of which included face-to-face meetings in 2018–19. Feedback provided by applicants was largely positive.

Ref	Evidence	Results
2.2.B	Customer service standards met	The APVMA Case Management and Administration Unit received over 5 600 phone calls and 8 100 emails in 2018–19. Phone messages and emails were checked daily and replies made within the 1-day standard for phone calls and 5-day standard for written enquiries. The APVMA received 23 Freedom of Information requests in 2018–19. 100% of requests received in 2018–19 were completed within legislative timeframes.
2.2.C	100% of correspondence provided to applicants and registrants assessed as comprehensive and easily understood	The APVMA continued to implement the knowledge management framework to support better quality correspondence to applicants and registrants.

Table 8: PM 2.3—Extent and satisfaction with APVMA consultative processes

Ref	Evidence	Results
2.3.A	100% of new or major changes to operational policies or guidelines provided to relevant stakeholders for consultation prior to finalisation	The APVMA consulted on all major changes to operational policy and guidelines prior to finalisation. We consulted publicly on 12 regulatory decisions and proposed changes to operational policy and development of guidelines including: • Chemical reviews for Methiocarb, Chlorpyrifos, and 2,4 - D • 3 Risk assessment manuals
2.3.B	Feedback from key industry stakeholders about the quality of significant APVMA consultation	Whilst formal feedback has not been sought in 2018–19, general feedback through consultation has been positive.

3.3 Performance indicator 3—Actions undertaken by regulators are proportionate to the regulatory risk being managed

Table 9: PM 3.1—Risk management frameworks and policies are in place and regularly reassessed

Ref	Evidence	Results
3.1.A	Risk framework applied to registration decision making is accessible to regulated entities	The APVMA Risk Analysis Framework outlines the approach taken by the APVMA to manage the risks associated with agricultural and veterinary (agvet) chemicals—in terms of both the likelihood of being exposed to them and the potential effects of exposure. The APVMA risk-based manufacturer audit framework is published on our website. The Risk-based scheduling of GMP audits and Audit ratings and scores can be found on our website.

Ref	Evidence	Results
3.1.B	Documented compliance and enforcement strategy, including options for graduated compliance	The compliance and enforcement plan is underpinned by a risk based approach is available under 'Corporate documents'.
3.1.C	Risk frameworks reviewed every three years	The Risk Management Framework continues to be implemented, with review and updating of the agency Risk Registers by the Executive Leadership Team quarterly. This has included a review and updated Risk Appetite Statement. In September 2019 a Governance section has been established, which has responsibility for continued implementation and review for agency-wide risk management framework.

Table 10: PM 3.2—Lower regulatory effort is applied to activities of lower regulatory risk

Ref	Evidence	Results
3.2.A	100% of applications assessed as low regulatory risk processed according to risk-based assessment framework tools and mechanisms	In 2018–19, the APVMA received 694 notifiable variations, and finalised 691. Notifiable variations are minor changes to active constituents, products and labels that are accepted by a simpler and faster process of notification, rather than an application. This year, the APVMA received 19 new applications under the fast-track pilot program, and finalised 29.
3.2.B	Documented approaches in place to review level of regulatory effort applied to agvet chemical registration and approval	Under the Agricultural Competitiveness White Paper Reforms the APVMA published range of new tailored guidance material, module descriptors guideline and improved e-label functionality to assist applicants. Additionally risk assessment manuals for chemistry, environment, health and residues and trade were published on our website in 2019.

Table 11: PM 3.3—Compliance and enforcement strategies are consistent with agreed risk management policies

Ref	Evidence	Results
3.3.A	Compliance and enforcement strategy to be accessible to regulated entities	The Compliance and Enforcement Strategy and Compliance Plan, is available on the APVMA website.
3.3.B	100% of allegations of noncompliance assessed and/or investigated according to APVMA Compliance and Enforcement Strategy	100% of allegations have been assessed or investigated under this strategy.
3.3.C	Documented policy for determining GMP audit schedules accessible by regulated entities	The GMP audit policy is available at 'Risk-based scheduling of GMP audits'.

3.4 Performance indicator 4—Compliance and monitoring approaches are streamline and coordinated

Table 12: PM 4.1: Monitoring and enforcement strategies allow for a range of regulatory responses

Ref	Evidence	Results
4.1.A	100% of allegations of non-compliance are risk-assessed and prioritised within five working days	The APVMA assesses 100% of non-compliance allegations on time. Most allegations (80%) were assessed as low risk and were resolved through education and negotiated compliance. We continued proactive monitoring and engagement with external law enforcement and regulatory bodies. The Compliance and Monitoring section assesses and prioritises allegations of non-compliance within five working days.

4.1.B	Usage of compliance tools	This year the Compliance and Monitoring team:
		• Investigated 207 new allegations of noncompliance and finalised 200 that led to:
		  • 11 voluntary recalls
		  • 2 formal warnings
		  • 5 infringement notices (totalling $33 000)
		  • 2 notice to produce
		  • 1 investigation warrants.

Table 13: PM 4.2—Compliance activities are responsive to business needs of regulated entities, where relevant

Ref	Evidence	Results
4.2.A	100% of audit and inspection schedules designed to minimise overlap with audits from other government regulators	The APVMA ensures audit and inspection schedules minimise overlap with other government regulators by: • accepting audit reports provided by the Therapeutic Goods Administration for manufacturers that hold a dual licence • up-to-date information on other countries' GMP compliance requirements is published on the APVMA website.

Ref	Evidence	Results
4.2.B	Evidence of compliance activities conducted jointly with other regulators	This year, the APVMA: • liaised directly with the Therapeutic Goods Administration and State/Territory authorities in relation to investigations • provided assistance to 2 State/Territory regulators • met with the Australian Sports and Anti-doping Authority, the Department of Agriculture and intelligence agencies to develop future capability and information sharing.

Table 14: PM 4.3—Information requested from regulated entities is necessary and acted upon

Ref	Evidence	Results
4.3.A	Average number of formal requests for information (including notices) provided for each registration application	For the purpose of determining an application in relation to an active constituent, chemical product, label or permit, the APVMA may seek correction or clarification of the information provided with the application under section 159 of the Agvet Code. In 2018–19, 17% of applications finalised had received a formal request for additional information under section 159. This is up from 13% in 2017–18.
4.3.B	Average number of compliance-related requests for information (including coercive notices) for each compliance action involving interaction with a regulated entity	Direct requests to regulated entities average approximately 3 per case. This average is highly dependent on the case risk and level of cooperation with the regulated entity.

3.5 Performance indicator 5—Regulators are open and transparent in their dealings with regulated entities

Table 15: PM 5.1—Performance information is published

Ref	Evidence	Results
5.1.A	Timeframe performance statistics published quarterly	Timeframe performance reports are published each quarter, and are available on our website under 'Performance statistics'.
5.1.B	Performance against customer service standards published quarterly	Performance data against customer service standards were not published quarterly in 2018–19.
5.1.C	Performance against RPF published annually	The 2017–18 RPF self-assessment was published by the APVMA in early-2019.

Ref	Evidence	Results
5.1.D	100% of decisions to approve or register an agvet chemical published within 10 working days of decision being made	100% of decisions to approve or register an agvet chemical were published in the APVMA Gazette. The Gazette is published every 10 working days and is available from our website. Decisions can be viewed on our product search database the day after a decision is made.

Table 16: PM 5.2—Feedback mechanisms are in place and used to improve service to regulated entities

Ref	Evidence	Results
5.2.A	Demonstrated process to collect stakeholder feedback	An online feedback register is in place to enable users to report problems, suggest improvements, lodge complaints and provide feedback via the APVMA website.
5.2.B	100% of feedback received through the online feedback system is assessed within five working days	Feedback is monitored and assessed within 5 working days and referred for action as required.

3.6 Performance indicator 6—Regulators actively contribute to the continuous improvement of regulatory frameworks

Table 17: PM 6.1—Level of stakeholder engagement in implementing regulatory frameworks

Ref	Evidence	Results
6.1.A	Documented stakeholder consultation procedures in place	Documented procedures are in place for all types of consultation undertaken by the APVMA.
6.1.B	100% of significant changes to APVMA regulatory frameworks involve stakeholder consultation	There were no significant changes to APVMA regulatory frameworks in 2018–19.

Table 18: PM 6.2—Feedback is provided to inform the development or amendment of regulatory frameworks

Ref	Evidence	Results
6.2.A	Documented procedures in place to facilitate engagement with the Department of Agriculture and relevant state and territory agencies	The APVMA and the Department of Agriculture meet on an ongoing basis about operational matters and proposed reforms. The APVMA has regular contact with state and territory coordinators for registration, permit issuance and chemical review activities.

Appendix

ABBREVIATIONS

APVMA	Australian Pesticides and Veterinary Medicines Authority
GJR	Global Joint Review
GMP	Good Manufacturing Practice
OECD	Organisation for Economic Cooperation and Development
PAA	Pre-Application Assistance
RPF	Regulator Performance Framework
TGA	Therapeutic Goods Administration

GLOSSARY

agvet chemicals	agricultural chemicals and veterinary medicines