Australian Government

Australian Pesticides and Veterinary Medicines Authority

OCTOBER 2016

APVMA Regulator Performance Framework

2015–16

Self-Assessment

ISBN 978-1-922188-36-3 (electronic)

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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 the 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.

This is the first APVMA RPF and it is anticipated refinement may occur in the initial years to better target performance measures and evidence. The APVMA RPF performance measures and evidence were agreed and published in May 2015.

The cost effectiveness of collecting evidence was taken into account in designing and selecting the performance measures contained in this framework.

[1] Regulator Performance Framework (2014), p4

1.4 Self-assessment method

The APVMA RPF performance measures and indicators align with the Corporate and Operational Plans and are reflected in the Annual Performance Statement in the 2015–16 Annual Report.

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. Achievement against each performance measure was monitored by the relevant APVMA executive, with oversight through the executive leadership team.

A key performance measure for the APVMA relates to timeframe performance for registration of agvet chemical products, approval of active constituents to be included in agvet chemical products and issuance of permits to support use of unregistered agvet chemical products for minor crops and species, research or in the case of emergency. In addition the APVMA receives a number of applications for minor variations and administrative changes to registered agvet chemicals, applications for GMP licences and to manage import and export of agvet chemicals. Timeframe performance statistics are reported quarterly and published to the APVMA website.

In 2015-16, the APVMA engaged Oakton to conduct an independent analysis of timeframe performance to compare the duration for assessment of applications submitted under the pre-1July 2014 legislative framework with applications submitted under the revised framework that commenced from that date. The report from Oakton is available on the APVMA website.

The APVMA has worked collaboratively with the Department of Agriculture and Water Resources in preparation of the APVMA RPF and self-assessment to support consistency in approach across the portfolio. This includes review of the self-assessment by the Agricultural Industry Advisory Council (AIAC), facilitated by the department.

In 2016–17 the APVMA intends to survey industry across all performance areas to seek their feedback, and to benchmark their perceptions of our performance.

2 SELF-ASSESSMENT SUMMARY

In 2015–16, the APVMA focussed on ways to lower the regulatory burden for industry, as well as improving the overall experience of applicants in interacting and transacting with the APVMA.

Since the introduction of reforms in 2014, we have continued to make steady progress in improving application assessment times and final quarter 2015–16 results showed an overall improvement in timeframe performance and the numbers of applications being finalised.

In addition, the Oakton report on analysis of how long it takes the APVMA to complete a product application showed large improvements in timeframe performance and the average time to finalise an application for applications lodged after 1 July 2014. The report showed that if timeframe performance for pre–1 July 2014 applications was measured in line with the current methodology, 33 percent of applications would have been considered to have been completed within legislative timeframes and the actual (or 'elapsed') time to finalise an application has decreased by 70 percent.

We have also invested effort in clearing overdue applications to ensure our performance against timeframes can improve over time. Recruitment of specialist staff and enhancements to systems and workflow processes, implemented in the second half of 2015–16, are designed to set up longer-term performance improvement.

In 2015–16, the APVMA initiated over 60 separate consultations to seek industry and stakeholder feedback and conducted public consultations around Australia, with industry, growers, government agencies and the community, to prioritise chemicals as part of our formal chemical review program.

We reviewed and strengthened 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.

We continued to contribute to global harmonisation in agvet chemical regulation, including chairing three OECD committees. The APVMA Chief Executive Officer became chair of the OECD Working Group on Pesticides—the main international gathering of pesticide regulators across the world and co-chaired two expert groups—one developing guidance for conducting rotational crop field trials, and the other in the emerging field of RNA interference (RNAi).

Our commitment to scientific excellence, combined with our ongoing drive for business and process improvement, will continue to support our long-term goals of reducing the regulatory burden for industry, improving access to chemicals and increasing productivity.

3 RESULTS

3.1 Performance Indicator 1 – Unnecessary impediments to the efficient operation of regulated entities are removed

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

Ref	Evidence	Results
1.1.A	Four stakeholder forums held each year to discuss issues affecting regulated entities	The APVMA held more than four stakeholder forums and meetings with key industry associations throughout 2015–16 to discuss operational and other matters affecting agvet chemical regulation
1.1.B	Three industry information and training seminars delivered each year	Three industry information and education sessions were held: • Melbourne 15 August 2015 • Canberra 15 October 2015 • Melbourne 16 May 2016
1.1.C	Four industry awareness workshops conducted by APVMA staff each year	The APVMA conducted more than four industry awareness sessions and workshops throughout the year, including a tailored workshop on the lifecycle of product development, and looking at the registration process from the applicant's perspective
1.1.D	Environmental scan published annually	The environmental scan was published as part of the *APVMA Operational Plan 2016–17*, see 'Corporate documents' at (apvma.gov.au/node/11026)

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	There were 492 international guidelines adopted by the APVMA and published on our website. These are available at 'Adopted international technical guidance material—agricultural' (apvma.gov.au/node/19991) and 'Adopted international technical guidance—veterinary' (apvma.gov.au/node/20056) Two rounds of public consultation on our policy on the use of international standards, guidelines and decisions were undertaken in 2015–16, and implementation will be done in 2016–17

1.2.B	Participation in Global Joint Reviews (GJRs)	Completed: oxathiapiprolin and metacam Ongoing: bicylopyrone, flupyradifurone and cyclaniliprole
1.2.C	100% of relevant international standards adopted for new chemical products and chemical review decisions	The APVMA is continuing to apply international standards in risk assessments undertaken for product applications and chemical reviews.
1.2.D	Documented justification for when international standards and guidelines are not adopted	There were no instances of non-adoption.

PM 1.3: Efficient and effective APVMA business processes

Ref.	Evidence	Results
1.3.A	Satisfaction with APVMA online systems for submitting and managing applications	The APVMA conducted a useability review of online systems in 2015–16 to better understand client needs and to inform improvements to the user experience Recommendations from the review will be delivered and prioritised in 2016–17
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' (apvma.gov.au/node/19741) Key timeframe performance statistics for 2015-16 are: • total applications: 68% • product applications: 66% • active constituent applications: 70% • permit applications: 70% • import consents: 86% • pre-application assistance: 41% • GMP audits: 80% • compliance statutory notices: 1 issued on time
1.3.C	Average decision time for applications by item	Average decision time for applications: • products: 5.2 months • actives: 8.8 months • permits: 3.7 months Further detail on application type by item is on the APVMA website at 'Performance statistics' (apvma.gov.au/node/19741). External analysis of duration statistics undertaken by Oakton shows the comparison between timeframe performance for applications submitted before and after 1 July 2014, noting improvement in applications completed within timeframe and reduction in the duration of assessments

3.2 Performance Indicator 2 – Communication with regulated entities is clear, targeted and effective

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	There is a feedback mechanism on every web page containing guidance material All feedback is assessed and referred to business owners for action The useability review will be completed in 2016–17 with recommendations informing further improvement to guidance material
2.1.B	100% of website content is reviewed by the nominated review date	Individual pages and sections of our website were updated as required A content management system is in place and full automation to prompt business owners to review content will be operational in early 2016–17
2.1.C	Usage of the APVMA website	There were approximately 180 000 unique visitors to the APVMA website in 2015–16 and almost 2 million hits to the chemicals database
2.1.D	Number of subscribers to the APVMA Regulatory Update	Almost 3000 subscribers are receiving the APVMA Regulatory Updates by email
2.1.E	Website meets relevant government online and accessibility standards	An online usability review conducted in June 2016 confirmed that the APVMA website (apvma.gov.au) is substantially compliant with government online and accessibility standards

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)	Of the voluntary feedback received on the PAA process: • 90% of applicants were satisfied with the clarity of advice provided
2.2.B	Customer service standards met	The APVMA enquiries team received around 10 000 calls and 12 000 emails in 2015–16 The APVMA implemented a help desk tool in 2015–16 to enable tracking and monitoring of email enquiries. The tracking tool provides the status of each enquiry and monitors response times against the service standards Phone messages were checked daily by the enquiries team and return calls were made within the one day standard An account manager model will be implemented in 2016–17 to further improve customer standards

2.2.C	100% of correspondence provided to applicants and registrants assessed as comprehensive and easily understood	A correspondence improvement project began in 2015–16 with a full audit of all outgoing letters, notices and emails Feedback from multiple sources and the recent useability review confirms there is significant scope for improvement and has identified priority products for action Implementation of improved correspondence products will commence in 2016–17

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.
2.3.B	Feedback from key industry stakeholders about the quality of significant APVMA consultation	There is an opportunity for feedback to be provided during all public consultations as part of the submission process Feedback can also be provided generally through the website and in response to targeted consultation and industry meetings The APVMA did not receive concerns about the quality of consultation on major changes that were the subject of public consultation in 2015–16

3.3 Performance Indicator 3 – Actions undertaken by regulators are proportionate to the regulatory risk being managed

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 accessible to regulated entities*	A conceptual risk assessment framework was developed in December 2015 and discussed with industry at APVMA-run industry sessions In consultation with industry, the APVMA will undertake a staged implementation of the framework
3.1.B	Documented compliance and enforcement strategy, including options for graduated compliance	The compliance and enforcement strategy, which is underpinned by a risk based approach is available under 'Corporate documents' (apvma.gov.au/node/11026)
3.1.C	Risk frameworks reviewed every three years	The APVMA undertakes continuous improvement of its risk frameworks

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*	The APVMA is continuing to explore alternative regulatory mechanisms and processes to reduce regulatory burden on industry
3.2.B	Documented approaches in place to review level of regulatory effort applied to agvet chemical registration and approval	Reports and progress updates for the lower regulatory approaches to registration project are available at 'Lower regulatory approaches to registration' (apvma.gov.au/node/20291)

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, which was released on 25 February 2016, is available under 'Corporate documents' (apvma.gov.au/node/11026)
3.3.B	100% of allegations of non-compliance 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' (apvma.gov.au/node/19701)

**To be implemented in 2016-17*

3.4 Performance Indicator 4 – Compliance and monitoring approaches are streamlined and coordinated

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	• 100% assessed on time • 79% of non-compliance cases were assessed as low risk with resolution achieved through education and negotiated compliance
4.1.B	Usage of compliance tools	• 1 statutory notice • 6 formal warnings • 2 infringement notices (totalling $27 000) • 1 investigative warrant • 230 cases of non-compliance resolved

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	100% of audits designed to minimise overlap. The APVMA coordinates audits with the: • Therapeutic Goods Administration (TGA) for 60 veterinary product manufacturers • National Association of Testing Authorities Australia (NATA) for 10 manufacturers • international government regulators of overseas sites importing products to Australia
4.2.B	Evidence of compliance activities conducted jointly with other regulators	• 17 compliance related activities collaboratively undertaken with Australian Border Force (ABF) • 6 evidentiary certificates provided to state regulators • Joint GMP audits not yet started

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	In 2015–16: • 509 first notices were issued based on processing approximately 2 500 applications, which is an approximate average of 0.2 requests for information per application or one in five applications received a formal request for information • 58 second notices were issued
4.3.B	Average number of compliance-related requests for information (including coercive notices) for each compliance action involving interaction with a regulated entity	An average of three requests for information

3.5 Performance Indicator 5 – Regulators are open and transparent in their dealings with regulated entities

PM 5.1: Performance information is published

Ref.	Evidence	Results
5.1.A	Timeframe performance statistics published quarterly	Statistics published as follows: • Q1 and Q2 published in February 2016 • Q3 published in June 2016—see 'Performance statistics' (apvma.gov.au/node/19741)

5.1.B	Performance against customer service standards published quarterly	The APVMA enquiries team received around 10,000 calls and 12 000 emails in 2015–16 The APVMA implemented a help desk tool in 2015–16 to enable tracking and monitoring of email enquiries The tracking tool provides the status of each enquiry and monitors response times against the service standards Phone messages were checked daily by the enquiries team and return calls were made within the one day standard An account manager model will be implemented in 2016–17 to further improve customer standards
5.1.C	Performance against RPF published annually	The performance against the RPF is scheduled to be published by the APVMA in late 2016
5.1.D	100% of decisions to approve or register an agvet chemical published within 10 working days of decision being made	• 100% achieved • All decisions to approve or register an agvet chemical are published every fortnight in the gazette, and can be viewed on our product search database the day after the decision is made

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 mechanism 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 daily and referred for action as required

3.6 Performance Indicator 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks

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 2015–16

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 Water Resources and relevant state and territory agencies	The APVMA and the Department of Agriculture and Water Resources meet monthly to discuss ongoing operational matters and proposed reforms The APVMA attended three reform sessions with industry hosted by the department in Canberra, Sydney and Melbourne The APVMA has regular contact with state and territory coordinators for registration, permit issuance and chemical review activities We held two face-to-face workshops with relevant state and territory agencies regarding chemical review prioritisation and ongoing operational matters The APVMA hosted a forum for state and territory coordinators to discuss regulatory approaches

APPENDIXES

ABBREVIATIONS

ABF	Australian Border Force
AIAC	Agricultural Industry Advisory Council
APVMA	Australian Pesticides and Veterinary Medicines Authority
GJR	Global Joint Review
GMP	Good Manufacturing Practice
NATA	National Association of Testing Authorities Australia
OECD	Organisation for Economic Cooperation and Development
PAA	Pre-application assistance
RNAi	Ribonucleic acid (RNA) interference
RPF	Regulator Performance Framework
TGA	Therapeutic Goods Administration

GLOSSARY

agvet chemicals	agricultural chemicals and veterinary medicines