



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



**APVMA Regulator
Performance Framework
2016-17
Self-Assessment**

November 2017

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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 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 Regulator Performance Framework (2014), p4

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

The APVMA RPF performance measures and indicators align with the Corporate Plan 2015–20 and are reflected in the Annual Performance Statement contained within the 2016–17 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 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; and
- sourced key material from the *Australian Pesticides and Veterinary Medicines Annual Report 2016–17*.

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 was considered by the APVMA Chief Executive Officer and circulated to the Department of Agriculture and Water Resources.

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

2 SELF-ASSESSMENT SUMMARY

The APVMA has progressed work that will contribute to the regulatory efficiency and enhanced client services of agricultural and veterinary chemical regulation in Australia. Regulatory performance by the APVMA has been satisfactory, however the agency acknowledges that fluctuating and at times deteriorating operational performance must be addressed to improve the timeliness of regulatory decision making and meet statutory obligations in full.

Results varied across the six performance indicators outlining strengths in the agency's compliance and monitoring programs and satisfactory delivery in client service, regulatory transparency and proportional risk management, refer **Table 1**.

Table 1: APVMA Self – Assessment against the regulator performance framework

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

This year the APVMA achieved the greatest improvement against Indicator 4 – through the development of new compliance and monitoring approaches that are reducing the burden on industry in meeting regulatory requirements. We have delivered on our statutory responsibilities for compliance and enforcement, and chemical reconsiderations, and come close to meeting our targets for audits and registrations.

Four areas received a satisfactory rating, Indicator 2 - Communication with regulated entities is clear, targeted and effective, Indicator 3 - Proportionate risk approaches, Indicator 5 – Open and transparent dealings, and Indicator 6 – Contributing to continuous improvement. This year the APVMA has invested in progressing a number of activities in these four areas and expects to see positive impacts from this investment into the future. Activities included:

- The implementation of a fast-track system for low-risk applications to help streamline regulatory assessment and product registration.
- Review of risk management frameworks to better support how the APVMA responds to risk.
- Improving guidance material for our clients, tailoring it to the information required to lodge the right application, with the right data and supporting evidence to meet APVMA criteria.
- The completion of an external review of the Good Manufacturing Practice (GMP) programs assessing auditing and licensing, comparing the approach of international regulators, and the identification of possible improvements to increase program effectiveness.
- Mapping of end-to-end business processes to facilitate the future streamlining of assessments.

RESULTS

2.1 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	<p>The APVMA held more than four stakeholder forums and meetings with key industry associations throughout 2016–17 to discuss operational and other matters affecting agvet chemical regulation.</p> <p>The APVMA consulted publicly on 45 regulatory decisions and proposed changes to operational policy and development of guidelines, including:</p> <ul style="list-style-type: none"> - finalising APVMA policies and guidance material for the use of international standards, assessments and data - review of the good manufacturing practice audit framework - consideration of a revised policy for prioritisation of APVMA workload and application assessments - continuation of pilot programs for applicants to source efficacy assessments before application and for fast-track registration systems for applications of low regulatory concern - a proposal to leverage assessments and decisions in New Zealand for non–food producing animals.
1.1.B	Three industry information and training seminars delivered each year	<p>A two-day industry information and engagement event was held in Canberra in November 2016. Of the attendees, including 180 stakeholders, 95.95% either strongly agreed or agreed that the session was a useful and worthwhile forum for consultation.</p> <p>The event allowed stakeholders to engage in two-way feedback, and provided a forum for the APVMA to listen to challenges and opportunities impacting the regulated industry. Industry sessions complemented the APVMA's traditional consultation channels in 2016–17.</p> <p>In February 2017 the APVMA held a workshop to establish client expectations for improved regulatory guidance material.</p>
1.1.C	Four industry awareness workshops conducted by APVMA staff each year	<p>Key client and stakeholder workshops and engagements included:</p> <ul style="list-style-type: none"> - conducting a pilot project and review of fast-track registration to reduce regulation through streamlined assessments and online self-registration - a workshop (Sydney, March 2017) with industry to

Ref	Evidence	Results
		<p>identify improved guidance material for the top 20 application types and establish a baseline of client requirements from the regulatory efficiency project.</p> <ul style="list-style-type: none"> - a workshop to consider proposed changes to safety and use instructions through the chemical reconsideration of dimethoate. <p>The APVMA regularly hosts seminars by industry representatives to increase awareness amongst staff of the registration process from the perspective of industry. These seminars included a presentation by Bayer Animal Health on 14 September 2016.</p>
1.1.D	Environmental scan published annually	The environmental scan was published as part of the <i>APVMA Corporate Plan 2015–20</i> , 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	<p>The APVMA has applied the policy of acceptance of international assessments through:</p> <ul style="list-style-type: none"> - defining acceptable international assessments, including their potential scope and a list of organisations whose assessment reports we will accept - developing and publishing guidelines for the submission of an international assessment, including criteria that the assessment must fulfil to be acceptable to the APVMA (e.g. the active constituent or product in the international assessment must be identical to the active constituent or product intended for approval or registration in Australia) - developing requirements covering the submission of multiple assessments and underlying data or studies - clarifying how data provided is used by the APVMA, including that each assessment must be fit for purpose and supported by studies that fulfil regulatory requirements - providing clarity to applicants on the Australian-only information contained in APVMA guidance material - the provision of new guidance to APVMA staff on how to process international assessments
1.2.B	Participation in Global Joint Reviews (GJRs)	The APVMA has participated in multiple reviews with other regulators including those for oxathiapipronil, meloxicam, bicyclopyrone, flupyradifurone and

Ref	Evidence	Results
		<p>cyclaniliprole.</p> <p>In 2016–17 APVMA staff contributed to the first ever Trilateral assessment and review of a veterinary products, Metcam.</p>
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.
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.

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	<p>In 2016–17 , several initiatives were completed by the APVMA to improve service delivery, including:</p> <ul style="list-style-type: none"> - an upgrade of the electronic document management system to ensure its effective operation on APVMA mobile tablet devices - development of an online induction module to introduce new staff to APVMA information management practices - introduction of new modules into the internal portal to support efficient management of product data, actives data and finance data associated with agvet applications - introduction of new workload management features into the internal portal to support the management of tasks and milestones within the end-to-end registration process - improvements to the online services site, including: <ul style="list-style-type: none"> • annual return of actives reporting • agvet application status dashboard reporting • up-front payment options to include full fees • increased registration renewal options • a fast-track application system for certain application types • a mechanism for applications and management of pre application assessments became available for online assistance - commencement of work to redevelop our record

Ref.	Evidence	Results
		<p>authority in preparation for the digitisation of paper records.</p> <ul style="list-style-type: none"> - commencement of enhancements to the website, addressing outcomes of the 2016 Useability Review, including: <ul style="list-style-type: none"> • integration of Google Search to increase and improve the quality of search results • introduction of new work processes to improve the consistency and clarity of written content across systems • creation of a visual style guide to assist in the development of on-brand and accessible products • user mapping and pathway discovery activities to inform future state business processes.
1.3.B	Regulatory decisions are completed within timeframes (all targets are 100%, except import consents which are a 90% target)	<p>The APVMA publishes quarterly performance statistics on regulatory decisions on its website. See 'Performance statistics' (apvma.gov.au/node/26876)</p> <p>The APVMA did not achieve 100% timeframes. In 2016–17, the APVMA:</p> <ul style="list-style-type: none"> - commenced assessment of 2910 applications for products, actives and permits, and finalised 2453 applications. - achieved overall performance rates of 69% within timeframe, including <ul style="list-style-type: none"> • 59% for product registration • 88% for active approvals • 71% for permits • 99% for preliminary assessments • 93 % of import consents <p>The APVMA continues to collect voluntary feedback about different aspects of the Pre-application Assistance (PAA) process. This year we received 12 submissions, and:</p> <ul style="list-style-type: none"> • 100% of applicants agreed that the information and guidance material for making a PAA request was clear • 100% of applicants advised that the advice received would assist them in preparing an application to the APVMA.
1.3.C	Average decision time for applications by item	<p>Average decision time for applications:</p> <ul style="list-style-type: none"> • products: 6.7 months • actives: 5.2 months

Ref.	Evidence	Results
		<ul style="list-style-type: none">permits: 3.8 months Further detail on application type by item is on the APVMA website at 'Performance statistics' (apvma.gov.au/node/19741).

2.2 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	<p>Feedback from stakeholders has identified that APVMA information and guidance material can be improved and we are working on a range of projects to bridge the gap between client expectations and experiences.</p> <p>This year:</p> <ul style="list-style-type: none"> - Google search was implemented on the website in February 2017 and analytics have demonstrated improvements to our user searches and discoverability of guidance material - a Guide was published for completing an online application and Guidance for submission of international data standards and assessments - project plans were developed for a series of Agricultural Competitiveness White Paper and business improvement activities to be implemented between 2017 and 2019 to improve satisfaction with regulatory guidance materials - satisfaction with online information and guidance material was monitored and feedback actioned by relevant business areas - the Our Science web pages were redesigned and content will be implemented in 2017–18
2.1.B	100% of website content is reviewed by the nominated review date	<p>Website content review systems were appropriately maintained and feedback from the website was monitored and acted on daily to improve online information.</p> <p>The usability of the APVMA website was reviewed (October 2016) to gain a clearer understanding of what applicants and other users need from the website and online services portal; recommendations were prioritised for implementation in early 2017.</p> <p>Content published to the APVMA website was continuously quality checked to ensure compliance with Australian Government online and accessibility standards.</p>
2.1.C	Usage of the APVMA website	<p>There were 879 533 unique visits to pages on the APVMA website in 2016–17, an increase of approximately 37 000 on the previous year.</p> <p>The APVMA chemical database received an estimated 2 million hits in 2016–17.</p>

Ref.	Evidence	Results
2.1.D	Number of subscribers to the APVMA Regulatory Update	Increased subscriptions to the APVMA Gazette by 6% (a total of 2354 subscribers)
2.1.E	Website meets relevant government online and accessibility standards	An online usability review conducted in October 2016 confirmed that the APVMA website (apvma.gov.au) is substantially compliant with government online and accessibility standards More work is required to achieve AAA compliance in the forward year.

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)	<p>The APVMA continues to collect voluntary feedback on the PAA process. This year we received 12 submissions, and:</p> <ul style="list-style-type: none"> - 100% of applicants agreed that the information and guidance material for making a PAA request was clear - 100% of applicants advised that the advice received would assist them in preparing an application to the APVMA - 92% agreed that the online system for submitting a PAA application was easy to use - 83% of applicants were satisfied with the clarity of the advice - 83% agreed that the format, fees and timeframes were appropriate.
2.2.B	Customer service standards met	<p>This year:</p> <ul style="list-style-type: none"> - phone messages and emails were checked daily by the enquiries team and replies made within the one-day standard for phone calls and five-day standard for written enquiries - we responded to 35 media inquiries; 70% of responses were within agreed deadlines - website content review systems were appropriately maintained and feedback from the website was monitored and acted on daily to improve online information - content published to the APVMA website was continuously quality checked to ensure compliance with Australian Government online and accessibility 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 has identified priority products for

Ref	Evidence	Results
		<p>action and we commenced work in 2016–17 to improve correspondence products.</p> <p>This year, we implemented newsletter, notice and email templates; initial data on the rate and nature of client responses indicate improvements in user comprehension.</p>

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 (100% of) 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	<p>The APVMA did not receive concerns about the quality of consultation on major changes that were the subject of public consultation in 2016–17 .</p> <p>There is an opportunity for feedback to be provided during all public consultations as part of the submission process.</p> <p>Feedback can also be provided generally through the website and in response to targeted consultation and industry meetings</p>

2.3 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	<p>The APVMA recommenced a project to publish Risk Assessment manuals for chemistry, human health and efficacy (aligned with international guidance) and to review the existing guidance for environmental risk.</p> <p>The Manufacturing Quality and Licensing section within the APVMA conducts audits and licenses manufacturers using a risk-based model. This year, we commenced a review of our new audit scheduling model to ensure that the agency manages licensing risks effectively. Data to inform a review of the strategy were collated and will be analysed in 2017–18.</p>
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	<p>The APVMA undertakes continuous improvement of its risk frameworks.</p> <p>The Compliance and enforcement strategy 2015–17 is reviewed every three years and will be next reviewed in 2017–18.</p>

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	<p>In September 2016, the APVMA expanded the list of notifiable variations—minor changes to active constituents, products and labels that are accepted by a simpler and faster process of notification, rather than an application—as an outcome of the lower regulatory approaches to registration project. Five new items were added to the list. The APVMA will continue to look for additional application types that may be suitable to be a notifiable variation.</p> <p>The APVMA has put into place a fast-track system for low-risk applications that will help streamline regulatory assessment and product registration. This system has been well received and is already reducing administrative burdens and accelerating registration for eligible products. In addition, we are consulting with industry about the use of listed standards to define the conditions under which a group of products can be fast-tracked.</p>

Ref	Evidence	Results
3.2.B	Documented approaches in place to review level of regulatory effort applied to agvet chemical registration and approval	<p>Low-risk cases are those that have a small number of products involved and that demonstrate a limited risk to human health, animals, the environment and trade. For such cases, education is the main compliance response. Education informs the noncompliant organisations of their regulatory responsibilities and helps to establish a pathway to future compliance. This year, 83% of the APVMA's 199 compliance cases were rated as low risk.</p> <p>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)</p>

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	<p>The Compliance and Enforcement Strategy, which was released on 25 February 2016, is available under 'Corporate documents' (apvma.gov.au/node/11026)</p> <p>The APVMA communicates about the forward compliance strategy at the industry sessions each year.</p>
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	<p>The GMP audit policy is available at 'Risk-based scheduling of GMP audits' (apvma.gov.au/node/19701)</p> <p>This year, the APVMA engaged external consultants to review the GMP programs and consider the APVMA approach to auditing and licensing, the approach of comparable international regulators, and possible improvements to increase program effectiveness. The completed review:</p> <ul style="list-style-type: none"> - recommended that we implement a second-party auditing model with a view to implementing a first-party auditing model within five years; this aims to improve international harmonisation of GMP for veterinary chemical products - describes 10 key steps to achieve implementation that need to be considered by the APVMA and its stakeholders. <p>The APVMA has commenced the initial consultation on these recommendations and proposed steps.</p>

2.4 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	<p>The APVMA assesses 100% of non-compliance allegations on time. Most allegations (83%) 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.</p> <p>The Compliance and Monitoring section assesses and prioritises allegations of non-compliance within five working days.</p>
4.1.B	Usage of compliance tools	<p>This year:</p> <ul style="list-style-type: none"> - 199 compliance cases were resolved; 100% of allegations were assessed on time - 83% of all allegations were assessed as low risk and were resolved through education and negotiated compliance - for matters assessed as medium or high risk, engagement and various enforcement strategies were used, including <ul style="list-style-type: none"> • four statutory notices • seven formal warnings • five infringement notices (totalling \$31 500) • two investigation warrants • two monitoring warrants • one compulsory stop supply.

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	<p>This year, the Compliance and Monitoring section:</p> <ul style="list-style-type: none"> - conducted proactive monitoring activities in response to concerns from industry and other regulators about certain product types in the marketplace, including: <ul style="list-style-type: none"> • sampling and testing approved trifluralin active and formulated products containing trifluralin and fipronil; the active and products analysed were found to be within specification and legislative requirements - continued engagement with external law enforcement and regulatory bodies to limit the supply of unregistered products in the Australian marketplace, including:

Ref	Evidence	Results
		<ul style="list-style-type: none"> • 27 engagements with the Australian Border Force in response to alert activations of suspected unregistered chemical products being imported into Australia; some of the unlawful products were re-exported and 16 letters were issued to the Customs Comptroller General to request the disposal of imported unregistered chemical product. • met with horse and greyhound racing regulators Australia-wide as part of a joint effort to disrupt the flow of unregistered veterinary chemical products in the racing industry • issued three evidentiary certificates to assist racing integrity units in their investigations. 100% of audits designed to minimise overlap.
4.2.B	Evidence of compliance activities conducted jointly with other regulators	<ul style="list-style-type: none"> • 27 compliance related activities collaboratively undertaken with Australian Border Force (ABF) • 2 evidentiary certificates provided to state regulators. • Work towards Operational Pangea that was delivered in 2017–18.

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 2016–17, 19% of registration applications received formal requests for additional information under section 159.
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 four per case. This average is highly dependent on the case risk and level of engagement with the regulated entity. Higher risk cases have more engagement, but are significantly less by volume of cases.

2.5 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	Timeframe performance reports are published each quarter, and are available on our website under 'Performance statistics'. (apvma.gov.au/node/19741).
5.1.B	Performance against customer service standards published quarterly	This year: <ul style="list-style-type: none"> - phone messages and emails were checked daily by the enquiries team and replies made within the one-day standard for phone calls and five-day standard for written enquiries - we responded to 35 media inquiries; 70% of responses were within agreed deadlines - website content review systems were appropriately maintained and feedback from the website was monitored and acted on daily to improve online information - content published to the APVMA website was continuously quality checked to ensure compliance with Australian Government online and accessibility standards.
5.1.C	Performance against RPF published annually	The 2015–16 RPF self-assessment was published by the APVMA in early 2017.
5.1.D	100% of decisions to approve or register an agvet chemical published within 10 working days of decision being made	The APVMA Gazette lists all APVMA notices and decisions as required under the Agvet Code, including registrations, reviews and changes to registration status. The gazette is published fortnightly and is available from our website and can be viewed on our product search database the day after a 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	This year, we: <ul style="list-style-type: none"> - used stakeholder feedback to improve guidance material and the user experience of online information registration systems - mapped end-to-end business processes to streamline assessment processes, and identified and implemented lower regulatory approaches - continued to engage clients and stakeholders to better understand their needs and our operating environment - extended our environmental scan as part of agency planning - invited registrants to present to APVMA staff on the

Ref	Evidence	Results
		process of product discovery, research and development, and post market activities to support a broader understanding of the operating environment for regulated entities.
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

2.6 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 2016–17.

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	<p>Procedures were put in place in 2017 and engagement is being undertaken in line with these procedures.</p> <p>The APVMA and the Department of Agriculture and Water Resources meet on an ongoing basis about operational matters and proposed reforms.</p> <p>The APVMA has regular contact with state and territory coordinators for registration, permit issuance and chemical review activities.</p>



APPENDIXES

ABBREVIATIONS

ABF	Australian Border Force
AIAC	Agricultural Industry Advisory Council
APVMA	Australian Pesticides and Veterinary Medicines Authority
EDRMS	Electronic Document and Records Management System
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
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