



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



MAY 2015

**APVMA Regulator  
Performance  
Framework**

2015-16

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ISBN 978-1-922188-12-0 (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'<sup>1</sup>.

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

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

## 1.3 The APVMA Performance Framework

The APVMA Performance Framework (the framework) 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 Performance Framework and it is anticipated refinement may occur in the initial years to better target performance measures and evidence. The cost effectiveness of collecting evidence was taken into account in designing and selecting the performance measures contained in this framework.

This framework was developed in consultation with key representatives of the sector for which the APVMA regulates. See Appendix A for a list of those consulted.

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<sup>1</sup> Regulator Performance Framework (2014), p4

## 2 PERFORMANCE MEASURES

RPF Key performance indicator	Performance measures	Evidence
1. Unnecessary impediments to the efficient operation of regulated entities are removed	1. Demonstrated understanding of the operating environment for the regulated entities.	<ul style="list-style-type: none"> <li>A. Four stakeholder forums held each year to discuss issues affecting regulated entities</li> <li>B. Three industry information and training seminars delivered each year</li> <li>C. Four industry awareness workshops conducted for APVMA staff each year</li> <li>D. Environmental scan published annually</li> </ul>
	2. International data guidelines, standards, assessments adopted to reduce effort to register agvet chemicals.	<ul style="list-style-type: none"> <li>A. Demonstrated application of the policy for use international standards, guidelines, assessments and decisions</li> <li>B. Participation in Global Joint Reviews</li> <li>C. 100% of relevant international standards adopted for new chemical products and chemical review decisions</li> <li>D. Documented justification for when international standards and guidelines are not adopted</li> </ul>
	3. Efficient and effective APVMA business processes.	<ul style="list-style-type: none"> <li>A. Satisfaction with APVMA on-line systems for submitting and managing applications</li> <li>B. Regulatory decisions are completed within timeframes</li> <li>C. Average decision time for applications by item</li> </ul>
2. Communication with regulated entities is clear, targeted and effective.	1. Level of satisfaction with information and guidance materials	<ul style="list-style-type: none"> <li>A. Feedback from stakeholders about the quality of guidance material</li> <li>B. 100% of website content is reviewed by the nominated review date</li> <li>C. Usage of the APVMA website</li> <li>D. Number of subscribers to the APVMA Regulatory Update</li> <li>E. Website meets relevant Government online and accessibility standards</li> </ul>
	2. Level of satisfaction with the quality and timeliness of advice on decisions.	<ul style="list-style-type: none"> <li>A. Feedback about the quality of pre-application assistance</li> <li>B. Customer service standards met</li> <li>C. 100% of correspondence provided to applicants and registrants assessed as comprehensive and easily understood</li> </ul>

RPF Key performance indicator	Performance measures	Evidence
	3. Extent and satisfaction with APVMA consultative processes.	<p>A. 100% of new or major changes to operational policies or guidelines provided to relevant stakeholders for consultation prior to finalisation</p> <p>B. Feedback from key industry stakeholders about the quality of significant APMVA consultation</p>
3. Actions undertaken by regulators are proportionate to the regulatory risk being managed.	1. Risk management frameworks and policies are in place and regularly reassessed.	<p>A. Risk framework applied to registration decision making accessible to regulated entities*</p> <p>B. Documented compliance and enforcement strategy, including options for graduated compliance</p> <p>C. Risk frameworks reviewed every three years</p>
	2. Lower regulatory effort is applied to activities of lower regulatory risk.	<p>A. 100% of applications assessed as low regulatory risk processed according to risk-based assessment framework tools and mechanisms*</p> <p>B. Documented approaches in place to review level of regulatory effort applied to agvet chemical registration and approval.</p>
	3. Compliance and enforcement strategies are consistent with agreed risk management policies.	<p>A. Compliance and enforcement strategy accessible to regulated entities</p> <p>B. 100% of allegations of non-compliance assessed and/or investigated according to APVMA Compliance and Enforcement Strategy</p> <p>C. Documented policy for determining GMP audit schedules accessible by regulated entities</p>
4. Compliance and monitoring approaches are streamlined and coordinated.	1. Monitoring and enforcement strategies allow for a range of regulatory responses.	<p>A. 100% of allegations of non-compliance are risk-assessed and prioritised within five working days</p> <p>B. Usage of compliance tools</p>
	2. Compliance activities are responsive to business needs of regulated entities, where relevant.	<p>A. 100% audit and inspection schedules designed to minimise overlap with audits from other government regulators</p> <p>B. Evidence of compliance activities conducted jointly with other regulators</p>
	3. Information requested from regulated entities is necessary and acted upon.	<p>A. Average number of formal requests for information (including notices) provided for each registration application</p> <p>B. Average number of compliance related requests for information (including coercive notices) for each compliance action involving interaction with a regulated entity</p>

RPF Key performance indicator	Performance measures	Evidence
5. Regulators are open and transparent in their dealings with regulated entities.	1. Performance information is published.	<ul style="list-style-type: none"> <li>A. Timeframe performance statistics published quarterly</li> <li>B. Performance against customer service standards published quarterly</li> <li>C. Performance against regulator performance framework published annually</li> <li>D. 100% of decisions to approve or register an agvet chemical published within 10 working days of decision being made</li> </ul>
	2. Feedback mechanisms are in place and used to improve service to regulated entities.	<ul style="list-style-type: none"> <li>A. Demonstrated processes to collect stakeholder feedback</li> <li>B. 100% of feedback received through the on-line feedback system is assessed within five working days</li> </ul>
6. Regulators actively contribute to the continuous improvement of regulatory frameworks.	1. Level of stakeholder engagement in implementing regulatory frameworks.	<ul style="list-style-type: none"> <li>A. Documented stakeholder consultation procedures in place</li> <li>B. 100% of significant changes to APVMA regulatory frameworks involve stakeholder consultation</li> </ul>
	2. Feedback is provided to inform the development or amendment of regulatory frameworks.	<ul style="list-style-type: none"> <li>A. Documented procedures in place to facilitate engagement with the Department of Agriculture and relevant state and territory agencies</li> </ul>

\* To be implemented from 2016-17

### **3 MEASUREMENT, ASSESSMENT AND REPORTING**

The detail of how the evidence to assess performance will be collected will be captured in a companion document.

In the first year the focus will be on setting accurate bench marks to assess evidence in future years.

APVMA will complete a self-assessment against this performance framework in consultation with key stakeholders prior to certification by the Chief Executive Officer and then provision to the Minister for Agriculture for approval. The framework review process is comprehensive and includes compulsory external validation through the Agricultural Industry Advisory Council and the potential to use external reviews.

The final performance report against the framework will be annexed in APVMA's annual report each year.





APPENDIXES

## APPENDIX A – STAKEHOLDER CONSULTATION

In developing the framework and metrics of assessment APVMA consulted with the following stakeholders:

Accord Australasia

Plastics and Chemicals Industries Association

Australian Veterinary Association

Animal Medicines Australia Ltd

Swimming Pool and Spa Association of Australia

Plant Health Australia

Veterinary Manufacturers and Distributors Association

Pet Food Industry Association of Australia

Animal Health Australia

CropLife Australia

Aerosol Association of Australia

Australian Paint Manufacturers' Federation

National Farmers' Federation

State and Territory Partners in the National Registration Scheme

Department of Agriculture

The APVMA Advisory Board

## ABBREVIATIONS

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APVMA	Australian Pesticides and Veterinary Medicines Authority
GMP	Good Manufacturer Practice
RPF	Regulator Performance Framework

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## GLOSSARY

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agvet	Agricultural chemicals and veterinary medicines
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