



Australian Government
Australian Pesticides and
Veterinary Medicines Authority



CORPORATE PLAN
2015–20



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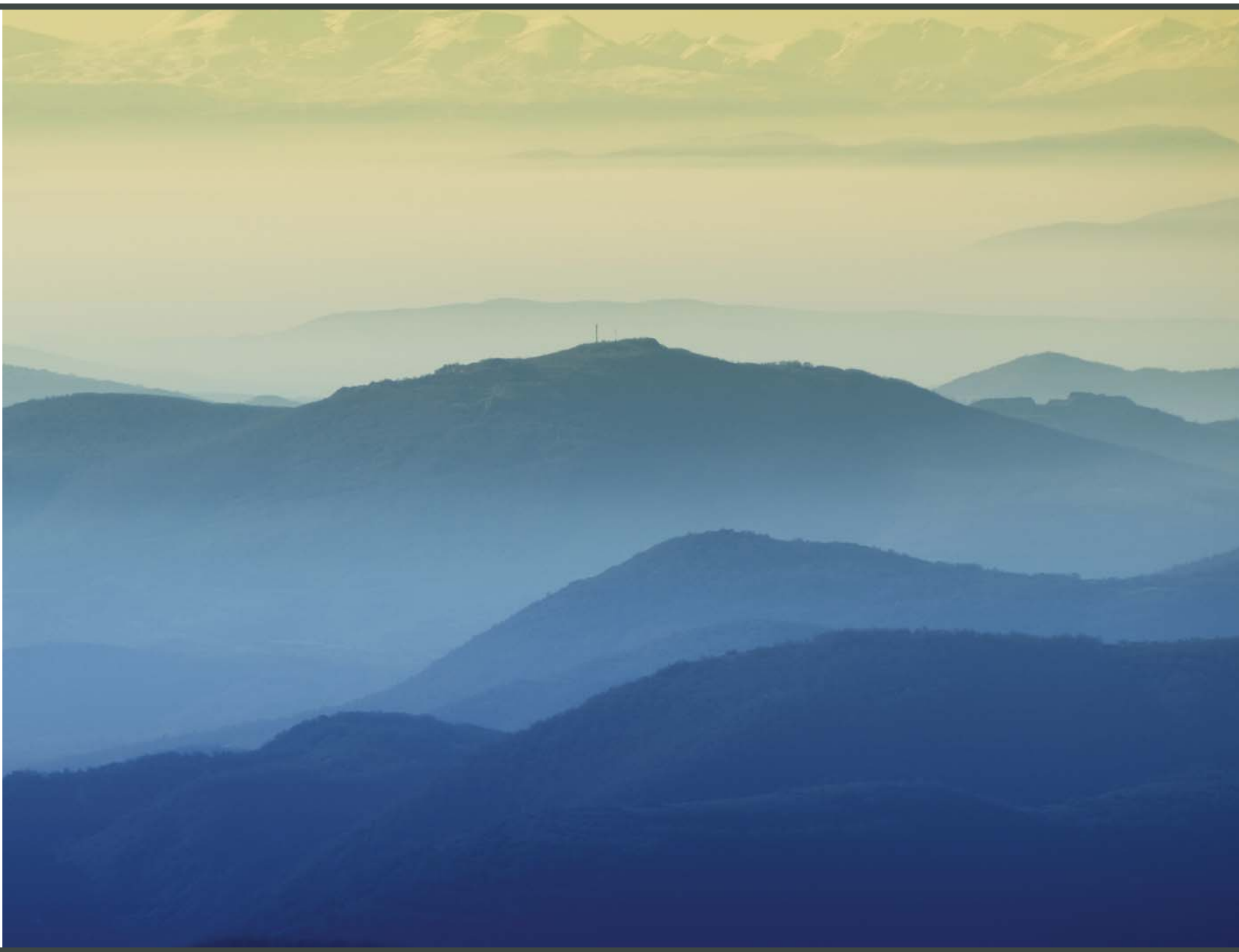
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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) corporate plan sets out what we will do over the next five years to transform our business and deliver on our ambition to be a contemporary world class regulator.

We will refocus our operations to better meet the needs of the sector we regulate, while continuing to ensure that Australians have confidence in the safety of the agricultural and veterinary (agvet) chemicals they use.

We will re-align our regulatory effort to be more proportionate to the regulatory risk we are managing.

We will implement ways to streamline the registration process to ensure Australian farmers have access to the chemicals they need in a more timely manner and preferably at the same time as they are available in other countries.

We are committed to change and will build a client focused culture that will encourage companies to bring new and innovative agvet chemical products into Australia.

This plan is a 'back to basics' plan, focusing on improving our ability to deliver more predictable and consistent decisions and ensuring the business is operating as efficiently and effectively as possible.

WE ARE COMMITTED TO CHANGE
AND WILL BUILD A CLIENT FOCUSED
CULTURE THAT WILL ENCOURAGE
COMPANIES TO BRING NEW AND
INNOVATIVE AGVET CHEMICAL
PRODUCTS INTO AUSTRALIA

INTRODUCTION

This plan sets out the strategic priorities for the APVMA for the period 2016–17 through to 2019–20.

A corporate plan is required under Paragraph 35(1)(a) Section 95(1)(a) of the *Public Governance, Performance and Accountability Act 2013* and Section 51 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. The plan is prepared in accordance with the *Public Governance, Performance and Accountability Rule 2014*.

An operational plan will be prepared each year based on the corporate plan, in accordance with Section 55 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Progress toward meeting the goals of the corporate plan will be reported each year in the annual report. Selected performance statistics will be published on a quarterly basis.

The performance measures contained in this plan are further described in the APVMA Regulator Performance Framework.

The corporate plan will be reviewed annually and adjusted as necessary.

OUR PURPOSE

The APVMA is the independent statutory authority responsible for assessing and registering pesticides and veterinary medicines proposed for supply and use in Australia.

We evaluate the safety and performance of chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected.

The APVMA also regularly reviews chemicals that are on the market to ensure they are safe to use. We also license and audit veterinary manufacturers and undertake a range of compliance activities up to and including the point of retail sale of the chemicals.

The functions of the APVMA are set out in Section 7 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

The APVMA operates under an Intergovernmental Agreement between the Commonwealth Government and all states and territories. Under this agreement, the APVMA is responsible for regulating agvet chemicals up to and including the point of sale. The states and territories are responsible for regulating agvet chemicals after they are sold, which is known as 'control of use'. The APVMA does not have responsibility for monitoring how chemicals are used.





OUR VISION

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

OUR MISSION

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

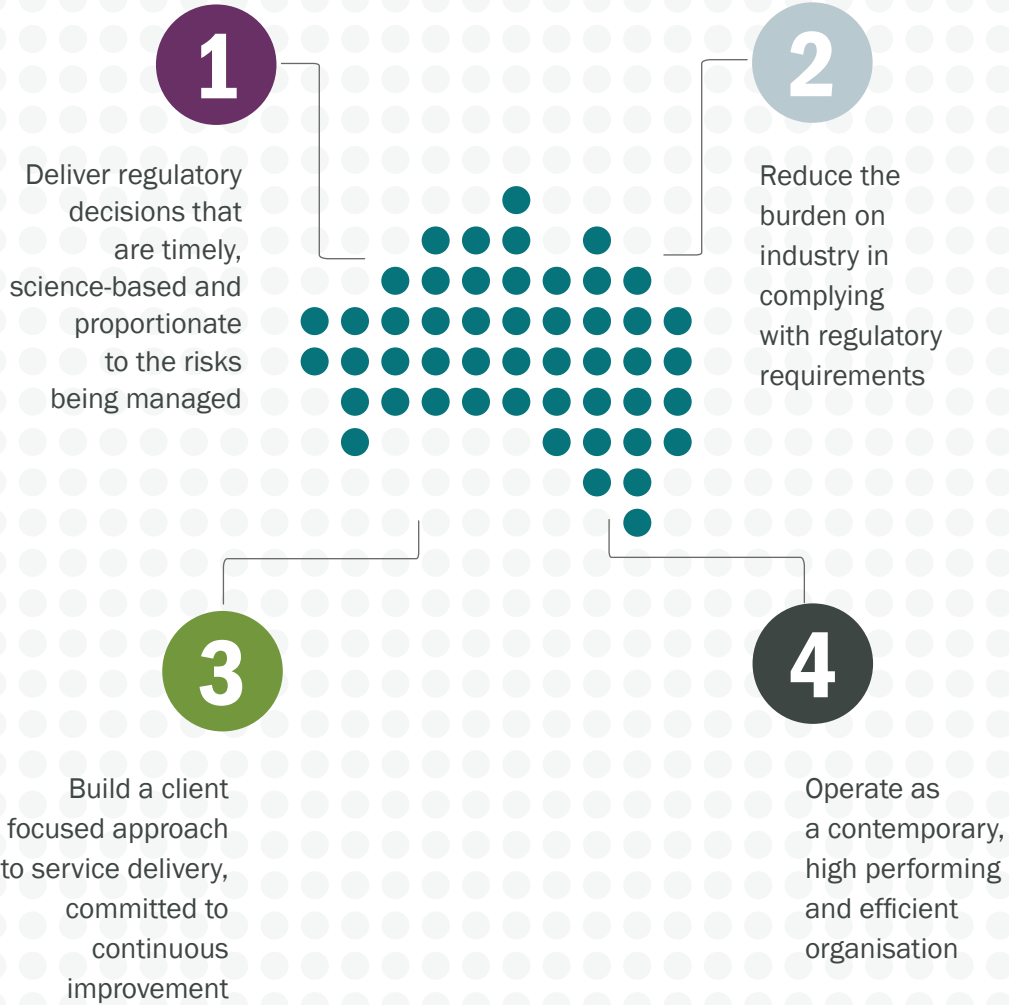
OUR VALUES

We are impartial, committed to service, accountable, respectful and ethical.

OUR GOALS

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

OUR STRATEGIES





MEASURING OUR PERFORMANCE

DECISION MAKING

- Regulatory decisions are completed within statutory timeframes
- Actions undertaken are proportionate to the regulatory risk being managed

REDUCING REGULATORY BURDEN

- Unnecessary impediments to the efficient operation of regulated entities are removed
- Streamlined and coordinated compliance and monitoring approaches are in place

CLIENT FOCUSED

- Communication with regulated entities is clear, targeted and effective
- Dealings with regulated entities are open and transparent
- Active contribution to continuous improvement of regulatory frameworks

HIGH PERFORMING ORGANISATION

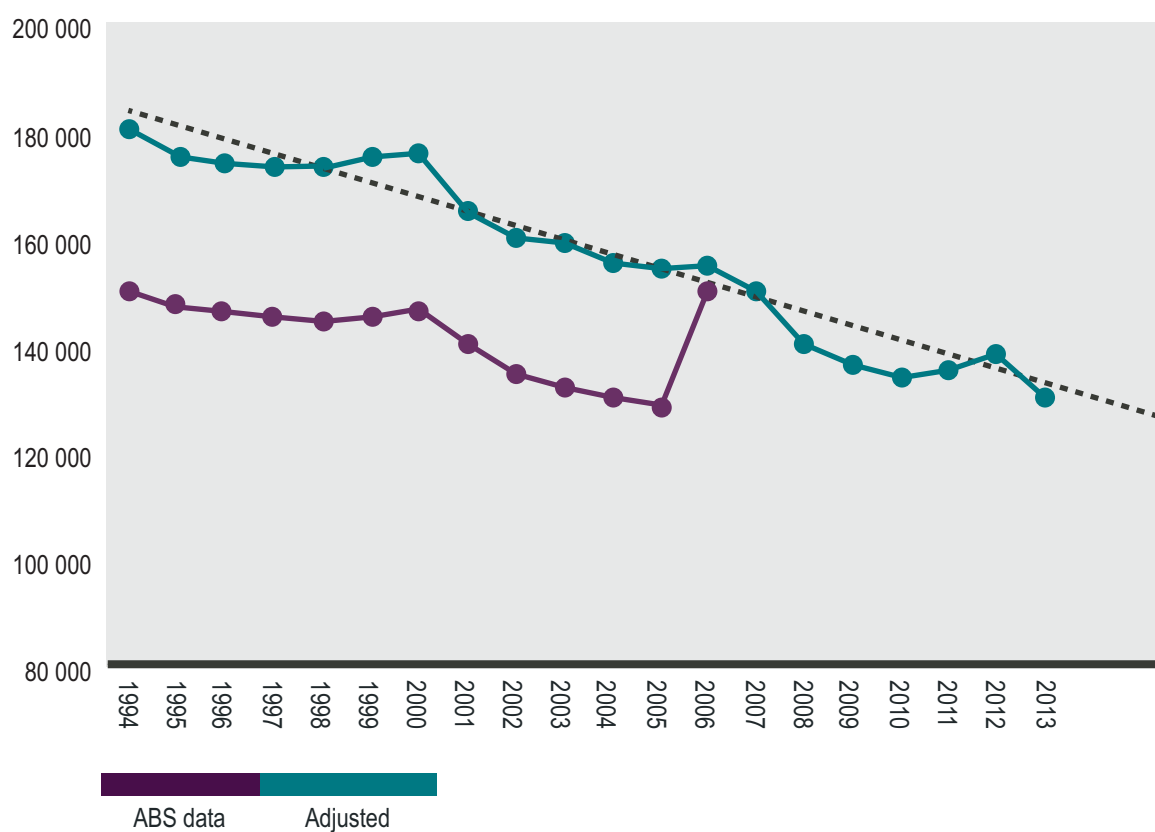
- Demonstrated organisational health and financial viability

OUR OPERATING ENVIRONMENT

The APVMA has been regulating agvet chemicals in Australia for over 20 years. Domestic and international trends are now challenging our traditional means of operation. We are committed to using these challenges as an opportunity to change and deliver better outcomes for government, industry and the community¹.

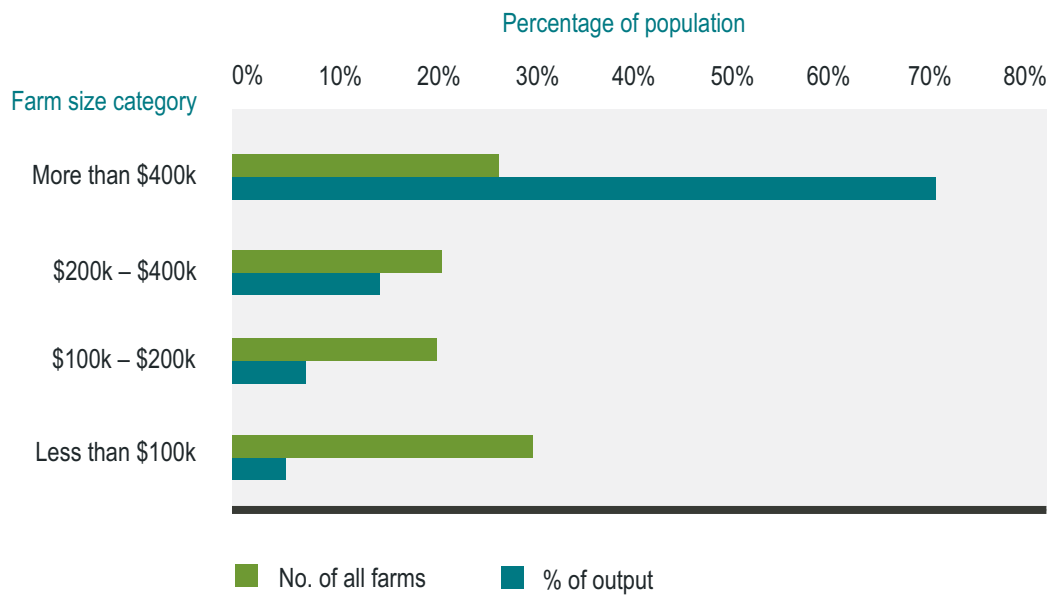
AGRICULTURE

Trends in Australian agriculture will impact on the APVMA. Agricultural production is becoming concentrated on fewer farms that are larger in scale and more commercially oriented. Less than 30 per cent of farms produce more than 70 per cent of farm output.

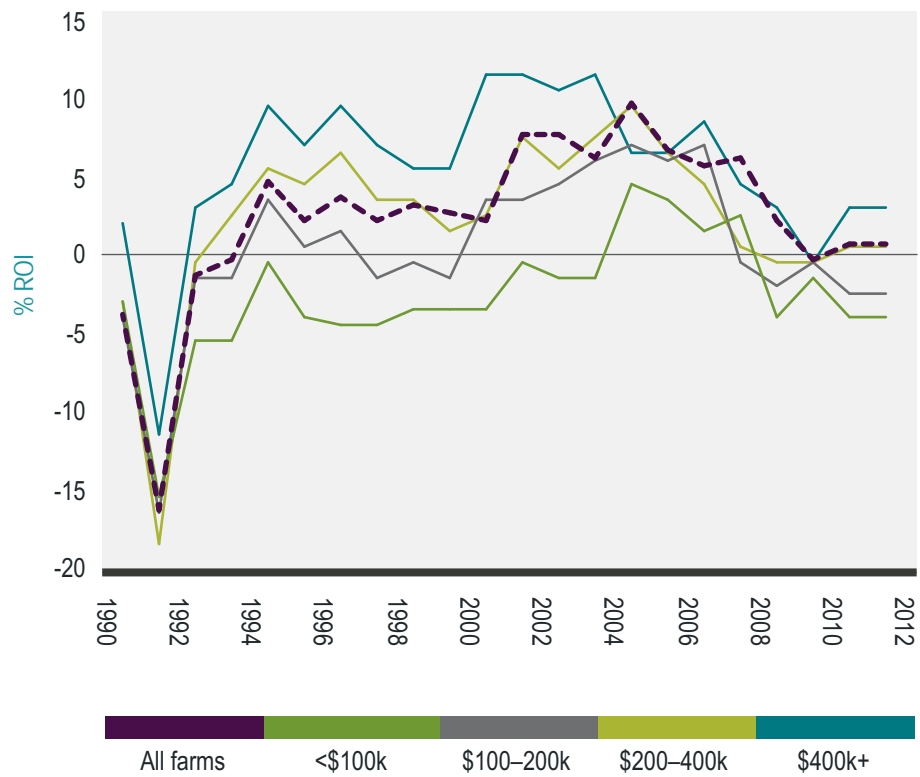


Number of farm business, Australia

¹ As part of the process of developing this corporate plan, the APVMA Advisory Board convened a Futures Forum in late 2014 to identify key themes across the operating environment. Presentations by Mr Mick Keogh of the Australian Farm Institute and Mr Matthew Phillips of Phillips McDougall Ltd. were the source of the statistics and diagrams used in the 'Operating Environment' section of this plan. Presentations by all the speakers at the forum can be viewed on the APVMA website at www.apvma.gov.au/node/11191.



Broadacre farm numbers and output



Farm performance by farm size

Productivity in Australian agriculture is growing at 0.2 per cent per annum (1994 to 2011), and return on investment is tightening.

While Australian agricultural exports have been growing, growth in exports from the rest of the world into major markets has been growing more strongly. Major Asian importing countries are importing the majority of their agricultural produce from the Americas.

A key focus for Australian agriculture is to improve productivity to take advantage of domestic and international opportunities.

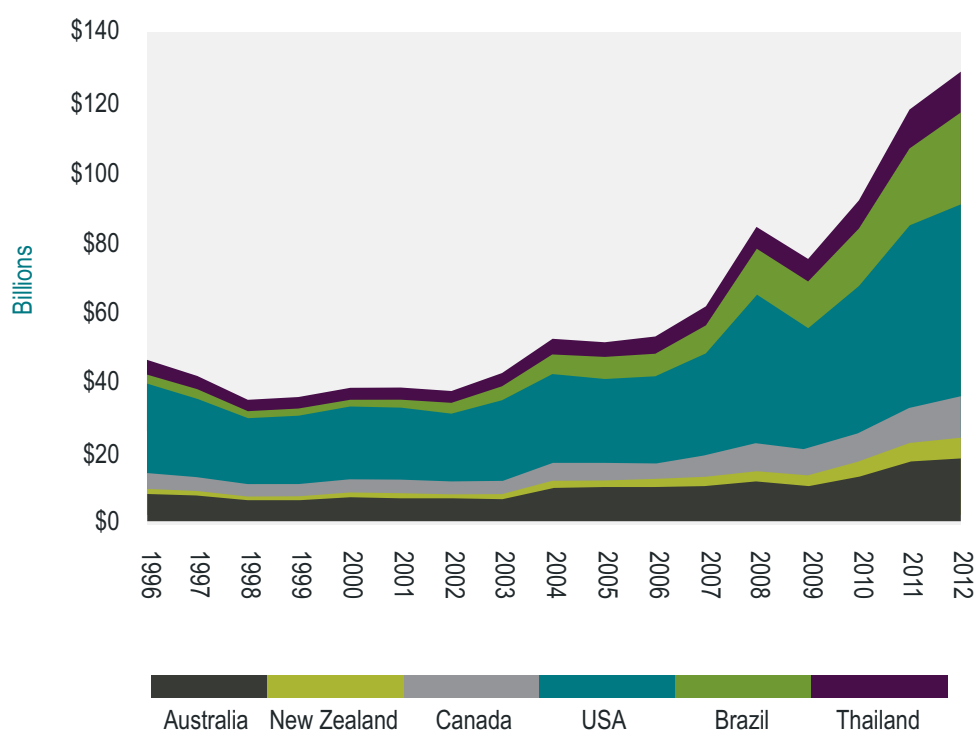
Optimising inputs and getting access to new technologies and systems will be essential to sustain future agriculture sector growth.

Given that the cost of chemicals (including fertilisers) is about one quarter of all crop input costs, the APVMA has a key role to play. It must ensure its approach to regulation provides timely access to chemicals by the agricultural sector, particularly if those chemicals are already available in competitor countries.

AGVET CHEMICAL INDUSTRY

The international market for crop protection products is growing at 2.6 per cent with Asia, Europe and the Americas the major markets. Behind that growth are some key trends of direct relevance to Australia.

For some time the international industry has been going through a period of



Source of agricultural imports, major Asian importers*

*China, India, Indonesia, Japan, Korea

Source: UN Comtrade

consolidation. This means that fewer companies are involved in research and development and, crucially, decisions about investment in research and development specific to Australia are increasingly made by parent companies based in Europe or the United States.

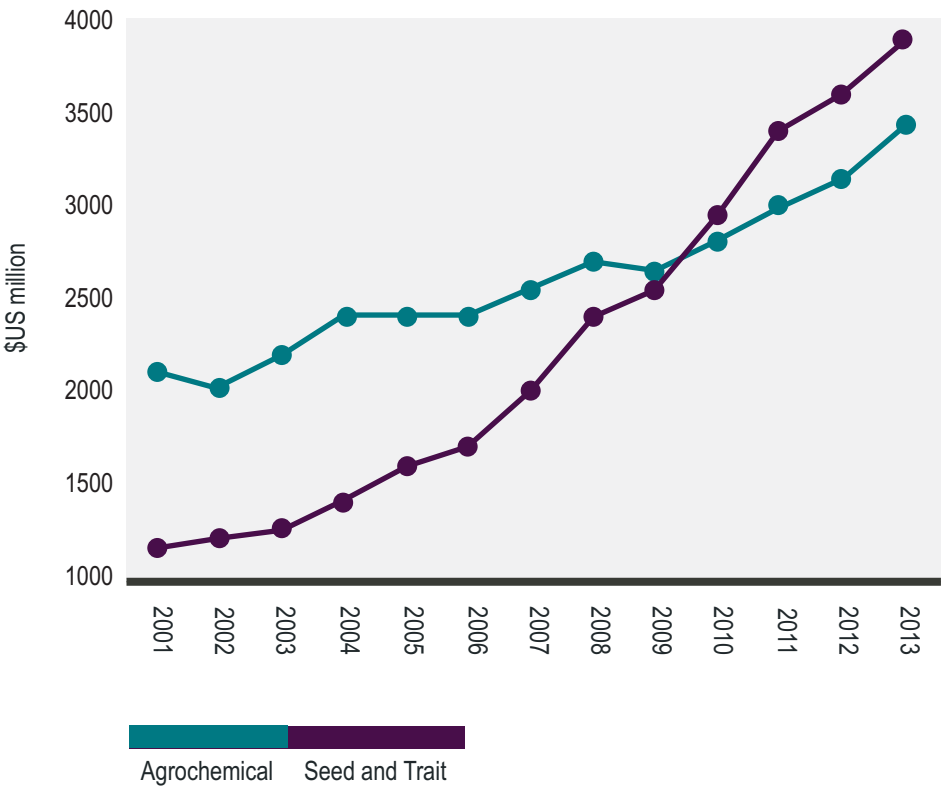
This trend toward globalisation also means that manufacturing and distribution networks are complex and often span many countries and players. The rise of electronic commerce, too, has made it easier for Australian consumers to access chemicals in use overseas which may not be registered here.

A significant international trend has been the decline in active ingredient introductions since the 1980s.

In a context where it can cost up to \$250m to bring a new product to market, research and development budgets in recent years have focused on genetically modified and biological controls as much as the traditional chemical technologies. Biological controls such as bio-insecticides and bio-herbicides, operating individually or in combination with existing chemical solutions, are increasingly being developed.

Herbicides and insecticides are the largest categories of agricultural chemicals available in Australia. For veterinary medicines, it is parasiticides and nutrition and metabolism products.

The Australian market is very small in international terms, and the APVMA



Agrochemical and Seed and Trait sales

plays but a small role in the supply chain of getting a new product to market. Nonetheless, it is the APVMA's responsibility to respond to any application in a manner that is timely, science based and proportionate to the risk being managed. That may mean the use of international data, assessments and standards, if applicable.

Given the importance of getting a product to market to meet seasonal demands, the APVMA's assessment process must be efficient, predictable and transparent.

The APVMA must also have more sophisticated compliance and monitoring strategies in place to deal with the global movement of chemicals.

COMMUNITY EXPECTATIONS

The Australian community derives many benefits from the use of agvet chemicals. The most obvious is increased agricultural productivity but others include protection from pests and diseases and the wellbeing of companion animals.

In enjoying those benefits, the community has certain expectations of the APVMA as the agvet chemical regulator. Even if some do not know its name, there is an expectation that it will act as an active gatekeeper ensuring that only those products that are safe are approved.

There are many players in the regulation of agvet chemicals in Australia, all with different roles. Even though the APVMA is responsible for one part of the national regulatory system, the community often attributes all agvet chemical issues to the APVMA. As a

regulator, it is important that the APVMA clearly communicates its area of responsibility to ensure the integrity of the regulatory system is maintained.

DEREGULATION AND PUBLIC ADMINISTRATION

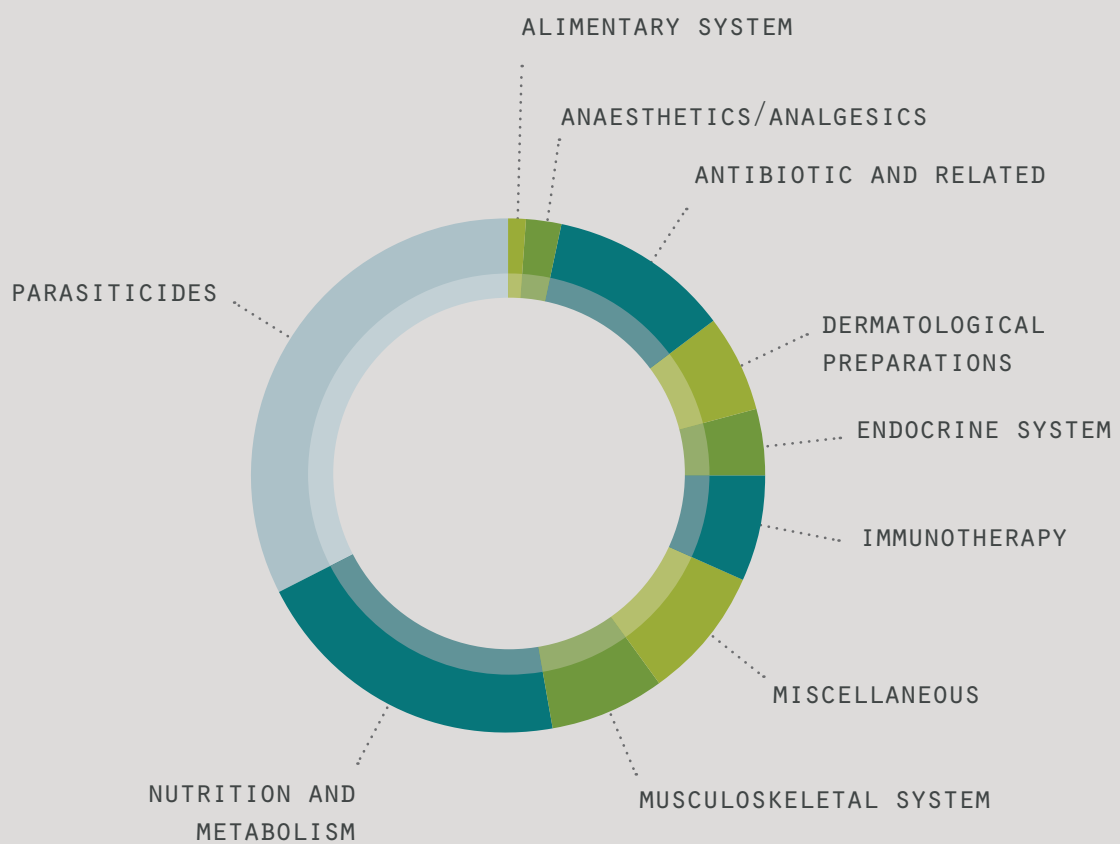
The government has a deregulation agenda that aims to increase productivity and competitiveness by reducing the regulatory burden on business, community organisations and individuals.

As a regulator of over 900 businesses that collectively sell over \$3 billion of product each year, the APVMA has the potential to reduce the regulatory costs faced by these companies in bringing their products to market. The key cost-reducing opportunities are improving our administrative processes and changing the way we approach risk.

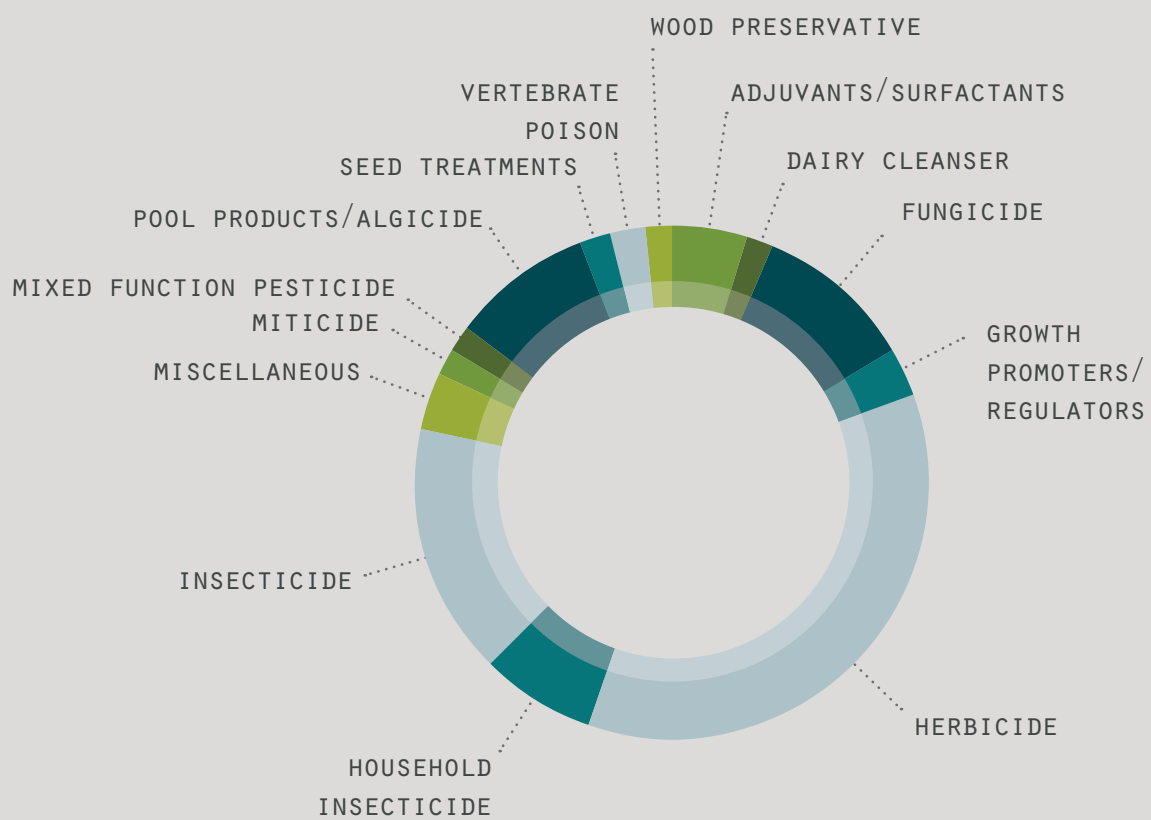
A review of APVMA registration business processes identified a range of areas for improvement. These included developing a proportionate risk assessment framework; stronger management and coordination of registration processes; better stakeholder contact; quality assurance; capability development and business performance.

Many initiatives to improve administrative processes and address the review findings require considerable upfront investment, particularly for IT systems and capability development. As a fully cost recovered agency, there are competing pressures to deliver more predictable and timely decisions while channelling limited resources to key areas of investment. This pressure is driving a fundamental change in how we approach our business.

SNAPSHOT OF AGVET CHEMICALS AVAILABLE IN AUSTRALIA
TOTAL PRODUCTS (AS AT 30 JUNE 2014)



VETERINARY MEDICINES



AGRICULTURAL CHEMICALS



STRATEGY ONE

BETTER REGULATORY DECISION MAKING

Improving the efficiency and predictability of the registration and approval processes will be a key focus of the APVMA. Companies need to know when to expect decisions so necessary planning can occur to bring the product to market.

Missing deadlines can result in considerable delays for companies and may also mean that Australian farmers are denied access to the chemicals they need for another season. We will reform our business processes to meet the expectations of government and industry and deliver on our statutory obligations.

Not all agvet chemicals are the same and they should therefore not be treated the same in a regulatory sense. We will build an overarching risk assessment framework that explains to applicants, industry and the public the rationale and approach adopted in arriving at risk-based decisions. This framework will deliver more proportional and effective regulatory responses, including more streamlined interventions for products of lower regulatory risk.

There are many pressures on the APVMA in its decision-making. The key to maintaining confidence in Australia's regulatory system is ensuring decisions are evidence-based and reflect contemporary science.

Regulatory science is a highly specialised field. APVMA scientists are qualified in a wide range of conventional scientific fields and undergo intensive training in how to apply that scientific knowledge to making a decision about whether to allow an agvet chemical to be registered—decisions that need to be made within a legislative

framework and often with less than complete information. A thorough understanding of risk assessment and risk mitigation is critical.

The APVMA will put in place a range of strategies to continuously improve its scientific capability and look to form partnerships with scientific institutions and other regulators to improve its approach to regulatory science.

WE WILL MEASURE OUR SUCCESS BY:

Regulatory decisions being completed within timeframes

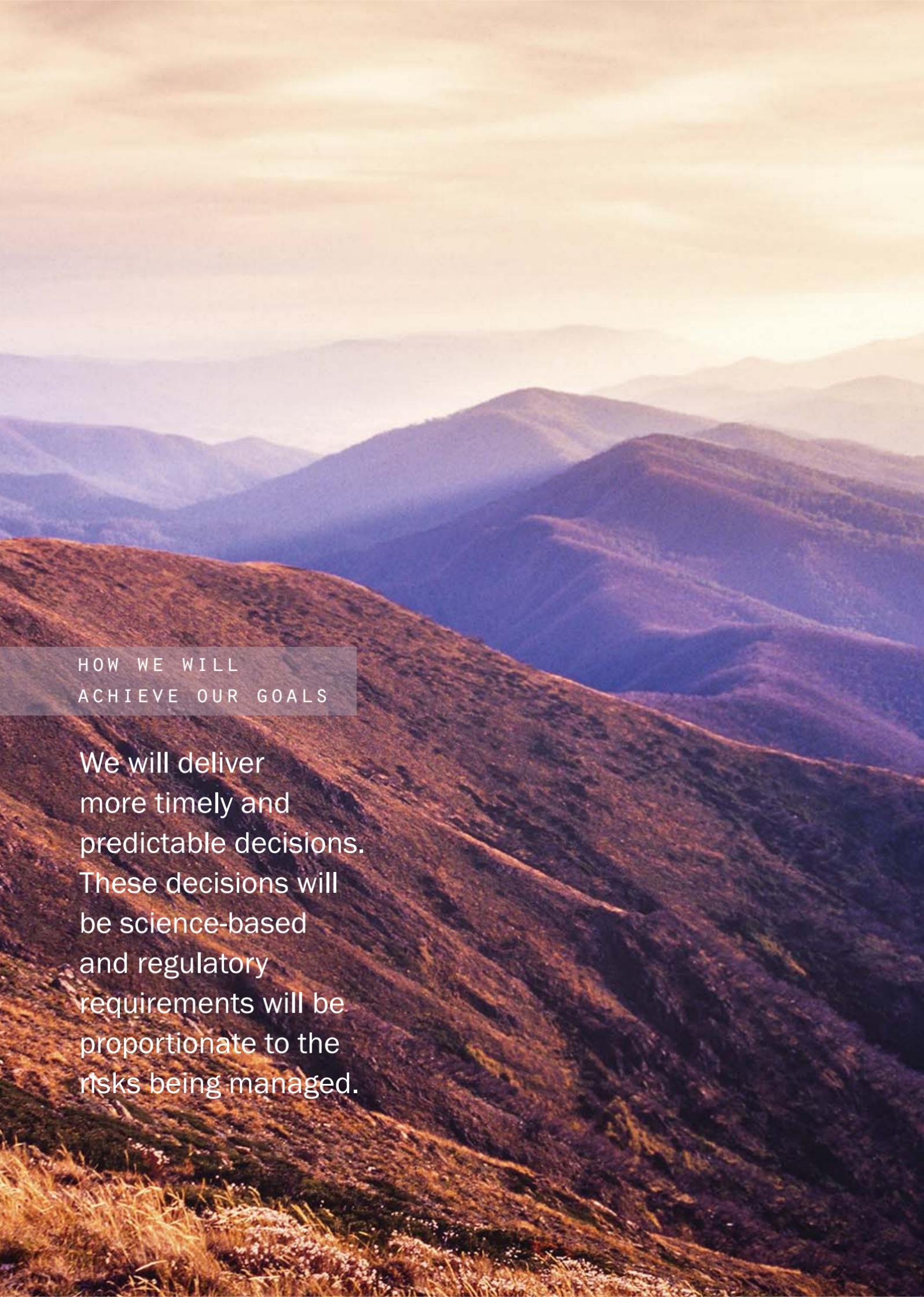
- Percentage of applications completed within timeframes
- Percentage of compliance and enforcement activities completed within timeframes.

Actions undertaken being proportionate to the regulated risk being managed

- Risk management frameworks and policies are in place and regularly assessed
- Lower regulatory effort is applied to activities of lower regulatory risk
- Compliance and enforcement strategies are consistent with agreed risk management policies.

Regulatory science underpinning quality regulatory decision making

- Improvements in regulatory science capability are consistent with agreed priorities and strategies.



HOW WE WILL
ACHIEVE OUR GOALS

We will deliver more timely and predictable decisions. These decisions will be science-based and regulatory requirements will be proportionate to the risks being managed.



STRATEGY TWO

REDUCE REGULATORY BURDEN ON INDUSTRY

The way a regulator implements and enforces its legislation can make a significant difference to the potential burden industry might face. The APVMA does not set the regulatory framework for agvet chemicals. Its role is to implement the legislation and associated regulations. A thorough understanding of the possible impact on the operations of the regulated sector is, therefore, important.

We will review all current requirements placed on industry to ensure they are justifiable and, where possible, streamline requirements to reduce compliance costs. We will ensure the impost on industry is taken into account when designing new requirements. We will ensure requests for information are necessary and that any information obtained is acted upon.

Compliance and monitoring are an important part of the APVMA's functions, and there are a range of treatments that can be taken in response to potential breaches of the regulations. We will develop a compliance and monitoring framework that recognises the risks that are being managed, while focusing on those areas which have the greatest potential to undermine the integrity of the Australian regulatory system.

Maintaining confidence in the regulatory system by government, industry and the community is critical to the success of the APVMA. We are committed to being open and transparent, and will publish key documents, policies and guidelines to ensure the regulated industry clearly understands their obligations. We will also regularly publish statistics so government, industry and the general public can assess our performance against key measures.

The APVMA is committed to ensuring agvet chemicals are available for use in Australia at, or near, the same time they are available in other countries.

The increased adoption of international risk assessments and standards presents a significant opportunity to reduce the burden on industry and get chemicals into Australia faster. Australia does have some key differences to overseas countries, especially in terms of our environment, farming systems and trade. This means that there may be limits to the extent to which some assessments can be adopted. We will employ a framework that will specify when international assessments and standards can be used, clearly stating when and why Australian specific requirements are necessary.

WE WILL MEASURE OUR SUCCESS BY:

Unnecessary impediments to the efficient operation of regulated entities being removed

- Demonstrated understanding of the operating environment for the regulated entities
- International data guidelines, standards and assessments adopted to reduce effort to register agvet chemicals
- Efficient and effective APVMA business processes.

Compliance and monitoring approaches being streamlined and coordinated

- Monitoring and enforcement strategies allow for a range of regulatory responses
- Compliance activities are responsive to business needs of regulated entities, where relevant
- Information requested from regulated entities is necessary and acted upon.



HOW WE WILL
ACHIEVE OUR GOALS

We will reduce compliance costs to business in dealing with the APVMA.
We will ensure our requirements are justifiable and understood.



STRATEGY THREE

SERVICE DELIVERY AND CONTINUOUS IMPROVEMENT

As a regulator, we make decisions that impact on many companies and, potentially, on many people on a daily basis. This carries with it a responsibility to ensure that the services we provide are as efficient and effective as possible.

In designing our service delivery, we will adopt as many of the preferences of our clients as are consistent with our legislative obligations. We understand, for example, that our clients value consistent decision-making, simplified requirements, accessible information, proportionate enforcement and APVMA staff that understand the impacts of regulation.

Consistent with these preferences, we will commit to develop appropriate technological tools that reduce costs and improve services, and allow clients to easily interact with the APVMA.

We will provide face-to-face contact with applicants, particularly in the planning phase of new applications where it is critical both parties understand the proposed use of a chemical and the necessary requirements to meet statutory criteria.

We will commit to effective communication as a corner stone of our service delivery practice. We will ensure that the regulated sector has access to quality guidance material written in business friendly language, and that it clearly understands what is required to comply with regulation.

We will ensure that reasons for regulatory decisions are clearly communicated.

We will consider the impact of any changes to operational policies and practices on the regulated sector and will engage with industry groups and representatives prior to making any changes.

The APVMA will actively seek advice from the regulated sector on ways that service might be improved. The APVMA will also openly engage with the regulated sector on the development of technical policy and guidelines.

WE WILL MEASURE OUR SUCCESS BY:

Communication with regulated entities being clear, targeted and effective

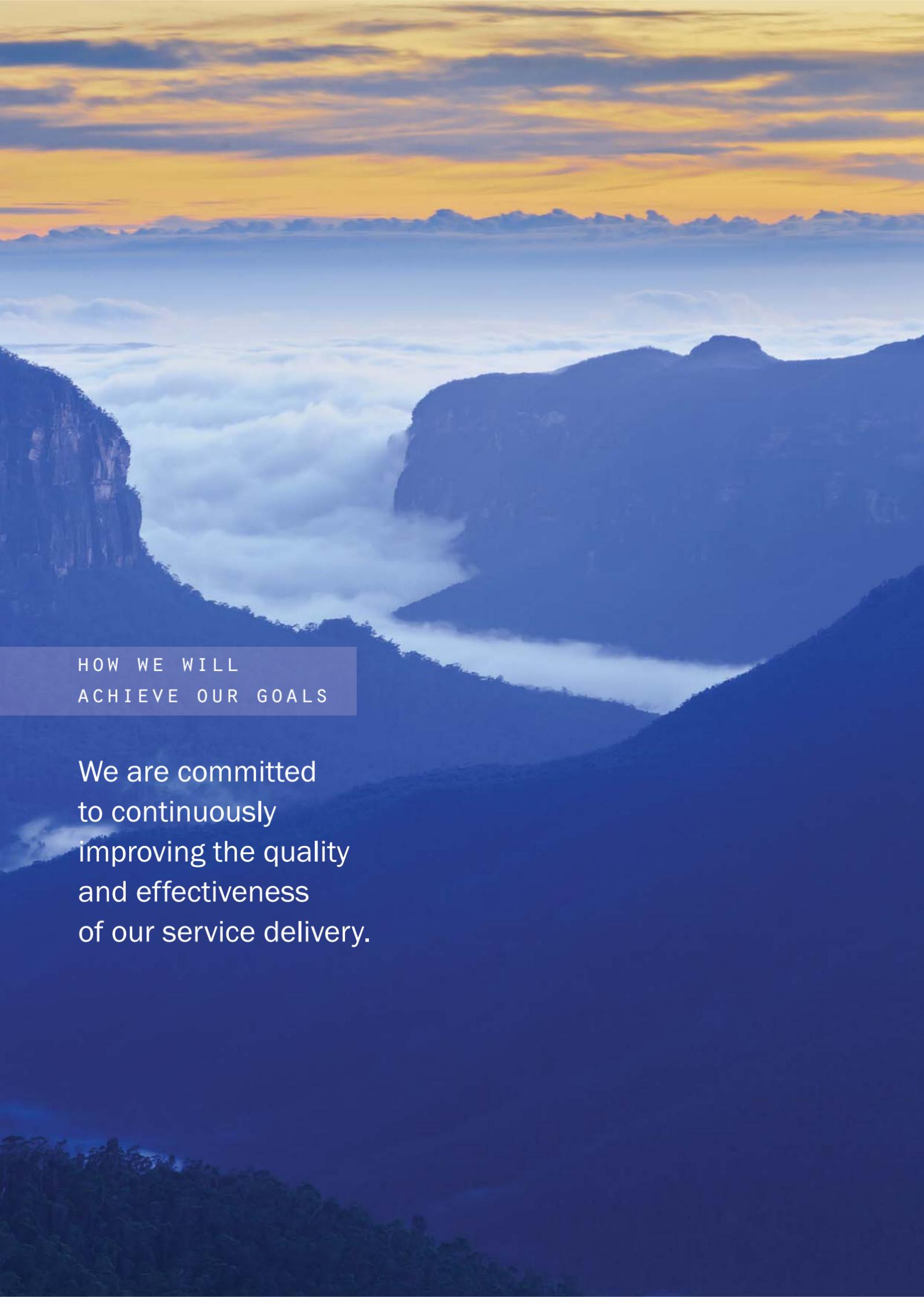
- Level of satisfaction with information and guidance materials
- Level of satisfaction with the quality and timeliness of advice on decisions
- Extent and satisfaction with APVMA consultative processes.

Active contribution to the continuous improvement of regulatory frameworks

- Level of stakeholder engagement in implementing regulatory frameworks
- Feedback is provided to inform the development or amendment of regulatory frameworks.

Openness and transparency in dealings with regulated entities

- Performance information is published
- Feedback mechanisms are in place and used to improve service delivery to regulated entities.



HOW WE WILL
ACHIEVE OUR GOALS

We are committed
to continuously
improving the quality
and effectiveness
of our service delivery.



STRATEGY FOUR

HIGH PERFORMANCE ORGANISATION

The APVMA is staffed by a team of highly qualified people dedicated to ensuring agvet chemicals are safe to use. This commitment is accompanied by a willingness to challenge ourselves and continually improve what we do.

Underpinning the APVMA's ambition to be a high performance organisation is a commitment to:

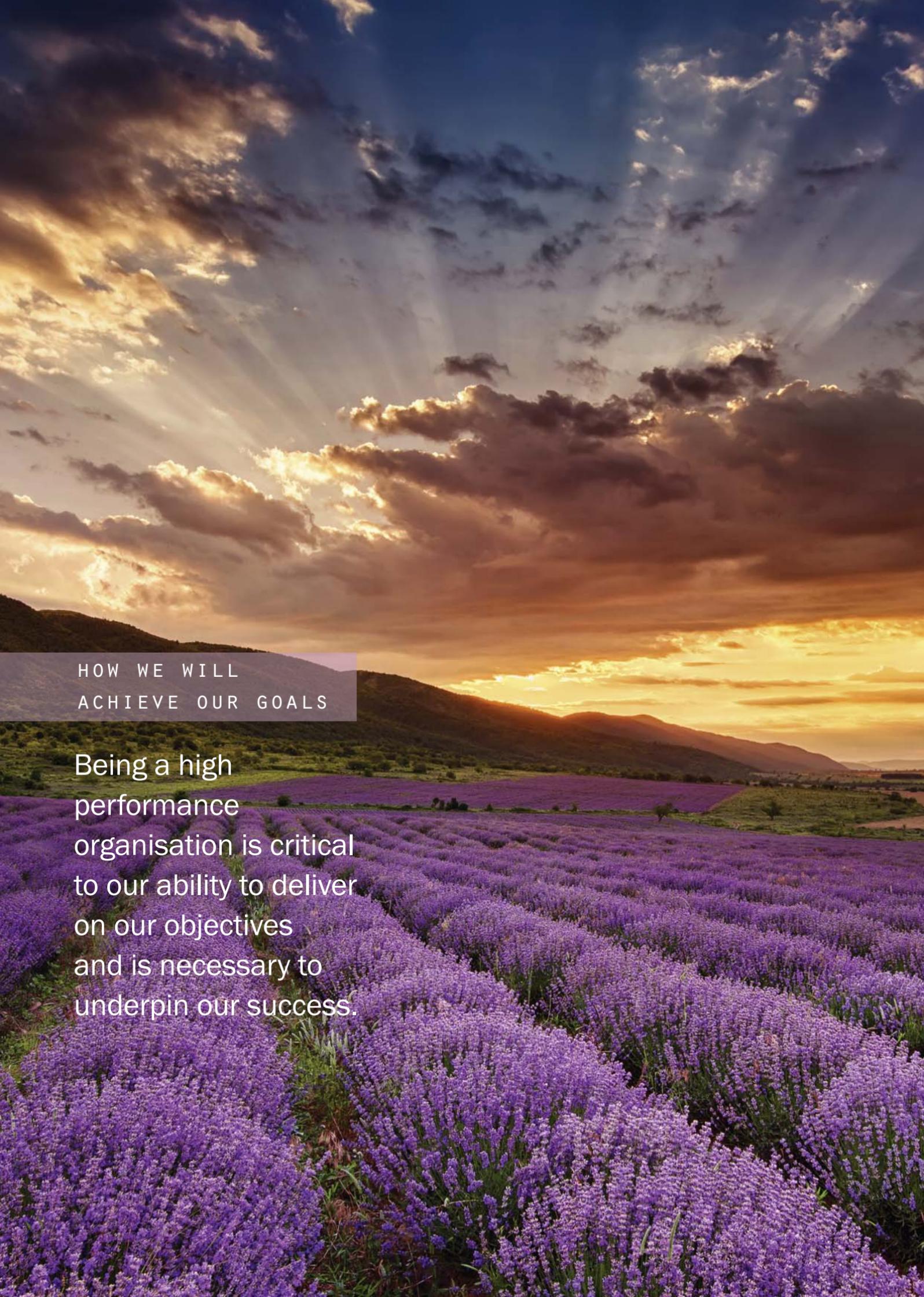
- leadership development
- clear roles, responsibilities and accountabilities
- attracting, developing and retaining highly skilled people
- a culture that promotes teamwork and continuous improvement in achieving our goals.

Being a fully cost-recovered agency, the APVMA seeks to manage its finances to minimise the financial impact on industry, without compromising our ability to deliver our legislative obligations and maintain financial sustainability.

WE WILL MEASURE OUR SUCCESS BY:

Level of organisational health and financial viability

- APVMA workforce is motivated and skilled
- Efficient and effective business processes and financial management systems in place
- Information technology supports information management, staff capability and service delivery.



HOW WE WILL
ACHIEVE OUR GOALS

Being a high performance organisation is critical to our ability to deliver on our objectives and is necessary to underpin our success.

UNDERPINNING OUR SUCCESS

RESOURCES

The APVMA is a cost-recovered agency. Registrants pay application fees to register new products and active constituents, amend a current registration, or apply for a permit. An annual fee is payable each year to renew the registration of a product. Registrants also pay an annual levy based on the sales (and other disposals) of their products.

Levies are imposed under the *Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994*, the *Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994* and the *Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994*. Levies are collected under the *Agricultural and Veterinary Chemical Products (Collection of Levies) Act 1994*. Levy rates are prescribed in the Regulations to this Act.

WORKFORCE CAPABILITY

The APVMA continually reviews its human resource capabilities to ensure that our staff have the right skills for the challenges that the regulation of new and emerging technologies pose to the organisation.

There will be a strong focus on ensuring strategic alignment of the human resource capability with the organisations overall objectives and to build capability and expertise where

gaps are identified especially within the various scientific streams required by the organisation.

We will continue to deliver comprehensive professional development programs to ensure our staff can deliver best practice regulation.

IT STRATEGY

The APVMA will continue to develop both its internal and external information technology capabilities. The focus will be on establishing web-based technology platforms that enable easier interactions with our stakeholders, decommissioning aging legacy systems and increasing business continuity and disaster recovery capabilities.

The new and enhanced internal capabilities will increase productivity using state-of-the-art electronic information management technology for processing applications and improved reporting on timeframes and organisation performance.

The external system capabilities will utilise industry-recognised user interfaces to simplify the registration process for applicants and provide advanced tracking and engagement capabilities. There will continue to be a strong focus on the use of mobile technologies to deliver the information that clients need irrespective of the technology platform or device used by our stakeholders.

Significantly improved business continuity and disaster recovery will be achieved through relocating critical



infrastructure to a secure, government accredited data centre and integrating approved cloud-based services and platforms where they are appropriate.

OUR GOVERNANCE

RISK OVERSIGHT AND MANAGEMENT

The APVMA wants to be recognised both nationally and internationally as a best practice regulator of pesticides and veterinary medicines, with the respect and confidence of governments, the community, the rural sector, chemical users and the chemical industry. It can only achieve this if the risks facing the organisation are also managed in accordance with best practice.

The APVMA's Senior Leadership Team meets on a regular basis to ensure that all risks facing the organisation are identified. These risks are assessed and scored. For high and unacceptable risks, treatments are developed and controls are documented. The risk treatments are regularly monitored to ensure they are implemented.

The APVMA also has a Fraud Control Plan, a quality management system (QMS) accredited against AS/NZS ISO 9001:2008 to ensure that legislative obligations are met and an Audit Committee.

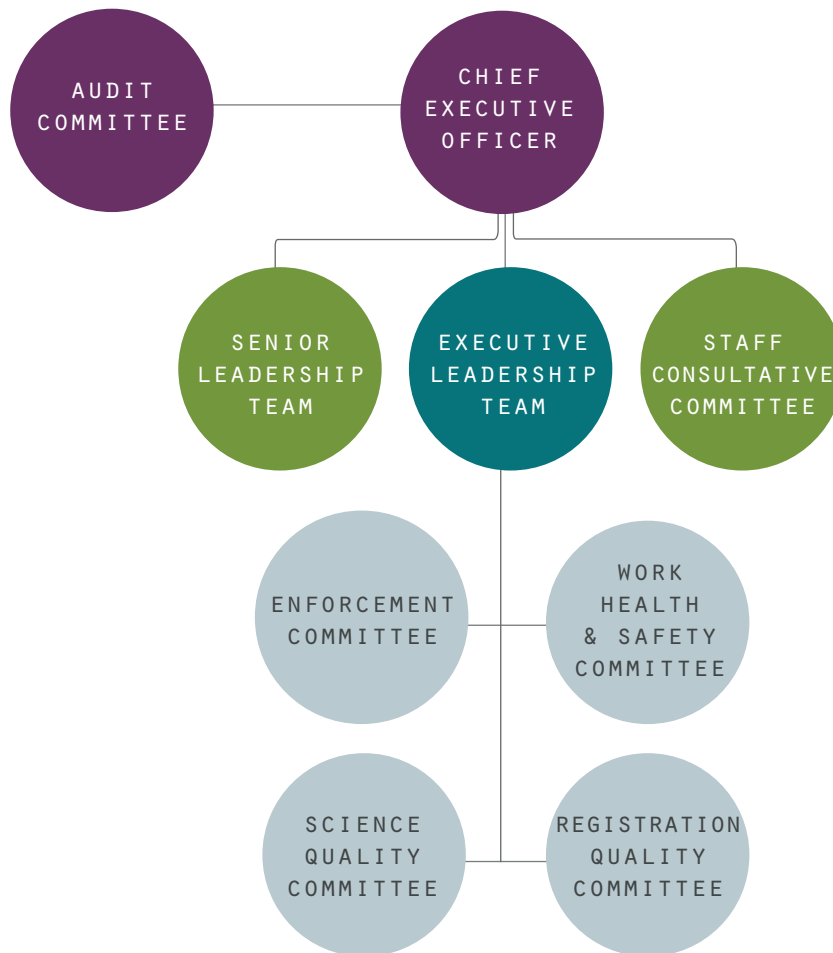
GOVERNANCE STRUCTURES

AUDIT COMMITTEE

The committee is a sub-committee reporting to the CEO to assist the Chief Executive Officer discharge its responsibilities under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Public Governance, Performance and Accountability Act 2013* in respect of financial reporting, performance reporting, risk oversight and management, internal control and compliance with relevant laws and policies. The committee is not responsible for the executive management of these functions.

EXECUTIVE LEADERSHIP TEAM

The Executive Leadership Team provides strategic, whole of organisation advice to the CEO to ensure effective decision-making, management and oversight of the department's operations and performance.



GOVERNANCE STRUCTURES

SENIOR LEADERSHIP TEAM

The Senior Leadership Team is a forum for sharing information, identifying opportunities for cross-agency collaboration, identifying areas for innovation and performance improvement, leadership development, and providing advice on organisational risk.

STAFF CONSULTATIVE COMMITTEE

The Staff Consultative Committee provides a forum to ensure that staff are appropriately consulted in relation to significant decisions that may affect the workplace.

WORK HEALTH AND SAFETY COMMITTEE

The Work Health and Safety Committee provides a framework to allow workers to be consulted on significant WHS decisions that affect their working lives.

ENFORCEMENT COMMITTEE

The Enforcement Committee provides oversight for critical decisions on compliance and enforcement matters.

REGISTRATION QUALITY COMMITTEE

The Registration Quality Committee oversees quality assurance and the administration of registration decision making to ensure decisions are consistent, timely, transparent and predictable.

SCIENCE QUALITY COMMITTEE

The Science Quality Committee is a forum to foster scientific excellence in the APVMA, enable debate of APVMA scientific issues and approve and prioritise proposals for the development or adoption of scientific methodology or standards by the APVMA or partner agencies.



CONTACT US

More information about the APVMA and how it discharges its important national role can be found in the government's Portfolio Budget Statement, our annual report and corporate plan. The latter documents can be found on the APVMA website at www.apvma.gov.au and the portfolio budget statement on www.daff.gov.au.

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