



Australian Government  
Australian Pesticides and  
Veterinary Medicines Authority



# OVERVIEW OF APVMA OPERATIONS AND FUTURE DIRECTION

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A TOOL FOR BUSINESS REFORM  
JANUARY 2012



This is an APVMA publication released to support the delivery of the Australian Government's Better Regulation Reform Agenda.

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# CHAPTER 1

# INTRODUCTION

## 1.1 Background

Agricultural and veterinary chemicals (agvet chemicals) are important in the management of pests and plant and animal diseases in Australia. Primary producers, pest controllers, home gardeners, householders and pet owners all depend on the effectiveness and safety of agvet chemicals. The Australian public rely on the correct use of these chemicals for reliable access to safe and high quality food for themselves and their families. Agvet chemicals registered for use in Australia provide many benefits, and Australians have an expectation their use will be safe and effective and not have unintended harmful effects. Similarly, people in other countries who buy Australia's agricultural produce need to be confident that agvet chemicals have been properly regulated and will not contain unacceptable levels of residues or contaminants.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government agency that assesses agvet chemicals to ensure those that are offered for sale are effective and can be used safely. It works with other Commonwealth and state agencies to ensure that only those chemicals assessed to be safe to people, animals and the environment and that do not prejudice trade with other countries are permitted in the Australian market.

As part of its Better Regulation Reform agenda in 2011 the Australian Government decided to introduce a range of reform measures aimed at providing a more efficient and effective regulatory system for agvet chemicals, with improvements to the governance framework and operational activities of the APVMA<sup>1</sup>. The reforms set out in the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011 will reduce the regulatory burden on business, while continuing to protect human health and the

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<sup>1</sup> Further information is available from the Department of Agriculture, Fisheries and Forestry website at [www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals](http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals)

environment. A new system of periodic assessment of agvet chemicals aims to ensure that chemicals in the marketplace can continue to be safely used and be effective. Other reforms target administrative aspects of the APVMA's activities and will improve timeliness and predictability of approvals, registrations and chemical reviews. A comprehensive risk framework (known as the *APVMA Risk Compendium*)<sup>2</sup> will describe the governance and operational activities of the APVMA and will contribute to the consistency, transparency and predictability of the APVMA's core activities. The reforms also extend and modernise the range of enforcement tools available to the APVMA so that responses to non-compliant activities and the associated penalties can be tailored to the seriousness of an offence.

## 1.2 Purpose

This document provides an overview of the current operations of the APVMA and how the reform agenda will transform those operations. The document forecasts how the APVMA will conduct its business under the proposed legislative framework and provides context to enhance consultation on the Australian Government agvet chemical reforms. The document describes:

- the legislation that underpins the roles and operations of the APVMA
- the regulatory responsibilities of the APVMA, including the range of chemicals it regulates and the operational arrangements through which it administers these responsibilities for
  - granting approvals and registrations
  - continuation of approvals and registrations
  - reconsideration of approvals and registrations
  - issuing permits
  - licensing manufacturers of veterinary chemicals
  - compliance and enforcement
- the governance of the APVMA including arrangements for
  - management and oversight
  - accountability and reporting
  - financial governance and budgeting
  - human resources
  - stakeholder engagement and consultation.

## 1.3 Scope

This document provides an introduction to the suite of reforms that will transform the operations of the APVMA and give effect to the Australian Government Better Regulation Reform agenda. This summary document provides context for a range of reform documentation that will be published to establish the operational context of the changes proposed under the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011.

The document introduces the *APVMA Risk Compendium* and is intended to assist stakeholders to engage and participate in the consultative process of reforming APVMA operations and business improvement.

<sup>2</sup> See Appendix 1 for further details

Additional documents that describe the detailed operations of the APVMA and how specific components of the reform will be given operational effect are being developed within the APVMA's *Risk Compendium* (see Appendix 1).



# CHAPTER 2

## GOVERNING LEGISLATION

The regulation of agvet chemicals in Australia takes place through an integrated national risk management scheme known as the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). Within this scheme the Commonwealth and the states and territories share responsibility for the regulation of agvet chemicals (further information about the scheme is provided in Appendix 2).

The *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) sets out the APVMA's role as an independent statutory authority for undertaking the responsibilities conferred on it by the states and territories under the NRS. The Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) prescribes the operational parameters of the APVMA, including provisions for the evaluation, registration, variation and control of agvet chemicals and the issuing of permits. These two pieces of primary legislation (and some associated Acts and Regulations) give effect to an Inter-governmental Agreement between the Commonwealth and states and territories that established a national regulator of agvet chemical products.

Within the NRS the APVMA has responsibility for the regulation of agvet chemicals up to and including the point of retail sale. The states and territories are responsible for the regulation of agvet chemicals after retail sale, including chemical use.



# CHAPTER 3

## ROLES AND RESPONSIBILITIES OF THE APVMA

### 3.1 Chemicals that the APVMA is responsible for regulating

The APVMA regulates manufactured agvet chemicals as well as products or substances based on natural extracts and biological materials. The scope of chemicals the APVMA regulates is quite broad and is defined by the Agvet Code<sup>3</sup>. The following are some examples of chemical products that fall within the scope of these definitions:

- Agricultural chemical products—insecticides, fungicides, herbicides, swimming pool sanitisers, certain disinfectants and sanitisers, marine anti-fouling compounds, snail baits and other chemicals that destroy or control pests. These are commonly referred to as pesticides or biocides.
- Veterinary chemical products—vaccines, antibiotics, products for control of internal and external parasites of animals, stock dips, animal liniments and wound dressings, some vitamins and minerals and other chemicals that have a therapeutic effect on animals or that affect the physiology or behaviour of animals. These are commonly referred to as veterinary medicines.

Although these terms apply to products used in primary industry, they also apply to products used in commercial, industrial, home garden or domestic situations. Therefore, products such as household fly

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<sup>3</sup> Section 4 of the Agvet Code defines an agricultural chemical product, and section 5 of the Agvet Code defines a veterinary chemical product.

sprays and products used on companion animals are within the APVMA's scope of regulation. Fertilizers and unmedicated stockfoods are not within the scope of the Agvet Code as they do not fit the definitions of agricultural or veterinary chemical products in the Agvet Code.

Some products are declared to be included within the definition such as personal insect repellents, on-farm dairy cleansers and veterinary probiotics. Similarly, some types of products that would ordinarily fit the definitions are declared not to be included, such as cut flower preservatives, pH adjusters for swimming pools and colour intensifiers for aviary birds. Details of included and excluded chemicals are contained in the *Agricultural and Veterinary Chemicals Code Regulations 1995* (the Regulations).

These inclusions and exclusions are necessary as the definitions of agricultural and veterinary chemicals are broad and can sometimes capture products that may not have been intended to be included in the scope of the scheme. When this occurs, the APVMA is able to seek policy guidance from the partners to the NRS. Confirmation can then be provided by amending the Regulations with specific inclusions or exclusions.

## 3.2 How the APVMA regulates agvet chemicals

The APVMA is responsible for the assessment and registration of agvet chemicals prior to sale as well as their regulation up to and including the point of retail sale. The APVMA may also issue permits to authorise the use of agvet chemicals that are not registered (for example, for research purposes) or where the use of a registered product has not been previously authorised (for example, an off-label use)<sup>4</sup>. In the case of veterinary medicines, Australian manufacturers must be licensed by the APVMA to manufacture these products<sup>5</sup>.

In meeting its obligations in the regulation of agvet chemicals, the APVMA evaluates the safety and effectiveness of chemicals that will be or are being sold or used, in order to protect the health and safety of people, animals and crops, the environment and trade. This is achieved through the consideration of regulatory proposals against a range of criteria (statutory tests) that are prescribed in the Agvet Code. The statutory tests are considered during the registration and variation of products, approval of active constituents, approval of labels, issuing of permits and during the reconsideration of an approval or registration (see Section 3.4 for further information)<sup>6</sup>. The APVMA makes all its regulatory decisions based on scientific risk assessments of information or data relating to the various criteria.

In considering a product for registration, the APVMA must evaluate and be satisfied of these legislative criteria for the active constituent (the substance that has the biological effect) as well as the formulated product. The APVMA must also evaluate and be satisfied of the adequacy of the instructions contained on the product label. Three regulatory decisions are required: approval of the active constituent, registration of the product, and approval of the label. All registered products must contain an approved active constituent and must carry an approved label. Approvals and registrations may also be subject to certain conditions that are prescribed by the Regulations or otherwise imposed by the APVMA. Examples of conditions include specifying the type of container the product must be supplied in or assigning a shelf life for the product.

The APVMA may 'reserve' products from registration, subject to conditions that the Minister for Agriculture, Fisheries and Forestry has approved and which are included in the Agvet Code Regulations<sup>7</sup>. Also, products may

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<sup>4</sup> The authority to issue permits is found in Part 7 of the Agvet Code

<sup>5</sup> The licensing of Australian manufacturers of veterinary chemical products is authorised by Part 8 of the Agvet Code

<sup>6</sup> The criteria (statutory tests) are set out in Part 2 Divisions 2, 3 and 4 of the Agvet Code

<sup>7</sup> The APVMA's authority to reserve chemical products from registration is prescribed by Part 2B of the Agvet Code

be granted 'listed registration', provided that they comply with a standard that the Minister for Agriculture, Fisheries and Forestry has approved and the chemical or class of chemical is included in the appropriate schedule in the Agvet Code Regulations<sup>8</sup>.

Similar to registration, when issuing a permit the APVMA evaluates the safety and effectiveness of the intended use pattern. In addition to instructions for product labels, permits usually contain very detailed instructions and may contain conditions limiting the quantities used, the area of treated crops or the numbers of animals treated.

The APVMA conducts reviews of existing agvet chemical products, their active constituents and labels where potential risks to safety and performance have been identified<sup>9</sup>. A review may be initiated when new research or information raises concerns about the use or safety of a particular chemical or product. In initiating a review the APVMA may require the approval holder or registrant to provide information or to conduct new scientific studies. The APVMA conducts a scientific risk assessment of the new and existing data, often in partnership with experts in other Commonwealth Departments or State Departments of Primary Industry. Depending on the conclusions reached from these risk assessments, reviews may result in an approval or registration being affirmed, cancelled or varied (including the modification of use patterns). Cancellation of product registration means that the product is no longer able to be marketed.

An important part of the APVMA's role is to ensure that when supplied to the marketplace, agvet chemicals comply with the provisions of the agvet legislation<sup>10</sup> and any conditions that have been imposed by the APVMA. These activities establish feedback loops and encourage public participation in ensuring that the chemical inventory remains safe and effective and that ongoing manufacturing activities are producing agvet chemicals of the expected high quality. Examples of these feedback loops include the Adverse Experience Reporting Program (AERP) and industry intelligence about non-compliance with manufacturing or supply standards or conditions.

Should the APVMA become aware that an agvet chemical poses imminent risk to public health or the environment, or that that conditions imposed by the APVMA have been breached, it may use enforcement provisions to stop supply of the product. This may involve suspension, cancellation and/or recall of the relevant products<sup>11</sup>. The APVMA's compliance strategies include prevention, quality facilitation and surveillance and enforcement. The aim is to maintain the quality, safety and effectiveness of all products in the marketplace.

The Better Regulation Reforms introduce new legislation to strengthen the APVMA's ability to ensure the ongoing safety of agvet chemicals by implementing a mandatory re-registration (continuation) regime that systematically assesses the entire chemical inventory for new information. Where no new information that raises concerns exists, the approvals and registrations will be continued for a specific period before they are re-examined. Where new information raises potential concerns the chemical will undergo a scientific evaluation through a chemical review. The new continuation regime therefore complements but does not replace the chemical review arrangements already in place (see Section 3.6).

## Regulatory Posture

The APVMA is developing a document that articulates its 'regulatory posture'—the manner in which the APVMA undertakes its regulatory role. In summary, the APVMA's regulatory posture is to be a 'firm and fair' regulator,

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<sup>8</sup> The APVMA's authority to grant a listable registration is prescribed in Part 2A of the Agvet Code

<sup>9</sup> The authority to conduct a chemical review is prescribed in Part 2 Division 4 of the Agvet Code

<sup>10</sup> The APVMA's requirement to ensure ongoing compliance with agvet legislation is described by Part 4 of the Agvet Code

<sup>11</sup> The authority to suspend or cancel an agvet chemical product is prescribed by Part 2 Division 5 of the Agvet Code

Reforms that align the regulatory burdens on business with risk, while ensuring the continued protection of human health and the environment.

delivering regulatory activities to protect the health and safety of people, animals and crops, the environment, and trade and to:

- make *transparent, consistent* and *predictable* science-based decisions founded on evidence
- demonstrate *fairness* and exercise good *judgement*
- be *responsive* and *innovative* to adjust to a changing operating environment
- *communicate* and *consult* extensively with stakeholders
- act *independently* and maintain the integrity of the regulatory framework
- *deliver* regulatory functions in a timely manner.

### 3.3 APVMA decision making

The APVMA uses risk analysis as the basis for its decision making. Risk analysis provides a scientific, structured, systematic and transparent methodology to guide decision-making. It allows the risks of agvet chemicals to be assessed and considered on the basis of scientific evidence within the overall context of human safety, environmental protection and trade.

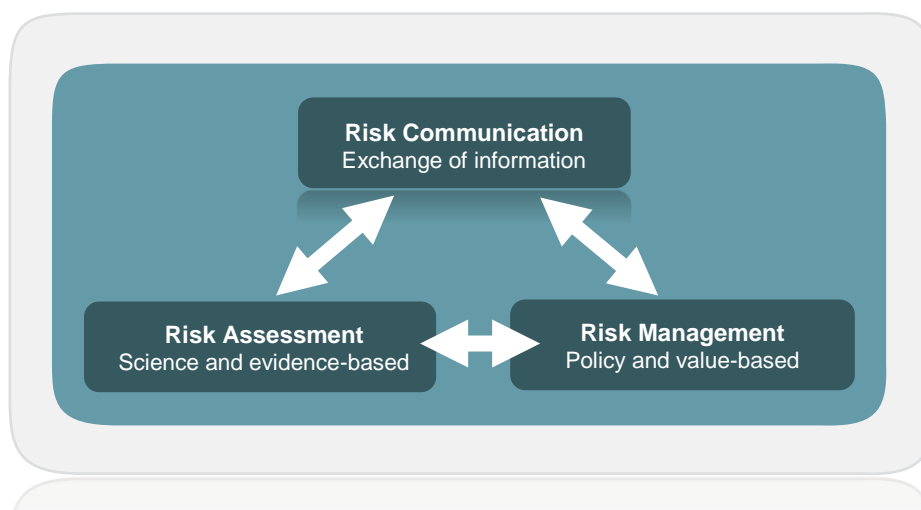
The concept of risk is at the centre of the APVMA's approach to decision-making. Risk is characterised as the combination of hazard—the potential for harm—and the period and nature of exposure to that hazard—the likelihood of harm.

Risk analysis is an investigation of hazard and likelihood of harm. It also identifies or seeks to identify appropriate risk mitigation measures to reduce this potential harm. During chemical reviews and evaluation of applications, the APVMA's risk analysis addresses risks to human and animal health, the environment and trade, as well as risks associated with product effectiveness. While the type of risk may differ in each case, the principles and broad framework for risk analysis apply to all.

The APVMA has developed and published its *Risk Analysis Framework* as a separate document<sup>12</sup>. In summary, the three distinct but interrelated components of risk analysis are risk assessment, risk management and risk communication. The inter-relationships of the three components of risk are illustrated in Figure 1 (modified from World Health Organisation).

<sup>12</sup> The *Risk Analysis Framework* is available from the APVMA website at [http://www.apvma.gov.au/consultation/docs/draft\\_risk\\_analysis\\_framework\\_20111125.pdf%20](http://www.apvma.gov.au/consultation/docs/draft_risk_analysis_framework_20111125.pdf%20)

Figure 1—the risk analysis framework<sup>13</sup>



Risk assessment identifies the hazards and exposure levels that will result from the proposed use. During risk assessment the APVMA uses experimental and other data to make conclusions about the potential risk associated with the use of an agvet chemical.

Risk management is considering the options for dealing with the identified risks and selecting management strategies to minimise the risk. This is also commonly called 'risk mitigation'.

Risk communication involves interaction between those involved in assessing risk and those managing risk, as well as providing information to the public and other stakeholders (mainly through the product label).

During its consideration of the risks associated with agvet chemicals in registration and chemical reviews, the APVMA seeks and relies on advice from relevant experts within the APVMA, in other government departments and in research organisations (see Appendix 3).

### 3.4 Legislative requirements

In considering agvet chemicals for use in Australia, the APVMA must be satisfied of certain legislative criteria set out in the Agvet Code. These criteria reflect the basic objectives the APVMA must meet to protect people, the environment, animals and trade and meet the objectives of the NRS. The criteria state that when a product is used according to the instructions contained on its label, it would:

- not be an undue hazard to the safety of people exposed to it during prescribed handling or to people using anything containing its residues
- not be likely to have an effect that is harmful to human beings
- not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment
- not unduly prejudice trade or commerce between Australia and places outside Australia, and
- be effective according to the criteria determined by the APVMA for the particular product.

The Agvet Code also requires that the APVMA ensure that the product label contains adequate instructions for the safe and effective handling and use of agvet chemicals.

<sup>13</sup> The original version of this diagram can be found at [www.who.int/foodsafety/micro/riskanalysis/en/](http://www.who.int/foodsafety/micro/riskanalysis/en/)

As part of the Better Regulation Reform agenda, the Australian Government decided that the trade and efficacy criteria should be considered as optional criteria in certain circumstances. This amendment will apply to active constituent approvals, registrations, permits and chemical reviews. The *Risk Compendium* will prescribe the particular circumstances in which these criteria will or will not need to be considered. As a transparency measure, the APVMA will also publish principles used to determine the relevance of these matters in the *Risk Compendium*.

### An example of the application of these new arrangements

The trade criterion would always be considered to be relevant for products that are applied to food-producing animals and food or fibre crops or commodities that are traded internationally. The trade criterion would not be considered relevant for products that are used only for companion animals or ornamental plants as such uses do not result in produce that is traded internationally or pose a risk to international trade.

## 3.5 Registration and approval

### Scientific considerations

The APVMA receives applications for approval of active constituents for use in chemical products, registration of chemical products, approval of labels for chemical products, and changes to these registrations and approvals. The statutory tests of the Agvet Code (refer to criteria at Section 3.4 of this document) establish the criteria by which the APVMA must assess each application. If the APVMA is not satisfied that an application and/or product complies with all the relevant criteria it refuses the application.

The APVMA provides written guidance on the types of data and information that may be required for each type of application. This information is available on the APVMA website.

Each application must contain sufficient information for the APVMA to undertake an evaluation that allows it to be satisfied that the product or active constituent when used as proposed will comply with the relevant criteria.

Applications are assessed by APVMA scientific staff. Where appropriate, the APVMA seeks specialist advice from Commonwealth, state and territory agencies and other relevant domestic and international organisations.

In determining whether it may be satisfied of the statutory criteria, the APVMA must have regard to:

- active constituent and product quality
- toxicity of the active constituent and product and its residues and the effect on humans, other organisms and the environment
- health standards and dietary exposure assessments
- results from product effectiveness trials
- any other matters considered relevant or prescribed in legislation or Regulations.

As part of the Better Regulation Reform agenda, the Australian Government decided to enhance the consistency, efficiency, effectiveness and transparency of the registration and approval processes through the publication of the *Risk Compendium* (see Appendix 1). This collection of documents will enable the APVMA, its regulatory partners and the agvet industry to have a common understanding of the data requirements, processes used by the regulator. This will improve predictability and enhance the quality of applications submitted to the APVMA.

The *Risk Compendium* will include a Registration and Approval Framework (to be developed) that will describe the principles that underpin registration and approval decision making in more detail. For example, the Australian Government decided that consideration of the prejudice to trade and efficacy criteria in certain circumstances would be optional (as described in Section 3.4 above). It has decided to make some of the matters that are considered by the APVMA in addressing the statutory criteria optional, including some dietary standards, assessment of product residues against established limits, product stability and container specifications. The *Risk Compendium* will clarify the specific circumstances when these considerations will and will not be relevant.

The APVMA will also extend and formalise its suite of methods for providing assistance or advice to applicants, registrants and permit holders.

## Administrative considerations

The Agvet Code Regulations provide for a number of categories that may be applied to applications for registration of products and approval of labels, approval of active constituents, and variations to registered products and approved active constituents<sup>14</sup>. The application categories reflect the level of assessment to evaluate the risks associated with each application. Application categories range from the approval of a new active constituent and registration of a product that has never been marketed in Australia, through to minor variations to existing products. Fees and timeframes for each category align to the relevant level of assessment.

During the evaluation of an application, the APVMA must consider the intellectual property rights of data providers (data protection), comply with the legislative timeframe for assessment, issue prescribed notices correctly and respect the applicant's rights of appeal. The evaluation must also consider any requirements linked to other legislation for example the poisons scheduling framework as set under state and territory health legislation, procedures related to the establishment of maximum residue limits for agvet chemicals under the *Food Standards Australia New Zealand Act 1991* and procedures relating to consultation with the Office of the Gene Technology Regulator (OGTR).

During certain types of evaluations, the APVMA must consult stakeholders by publishing a notice and inviting written submissions on its assessment against the statutory criteria. An example of a type of evaluation where this occurs is in the consideration of a new product containing a new active constituent. The APVMA must take into account all relevant submissions.

The APVMA is also required to publish a summary of the advice relied upon that was given to it by a person, body or government it consulted within the context of an application.

As part of the Better Regulation Reform agenda the Australian Government decided to enhance the consistency, efficiency, effectiveness and transparency of the registration and approval processes through the introduction of a range of measures to improve timeliness of these processes. These include changes to some of the administrative aspects of registrations and approvals, such as

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<sup>14</sup> Schedule 6 of the Regulations describes the range of application categories.

...introducing a new system for the periodic assessment of agvet chemicals in the marketplace to ensure their ongoing safety and effectiveness.

- the increased use of electronic communication and lodgement of applications
- introduction of an administrative 'completeness check' of applications
- mandatory refusal of incomplete or improperly made applications
- enhancements to data protection
- a revision of legislative timeframes
- limitation of the opportunities to revise applications or provide additional information and introduction of a fixed extension of timeframe for submission of additional information required by the APVMA
- some changes to the applicant's rights of appeal.

The *Risk Compendium* will include a Registration and Approval Process document (to be developed) that will describe the processes that underpin registration and approval decision-making in more detail.

### 3.6 Continuation of approval or registration ('Re-registration')

As part of the Better Regulation Reform agenda the Australian Government decided to introduce a mandatory scheme of continuation of approval and registration. The aim of the scheme is to consider the on-going suitability of the entire inventory of agvet chemicals in the Australian marketplace.

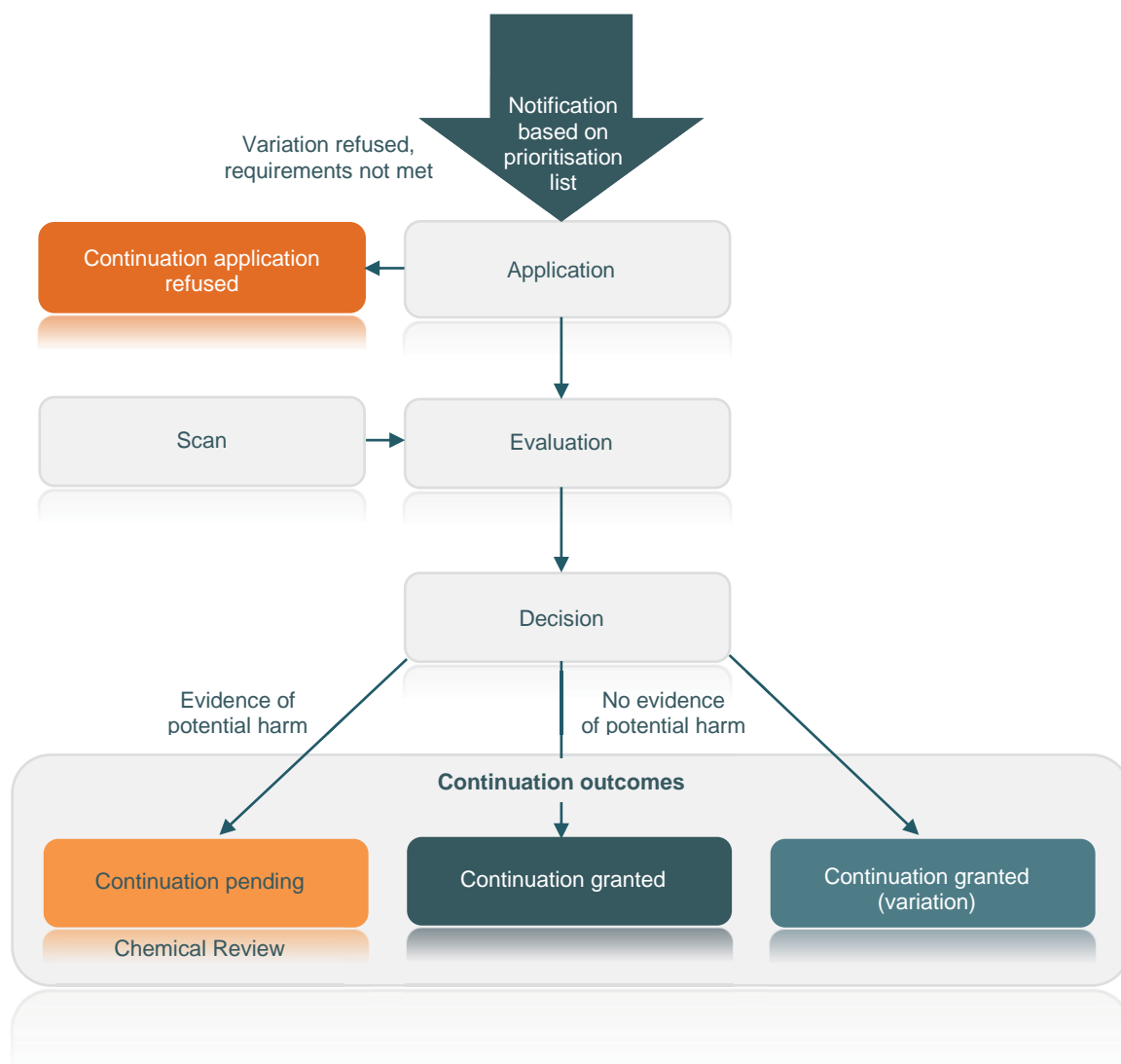
The scheme (see Figure 2) operates by systematically inviting all approval holders and registrants to make an application to continue their active constituent approval or product registration. The order in which chemicals are prioritised for assessment for continuation will be risk-based and published on the APVMA website, forming part of the *Risk Compendium*. The evaluation of the applications for continuation will validate active constituent and product details and identify whether there are any grounds for believing the active constituent or product no longer satisfy the APVMA's statutory criteria (Section 3.4 above) and pose an unacceptable risk to the Australian community. Grounds for doubt must be based in evidence and be scientifically robust.

There are three possible outcomes from an application for continuation. Where there are no grounds for concern identified, the approval of an active constituent or registration of a product will be continued for a defined period. In some cases an active constituent or product may be able to be continued with changes to particulars or conditions of approval or registration. Where the APVMA identifies scientifically valid reasons for concern, the active constituent or product will be referred to Chemical Review (see Section 3.7).

Should imminent risk to the Australian community be identified, the APVMA can act to remove the active constituent or product from the market.

Further details about the Continuation Scheme are available in the Continuation Framework document (available from the APVMA website).

Figure 2—The Continuation Scheme



### 3.7 Chemical review

#### Scientific considerations

The APVMA can reconsider the registration or approval of agvet chemicals where evidence suggests that the statutory criteria are no longer satisfied. This process is referred to as a 'chemical review'. A chemical review may be initiated when new research or evidence has raised concerns about the ongoing use or safety of a particular chemical or product. Chemical reviews may focus on one or more areas of concern including environmental safety, worker safety, public health, residues, trade, or less commonly, product effectiveness. The scope of a review is determined by the specific concerns raised about the chemical and its use.

A transparent and predictable system for chemical registration and review that enhances confidence in the regulatory process.

The APVMA has the power to reconsider the approval of active constituents, registration of products and approval of labels, and to require approval holders and registrants to provide relevant information. New scientific information (including new studies) may be required to allow the APVMA to appropriately investigate matters of concern.

When the APVMA becomes aware of concerns about a chemical, product or label, it decides whether a chemical review is warranted and its priority. To commence the review the APVMA notifies chemical companies with affected active constituent approvals and registered products and requires them to submit relevant data. The APVMA may call for public submissions on the continued use of the chemical under review. All relevant submissions and scientific data are evaluated.

During a chemical review the APVMA draws on the specialist expertise of its own staff and that of other Commonwealth, state and territory government agencies in the same way it does as part of the registration process. The review process generally includes extensive consultation with the chemical industry, those who use the chemical and the community. Where possible during a chemical review, the APVMA applies risk mitigation strategies (potentially changing use patterns, rates and application methodologies) rather than cancelling the registration of an agvet product that may be critical for a particular industry.

As part of the Better Regulation Reform agenda the Australian Government decided to introduce some changes to the use of the statutory criteria for chemical reviews. As for registration, the prejudice to international trade and efficacy legislative criteria will also be optional for chemical reviews (see Section 3.4 above). Consideration of individual criteria will reflect the scope of each chemical review.

### Administrative considerations

A draft report and proposed regulatory approach is typically released for public comment and targeted consultation may be undertaken. Information provided during the public consultation is taken into account before the APVMA makes its final decision. The outcomes are then communicated and implemented.

Depending on the findings of a chemical review, agvet chemicals might:

- be affirmed as safe and appropriate for registered use when used according to label instructions
- have their conditions of approval or registration amended
- be restricted in use (by a label change), or
- be cancelled (with a possible phased withdrawal from sale).

As part of the Better Regulation Reform agenda, the Australian Government decided to introduce statutory timeframes for chemical reviews, which will be reflective of the scope of the review. The Government also decided that

the data protection arrangements within chemical review would be more closely aligned with registration, enhancing the value of data submitted to a chemical review.

The *Risk Compendium* will include a Chemical Review Framework (to be developed) that will describe the principles and processes that underpin chemical review decision-making in more detail.

### 3.8 Permits

In most states, registered agvet chemical products must only be used for purposes that are specified on the product label. In practice, situations often arise where chemicals may be needed for a use not specified on the label. These are termed 'off-label' uses. The APVMA can consider applications for permits that allow chemicals to be used in ways different from the uses set out on the product label. The limited use of an unregistered chemical may also be allowed by an APVMA-issued permit.

Examples of circumstances in which a permit may be considered by the APVMA are:

- 'minor use' - situations usually involving low acreage crops, small portions of high acreage crops, or animal species which are not covered by the product label
- emergency use - situations such as outbreaks of exotic pests or diseases
- research - to allow for chemical products to be used in research trials of varying size for scientific purposes, such as determining the suitability of a product for a new use or generating the data necessary to register the product
- certain other prescribed circumstances that would otherwise constitute an offence under the Agvet Code.

Applications for permits are subject to the same statutory criteria as for the registration of products or approval of active constituents. However, as exposure under permit may be limited by the scale, duration or availability of the permit and can be subjected to specific additional conditions, data requirements may differ from what is otherwise required for registration, approval or variation. This gives the APVMA more opportunities to manage or mitigate the risk that may be associated with a proposed use pattern under a permit, enhancing flexibility. In this way, the data and assessment required for a minor use permit is tailored to suit the regulatory status of the product and the risks associated with the current and proposed use.

In considering applications for minor or emergency use permits the APVMA may consult with relevant state or territory government authorities on a range of regulatory issues (see Appendix 3).

As with registration, permit timeframes reflect the level of assessment required to evaluate the risk of each application. The APVMA assigns emergency use permit applications a high priority. Emergency use permit applications must meet strict emergency criteria.

As part of the Better Regulation Reform agenda, the Australian Government decided to introduce some changes to the use of the statutory criteria in decision-making about agvet chemicals. As for registration, the prejudice to international trade and efficacy legislative criteria will also be optional for permits (see Section 3.4 above). The circumstances when these criteria will not be considered will be specified in the *Risk Compendium*.

The *Risk Compendium* will include a Permit Framework (to be developed) that will describe the principles and processes that underpin permit decision-making in more detail.

Modern enforcement tools that enable the APVMA to apply a graduated response to non-compliance that reflects the seriousness of the offence.

### 3.9 Licensing manufacturers of veterinary chemical products

The quality of a veterinary chemical product has a direct bearing on both its safety and effectiveness. The APVMA considers product quality as part of the registration assessment. This includes ensuring that veterinary chemical products are manufactured according to Good Manufacturing Practice (GMP). Compliance with GMP provides confidence that products are manufactured consistently, by a specified method, using suitable equipment, under adequate supervision and with effective quality control procedures.

The Agvet Code requires that Australian manufacturers of veterinary chemical products are licensed. Licensing is controlled by the APVMA through the Manufacturers Licensing Scheme (MLS)<sup>15</sup>. The objectives of the MLS are:

- to assure (give confidence in) the quality of veterinary chemical products manufactured and supplied in Australia
- to facilitate exports of Australian made veterinary chemical products through international harmonisation and GMP compliance.

An APVMA licence to manufacture veterinary chemical products is required by anyone engaged in any step of the manufacture of a veterinary chemical product in Australia. In order to gain and maintain a licence, manufacturers must undergo regular GMP audits by the APVMA and authorised auditors to confirm compliance with the Manufacturing Principles and the relevant Code of GMP. These manufacturing requirements take into account the nature, use and consumer expectations for the quality of the veterinary chemical products being manufactured.

The APVMA cannot license overseas-based manufacturers supplying to the Australian marketplace. For veterinary chemical products manufactured overseas, the registrant must demonstrate that the product is manufactured to quality standards comparable to those applying to veterinary chemical products manufactured in Australia. Registrants of products manufactured overseas are required to maintain evidence of ongoing GMP compliance for the life of the product.

The Risk Compendium will include a Manufacturers Licensing Scheme Framework (to be developed) that will describe the principles and processes that underpin manufacturing licencing and compliance in more detail.

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<sup>15</sup> The MLS is administered under Part 8 of the Agvet Code.

### 3.10 Compliance and enforcement

The APVMA monitors the Australian marketplace for breaches of the Agvet Code and related legislation. When breaches are identified the APVMA responds through a range of enforcement activities that aim to address past non-compliant behaviour and ensure future compliance. In determining the appropriate response or combination of responses to a breach of legislation, the APVMA considers all relevant factors. This typically includes:

- the type and level of risk posed by the behaviour
- the type and severity of any harm done
- the clarity of the law surrounding the breach
- the potential to undermine the regulatory system
- any aggravating or mitigating circumstances.

When the APVMA becomes aware of imminent risk to human health or the environment from a product, it may use its enforcement provisions to stop supply of the product, suspend or cancel the registration of the product or recall the product from points of supply or even from users.

As part of the Better Regulation Reform agenda the Australian Government decided to introduce a modern graduated compliance regime for agvet chemicals. This regime will significantly extend the range of tools available to the APVMA in responding to non-compliant activities. With the adoption of the new tools, responses within the graduated compliance regime will range from education through diversion strategies to court proceedings (Figure 3). This new regime will improve the APVMA's ability to match the scale and strength of its enforcement responses to the severity and circumstances of the non-compliant behaviour.

Figure 3—Enforcement measures



The *Risk Compendium* will include a Compliance and Enforcement Framework (to be developed) that will describe the principles and processes that underpin the compliance and enforcement policy and decision-making in more detail.



# CHAPTER 4

## APVMA GOVERNANCE

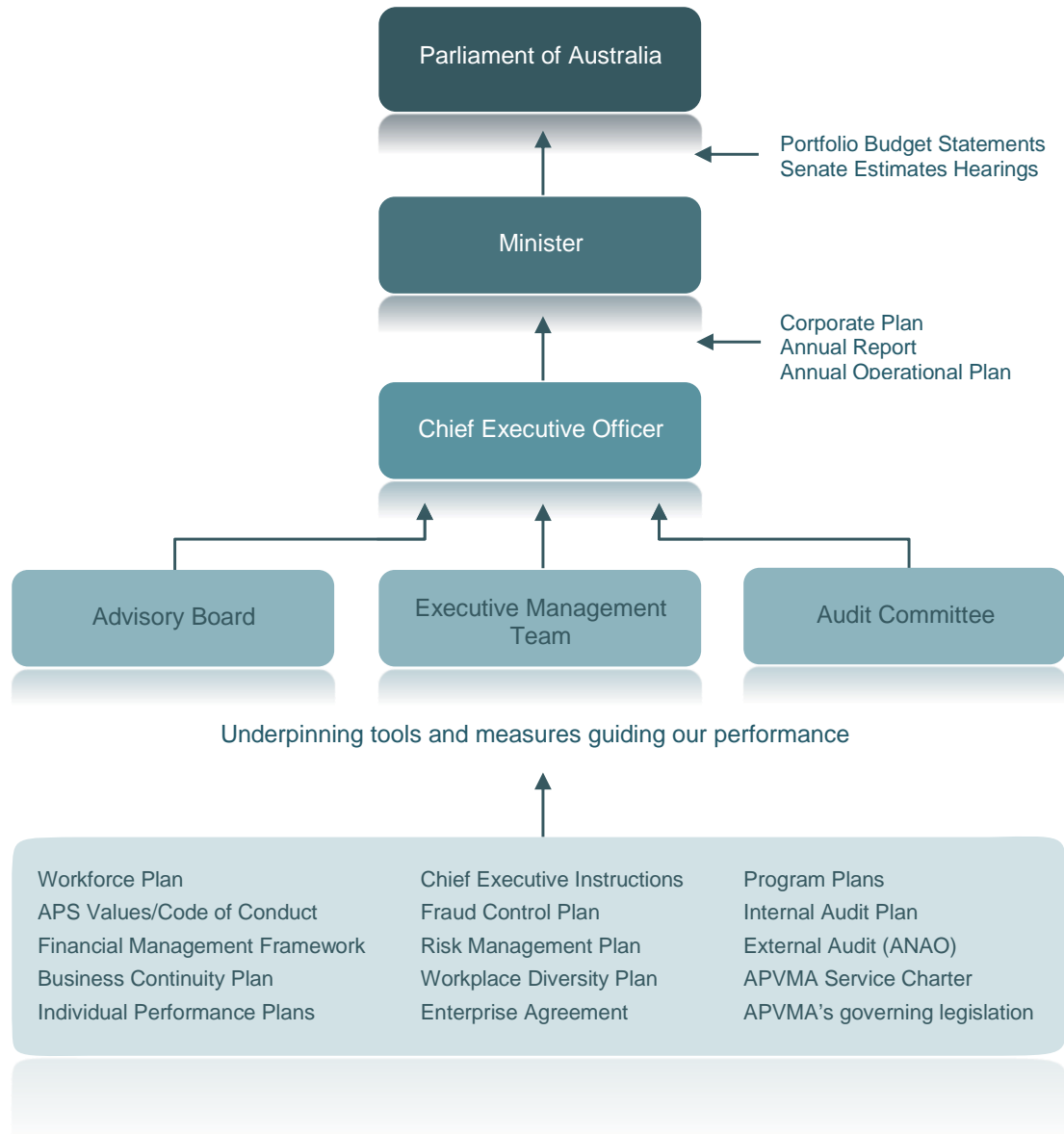
The APVMA is a statutory authority within the portfolio of the Minister for Agriculture, Fisheries and Forestry. It is a body corporate constituted by an executive manager, the Chief Executive Officer (CEO), who has responsibility for the management and governance of the authority.

Overall policy oversight of the APVMA is led by Commonwealth and state and territory governments through the Standing Council on Primary Industries (SCPI) and its subcommittees—giving effect to the inter-governmental agreement made in 1991. The Commonwealth and state and territory governments agreed to enact complementary legislation that provides for a national scheme for the regulation of agvet chemicals, and to consult regarding changes to the operation of the scheme.

Further information about the agvet chemical regulation framework and its history is provided in Appendix 2.

The following diagram provides an outline of the broad management structure of the APVMA, as well as showing the agency's relationships to the Minister and the Parliament. The diagram also identifies the organisational and business tools that underpin the APVMA's day-to-day operations.

Figure 4—APVMA accountability structure



#### 4.1 Chief Executive Officer and Advisory Board - roles and responsibilities

The CEO is responsible for the governance and management of the APVMA, including the performance of its functions and the exercise of its powers<sup>16</sup>. The CEO consults with the APVMA Advisory Board and key stakeholders to set the organisation's vision, objectives and strategies to meet its legislative responsibilities.

<sup>16</sup> *Agricultural and Veterinary Chemicals (Administration) Act 1992* Part 4

The CEO's principal responsibilities are to approve the preparation of strategic, financial and operational plans and budgets; monitor financial and operational performance; and oversee program performance to ensure that the APVMA meets its objectives.

The CEO is appointed by the Minister for Agriculture, Fisheries and Forestry and reports to the Minister.

The role of the Advisory Board is to support the CEO by providing expert advice, making recommendations, and providing input into the APVMA's focus and strategic direction. Arrangements for appointment to the Advisory Board, its function and procedure, as well as its interaction with the CEO, are prescribed by legislation<sup>17</sup>. The Advisory Board does not have decision-making power.

The Minister appoints Advisory Board members for their experience in specific fields defined in the legislation. These fields include the regulation of chemical products at state and territory level, the agricultural chemical industry, the veterinary medicine industry, primary production, environmental toxicology, protection of consumer interests, public health and occupational health and safety industries.

## 4.2 Accountability and reporting

The APVMA must develop a Corporate Plan that sets out the principal objectives of the APVMA in performing its functions and that gives a broad outline of the strategies to be pursued by the APVMA to achieve those objectives<sup>18</sup>. The Corporate Plan may be for one year or more (the Corporate Plan is usually for a period of three years) and comes into force once approved by the Minister.

The APVMA must also develop an annual Operational Plan<sup>19</sup>. The Operational Plan must set out the activities the APVMA intends to pursue to give effect to the goals set out in the Corporate Plan and include performance indicators against which performance can be assessed. The Operational Plan comes into force once approved by the Minister.

At the end of every financial year the APVMA is required to give the Minister an Annual Report on its operation for that year reporting against strategies contained in relevant operational plans, and on financial performance<sup>20</sup>. This Annual Report is tabled in Federal Parliament.

## 4.3 Financial governance and budget

The APVMA is a prescribed agency under the *Financial Management and Accountability Act 1997* (FMA Act). This Act provides a framework for the proper management of public money and public property. Under the Act, the CEO must manage the affairs of the agency in a way that promotes the efficient, effective, ethical and economical use of the Commonwealth resources, consistent with the policies of the Commonwealth. The Act also places specific reporting obligations on the APVMA. The APVMA is required to have its financial statements audited each year. This is done by the Australian National Audit Office and included in the Annual Report.

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<sup>17</sup> *Agricultural and Veterinary Chemicals (Administration) Act 1992* Part 3 Divisions 3 and 4

<sup>18</sup> *Agricultural and Veterinary Chemicals (Administration) Act 1992* Part 6

<sup>19</sup> *Agricultural and Veterinary Chemicals (Administration) Act 1992* Part 6

<sup>20</sup> *Agricultural and Veterinary Chemicals (Administration) Act 1992* Part 7

Other specific responsibilities of CEOs under the FMA Act include:

- instituting a fraud control plan
- establishing an audit committee
- pursuing the recovery of debts owed to the Commonwealth
- ensuring accounts and records are kept in accordance with the Finance Minister’s Orders
- providing the Auditor-General with financial statements in the required form.

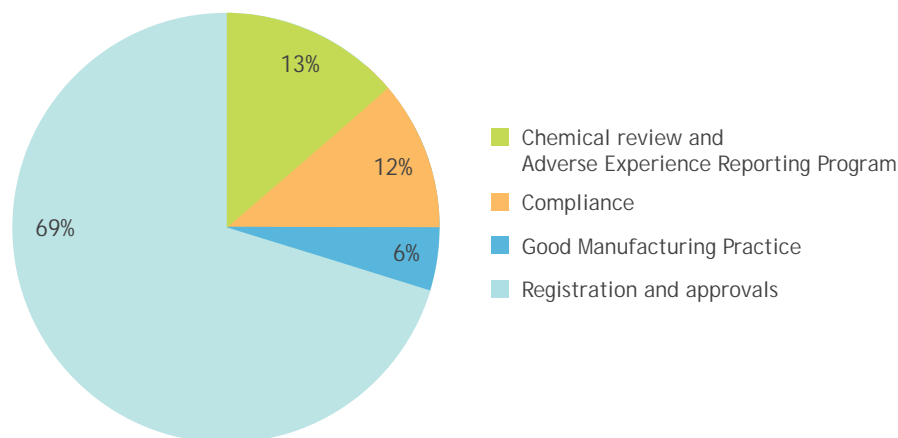
As a prescribed agency under the FMA Act, the APVMA must comply with the Commonwealth Procurement Guidelines (CPGs) on matters relating to the procurement of property and services. The CPGs establish principles that ensure agencies receive value for money, encourage competition and are accountable and transparent when conducting procurements.

The APVMA budget is detailed in the Portfolio Budget Statements (PBS) and (if necessary) the Portfolio Additional Estimates Statements (PAES) of the Agriculture, Fisheries and Forestry Portfolio.

The APVMA recovers most of the cost of its business from fees and levy payments from the agvet chemical industry. The APVMA receives a small government appropriation each year to undertake specific projects. As a cost recovered agency the APVMA must follow the Australian Government Cost Recovery Guidelines when establishing new fees or revising existing fees.

Approximately 70% of the APVMA’s budget is typically allocated to activities associated with assessing applications for registration, approvals or permits (Figure 5). The balance is devoted to post-registration activities such as chemical review and compliance.

Figure 5—APVMA budget expenditure for a typical financial year



#### 4.4 Audit Committee

The APVMA Audit Committee is an essential part of the APVMA’s governance and risk framework. It has an independent chair and includes external members and provides assurance to the CEO in relation to internal controls and compliance framework, financial and management responsibilities and its external accountability responsibilities.

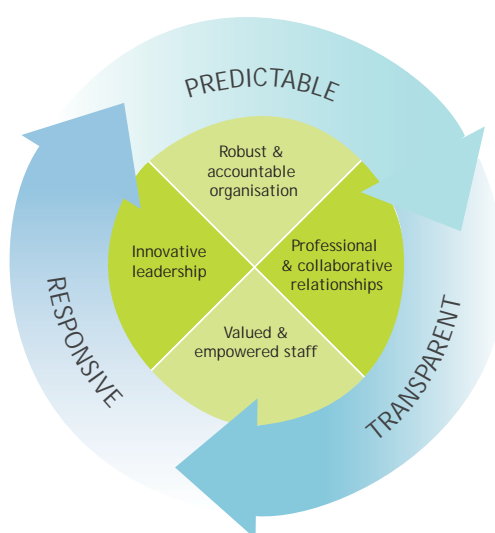
## 4.5 APVMA people

The APVMA's staff are employed under the *Public Service Act 1999*. The CEO is supported by Executive Managers, legal experts, enforcement experts, technical specialists and support staff. Details of the human resources and human resources management are provided in the Annual Report each year.

The APVMA employs approximately 160 staff and operates out of Canberra.

The APVMA is committed to demonstrating predictability, responsiveness and transparency in its administration of the regulatory framework and in the conduct of regulatory activities (Figure 6). APVMA staff also adhere to the Australian Public Service Values and Code of Conduct.

Figure 6—APVMA values



## 4.6 Stakeholder engagement

The APVMA places a high importance on stakeholder engagement. In undertaking its varied regulatory functions, the APVMA consults with a range of stakeholders including the community, the chemicals industry, government, users of agvet chemicals and international regulators.

The APVMA operates several consultative and liaison committees that provide forums for two-way communication with representatives from the community, government, rural industries and the chemical industry<sup>21</sup>. These include the Community Consultative Committee (CCC), the Registration Liaison Committee (RLC), the Industry Liaison Committee (ILC) and the Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC).

In addition to consultative and liaison committees, the APVMA conducts specific public consultation when highly significant regulatory decisions are being made. Examples of such decisions include approving new active constituents and registering products that contain new active constituents, major changes to product

<sup>21</sup> *Agricultural and Veterinary Chemicals (Administration) Act 1992* Part 3 Division 5

labels that may impact Australia's trade, finalising chemical reviews and major changes to operational or cost recovery arrangements. The APVMA conducts public consultations in a number of formats, depending on the matter being considered. Formats include targeted stakeholder feedback, media releases, regulatory updates, fora and workshops. All issues for consultation are published on the APVMA website. The APVMA Gazette lists all APVMA notices and decisions including registration, reviews and changes to registration status that are required by the Agvet Code.

# APPENDIX 1

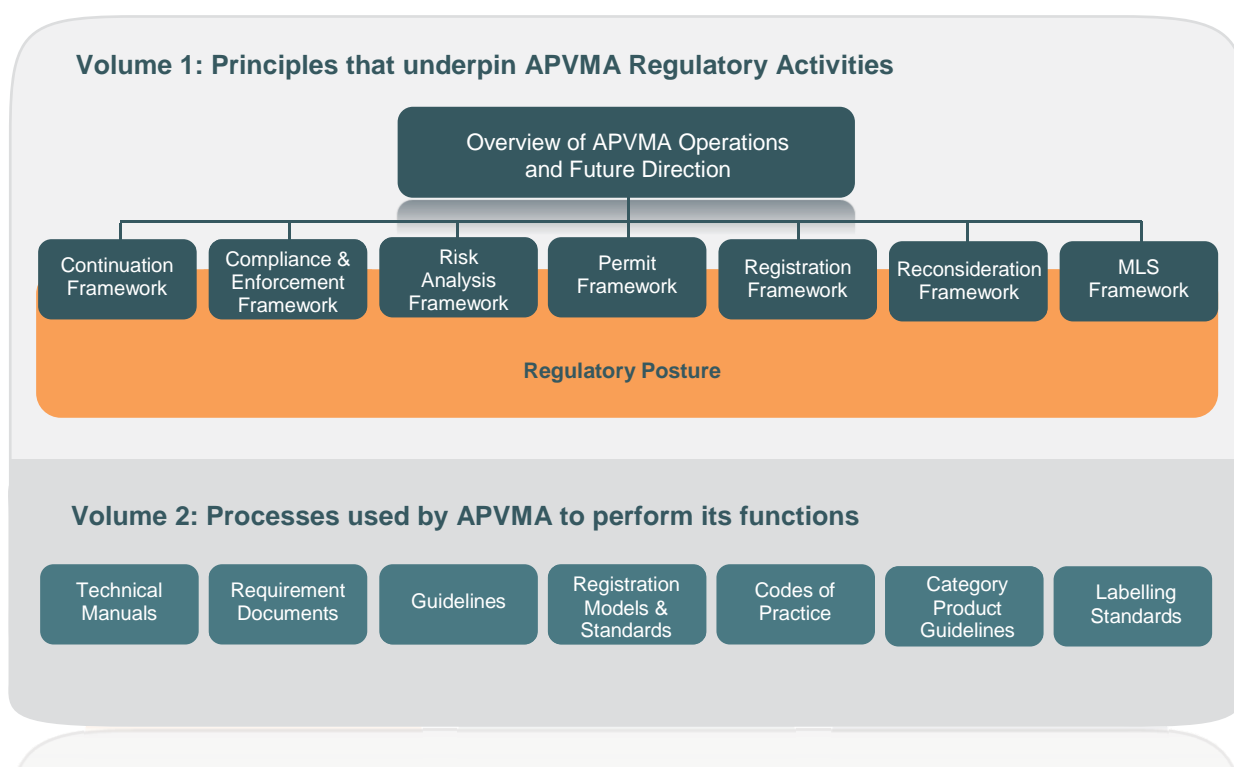
## APVMA RISK COMPENDIUM

The APVMA will develop a comprehensive *Risk Compendium* that describes the principles and processes of the APVMA's range of activities (Figure 7). The *Risk Compendium* will describe in detail the operational processes, data requirements and risk assessment processes used by the APVMA and will explain how the APVMA aligns regulatory effort with risk. The *Risk Compendium* will consolidate all the decision-making methodologies, guidelines and standards that are used by the APVMA in the evaluation and review of agvet chemicals. It will also define the policy and standard-setting responsibilities of the APVMA and its regulatory partners.

The *Risk Compendium* will be developed through co-operation and consultation with partner government agencies and other stakeholders and would be largely completed in 2014.

This collection of documents will improve the transparency and consistency of the APVMA's activities and provide greater certainty for stakeholders in their interactions with the APVMA.

Figure 7—The structure of the APVMA's *Risk Compendium* (under development)



# APPENDIX 2

## AUSTRALIAN AGVET CHEMICAL REGULATION

The regulation of agvet chemicals in Australia takes place through an integrated national risk management system known as the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). Participants in the system include the Australian Government, state and territory governments, manufacturers and users of these chemicals, and the general community. The NRS is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities.

### The National Registration Scheme

Since 1945 all Australian states have had legislation governing agvet chemicals. In the 1950s the Commonwealth became increasingly involved in regulating agvet chemicals through the National Health and Medical Research Council (NHMRC), involvement in poisons scheduling, setting of maximum residue limits (MRLs) and promotion of nationally consistent standards and labelling.

In 1988 the Commonwealth's involvement in the regulation of agvet chemicals increased further through the enactment of the *Agricultural and Veterinary Chemicals Act 1988* and the establishment of the Australian Agricultural and Veterinary Chemicals Council (AAVCC). Under these arrangements the Commonwealth provided clearances for agvet chemicals which were accepted as evidence of a comprehensive assessment and used by the states and territories as the basis of product registration.

In the early 1990s following the *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia* (1991), the Commonwealth, states and territories agreed to establish the NRS. The NRS commenced full operation on 15 March 1995. Under this arrangement the Commonwealth gained full responsibility for pre-market assessment and authorisation and the states and territories retained control of use functions.

### The National Regulator

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) was established by the Commonwealth on 15 June 1993 under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. At the same time the *Agricultural and Veterinary Chemicals Act 1988* was amended to provide the legislative basis for the NRA to take on the powers and functions of the outgoing AAVCC and centralise the assessment and registration of agvet chemical products.

The NRA was established as an independent statutory authority with responsibility for the evaluation, registration and review of agvet chemical products, and their control up to and including the point of retail sale. The authority is a portfolio agency reporting to the Commonwealth Minister for Agriculture, Fisheries and Forestry. The states and territories retain responsibility for control-of-use activities, such as monitoring to ensure that product use is consistent with label instructions.

With the creation of the NRA, it was decided that existing products that had been registered under the previous state schemes would be recognised under the new national arrangements as they were deemed to meet the

statutory requirements. Approximately 5000 products were taken to be registered and their labels taken to be approved on this basis.

The Chemical Review scheme was subsequently introduced to allow the NRA to reconsider market authorisations when new information became available that changed the regulator's satisfaction with the market authorisation granted previously.

In 2003 the name of the NRA was changed to the Australian Pesticides and Veterinary Medicines Authority.

Assessment, management and communication of the risks associated with agvet chemicals are the APVMA's core functions. When conducting assessments, APVMA technical staff draw on knowledge and expertise of a range of relevant scientific organisations, Commonwealth government departments and state agriculture departments. This reflects the co-operative nature of the NRS.

# APPENDIX 3

## SOURCES OF ADVICE

To inform its regulation of agvet chemicals the APVMA seeks advice and input from a range of sources including Australian Government agencies and scientific experts, as well as with stakeholder groups more broadly through specific consultative committees (see Section 4.6 above).

### Australian Government agencies

The APVMA seeks input and advice from Australian Government agencies in relation to matters within their areas of expertise. These agencies include:

#### Department of Health and Ageing (DoHA)

Sections of DoHA that advise the APVMA include the Office of Chemical Safety (OCS), Food Standards Australia and New Zealand (FSANZ) and the Office of the Gene Technology Regulator (OGTR).

OCS provides advice that identifies hazards and risks to human health, ways of managing these risks including the establishment of health standards such as the Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD) and poisons scheduling, and recommending first aid instructions and safety directions.

FSANZ provides advice on the dietary risk assessment and administers the Food Standards Code.

OGTR provides advice on the management of those genetically modified organisms that fall within the APVMA's scope of regulation.

#### Department of Sustainability, Environment, Water, Population and Communities (SEWPaC).

The Chemical Assessment Section within SEWPaC provides advice on environmental hazards and risks associated with the use of agvet chemical products. They perform environmental exposure and hazard assessments, characterise the identified risks and provide advice on suitable risk management strategies.

### State and territory agencies

The APVMA seeks advice from state and territory agencies, particularly those that have responsibility for control of use of agvet chemicals, on matters of relevance to their jurisdictions. This can include advice on the likely effectiveness of products and on their suitability for use in that state or territory and the enforceability of label instructions. Advice is also sought on the possible impacts of restricting or removing uses of a chemical product being considered under the chemical review program.

### Scientific experts

The APVMA obtains advice from several panels of scientific experts and science fellows. Panels may comprise domestic

and international scientific experts from academia, state and territory departments, and scientific organisations. These panels enhance the quality of the APVMA's regulatory science and build public confidence. Science Fellows are eminent national and international scientists with relevant expertise who have been appointed to assist with the training of APVMA staff and to provide high-level external scientific advice. The APVMA also routinely seeks advice from specialist scientists on the effectiveness of agvet chemical products.

### **Independent Science Panel**

The Better Regulation Reforms introduce an independent science panel. The panel is to report progress with reviews and registrations and the assessment of chemicals according to risk. The panel is independent of the APVMA. The Department of Agriculture, Fisheries and Forestry will administer the panel.

# ABBREVIATIONS

AAVCC	Australian Agricultural and Veterinary Chemicals Council
ADI	Acceptable Daily Intake
AERP	Adverse Experience Reporting Program
Agvet	Agricultural and veterinary
Agvet Code	Schedule to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
CPGs	Commonwealth Procurement Guidelines
DoHA	Department of Health and Ageing
FMA Act	<i>Financial Management and Accountability Act 1997</i>
FSANZ	Food Standards Australia and New Zealand
GMP	Good Manufacturing Practice
MLS	Manufacturers Licensing Scheme
MRL	Maximum Residue Limit
NHMRC	National Health and Medical Research Council
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
OCS	Office of Chemical Safety
OGTR	Office of the Gene Technology Regulator
PAES	Portfolio Additional Estimates Statements
PBS	Portfolio Budget Statements
SEWPaC	Department of Sustainability, Environment, Water, Population and Communities

# GLOSSARY

Acceptable Daily Intake (ADI)	A health standard, which is derived from studies with animals to determine the most sensitive species and the level at which the chemical does not affect the animal. Once this is determined, a safety factor is applied in establishing a maximum residue limit to allow for any differences between animals and people.
active constituent	The component of an agricultural or veterinary chemical product responsible for its physiological or pharmacological action.
Acute Reference Dose (ARfD)	A health standard that is an estimate of the amount of a substance in food or drinking water that can be ingested over a short period of time without appreciable health risk to the consumer, on the basis of all known facts at the time of the evaluation. It is usually expressed in milligrams of the chemical per kilogram of body weight.
agvet chemicals	Agricultural chemical products and veterinary chemical products, as defined in the Agvet Code. It encompasses all chemicals regulated by the APVMA.
compliance	The full implementation of legal requirements.
enforcement	Set of actions to achieve compliance by the regulated community with pesticide regulatory requirements. Government enforcement usually includes activities like investigations, negotiations and legal actions.
Food Standards Code	The Australia New Zealand Food Standards Code is a legislative instrument that contains general food standards (including for food additives and contaminants, and labelling requirements), compositional requirements for certain foods, food safety standards (including requirements for food handling) and primary production and processing standards. Maximum residue limits for agvet chemicals in food are included in the Code.
Listed registration	Registration of a product of a type for which a standard has been prescribed in a schedule of listed products in the Agvet Code Regulations.
Maximum Residue Limit (MRL)	Maximum permitted concentration of a residue, resulting from the registered use of an agricultural or veterinary chemical, usually expressed in units of mg/kg or µg/kg on a fresh weight basis.
National Registration Scheme for Agricultural and Veterinary Chemicals (NRS)	The NRS sets out the regulatory arrangements for the management of pesticides and veterinary medicines in Australia. The APVMA administers the scheme's legislation in partnership with state and territory governments, and other Australian government agencies.

Poisons Schedule

A national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules according to the level of regulatory control over the availability of the medicine or chemical that is required to protect public health and safety.

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risk

The likelihood of harm from an activity.

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