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**Australian Pesticides and
Veterinary Medicines Authority**



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**Compliance and
Enforcement Strategy
2015-17**

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CONTENTS

FOREWORD	4
1 INTRODUCTION	5
1.1 About the APVMA	5
1.2 Legislation administered by the APVMA	5
1.3 Compliance and enforcement strategy	6
1.4 Using a risk based approach	6
1.5 Compliance and enforcement principles	7
2 COMPLIANCE AND ENFORCEMENT STRATEGIES	8
2.1 Education	9
Case study—pool and spa chemicals campaign	9
2.2 Engagement	10
Case study—monitoring label compliance	10
Use of technology	11
2.3 Enforcement	12
Case study—infringement notices—dairy sanitisers	12
Case study—enforceable undertakings	12
Annual compliance plan	12
Partnerships	13
3 MEASURING OUR PERFORMANCE	14
Case study—online retailer’s compliance—2013–15	14
4 DEFINITIONS	16

FOREWORD

The APVMA is committed to being a contemporary world class regulator. A large part of that ambition is tied to how well we undertake our compliance and enforcement activities, engage with partner agencies and ensure that agricultural and veterinary chemicals are safe to use.

The APVMA Compliance and Enforcement Strategy sets out the APVMA's approach to compliance and enforcement for 2015–17.

The key themes of our Compliance and Enforcement Strategy are:

- ensuring information and educational material is made available to industry members and the community to assist with informed decisions being made regarding compliance obligations;
- guiding the APVMA's engagement with industry members and the community to facilitate compliance with the agvet laws; and
- taking enforcement action where regulated entities operate in contravention of agvet laws.

This strategy outlines objectives that the APVMA will pursue to promote voluntary compliance, change non-compliant behaviour and deter illegal activities affecting the import, manufacture and supply of agricultural and veterinary chemical products.

1 INTRODUCTION

1.1 About the APVMA

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 Australian veterinary manufacturers and undertake a range of compliance activities up to and including the point of retail sale.

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.

VISION

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

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.

Figure 1: APVMA vision and mission

1.2 Legislation administered by the APVMA

The APVMA is primarily responsible for administering the following pieces of legislation:

[Agricultural and Veterinary Chemicals \(Administration\) Act 1992](#) (external site)

[Agricultural and Veterinary Chemicals Act 1994](#) (external site)

[Agricultural and Veterinary Chemicals Code Act 1994](#) (external site)

[Agricultural and Veterinary Chemical Products \(Collection of Levy\) Act 1994](#) (external site)

1.3 Compliance and enforcement strategy

The APVMA's Compliance and Enforcement Strategy outlines how the APVMA will conduct its compliance and enforcement activities to fulfil its role of regulating agricultural and veterinary chemicals in order to protect the health and safety of people, animals and crops, the environment and trade.

The way a regulator implements and enforces its legislation can make a significant difference to industry. The APVMA has a modern graduated set of compliance and enforcement powers, supporting proportionate responses to non-compliance.

This strategy provides a map for how the APVMA will implement its commitments in the 2015–19 Corporate Plan to ensure that the integrity of the regulatory system is maintained.

1.4 Using a risk based approach

The APVMA's compliance approach is to assess risks in the regulatory environment and respond to them in a proportionate manner based on that assessment.

In the compliance context, risk based regulation involves an approach of:

- undertaking compliance assessments based on relevant information and intelligence analysis;
- identifying current and emerging compliance risks based on those compliance assessments;
- developing innovative and targeted strategies to effectively address compliance priorities using the full range of tools available to the APVMA within the capacity of available resources;
- implementing those targeted strategies using a planned approach with clear goals; and
- closing projects, including conducting a review of the process and evaluation of the outcomes.

The APVMA will ensure dedicated resources are allocated to undertaking information and intelligence analysis to underpin its broader compliance activities of education, engagement and enforcement.

1.5 Compliance and enforcement principles

Principle	Description
Risk-based	The level of risk will direct the response that is taken to rectify any contraventions.
Proportionate	The compliance response will be proportionate to the actual contraventions identified. A graduated risk-based approach will be used to ensure regulated entities comply with their compliance obligations. If a less severe or intensive regulatory option does not resolve the compliance issue, stronger regulatory action will be taken until the risks associated with the unlawful activity are addressed.
Consistent	Compliance issues are often unique and require tailored responses. The APVMA's risk-based approach enhances consistency in decision-making because its response will be determined by the level of risk associated with each identified contravention. Decisions to take action will be informed by previous cases to provide regulated entities with a level of certainty and predictability regarding the enforcement actions the APVMA is likely to take.
Fair	Fair procedures regarding investigations and decision-making will be used to provide regulated entities with the opportunity to be heard and to express concerns where appropriate and in accordance with the regulatory framework and to take action on a voluntary basis to address problems.
Transparent	Dealings with regulated entities will employ appropriate levels of transparency, while respecting the confidentiality of different situations as needed. Where required under the regulatory framework and laws, written reasons for regulatory decisions will be provided. Information regarding certain compliance and enforcement activities will be published where appropriate.
Proactive	A strong compliance culture among regulated entities is expected. Our preference is to see voluntary compliance being achieved and we will check on this. Responsibility rests with regulated entities to comply with their obligations under the regulatory framework. Proactive compliance work will be undertaken to reduce the number of contraventions.
Engaged	Engagement is necessary to understand emerging risks, inform prioritisation of compliance activities and adjust regulatory activities. Communication with regulated entities and other stakeholders about upcoming regulatory activities, the outcomes from those activities, changes to relevant laws and general information is important to underpin any compliance strategy.
Efficient	Compliance and enforcement activities must be undertaken in a way that has the minimal cost imposed possible on regulated entities and the APVMA. Alternative approaches will be considered to ensure the most efficient option is pursued.

2 COMPLIANCE AND ENFORCEMENT STRATEGIES

The APVMA’s program of compliance and enforcement will be based on three core strategies that align with risks set out within the agvet laws. As risk escalates, so will the compliance and enforcement response based on the strategy’s core components.

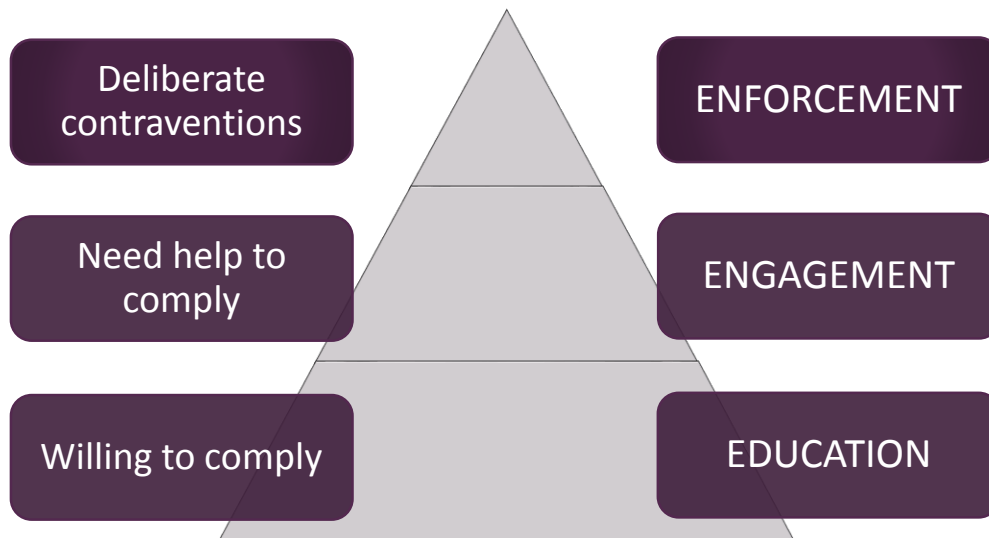


Figure 2 – APVMA compliance strategies associated with attitude to compliance

Our main priority is to work with those people who are willing to comply with the agvet laws but do not have the information to guide them. This means providing information to educate people so they can comply. Educational activities may include information on the APVMA website and the publication of agvet specific information through different media channels and reputable industry sources of information.

Regulated entities are required to operate in accordance with the agvet laws. This includes understanding what is allowed as part of any approval, registration, permit or licence issued by the APVMA. Regulated entities with strong compliance cultures who remain compliant with their obligations will be less likely to see APVMA Inspectors unless they specifically seek out support from the APVMA.

Those who want to comply but need guidance and assistance will be engaged and provided with the direction required to return to compliance with the agvet laws. This may be through monitoring programs, audits or compliance campaigns.

Contraventions of the agvet laws where no effort is made to return to compliance or inform the APVMA will be subject to strong enforcement action by the APVMA. We will take proportionate enforcement action to resolve contraventions and set a deterrence for others not to breach agvet laws.

2.1 Education

The APVMA will undertake a range of proactive informational and educational projects to assist regulated entities comply with agvet laws and advise the broader community of how agvet laws protect them.

These informational and educational projects will include:

- integrating face-to-face visits into our field work, so that Inspectors are visible at retail outlets, manufacturing sites and industry events. We will explore opportunities for joint participation with partner agencies;
- developing fact sheets to provide during our engagements to give people a ready reference with key information;
- contributing to the initial information that new holders receive from the APVMA to introduce them to their new requirements under agvet laws. We will take opportunities to engage with these new holders with face-to-face meetings to answer their questions and provide information;
- setting focus areas for our education and communication activities. This may include specific information about a particular chemical or issue that is of concern for the community. For instance, if there is a problem with a certain chemical, we may provide information about the issue and guide users on what to do with any chemical products that they are holding;
- providing information on the APVMA website and to media outlets, industry journals, magazines and relevant publications to inform readers of topical issues. This may include topics such as the reasons for using APVMA registered veterinary products on family pets to ensure the safety of the pet and the family; and
- communicating our compliance outcomes to inform the broad community of what APVMA compliance activities have achieved. This information aims to set expectations and provide those who decide not to comply with examples of what could happen if they are found to be non-compliant.

Case study—pool and spa chemicals campaign

The APVMA generally receives several reports of non-compliance relating to pool and spa chemicals each year.

The swimming pool campaign was run proactively and firstly involved compliance staff attending the 'SPLASH' pool and spa industry tradeshow to gain a better understanding of the sector while providing information about the agvet laws.

We then mailed out fact sheets and guidance materials to around 435 pool and spa stores nationally. The message was also picked up in industry association communications.

In March 2015, we followed up with inspections of retail premises in Queensland and Western Australia. The retailers inspected demonstrated a generally high level of compliance.

The campaign was used as a learning opportunity for the APVMA to determine how to undertake information campaigns.

The campaign resulted in a number of compliance cases focussed on the alleged supply of unregistered pool chemicals or labelling issues.

2.2 Engagement

The APVMA will engage with regulated entities who need guidance and support to achieve compliance with agvet laws. We will undertake various compliance activities focussed on assisting regulated entities to remain compliant or return to compliance without using regulatory powers.

Different approaches will be used to engage with regulated entities:

- regulated entities who are unaware of the APVMA and agvet laws may require direct engagement with APVMA Inspectors to assist them on the path toward achieving compliance;
- regulated entities who have a track record of doing the right thing and not requiring guidance on meeting their obligations should expect to see APVMA Inspectors less, but remain engaged through the distribution of information through various APVMA communications channels. If there are issues, Inspectors are only a phone call or email away to provide advice; and
- conducting audits of APVMA issued approvals, registrations, permits and licences to check on compliance with conditions. During the audit process, we will work with the holders of these authorisations to ensure they are meeting their obligations.

Case study—monitoring label compliance

The APVMA will undertake monitoring of label compliance in the marketplace. This will involve audits of labels which have been the subject of chemical review. The APVMA's aim will be to assist companies to return to compliance through advising them of any deficiencies and informing them of the labelling requirements.

In 2014–15, the APVMA ran a pilot project to monitor label compliance. The pilot project audited 108 registered chemical products containing carbendazim, diuron or dichlorvos, marketed by 63 companies. These products were selected as a result of previous chemical reviews, where changes were required to labelling of the products.

Our audit revealed that two products were still being marketed with labels that had not been updated. We required stocks of these products to be recalled and relabelled.

We found that there was generally a good rate of compliance, although 60 per cent of the labels we examined had minor issues with wording. These minor issues would not be likely to pose risk to users or the environment, but were non-compliant with the legislated labelling requirements. We contacted those companies advising of the action needed to correct the labels and helped them to make the necessary changes.

This pilot project was very effective and the APVMA will continue to routinely monitor marketed product labels.

Use of technology

As society is increasingly using and relying on technology, we will investigate an on-line tool that allows users to report concerns about non-compliance and adverse experiences. This tool would promote reporting of issues across the community and allow immediate reporting so that we can respond to issues more quickly.

We will also make use of 'e-learning' options to provide information to holders on their rights and responsibilities under agvet laws. Such an openly available option allows the APVMA to reach more people involved in the agvet chemical industry and help them to increase their understanding of what is required when manufacturing or supplying agvet chemical products.

2.3 Enforcement

Regulated entities that contravene agvet laws can expect to be subject to strong enforcement action by the APVMA. We will take enforcement action to resolve contraventions and set a deterrence for others not to breach agvet laws.

Our enforcement actions will be proportionate to the seriousness of the breaches.

We will select a regulatory response from the enforcement tools provided to us by the legislation based on the specific circumstances of the case. The enforcement tools will be used fairly, with decisions to use them being based on consideration of the available evidence.

We will continue to develop and share case studies about how we have used our enforcement tools. This transparency will support a consistent approach to enforcement action over time.

Case study—infraction notices—dairy sanitisers

In late 2014–early 2015, Inspectors undertook an investigation into the supply of a dairy sanitiser containing an unapproved formula in a container that also had labelling issues.

Taking relevant facts of the case into consideration, APVMA Inspectors issued two infraction notices for contraventions of the Agvet Code.

Case study—enforceable undertakings

An enforceable undertaking is a binding written agreement between a person and the APVMA. By offering and entering into the undertaking, you are saying that you will do or not do specified things to comply with the agvet laws. This is an alternative to prosecution and provides a transparent and efficient resolution of alleged or actual non-compliance.

Enforceable Undertakings may include a financial component that is used to fund prepared public educational material for distribution. Other components of an enforceable undertaking may include a staff educational program on agvet laws or a reporting regime to provide the APVMA with confidence that you can continue to comply with your legislative requirements.

Annual compliance plan

The APVMA will develop and publish a summary of its annual compliance plan so that our stakeholders can quickly see what we are planning for the coming year.

The publication of the annual compliance plan is a signal to industry members what the APVMA will be paying particular attention to. The identified areas will not restrict the APVMA from taking compliance or enforcement action where there is evidence of contraventions.

The APVMA will set its annual compliance plan based on legislative and policy guidance and with due consideration of the resources available to the APVMA. Emerging issues may be identified through the intelligence

assessment process, or areas that have had little or no compliance activity historically, or have not been subject to compliance activities for an extended period. These identified areas may be selected to ensure that they remain engaged with the APVMA as the regulator.

The annual compliance plan will be published in summary for the information of industry and the community. Where possible, the annual compliance plan will be published prior to the operational year.

In 2015–17, we will also continue our focus on assisting regulated entities through the processes of agvet regulatory reform and on the quality of marketed chemical products (including substandard and illegal chemicals).

Partnerships

The APVMA is guided by the agvet laws to focus its compliance activities on the importation, advertising and supply of agvet chemicals through the supply chain from point of manufacture to retail sale. Our state and territory partners regulate the use, transport and storage of agvet chemicals.

The APVMA may participate in joint agency investigations with partner agencies in cases where there is mutual interest. This may include Commonwealth agencies in relation to the importation of unregistered chemical products or state and territory based regulators for investigations relating to supply and use of chemical products outside of their permitted use.

We will establish formal arrangements to undertake joint investigations and information sharing with partner agencies to ensure these activities are undertaken legally and that information is protected.

The APVMA will contribute to international compliance activities, where relevant and lawfully possible. Cooperation with international partners and networks may involve information sharing and joint operations focussing on illegal agvet chemical trade.

3 MEASURING OUR PERFORMANCE

The APVMA is committed to self-assessment and accountability for its Compliance and Enforcement Strategy.

Regulated entities are responsible for their own compliance with agvet laws. The community expects the agvet chemicals industry to promote compliance across all holders. While the APVMA aims for 100 per cent compliance, we understand that this may not be possible to achieve or accurately assess. Through its compliance activities, the APVMA will seek to measure and increase rates of compliance across the sector more broadly.

When the APVMA is developing projects, we will determine how the outcomes of these projects will be measured. For example, where a regulatory project is undertaken in relation to an issue that has attracted a relatively high volume of complaints, an objective of that project might be to show a measurable reduction in complaints as a result of the APVMA's intervention. This may require identifying a baseline rate of compliance at the start of the project, then reviewing the rate of compliance to determine if a change has been achieved.

Case study—online retailer's compliance—2013–15

The APVMA participated in the Interpol coordinated Operation Pangea in both 2013 and 2015. Operation Pangea focussed on the online trade and supply of illegal pharmaceuticals. The APVMA focussed on veterinary tick and flea treatments and heart worming medications.

In 2013, a preliminary intelligence assessment of Australian online sellers identified approximately 70 per cent of sellers were selling unregistered veterinary chemical products. These sellers were engaged and either brought into compliance or exited the market.

In 2015, a new intelligence assessment was undertaken following the same process as that of 2013 and identified that there was a high level of compliance with the agvet laws by online sellers. Only a small number of sellers were readily identifiable at the time of assessment. This provided Inspectors with a list of entities to engage with after our joint operations with the then Australian Customs and Border Protection Service and Therapeutic Goods Administration at the border.

Based on the intelligence assessment identifying rates of compliance, our engagement with online sellers and involvement in Operation Pangea contributed to the increase in compliance across this retail sector.

This model can be utilised for future compliance operations focussed on specific commodity types to establish a baseline of information to assess the change in rates of compliance over time.

Through the APVMA Regulator Performance Framework, the APVMA will also seek feedback from regulated entities and other stakeholders about its performance through surveys or via industry presentations and forums to ensure that:

- actions undertaken are proportionate to the regulatory risk being managed;
- our compliance and monitoring approaches are streamlined and coordinated;
- our communication with regulated entities is clear, targeted and effective;
- our dealings are open and transparent;
- monitoring and enforcement strategies allow for a range of regulatory responses;
- compliance activities are responsive to business needs of regulated entities, where relevant; and
- information requested from regulated entities is necessary and acted upon.

More information on the collection and the reporting of this data is on the APVMA website.

4 DEFINITIONS

Word or Phrase	Definition
agvet laws	<p>The agvet laws comprise the statutory scheme in place for the evaluation, registration and control of agricultural and veterinary chemical products. This suite of legislation includes the:</p> <p><i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i> (the Administration Act)</p> <p>Agricultural and Veterinary Chemicals Code (the Agvet Code) as scheduled to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i> (the Code Act)</p> <p><i>Agricultural and Veterinary Chemicals Act 1994</i>.</p>
Annual Compliance Plan	A yearly plan of major compliance activities for the operational year.
audits	A systematic review of an approval, registration, permit or licence to ensure the holder is operating in accordance with their obligations.
complaint	An allegation that a person or company may have contravened the law.
contravention	An activity that is unlawful.
enforcement action	The use of one or more enforcement tools to remedy a contravention.
holder(s)	<p>The person or company responsible for an approved active constituent, registered agvet chemical product, approved permit or approved manufacturing licence within the Australian marketplace.</p> <p>Holders are listed on the APVMA's Record or Register and have obligations under the agvet laws.</p>
intelligence assessment	The process of collating information for analysis to produce findings that inform compliance activities.
monitoring	Checks and inspections of the actions of regulated entities.
partner agency	Agencies with mutual interests and ability to share information.
regulated entity	A person or company whose actions are regulated by the agvet laws.

