



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

APVMA Policy

Compliance and Enforcement Policy

Direction to staff

This document is instructional material for the Australian Pesticides and Veterinary Medicines Authority (APVMA) under its Knowledge Management Framework. All staff must comply with it.

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Purpose

The purpose of this policy is to:

- set out the principles and objectives of compliance and enforcement for the APVMA
- provide a guide for the use of APVMA investigation and enforcement powers
- outline how the APVMA will account for enforcement action taken.

This policy sets out the guiding principles adopted by the APVMA to optimise compliance with agvet legislation and to outline the APVMAs approach to monitoring and enforcement. The policy sits within the broader Australian Government law enforcement policy context and should be read in conjunction with other relevant documents.¹

Overview

The APVMA is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemicals proposed for supply in Australia. The APVMA regulates agvet chemical products up to and including the point of retail sale. Individual state or territory agvet chemical regulators are responsible for control of use.

The APVMA exercises its powers under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cth) (the Administration Act), the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (the Agvet Code), and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Cth), and subordinate legislation (together, the Agvet Laws).

The APVMA's jurisdiction in respect of agvet chemicals is provided for by the Agvet Laws and is consistent with the [Intergovernmental Agreement \(IGA\) to the Council of Australian Governments \(COAG\)](#). The Agvet Laws and subordinate instruments are available through the Federal Register of Legislation. Consistent with the IGA, state and territory governments are responsible for the control of use of agvet chemicals.

The APVMA administers its enabling legislation and has a duty to manage potential risks and enforce compliance when required. Investigations conducted by the APVMA contribute to the continued safety and effectiveness of agricultural and veterinary chemical products by taking action in relation to alleged contraventions of the Agvet Laws.

This policy forms part of the APVMA Compliance Framework.

¹ Australian Government Investigation Standards (AGIS)

Prosecution Policy of the Commonwealth

Legal Services Directions 2017

Commonwealth Fraud Control Guidelines

Protective Security Policy Framework

Australian Privacy Principles (APPs)

Australian Government APVMA Performance Guide (RPG)

Approach

The underpinning philosophy for this policy is to encourage the regulated community to voluntarily comply with the legislative requirements. Where contraventions occur, these will be handled proportionately.

The APVMA has a range of options to optimise compliance which are informed by intelligence analysis. These include engagement and education, monitoring of compliance and where necessary, enforcement. The APVMA's approach to compliance is guided by 3 principles:

1. Voluntary compliance is the objective of the APVMA
2. Not all allegations or referrals can or will be investigated
3. All compliance decisions will be risk-based, evidence and data-driven

The APVMA appoints Inspectors under section 69F of the Administration Act. Inspectors have investigation powers which enable them to secure evidence relating to alleged contraventions of the Agvet Laws in order to minimise the potential risk to the health and safety of people, animals and the environment or Australia's trade or commerce relationships. APVMA Inspectors also have monitoring and enforcement powers.

Compliance activity can include the provision of advice, sending educational material regarding potential non-compliance, conducting desktop audits, inspections by consent, stakeholder engagement, or similar administrative compliance actions.

Implementation

The APVMA will implement this policy through:

- encouraging voluntary compliance with its legislation by engaging with the regulated community to educate and guide
- monitoring compliance with obligations under the legislation to identify potential contraventions in a timely manner
- responding proportionately to suspected contraventions.

Response to contraventions

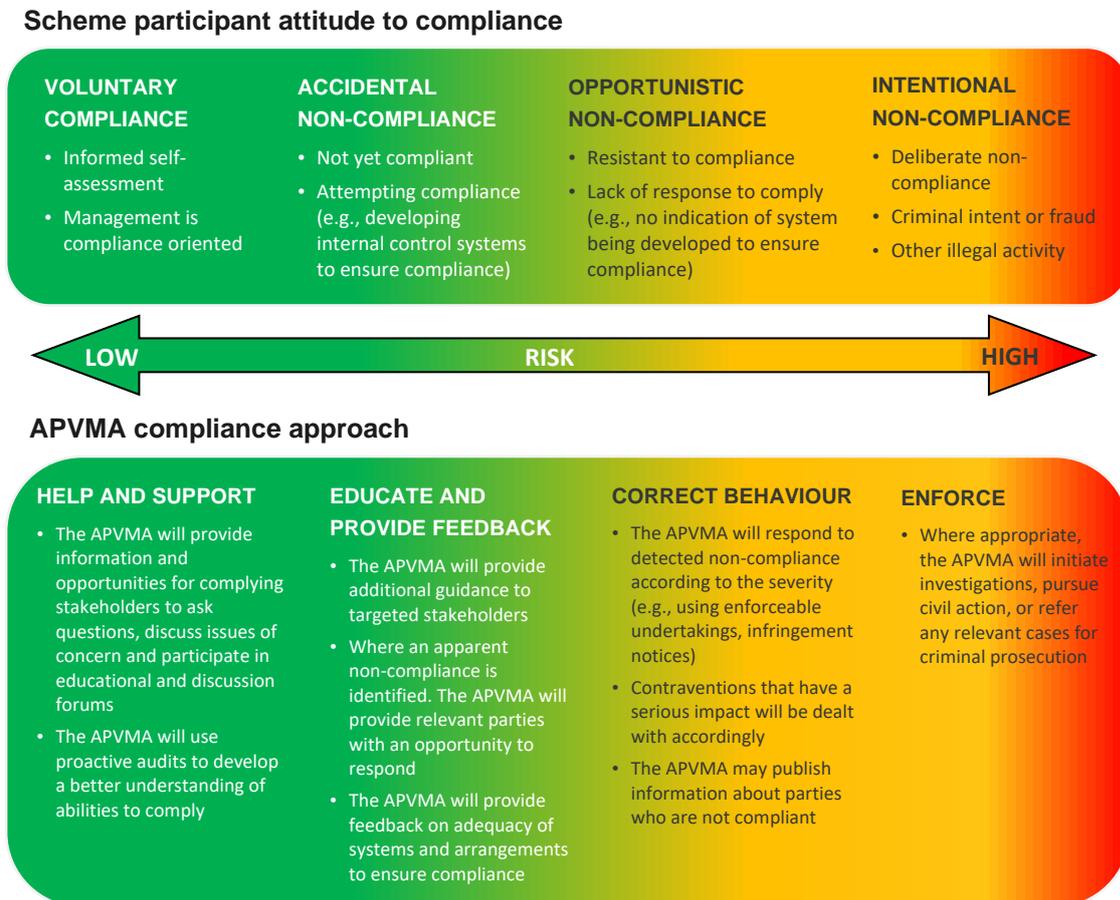
The APVMA will determine the most appropriate response based on the particular circumstances of each case. An education or targeted education response will be used in the first instance for less serious contraventions. This approach will ensure that entities are made aware of their legislative obligations and are given guidance to assist them in meeting these obligations in the future.

For more serious or continuing contraventions, deterrent actions will be utilised, including infringement notices, enforceable undertakings or recall notices. All cases of non-compliance will be assessed by the APVMA and, where necessary, investigations initiated, and cases referred to the Commonwealth Department of Public Prosecutions (CDPP).

Determining appropriate response

In determining appropriate responses to non-compliance, the APVMA will use a risk-based approach that considers the regulated community's behaviours and motivations. The continuum at Figure 1 (below) shows these behaviours and motivations and the APVMA's potential response according to the level of risk these behaviours pose.

Figure 1 – APVMA compliance methodology



Engagement and education

The APVMA places strong emphasis on engaging with the regulated community to assist them to meet their obligations. The APVMA publishes information in the form of factsheets and guidelines on its website. Additionally, the APVMA ensures that its regulated community has the opportunity to raise concerns and participate in workshops and communities of practice.

The majority of allegations made to the APVMA involve advertising and supply of unregistered agvet chemicals. Where possible, the APVMA engages directly with the entity advertising and/or the host publisher with a view to removing or amending claims as appropriate.

The APVMA has also established relationships with retailers that enable it to disrupt the advertising and/or supply with the cooperation of the retailer, in accordance with the legislation and the retailer's policies.

Monitoring compliance

The APVMA monitors compliance with the agvet legislation to:

- determine levels of compliance and identify patterns of behaviour and contraventions
- identify what type of, education and/or enforcement action may be required
- assess the effectiveness of operations and programs and identify opportunities for improvement.

Compliance monitoring may occur through:

- checking of information provided in applications under the various schemes
- analysis of information reported by persons and entities
- information from other sources, such as the general public, peak bodies, and industry groups, non-government organisations and other government agencies
- independent audits.

Intelligence

The role of Intelligence is to identify, collect, collate, evaluate, analyse and report to inform APVMA decision makers and investigations. Operationally, intelligence within the APVMA is used to identify emerging patterns and trends to proactively disrupt and deter non-compliance.

Investigation

Suspected contraventions of APVMA legislation will be assessed to determine the appropriate response. A preliminary assessment of known facts will be undertaken to decide on the likelihood that a contravention has occurred or is about to occur, its seriousness and its likely consequences.

Where alleged contraventions of the agvet legislation have occurred, they will be prioritised for investigation using a risk management approach.

While all suspected contraventions will be carefully assessed, the APVMA will exercise its discretion in allocating the resources available for investigation and resolution of matters so as to ensure the greatest overall benefit to the objectives of the respective legislation and balance cost with effective regulation.

The APVMA will use specialist staff to investigate all cases of non-compliance and, where necessary, refer these to enforcement agencies for consideration of action in appropriate courts in line with the Australian Government Investigation Standards (AGIS).

Investigations process

While there are common principles in all investigations, the actual process of investigating alleged contraventions of agvet legislation can differ greatly.

Factors affecting the investigation process can include the:

- priority of the matter
- the scope and size of the alleged non-compliance
- proofs and defences for the non-compliance
- available sources of evidence.

The following sections summarise the generic process. Some cover the planning and management of investigations, while some cover particular methods of gathering court-admissible evidence.

Referral of matters to another agency

The APVMA can refer serious crimes or complex criminal investigations to the Australian Federal Police (AFP), except where:

- the APVMA has the capacity and the appropriate skills and resources needed to investigate serious crimes or conduct complex criminal investigations and meets the requirements of the CDPP in gathering evidence and preparing briefs of evidence
- the issue involves alleged breaches of the [Commonwealth Electoral Act 1918 \(Cth\)](#)
- a fraud investigation is a separate inquiry into allegations of fraud undertaken by an entity, or by a law enforcement or external consultant. A single investigation may relate to one or more suspects and involve one or more allegations of fraud that are managed together.

Where another agency or jurisdiction is closer to the alleged contravention or offence (both physically and jurisdictionally), is in a better position to respond or the APVMA has no jurisdiction to investigate, the APVMA will refer the matter to the appropriate entity.

Agency relationships and information sharing

The APVMA is engaged in ongoing partnership arrangements including those provided for in the Agvet Laws, by memoranda of understanding (MOU) or other agreements with domestic and international bodies. The purpose of these arrangements is to assist the APVMA in meeting its responsibilities.

Partnerships with stakeholders will be pursued where appropriate. Investigators must remain impartial and must disclose any potential conflicts of interest that may arise, including internal conflicts, which may impede the investigation or the final decision-making process. Information and intelligence sharing arrangements occur consistently with the relevant legislation, including the [Privacy Act 1988 \(Cth\)](#), the Australian Privacy Principles, and with the objective of achieving the APVMA's legislative responsibilities.

Cross-border disclosure of personal information

The APVMA may be requested to provide information in accordance with the [Mutual Assistance in Criminal Matters Act 1987 \(Cth\)](#), and other legislation. Where this occurs, the APVMA complies with [Australian Privacy Principles \(see APP 8\)](#).

International inquiries and foreign evidence

Informal requests to international law enforcement, intelligence or other agencies must be made through the Interpol National Central Bureau which is managed through the Australian Federal Police.

Where evidence is sought in a form that is admissible under the [Foreign Evidence Act 1994 \(Cth\)](#), a request must be prepared and submitted under the mutual assistance regime through the International Crime Cooperation Central Authority in the Attorney-General's department.

Use of warrant and coercive powers

The Agvet Laws enable APVMA inspectors to execute investigation and monitoring warrants and utilise coercive powers. This includes the powers included at Part 9 and 9A of the Agvet Code, and Parts 7AA and 7AB of the Administration Act.

Compliance and enforcement measures

Proactive measures utilised by the APVMA to monitor compliance include the use of monitoring powers including warrants, field work, audits and active participation in multiagency operations.

APVMA Compliance will consider a proactive approach to matters of repeated non-compliance with the Agvet Laws. This may include product testing or implementing strategies to capture admissible evidence relating to the alleged contravention of the Agvet Laws. This is in accordance with [Australian National Audit Office](#) findings and the [Commonwealth APVMA Performance Guide \(2021\)](#).

Ethical conduct

A proper examination of all issues means Compliance must give a proper and genuine consideration to the evidence, regardless of whose case it may favour. The purpose of investigating is to discover facts. The APVMA uses guidance documents and work instructions to ensure quality investigative practices and outcomes. APVMA inspectors and officers conducting investigation activities must do so in accordance with the utmost professionalism, integrity and ethical standards and in line with the [Australian Public Service \(APS\) Values](#) and the [APS Code of Conduct](#).

Where an entity wishes to make a complaint about the conduct of an investigation, they may lodge this via the [APVMA Complaints](#) webpage.

Documents, records and their release are handled in accordance with the [Archives Act 1983 \(Cth\)](#), the [Freedom of Information Act 1982 \(Cth\)](#), the [Privacy Act 1988 \(Cth\)](#), the [APVMA Privacy Policy](#) and the [Protective Security Policy Framework](#).

Natural justice and procedural fairness

The management of allegations and own motion investigations must be conducted in accordance with the principles of natural justice. This refers to 3 key principles:

1. The subject of the investigation is provided an opportunity to respond or be heard before any adverse findings is made and before any adverse action is taken (fair hearing).
2. Those involved in the investigation or deciding the outcome are objective and impartial (absence of bias).
3. Any adverse action taken is based on evidence (not speculative).

Performance measures and quality assurance

Monitoring the performance of investigations and sanctions undertaken by the APVMA ensures outcomes are based on optimal compliance methodologies.

When matters are finalised and where appropriate, information is published.

Performance measures include quality of briefing material both internal and external, quality of briefing material and referrals to the CDPP, and ensuring statutory timeframes are met.

The APVMA conducts routine internal reviews of guidance material, work instructions and investigations in accordance with the APVMA Quality Management System.

Privacy

Personal information is protected by law, including by the *Privacy Act 1988 (Cth)* and the [Australian Privacy Principles \(APPs\)](#). The APVMA will limit the collection, use and disclosure of personal information to what is necessary to undertake the APVMA's compliance and investigation functions. Individuals providing information to the APVMA have the option to do so anonymously or by using a pseudonym, unless the APVMA is required or authorised by or under an Australian law, to deal with individuals who have identified themselves.

Following reports of suspected non-compliance resulting in enforcement action, the APVMA may disclose personal information included in details of investigative activities to Australian Commonwealth, state, or territory government agencies for law enforcement purposes. The APVMA has developed memoranda of understanding (MOU) with other agvet chemical regulators and agencies clarifying obligations and procedures for handling information exchanged for law enforcement and other purposes.

The APVMA is required by law to publish certain information about compliance and investigation outcomes, including in the APVMA Annual Report. No personal information will be included in these publications, unless the APVMA is required to publish such details under Australian law.

The [APVMA Privacy Policy](#) contains further information about how the APVMA will handle personal information and contained information about how an individual may access or amend personal information held by the APVMA or make a complaint about the APVMA's handling of personal information.

Document information

The following table contains administrative metadata.

Objective ID	Instructional material owner
A2253616	Director, Compliance

Version history

The following table details the published date and amendment details for this document.

Version	Date	Amendment details
1.0	16/11/2021	First publication of this policy. Created in alignment with the requirements of AGIS.
2.0	13/07/2022	Revised, renamed, and updated