Australian Government

Australian Pesticides and Veterinary Medicines Authority

Compliance Case Categorisation and Prioritisation Model

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Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is Australia's national regulator of agricultural and veterinary (agvet) chemicals, and the lead agency for the investigation of allegations of non-compliance with Australia's Agvet Laws. The Assessment, Investigation and Monitoring Section is responsible for achieving these outcomes under the Agvet Code.

The APVMA applies the principles of the Regulator Performance Guide (**RPG**) in the course of performing compliance, enforcement, investigation and monitoring functions.

The APVMA cannot pursue all matters that come to its attention. The APVMA focuses on those circumstances that will, or have the potential to, impact its legislative and policy responsibilities. The APVMA exercises discretion to direct resources to matters that provide the greatest overall benefit to the operation of the agvet scheme.

To achieve appropriate allocation of resources, the APVMA, through the Case Assessment Group (**CAG**), assesses these matters against its Compliance Case Categorisation and Prioritisation Model (**CCPM**). This methodology is adopted across Commonwealth agencies with law enforcement, investigative, regulatory and compliance responsibilities.

The APVMA CCPM provides for a consistent and transparent risk-based approach to addressing allegations and referrals to the APVMA, and demonstrates the objective factors used by the APVMA in determining risk, response and resource allocation.

The Case Assessment Group

This policy establishes the Case Assessment Group (CAG), consisting of:

- the Executive Director, Compliance
- the Director Assessment, Investigation and Monitoring
- Assistant Director/s Assessment, Investigation and Monitoring
- other APVMA officers on invitation.

The purpose and role of the CAG is to evaluate, categorise and prioritise each referral and allegation against the CCPM, in accordance with this policy and the Australian Government Investigation Standards (**AGIS**).

The CAG may decide to:

- accept a matter for investigation
- decline to investigate
- defer making a decision (e.g., pending receipt of further information)
- refer a matter to another agency
- refer the matter to another part of the APVMA
- proactively address the matter as a voluntary compliance outcome or by providing education material.

In making this determination, the CAG applies the following principles:

- The administration and enforcement of legislation in a coherent, consistent and objective way
- Those within the RPG
- Operating as transparently as possible so as to be accountable to the government and the public
- The APVMA risk appetite and tolerance statement
- Taking appropriate action against offenders and contraveners
- Operating efficiently, effectively, ethically and within available resources.

The CCPM

The APVMA CCPM guides decision makers in assessing referrals, allegations and complaints of non-compliance or contraventions of the Agvet Laws (section 3 of the *Agricultural and Veterinary Chemicals Code Act 1994* refers). The CCPM is not intended to replace the discretion of decision makers in considering the subjective and objective factors of a matter.

The ultimate decision to accept, defer, or reject an allegation remains with the relevant decision maker.

CCPM considerations

The CCPM takes into account:

- the legislative objectives of the agvet laws
- the registration, permit or approval status of the active constituent or chemical product
- the evasion of registration, fees or levies and market penetration
- whether the conduct involves fraud or deception
- any relevant history of previous non-compliance with the agvet laws
- the degree of culpability in the alleged conduct
- enduring and emerging priorities
- subjective and objective factors (Appendix A).

How and when the CCPM is applied

The APVMA CAG meets weekly to consider allegations and referrals received by the APVMA. For matters suspected as being of high priority, the Executive Director, Director and/or Assistant Directors of Assessment, Investigation and Monitoring, are authorised to determine an interim category and priority to provide for an immediate response. Following such, the matter will be reviewed at the next meeting of the CAG, where the interim decision will be affirmed, varied or revoked.

The CCPM is applied on the facts, intelligence and information known at the time to categorise and prioritise the APVMA response to the matter.

The science

The CAG considers a variety of sources of information to inform its recommendations, including:

- prior scientific assessment by the APVMA, internal advice, or information from other agencies
- chemicals whose registration or approval is under reconsideration by the APVMA
- the mode of action

- World Health Organization Advisory groups
- Australian Government Department of Health Australian Strategic and Technical Advisory Group ratings, and Australian Government Chemicals of Security Concern.

The CAG may take into account any relevant information in addition to the CCPM in considering the circumstances of a particular matter holistically.

Enduring priorities

The APVMA places science and evidence at the centre of its regulatory approach. The regulatory effort is proportionate to the risks identified through a scientific assessment of the problems with active constituents, products, or labels identified through investigations.

The APVMA treats enduring priorities as matters, which will generally:

- be classified, at minimum, as a moderate risk
- be unlikely to be treated as an education or voluntary compliance outcome
- have been subject to previous education or compliance activity
- be more likely to receive escalated steps towards administrative, civil, enforcement or criminal sanctions.

Dishonest conduct

Dishonesty, deceptive conduct or conduct that subverts the regulatory scheme is considered high risk. This type of conduct is embarked upon deliberately with an intention to deceive, avoid legal responsibilities, derive a benefit or avoid a liability.

Unregistered products

Due to the lack of assessment with respect to the safety and efficacy of the formulation, the APVMA considers unregistered agricultural or veterinary chemicals to be of high regulatory risk. As a result, unregistered chemical products are an enduring priority.

Importation of unregistered products

The APVMA takes escalated compliance or enforcement actions in relation to the importation of unregistered chemical products, particularly when detections are made at the border, for reasons including:

- the APVMA shares responsibility with other agencies in preventing unregistered chemical products reaching the domestic market or consumers, so it must make itself available to assist where it is reasonably practicable to do so
- detection in those circumstances is resource intensive
- sales connected with unregistered chemical products in those circumstances are often conducted online, and once in Australia are often difficult to detect.

Emerging or critical events

The APVMA maintains relationships with international and domestic partners, enabling assessment of emerging or imminent issues. Where necessary, the CAG may determine an event, phenomenon or set of circumstances to be

an emerging or critical event and recommend dedicated resources to that response. In those circumstances, the APVMA's resources will necessarily be directed to the high priority matter.

Reception and response timelines

A Reception Officer monitors referrals and enquiries arriving within the APVMA. The Reception Officer is responsible for acknowledging, assessing and recording all enquiries within one business day of receipt, providing an initial point of contact for internal referrals and supporting the CAG.

The risk assessment matrix used to classify referrals and reports of suspected non-compliance is in a standardised format (Appendix B). Risk- and complexity-based guidelines for the commencement and finalisation of investigations[1] are outlined in Table 1.

Table 1: Risk and complexity-based guidelines

Risk assessment	Commencement within	Complexity	Timeframe for finalisation
Low	90 days	Low	6 months
Medium	30 days	Medium	6 to 9 months
High	48 hours	High	12 months

High risk matters must be briefed to an Assistant Director (or higher) upon identification for the purpose of determining the next actions. Assistant Directors within the Assessment, Investigation and Monitoring section are authorised to escalate the response to high-risk allegations. Primarily this would be to:

- achieve the objectives of the agvet laws
- achieve the objectives of the APVMA
- prevent the loss, concealment, destruction or fabrication of evidence.

Accepting, deferring, or declining investigations

The APVMA may choose to accept, defer, or decline further investigation of a report of suspected non-compliance. At any time within the statutory timeframes, the APVMA may reconsider an initial decision.

The APVMA may decline to investigate or defer commencing an investigation for reasons articulated within this policy and additionally:

- where capacity does not exist due to other priorities

[1] See the APVMA Investigations Policy, including Investigation Standards:

An investigation is a distinct activity from steps that the APVMA may take to treat risk. For example, the APVMA may issue an enforceable direction (see s 145H Agvet Code), stop supply/recall notices (see ss 101 to 103 Agvet Code, substantiation notices (s 69EN Admin Act, s 145G Agvet Code)).

- where it is not in the public interest to investigate
- due to subjective and objective factors
- in circumstances where another agency is investigating, and they are the most appropriate agency to continue an investigation
- where the entities concerned are being investigated for other matters and the APVMA confines the scope of an investigation to selected contraventions or offending.

Appendix

Appendix A – Subjective and objective factors

Operational category	Case-specific factors

All	**Profile of regulated entity/person suspected of breaching provision**
	• Company size and type (e.g., international/domestic)
	• Nature of approval or registration
	• Nature of licence or permit
	• Past compliance history
	• Approach towards previous non-compliance
	• History of prior correspondence in relation to the same or similar matters with the APVMA
	Conduct of regulated entity (culpability)
	• Intention
	  • Unintentional non-compliance
	  • Ignorance
	  • Reckless non-compliance
	  • Wilful non-compliance
	  • Fraud
	• Degree of co-operation (assess through case)
	• Audit
	• Degree of proactivity:
	  • in avoiding non-compliance
	  • in limiting future non-compliance
	  • existence of contingency plans.
	• Way in which conduct came to the attention of the regulator
	  • Self-reported versus third party
	  • Time between non-compliance and reporting to regulator
	Type of chemical or active constituent involved
	• Toxicity or contamination
	• Use instructions for product
	• Use patterns
	• Compliance with registered label particulars
	• Volume and value of chemical or active constituent
	• Packaging
	• Method of manufacture
	• Poisons Classification
	• VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products)
	• Australian Strategic and Technical Advisory Group on AMR (ASTAG)

Operational category	Case-specific factors

	• Chemicals of security concern
	• Relevant detail in approval documents
	Impact of conduct: nature of non-compliance (administrative, substantive, risk to safety, health, trade, or the environment).
	• Nature and scale of event:
	  • Large-scale or isolated event; duration of event
	  • Animals or people affected (e.g., contamination of food)
	  • Environmental consequences
	  • Nature of risk/harm/injury/damage
	  • Volume of chemical involved
	  • Trade implications
	• Financial or political repercussions

Import/export	**Export: market access repercussions** • Risk of rejection of product by importing country • Impact on international reputation (e.g., quantity) **Import** • Quantity • Potential for profit
Labelling	**Impact: degree of non-compliance** • No label or wrong label (e.g., absent or inaccurate safety warnings) • Degree of error of information or instructions • History of incorrect product or label

Appendix B – Risk assessment matrix

1.1 Potential harms	
A – Human death or injury	**Score**[2]
Unregistered product; mode of action; lack of appropriate warnings or signal headings; handling or use hazard; chemical of security concern, ASTAG/AGISAR rating; incorrect registered or label particulars.	**7**
B – Significant animal death or serious injury	
Unregistered product; mode of action; lack of appropriate warnings or signal headings; chemical of security concern, ASTAG/AGISAR rating; incorrect registered or label particulars.	**4**
C – Harm to crops	
Mode of action; timing of use; method of application; nature of product; ineffective product.	**3**
D – Harm to trade	
Issues relating to residue levels; domestic manufacture and formulation; product quality and price; chemical of security concern, ASTAG/AGISAR rating.	**3**
E – Environmental harm	
Unregistered product; high toxicity; no warnings or contacts; handling or use hazard.	**3**
F – Regulatory	
Activity undermines regulatory system; fraud, false and misleading; high public interest; =; chemical of security concern, ASTAG/AGISAR rating; other issue with safety, efficacy, trade, or labelling criteria.	**2**
G – Marketplace advantage	
Incomplete participation or avoidance of regulatory scheme.	**1**
H – Subtotal 1.1	
1.2 Likelihood of harm occurring	
I – High likelihood	*if not, got to J*
High volume; company, wide market exposure; major suppliers; high toxicity; vulnerable or inexperienced users; claims made; insecure/unlabelled packaging; price incentives; possible organised nature.	**35**
J – Medium likelihood	*if not, got to K*
High volume; moderate distribution; moderate market exposure; minor suppliers; low toxicity; claims made; insecure/unlabelled packaging; price incentive.	**21**
K – Low likelihood	

[2] Scoring is from 1 to 7, where 1 is the lowest risk and 7 is the highest risk.

Low volume; individual, limited market exposure; low or no toxicity; low price incentive; secure packing/labels; informed users.	**7**
L – Subtotal 1.2	
1.3 – Character of behaviour	
M – Negligent behaviour Willing or resigned to comply; low monetary value; no previous offences.	*enter if applicable to go to 2* **7**
N – Combined factors from M and O Minor previous non-compliance; intermediate monetary value; other unknowns.	*enter if applicable to go to 2* **14**
O – Reckless behaviour Potential consequences should have been foreseeable; deliberate actions; disengaged from regulator or regulatory scheme; high monetary value; organised nature of offence; multiple offences over time.	*enter if applicable to go to 2* **21**
P – Subtotal 1.3	
2 – Total risk assessment rating (H+L+P)	