Australian Government

Australian Pesticides and Veterinary Medicines Authority

Compliance Case Categorisation and Prioritisation Model

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1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is Australia's national regulator of agricultural and veterinary chemicals, and the lead agency for the investigation of allegations of non-compliance with those laws. The Compliance and Monitoring Section is responsible for achieving these outcomes and is also responsible for recalls under the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).

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 risk based approach to addressing allegations and referrals to the authority, is transparent and demonstrates the objective factors used by the APVMA in determining risk, response and resource allocation.

2 THE CASE ASSESSMENT GROUP

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

- the Chief Regulatory Scientist
- the Director Compliance and Monitoring
- Assistant Director/s Compliance and Monitoring
- other members of APVMA staff as required.

The purpose and role of the CAG is to categorise and prioritise each referral and allegation against the CCPM, in accordance with this policy and the Australian Government Investigation Standards[1] (AGIS).

The CAG may decide to:

- accept a matter for investigation
- refer a matter to another agency or part of the APVMA
- accept and/or defer a matter for consideration
- decline to act on the information or allegation.

In making this determination the CCPM considers the following principles:

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

[1] ag.gov.au/RightsAndProtections/FOI/Documents/AGIS%202011.pdf

3 THE COMPLIANCE CASE CATEGORISATION AND PRIORITISATION MODEL

The APVMA Compliance Case Categorisation and Prioritisation Model (CCPM) guides decision makers in assessing referrals, allegations and complaints of non-compliance or contraventions of the Agvet Laws. 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, reject or conclude (by any means) a matter remains with the CAG.

3.1 Compliance Case Categorisation and Prioritisation Model considerations

The CCPM considers the legislative criteria set out in the Agvet Code, namely:

- the health and safety of humans, animals, the environment and Australia's trade
- safety, efficacy, trade and labelling criteria
- the registration, permit or approval status of the chemical product
- the evasion of registration, fees or levies and market penetration
- if the conduct involves fraud or deception
- the degree of culpability in the alleged conduct
- enduring and emerging priorities
- subjective and objective factors (Appendix A).

3.2 How and when the Compliance Case Categorisation and Prioritisation Model is applied

The APVMA CAG meets weekly to consider allegations and referrals received by the authority. For matters suspected as being of high priority the Director and Assistant Directors of Compliance and Monitoring, (jointly or severally) are authorised to determine an interim category and priority and the matter will be further considered at the next meeting.

The CCPM is applied on facts, intelligence and information known at the time to categorise and prioritise the APVMA Compliance and Monitoring Section response to the matter. The response may include referring the information to another part of the APVMA.

3.3 The science

The CAG considers a variety of scientific sources to inform decisions, including but not limited to:

- prior scientific assessment by the APVMA, internal advice, or information from other agencies

- chemicals under review by the APVMA[2]
- the mode of action[3]
- World Health Organization Advisory groups[4]
- Australian Government Department of Health Australian Strategic and Technical Advisory Group ratings[5] and Australian Government Chemicals of Security Concern[6].

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

3.4 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
- 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 are 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 greater risk. As a result unregistered chemical products are an enduring priority.

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[2] apvma.gov.au/chemicals-and-products/chemical-review/listing?field_cr_status_tid=5729

[3] irac-online.org/modes-of-action/

[4] For example, who.int/foodsafety/areas_work/antimicrobial-resistance/cia/en/

[5] amr.gov.au/file/1316/download?token=igIp8VA3

[6] nationalsecurity.gov.au/Securityandyourcommunity/ChemicalSecurity/Pages/default.aspx

3.5 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 dedicate resources to that response. In those circumstances business as usual assessments of matters arriving within the APVMA would not be treated in the ordinary way due to resources being focussed on emerging or critical events.

3.6 Reception and response timelines

A reception officer who is a suitably qualified employee monitors referrals and enquiries arriving within the APVMA (including recalls[7]). The reception officer is responsible for acknowledging, assessing and recording all enquiries within one business day of receipt.

The risk assessment matrix used to classify referrals and reports of suspected noncompliance is in a standardised format (Attachment 2). Risk- and complexity-based targets for the commencement and resolution of investigations follow.

Table 1: Risk assessment matrix

Risk assessment	Commencement within	Complexity	Timeframe for finalisation
Low	90 days	Low	3 months
Medium	30 days	Medium	3 to 6 months
High	48 hours	High	6 to 12 months

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

- achieve the objectives of the Agvet legislation,
- achieve the objectives of the APVMA,
- prevent the loss, concealment, destruction or fabrication of evidence.

3.7 Accepting, deferring or declining investigations

In line with the enduring priorities and emerging or critical events, the APVMA may choose to accept, defer, or decline further investigation of a report of suspected noncompliance. At any time within the statutory timeframes, the APVMA may reconsider an initial decision.

[7] apvma.gov.au/node/1081

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
- where it is not in the public interest to investigate[8]
- due to subjective and objective factors
- in circumstances where another agency is investigating and they are the most appropriate agency to continue an investigation
- whether the entities concerned are being investigated in respect to other matters and confines the scope of an investigation to selected contraventions or offending.

[8] cdpp.gov.au/prosecution-process/prosecution-policy

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 (eg 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)
	• Reliance on regulator
	• 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
	• International ICH VICH
	• 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 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
	• Financial or political repercussions

Import/export	Export: market access repercussions • Risk of rejection of product by importing country • Impact on international reputation (eg quantity) Import • Quantity • Potential for profit
Labelling	Impact degree of non-compliance • No label or wrong label (eg 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	Score
A: Human death or injury 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: 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: Serious 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: Serious 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; CCI Information; chemical of security concern, ASTAG/AGISAR rating.	**2**
G: Marketplace advantage Incomplete participation or avoidance of regulatory scheme.	**1**
H: Subtotal 1.1 (maximum 23)	

1.2 Likelihood of harm occurring	Score
I: High likelihood High volume; company, wide market exposure; major suppliers; high toxicity; vulnerable or inexperienced users; claims made; insecure/unlabelled packaging; price incentives; possible organised nature..	If no, go to J **35**
J: Medium likelihood High volume; moderate distribution; moderate market exposure; minor suppliers; low toxicity; claims made; insecure/unlabelled packaging; price incentive.	If no, go to K **21**
K: Low likelihood 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	Score
M: Negligent behaviour Willing or resigned to comply; low monetary value; no previous offences.	Enter if applicable to go to 2
	7
N: Combine 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)	