Australian Government
Department of Agriculture, Fisheries and Forestry

Detailed response to the final report on future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority

Cataloguing data

This publication (and any material sourced from it) should be attributed as: DAFF 2024, *Detailed response to the final report on future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority*, Department of Agriculture, Fisheries and Forestry, Canberra, November. CC BY 4.0.

This publication is available at agriculture.gov.au/apvma-detailed-response.

Department of Agriculture, Fisheries and Forestry
GPO Box 858 Canberra ACT 2601
Telephone 1800 900 090
Web agriculture.gov.au

Acknowledgement of Country

We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

Contents

Tables

Boxes

Executive summary

This *Detailed response to the final report on future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority* (Detailed Response) captures recommendations made across 3 reviews of the Australian Pesticides and Veterinary Medicines Authority (APVMA) and Australia's agricultural and veterinary chemicals (agvet chemicals) regulatory system undertaken between 2019 and 2023. The reviews were undertaken for different purposes:

- The Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia (Independent Review) (DAWE 2021) examined Australia's agvet chemicals regulatory system and provided 'recommendations for reform to ensure it is contemporary, fit-for-purpose, reduces unnecessary red tape, and increases the value of Australian agriculture' (DAWE 2021:iii).
- The Australian Pesticides and Veterinary Medicines Authority Strategic Review (Strategic Review) (Clayton Utz 2023) considered APVMA's allocation of regulatory priorities, its capability to carry out the full scope of its regulatory functions, and its operations.
- The *Final report on future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority* (Rapid Evaluation) (Matthews 2023) was an independent, rapid evaluation of the Clayton Utz (Strategic Review) findings and provided recommendations on future governance arrangements for the APVMA.

The reviews identified areas for improvement across the agvet chemicals regulatory system, including opportunities for alignment with regulatory best practice, ensuring consistent regulatory approaches between jurisdictions, equitable engagement across stakeholders and efficiency of regulatory practices.

Opportunities to strengthen APVMA governance arrangements were categorised within the Strategic Review and Rapid Evaluation. It was recommended that the APVMA governance arrangements be bolstered through greater engagement with the Australian Public Service (APS) and international regulatory bodies, and responsibilities be clarified so that APVMA management and the APVMA Board can fulfil their complete range of duties.

The Strategic Review and Rapid Evaluation also identified opportunities to improve APVMA operations. The reports proposed improvements to people and culture practices, including to people management policies and processes. The reports also recommended improvements to financial management and procurement processes and to ensure the APVMA's cost-recovery framework is sustainable.

The Detailed Response outlines work already undertaken by the government, the Department of Agriculture, Fisheries and Forestry (the department) and the APVMA to address recommendations made across all 3 reports. These include the establishment of the APVMA Board, supported by the Independent Review; and the repeal of the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016 (the 2016 Order), which dictated the APVMA's location on 4 June 2024, via the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Repeal Order 2024. The APVMA has undertaken a

range of actions to improve performance. These include finalisation of the APVMA Strategy 2030 (APVMA 2023) and associated implementation plan, the establishment of regular formal reporting to the minister on board meeting outcomes, the development of a more appropriate regulatory posture by prioritising and actioning regulatory enforcement when needed, and a review of all existing human resources policies and procedures, to modernise those arrangements and bring them into line with the broader APS.

The Detailed Response outlines a future program of reforms to be undertaken by the department and the APVMA. The reforms include an improved performance framework, the development of a balanced regulatory posture, enriched stakeholder engagement, and work to identify possible efficiencies within regulatory processes. This report also outlines proposed improvements to regulatory policy areas that will be considered in line with government best practice. The regulatory policy areas to be considered include consistency and efficiency in control-of-use regulation, monitoring the effectiveness of the regulatory system, and chemical review improvements.

Improvements in the APVMA's governance arrangements have been proposed, building on the work already undertaken. The proposed reforms include the development of a governance framework to describe all governing arrangements within the APVMA and to integrate governance processes. Future ministerial statements of expectations will continue to be accompanied by a statement of intent that articulates how the APVMA will respond to the ministerial guidance. The governance arrangements will reinforce the responsibilities of the APVMA, its board and chief executive officer (CEO), the minister and the department, to aid productive communication and provide assurance of the APVMA's regulatory independence.

Effective and efficient operations will be a foundation for the proposed regulatory and governance reforms. The APVMA will provide staff with ongoing training and learning opportunities to align skills development with contemporary APS approaches, continue to strengthen its human resources (HR) policy framework, and implement an effective people strategy that includes a focus on diversity and inclusion. The Detailed Response outlines activities underway to achieve a funding framework that provides the APVMA with financial stability, and the timing of information and communications technology (ICT) upgrades and reforms that allow the APVMA to track and record procurement approvals and expenditure.

Reforms will continue to support Australia's agvet chemical regulatory framework and the APVMA to ensure Australia's public health, food and environmental safety.

Introduction

Australia's agvet chemicals regulatory system is instrumental in protecting the health and safety of people, animals and the environment from risks associated with agvet chemicals. A well-functioning regulatory system increases the value of the Australian agricultural industry through access to safe and effective chemicals to control pests and diseases in animals and plants, minimising regulatory costs and protecting human, animal and environmental health with respect to the use of agvet chemicals.

The department, the APVMA and states and territories play independent and complementary roles within Australia's agvet chemicals regulatory system. The department has primary responsibility for the overall direction of Australian Government policy for the management of agvet chemicals. This includes the development and delivery of the government's policy priorities to ensure efficient and effective regulation and to address emerging challenges and opportunities within the Commonwealth agvet chemicals legislative framework.

The APVMA is established under the Agricultural and Veterinary Chemicals (Administration) Act 1992 (Administration Act) as the independent statutory authority responsible for administering the Commonwealth agvet chemicals legislative framework. The APVMA is responsible for regulating control of agvet chemicals in Australia up to and including the point of supply – for example, retail sale. This includes the registration of agvet chemical products manufactured, imported, supplied, sold or used in Australia and the monitoring and enforcement of the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code). The APVMA also plays an important role in identifying emerging challenges and opportunities regarding policy and legislation development and implementing regulatory solutions.

This Detailed Response to the Rapid Evaluation has been developed to complement the Australian Government's APS regulatory reform agenda and provides a direct response to recent reviews of the APVMA and the agvet chemicals regulatory system. A summary timeline and details of recent reviews are at Box 1. This response also considers recommendations raised in the Independent Review and the Strategic Review related to those in the Rapid Evaluation, although this is not its primary aim.

Under the previous government the then Minister for Agriculture, Senator the Hon Bridget McKenzie, appointed an independent panel to undertake a first principles review of the regulatory framework underpinning the National Registration Scheme for Agricultural and Veterinary Chemicals. The independent panel submitted the Independent Review on 28 May 2021. The Independent Review made 58 recommendations for reform of the agvet chemicals regulatory system.

The APVMA Board, established following the Independent Review, commissioned Clayton Utz to undertake an independent strategic review of the APVMA's allocation of regulatory priorities, its capability to carry out the full scope of its regulatory functions, and its operations. The review was commissioned at the request of the then Minister for Agriculture, Fisheries and Forestry, Senator the Hon Murray Watt, on 8 February 2023, in response to serious allegations raised during the Senate estimates hearing of the Rural and Regional Affairs and Transport Legislation Committee on 8 November 2022 (Senate Rural and Regional Affairs and Transport Legislation Committee 2022).

Clayton Utz's Strategic Review was released on 14 July 2023. It contained statements made by Clayton Utz, based on their desktop review, relating to the regulatory performance, financial management and procurement, and operations of the APVMA.

Following the release of the Strategic Review, Minister Watt commissioned an independent rapid evaluation of the APVMA to provide recommendations for the future governance, structure and funding arrangements of the APVMA. The rapid evaluation was undertaken by Mr Ken Matthews AO, and the Rapid Evaluation report was delivered on 20 October 2023. The Rapid Evaluation made 33 formal recommendations focused on improving the APVMA's performance and workplace culture.

On 17 April 2024, Minister Watt released the Rapid Evaluation and announced a preliminary response to the recommendations. The response included confirmation that the APVMA would remain in its current legal form (a corporate Commonwealth body, separate from the department), and the government's proposal to repeal the 2016 Order, which dictated the APVMA's location. Following consultation, the 2016 Order was repealed on 4 June 2024 via the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Repeal Order 2024. The repeal of the 2016 Order removed the restriction on where the APVMA must be located and enables the APVMA Board and CEO to make decisions on staff and office locations that best suit the APVMA's operational needs.

The Rapid Evaluation identified regulatory challenges and areas for improvement and provided the basis for the reform agenda outlined in this Detailed Response. This response addresses issues canvassed by the reviews and responds to formal and informal recommendations made across all 3 reports (see Appendix B) proposing reform activities to be undertaken by the department and the APVMA in the immediate and longer term.

The government and the APVMA have already taken significant steps to address the findings of the reviews and improve the APVMA's workplace culture, governance, transparency, accountability and stakeholder engagement. The Detailed Response provides a pathway forward for the APVMA to continue its reform journey and to ensure that its performance and operational stability are sustained into the future.

Reform activities outlined in this response will be implemented in a timely and sequenced approach, with the APVMA and the department managing resources to ensure business-as-usual work is not compromised. To allow monitoring of reform activities, the department and the APVMA will provide quarterly coordinated progress reports to the minister. The department and the APVMA will work with state and territory governments, regulated entities and interest groups to explore approaches to progress reform activities outlined in this Detailed Response. A modernised and fit-for-purpose agvet chemicals regulatory system will build public confidence in the government's regulation of agvet chemicals and provide continued assurance of Australia's public health, food and environmental safety.

Box 1 Summary timeline of recent reviews of the APVMA and agvet chemicals regulatory system

28 May 2021	14 July 2023	20 October 2023	17 April 2024	November 2024
Final report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia (Independent Review) Ken Matthews AO (Chair), Dr Anne Astin AM PSM, Dr Mary Corbett, Dr Craig Suann	Australian Pesticides and Veterinary Medicines Authority Strategic Review report (Strategic Review) Clayton Utz	*Final report on future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority* (Rapid Evaluation) Ken Matthews AO	*Preliminary government response to final report on future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority*	*Detailed government response to final report on future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority*
The previous government appointed an independent panel to undertake a first principles review of the regulatory framework underpinning the National Registration Scheme for Agricultural and Veterinary Chemicals. The Independent Review made 58 recommendations for reform of the agvet chemicals regulatory system.	The report is a strategic review of the APVMA's allocation of regulatory priorities, its capability to carry out the full scope of its regulatory functions, and its operations. The report was commissioned by the APVMA Board at the request of the minister, in response to serious allegations raised during the Senate estimates hearing of the Rural and Regional Affairs and Transport Legislation Committee in November 2022, and further serious allegations raised during the independent review undertaken by Ms Mary Brennan between December 2022 and February 2023.	The report was commissioned by the government following the release of the Strategic Review. Mr Ken Matthews AO was engaged to complete an independent rapid evaluation of the Clayton Utz findings and to advise on future structure and governance arrangements for the APVMA. The Rapid Evaluation makes 33 recommendations aimed at improving governance, organisational capacity, regulatory performance, and cultural shortcomings of the APVMA.	The preliminary response indicates whether the government supports, supports in principle, partially supports, or does not support each of the 33 recommendations of the Rapid Evaluation.	This Detailed Response captures recommendations made across 3 reviews of the Australian Pesticides and Veterinary Medicines Authority (APVMA) and Australia's agricultural and veterinary chemicals (agvet chemicals) regulatory system undertaken between 2019 and 2023. The Detailed Response outlines the government's reform agenda for the APVMA, including reforms already underway, additional policy analysis and research, and future consultation processes with stakeholders to develop policy positions for consideration by the government.

1 Improvement in regulatory practices

The integrity of Australia's agricultural and veterinary chemicals regulatory system is essential to the ongoing confidence of the Australian public and our trading partners that agvet chemicals do not pose an unacceptable risk to public health and safety, animal health and the environment. The Independent Review, Strategic Review and Rapid Evaluation all made recommendations that would modernise current regulation, underpinned by a fit-for-purpose legislative framework. The government is committed to continuous improvement in regulatory practices. This will be achieved through early, regular and meaningful stakeholder engagement, supported by evidence-based and data-driven solutions. The holistic approach described in this chapter will allow the department and the APVMA to work collaboratively to improve and sustain regulatory performance.

Box 2 Agvet chemicals legislative framework

The current agvet chemicals legislative framework comprises 9 Acts, 4 sets of regulations and 15 other legislative instruments, such as determinations and orders. The Acts and regulations, while amended from time to time, have been in place since the 1990s. The operation of the framework and how each piece of legislation interacts with the others is complex. Incremental amendments to the framework have added to this complexity.

As indicated throughout the Detailed Response, the government notes that further consideration and stakeholder engagement, including with states and territories, is required for some of the reforms recommended by the recent reports. This may also present an opportunity to consider the need to modernise and provide a less complex agvet chemicals legislative framework.

1.1 Diversion from regulatory best practice

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
12, 16, 17, 19, 21	1, 2, 3, 5	Nil

1.1.1 Scope for improved performance framework

The Strategic Review and Rapid Evaluation identified opportunities to improve the APVMA's performance framework. An updated and balanced performance framework, with new measures, is under development and will be implemented by the 2025–26 reporting period.

Two reports commissioned by government have indicated that the APVMA's performance framework could be improved. The Strategic Review suggested that the APVMA's performance indicators were limited to timeframe performance targets that are focused on agvet chemical product registrations, assessments and approvals (Clayton Utz 2023:3). 'Four of the APVMA's self-imposed 6 key performance measures in relation to regulation are related to timeliness or compliance with statutory timeframes' (Clayton Utz 2023:14). Quarterly performance statistics in relation to timeframe compliance had been published and included in regulatory newsletters.

> The APVMA has not to our knowledge published any data concerning quality, challenges, compliance, enforcement or risk management – the inference being that this data subset was not a focus or concern for the APVMA. (Clayton Utz 2023:16)

> Although it is not possible to conclusively make a determination on the basis of the material reviewed for this Report, the information available suggests that there is a risk that the APVMA's objective of timeliness may have been pursued to the detriment of other regulatory activities, including investigations, monitoring, compliance and enforcement. (Clayton Utz 2023:16)

The Strategic Review noted concerns that the APVMA's timeframe performance targets do not reflect regulatory best practice or resourcing (Clayton Utz 2023:3).

> Best practice regulation requires regulators to focus on cases that offer strategic opportunities to create public value. Regulatory culture that is too focused on procedures and timelines for performance can hinder regulators from adopting a responsive posture or focusing on opportunities for systemic change. (Clayton Utz 2023:15)

Consistent with government requirements, the APVMA's performance reporting, including the corporate plan and annual report, continues to be incorporated into its reporting processes as required under the Public Governance, Performance and Accountability Act 2013 (PGPA Act) and Public Governance, Performance and Accountability Rule 2014 (PGPA Rule). It has also continued to publish performance reporting on the APVMA website to support transparency and accountability of regulatory performance.

The APVMA has also begun to develop a more balanced performance framework, and has updated, replaced and added performance measures to its 2024–25 Corporate Plan, which is published on the APVMA website. An important step in developing a more balanced approach has been reducing the performance target of the proportion of all applications processed by the APVMA finalised within legislative timeframes from 100% compliance to 90% compliance.

An updated and balanced performance framework will be finalised and implemented by the 2025–26 reporting period. The performance framework will clearly demonstrate how the APVMA is meeting the government's expectations set out in RMG 128 Regulator Performance (Department of Finance 2023e). During the design process, the APVMA will develop, in consultation with stakeholders, tailored performance monitoring and reporting processes that are appropriately scaled to the APVMA's role, regulatory posture, specific legislative functions and environment.

The performance framework will include outcomes-focused performance indicators for reporting purposes and, where reasonably practicable, contain a mix of qualitative and quantitative performance indicators. Performance indicators that measure the quality of performance will be considered across several areas, including but not limited to average time difference between actual and target (statutory or operational) timeframes for all activities, compliance and enforcement activities, resource commitments (including staff numbers) to the APVMA's functions that match ministerial statements of expectations and annual plans, staff welfare, and stakeholder engagement activities across the full range of stakeholder groups.

At the end of the performance framework life cycle, the department will undertake an evaluation of the APVMA in line with the Commonwealth Evaluation Policy (Australian Centre for Evaluation 2021) and RMG 130 (Department of Finance 2023c). The evaluation will measure, assess and report on the APVMA's performance under the performance framework. The learnings from the evaluation will be used to support continuous improvement by testing and improving the quality of the APVMA's performance framework.

An updated performance framework that meets government guidance and principles for regulation, and includes comprehensive performance indicators will demonstrate to the minister and the Australian public that the APVMA is:

- meeting its regulatory responsibilities as set out by legislation and the responsible minister
- being efficiently and effectively operated
- discharging activities in a manner proportionate to the regulatory risk being managed
- coordinating compliance and monitoring approaches
- managing relationships with stakeholders in a transparent and open manner
- undertaking reviews of and continuous improvement to Australia's agvet chemicals regulatory activities.

1.1.2 Balance of regulatory posture across assessment, compliance and enforcement activities

Over the past 12 months, the APVMA has realigned its compliance approach to ensure it is consistent and comprehensive. Additional reforms, including a new ministerial statement of expectations and regulatory practice statement, will continue to support transparency and balance in how the APVMA approaches its regulatory responsibilities.

The APVMA regulates agricultural and veterinary chemical products up to and including the point of supply. It also has authority to monitor and enforce compliance under the Agvet Code and other legislation under its remit. The relevant minister, secretary and head of regulator have responsibility for identifying and settling the regulatory functions within a portfolio. In relation to the APVMA's compliance and enforcement function, the Strategic Review suggested 'it appears that there has been a very low-risk appetite for compliance action' and that 'there had been a failure to take appropriate and proportionate regulatory action in relation to non-compliance' (Clayton Utz 2023:21). The Strategic Review went on to note: 'The material we have been provided supports a conclusion that the APVMA does not appear to approach enforcement or compliance through penalties as a core part of its business' (Clayton Utz 2023:21). Compliance activity decreased from 2020–21 to 2022–23, which also saw a significant increase in the APVMA's practice of sending education letters rather than taking more formal regulatory action (Clayton Utz 2023:26). The Strategic Review suggested that based on APVMA enforcement outcomes data, 'there was an apparent unwillingness to utilise all regulatory levers available' (Clayton Utz 2023:26).

Over the past 12 months, the APVMA has aligned its compliance approach to conform with the requirements of the Australian Government Investigations Standards (AFP 2022). The realignment of the APVMA's compliance approach has included a review of its Compliance and Enforcement Policy

and Enforcement Guidelines and of its Compliance Case Categorisation and Prioritisation Model, to maintain a consistent approach to assessing and investigating non-compliance. This reform work has led to the APVMA undertaking compliance actions, securing Federal Court orders imposing a significant financial penalty on a supplier for providing and offering to provide unauthorised products, and issuing an injunction to prevent the sale or offer for sale of unauthorised products. Briefings on significant matters are provided to the minister where appropriate. The government also notes that following the realignment of the APVMA's compliance approach, a 2024 internal audit on compliance and enforcement operations in the APVMA (by an independent external provider) made no recommendations for improvement; it found that the APVMA's operations in this area were at or exceeding best practice.

Future reform activities are intended to support the APVMA to have a balanced regulatory posture. These include a new Ministerial Statement of Expectations for the APVMA that, while recognising the independence of the APVMA, will clearly articulate the government's expectation that the role and focus of the APVMA is regulating agvet chemicals for the protection and safety of Australia's people, animals and environment.

The APVMA is also in the process of developing a regulatory practice statement that will outline APVMA's regulatory posture, its regulatory principles, and the way it approaches its regulatory responsibilities. The practice statement will be informed by the Australian Government's 3 principles of best practice outlined in RMG 128 Regulator Performance (Department of Finance 2023e). Once this is finalised, the APVMA will develop a regulatory assurance plan to ensure that its regulatory activities are undertaken in line with its regulatory posture.

The APVMA will also ensure that the updated performance framework (see 1.1.1) will include indicators that will demonstrate that it is meeting all its regulatory obligations as per legislation and the ministerial statement of expectations. This will be a transparent mechanism for the accountable minister to use to monitor the APVMA's activities and ensure it is meeting its regulatory obligations.

The reform activities outlined in this chapter will provide a structure that ensures the APVMA performs its legislated responsibilities, including monitoring and enforcing compliance with the Agvet Code and other legislation.

1.1.3 Public confidence in the agvet chemicals regulatory system

The reviews identified the need for a clear strategy to improve public confidence in the agvet chemicals regulatory system. Further work will consider how a Principal Scientist position, expert advisory panel or other mechanisms could play a role in continuous improvement and greater transparency.

The first of 3 best practice principles for regulator performance is 'continuous improvement and building trust' (Department of Finance 2023e). The guidance notes that 'regulators should take into account and respond to community expectations of good regulatory practice to build trust and public confidence in their operations and in Australia's regulatory system' (Department of Finance 2023e). 'While neither Clayton Utz nor myself found evidence of deficient science decision making, the maintenance of public confidence is a vital policy goal in its own right' (Matthews 2023:33).

> Government and the community would expect that the regulator has formal arrangements for validating, substantiating, confirming, testing, and auditing scientific decision-making processes across the full range of its regulatory functions. Designed correctly, the arrangements should provide assurance about the quality and integrity of the regulator's scientific methods and practices, provide the means to benchmark Australian assessment methods against international methods, and strengthen public confidence in decision-making processes. (Matthews 2023:33–34)

The reviews identified the need for a clear strategy to improve public confidence in the agvet chemicals regulatory system. Activities need to be undertaken that provide transparency of regulatory decisions made by the APVMA, increase access to information relied upon by the APVMA to make decisions (where possible), and strengthen continuous improvement processes for regulatory decision-making. This includes horizon scanning to identify technological improvements and emerging opportunities and challenges in the agvet chemicals regulatory space.

The Rapid Evaluation recommended the re-establishment of a 'Principal Scientist position that is functionally separate from the Authority's roles in registration, review of chemicals and compliance' (Matthews 2023:34). The government will undertake work to understand the cost and benefits of a Principal Scientist. The cost–benefit analysis will also consider lessons learned from when the APVMA previously had a Chief/Principal Scientist, to understand limitations that may have led to the position being eliminated.

The government will consider establishing an independent expert advisory panel or panels that would provide an advisory role that champions continuous improvement across the APVMA and improved stakeholder engagement (outlined in 1.3.1). Implementation of these matters may require legislative amendment, and this will be explored at the relevant time.

Any agreed reform activities would be designed to increase public confidence in the regulatory practices of the APVMA through accountability, transparency and continuous improvement in approaches.

1.2 Diverse regulatory approaches across states and territories

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
Nil	Nil	4, 5, 6, 13, 18, 19, 20, 21, 30, 31, 32, 33, 43

1.2.1 Improving consistency and efficiency in control of use

There is an opportunity to improve national consistency in relation to agvet chemicals control of use. A new Agvet Chemicals Subcommittee, made up of senior representatives across Commonwealth, state and territory governments, would be an appropriate forum to discuss agvet chemical policy matters, including exploring approaches to achieve national consistency.

Under Australia's agricultural and veterinary chemicals regulatory system, states and territories are responsible for the regulation of agvet chemicals post point of sale. This includes off-label use,

recognition of training and licences, veterinary prescribing rights, compliance and enforcement (both resourcing and consistency in application), monitoring outcomes and user obligations.

The Independent Review Panel 'heard, almost unanimously from stakeholders, that the biggest failing of the current regulatory system is the lack of national consistency in control-of-use functions' (DAWE 2021:43). Differences between the control-of-use arrangements of the states and territories have led to complexity of requirements and inconsistency in application, such as in off-label use, rates of application, use patterns, disposal practices, training requirements, licensing, and veterinary prescribing practices.

Stakeholders have expressed discontent with the current approach to control of use, and support nationally consistent regulation (DAWE 2021:45).

> The current inconsistencies, and steadily declining allocation of resources, in control-of-use regulation across the states and territories weakens the overall system and continues to frustrate manufacturers, users, some state/territory governments, and the community at large. (DAWE 2021:20)
>
> Almost all stakeholders remarked that to-date, attempts by the states and territory officials to harmonise control-of-use have been exceedingly slow and have achieved only minor advances in some non-contentious areas. This has been despite clear guidance from ministers that harmonisation was to be pursued. (DAWE 2021:20)

Under the legislation governing the operations of the APVMA, its risk assessments of individual agvet chemical products presuppose that label instructions will be complied with in full. National inconsistency in the enforceability of label statements, as well as differences across jurisdictional regulation, may lead to unintended consequences.

The government notes that several of the recommendations made in the Independent Review are dependent on the implementation of a single national applied law model. This includes recommendations regarding a licensing framework, training standards, general product obligations, and a veterinary chemicals prescription protocol.

Currently, harmonisation is achieved in the regulation of agvet chemicals up to the point of sale (also known as the 'supply side' of agvet chemicals regulation) as the states and the Northern Territory apply the Commonwealth law (Australian Capital Territory law) as a law of their own jurisdictions.

As a joint steward of Australia's agricultural and veterinary chemicals regulatory system, the government notes that engagement with states and territories is required to explore approaches to achieving national consistency. The department is seeking to establish an Agvet Chemicals Subcommittee (ACS) under the existing Agriculture Senior Officials Committee (AGSOC). The ACS would be the key senior executive forum for collaborative engagement between Commonwealth, state and territory governments on agvet chemicals policy. The ACS may also consider updating the intergovernmental agreement in consultation with the AGSOC.

The ACS, in consultation with the AGSOC, would be well suited to consider and explore options to achieve national consistency for the agvet chemicals legislative framework. If feasible, nationally

consistent legislation would aim to support improved safety in the use of agvet chemicals and offer a range of benefits for business, users and governments.

1.2.2 Improving adverse experience reporting

There is scope to consider further improvements in adverse experience reporting at the national level to build on the work already undertaken by the APVMA on its adverse experience reporting program (AERP). This includes exploring efficiencies, enhanced data management and trend analysis, and increasing communication and awareness among the regulated industry, agricultural industry and Australian community.

The reporting of adverse experiences from the use of agvet chemicals is a valuable feedback tool for both the Commonwealth and state and territory regulators to undertake formal reviews of the safe use and effectiveness of agvet chemicals. However, a uniform national adverse reporting approach does not exist: adverse experience reporting arrangements differ at the national and state and territory levels (DAWE 2021:88). This has resulted in ad hoc collection of data and no national consistency in collecting, analysing and maintaining data on adverse experiences.

The Independent Review identified areas for improvement and greater efficiency in the current approach to reporting adverse experiences from the use of agvet chemicals, particularly pesticides. The Independent Review notes:

> Submissions and views expressed by various stakeholders throughout the Panel's consultations suggest that the current adverse experience reporting scheme for pesticides is slow, inconsistent, and cumbersome to use and users see little meaningful action being taken in response to reports. There is confusion for intending users of the scheme about whether to use state or local government reporting channels, or the national reporting channel. Even when the right channels are found, responses to reports can take an inordinately long time. (DAWE 2021:88)

Further, 'the national and various state schemes do not correlate or integrate well with each other. There is overlap, duplication and confusion' (DAWE 2021:88).

Most adverse experience reports received by the APVMA relate to veterinary chemicals. The smaller number of pesticide-related adverse experience reports is not necessarily evidence of a smaller number of adverse experiences, but rather may reflect the under-reporting of adverse experiences from pesticide use (DAWE 2021:88).

Adverse experience report data and subsequent analysis to identify trends allows the APVMA to record, assess and classify adverse experiences to detect uncommon events that were not evident during the initial registration process. Adverse experience reports for agvet chemical products may result in further regulatory action by the APVMA in accordance with the Agvet Code, for instance, through compliance action or chemical review.

Resolving adverse experience reporting issues at the national level would provide a more efficient interface between the Commonwealth and state and territory governments and enhance data management to improve trend analysis.

The APVMA has undertaken work to progress improvements to the existing AERP. This includes improved data analytics, website content, instructional material, and stakeholder engagement. Scanning of international adverse events by the APVMA is well advanced in both the veterinary chemicals and pesticides spaces, with most comparable overseas regulators having well-established systems. The APVMA is exploring the use of a variety of ICT reporting and tracking tools/systems for pesticides and veterinary medicines.

The APVMA has undertaken work to strengthen its collaboration and active participation with various domestic and international bodies for the purposes of information sharing and transfer of relevant adverse experience data. These include Safe Work Australia and the NSW Environment Protection Authority to enable sharing of information surrounding exposure incidents involving agvet chemical products. The APVMA is also a member of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration.

The government notes that the APVMA has already undertaken work to improve the AERP, and that further improvements will be considered over time as needed. The government supports increasing communication and awareness among the regulated industry, agricultural industry and the Australian community to support improved adverse experience reporting.

1.3 Approach to stakeholder engagement

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
14a, 16, 18, 20	4	10

1.3.1 Equitable dealings with stakeholders

The APVMA is committed to balanced and transparent engagement with stakeholders. Work has already been undertaken to update existing stakeholder forums and to provide opportunities for all stakeholders to engage with the APVMA. Further steps are underway to strengthen the department and the APVMA's stakeholder engagement approach.

In line with the APS Framework for Engagement and Participation, it is important to recognise that stakeholders offer value beyond being consulted and managed – their expertise can lead to better policy, programs and services (DISR 2021). Government has long used engagement and participation to earn trust and overcome complexity. As outlined in RMG 128, 'best practice regulators are transparent, open and responsive to feedback on how they operate, engaging in genuine 2-way dialogue with stakeholders and the broader community on their performance' (Department of Finance 2023e).

A trusted agricultural and veterinary chemicals regulatory system is critical to Australia's agricultural industry. It is vital that the department and the APVMA undertake proactive engagement, transparency and openness, and meaningful consultation on complex problems that require adaptive thinking, balancing values, interests and priorities. The Strategic Review raised concerns about an unbalanced approach to stakeholder consultation across the regulatory system (Clayton Utz 2023:13).

The Independent Review found that 'many stakeholders wanted more structured and effective engagement and consultation arrangements on matters relating to the regulatory system' (DAWE 2021:66). Past reforms have been perceived as only 'making improvements for the regulated community or user industries' (DAWE 2021:67). Engagement was undertaken on an as-needed basis and there was 'an absence of effective continuing dialogue between regulators, industry, users, and the community' (DAWE 2021:67). 'Discussions with stakeholders highlighted that in consultations on regulatory matters to date, many groups felt under-represented at best, and excluded at worst' (DAWE 2021:66). The Independent Review noted feedback from environmental and community non-government organisations that 'they felt the Department and the APVMA have not sufficiently considered their views and concerns' and they were 'frustrated at the amount of effort and time they had repeatedly spent to put their view to government with little acknowledgement of the issues they raised' (DAWE 2021:67). These perceptions were exacerbated as 'most could not see easy mechanisms to comment on system-wide issues beyond the APVMA' (DAWE 2021:66).

The APVMA has legislated requirements to publicly consult on various regulatory matters. However, these requirements largely relate to specific technical issues and concerns that mostly involve discussions with the chemicals industry or specific users of agvet chemicals. The APVMA also runs forums (e.g. the Agvet Users Forum and the APVMA Consultative Forum) that provide an opportunity for industry and agvet chemical product users to engage directly with the regulator but has 'no equivalent consultation mechanism for public health and environmental groups' (Matthews 2023:17).

The Strategic Review noted that transparency, communication and engagement with stakeholders had been a regulatory priority for the APVMA at a public, an organisational and an executive level (Clayton Utz 2023:12–13); however, its approach to regulation potentially focused on collaboration and engagement with industry (Clayton Utz 2023:5–6, 33). As an independent regulator, it is important that the APVMA maintains objectivity and impartiality, as part of its independence, to ensure there is public confidence in the regulator's decisions, and trust in the regulatory system (OECD 2017).

The department's stakeholder management has also been identified as requiring strengthening. The Independent Review noted that when developing reforms to the regulatory system, the department has not effectively engaged with stakeholders beyond key industry groups or with the broader community (DAWE 2021:67).

The APVMA and the department are actively taking steps to strengthen their approach to stakeholder engagement. This includes a commitment to the implementation of processes that seek to unearth and exchange expertise to design, improve and test policy, programs and activities. The APVMA and the department will also share information with the public about policies, programs or activities more widely.

The APVMA is committed to maintaining a professional arms-length relationship with the industry groups it regulates. It has finalised its Stakeholder Engagement Framework (2024–2030) guidance material, and training on best-practice engagement with stakeholders. The APVMA is also reviewing the process through which APVMA Consultative Forum and Agvet Users Forum members are selected, with a view to introducing a transparent application process for membership selection. A centralised stakeholder engagement function has been established to record, monitor and evaluate

the APVMA's engagement activities. This includes collecting targeted stakeholder information so that the APVMA may respond to specific stakeholder concerns.

The APVMA has demonstrated its willingness to capture more meaningful external feedback through revising its regular stakeholder survey. A wider range of interested stakeholders were asked to participate in the survey, which tested perception, awareness, and understanding of the APVMA's expertise, regulation and stakeholder experience. The survey will be undertaken every 2 years, with an improvement action plan to be delivered within 2 months of receipt of the survey results. Survey results and the improvement action plan will be included in the APVMA Annual Report.

Stakeholder engagement reforms will also include effectively conveying the benefits of regulatory reforms to the community and Australia more broadly so that reforms are not perceived as merely improvements for the regulated community or user industries.

The reform work being undertaken by the APVMA and the department aims to ensure transparency and equity in the interactions across stakeholders. Views expressed by stakeholders, including community concerns, will be considered and incorporated into routine policy development. The department and, where appropriate, the APVMA will consult with stakeholders on future policy options for potential reforms. This will provide a consistent, balanced approach to engagement that ensures access for all stakeholder groups to the wider policy settings of the agvet chemicals regulatory scheme. This includes the establishment of various communication channels that guarantee stakeholders interested in engagement are not excluded.

The work has already progressed, and further proposed best practice stakeholder engagement will lead to enriched policy and regulatory outcomes that improve public trust in the agricultural and veterinary chemicals regulatory system.

1.4 Efficiency of regulatory processes

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
Nil	Nil	35, 36, 44, 48

1.4.1 Regulatory responsibility for GMOs

The APVMA and the Office of the Gene Technology Regulator (OGTR) have differing regulatory responsibilities and expertise. While acknowledging the existing statutory requirements to seek advice from each other when considering certain applications, work is already underway to address potential duplication of regulatory effort.

Under Australia's agricultural and veterinary chemicals regulatory system, both the APVMA and the OGTR regulate genetically modified organisms (GMOs) that contain a substance defined as an agricultural chemical product or veterinary chemical product. The government acknowledges that the APVMA and the OGTR have regulatory responsibility for different and separate matters.

The Independent Review Panel:

> recognises that, in some situations, assessments by the OGTR and the APVMA can have duplicative elements – with the APVMA and the OGTR essentially performing the

> same types of assessment to manage the risks that a GMO may pose to people and the environment. However, there are also complementary elements as, for example, the APVMA also considers the product and active constituent(s) in their entirety (not just the GMO), the safety of target animals and crops, trade implications and efficacy, which are not assessed by the OGTR. (DAWE 2021:150)

The Independent Review noted that:

> Stakeholders have advised that where both regulators are responsible for a pesticide or veterinary medicine product that contains a GMO, approvals can be duplicative and slow. The Panel is aware that both regulators have had arrangements in place to reduce duplication. For example, the APVMA seeks to maximise the use of OGTR assessments, similarly to the way it can use international assessments. (DAWE 2021:143)

The Independent Review recommends that 'regulatory duplication should be avoided and a single regulator approach be made the default arrangement, with departures only when necessary' (DAWE 2021:151).

The current regulatory frameworks require the APVMA and the OGTR to seek advice from each other when considering certain applications, in recognition of the expertise located within each agency. As part of the APVMA's assessment process for materials that consist of or contain a GMO, the APVMA uses the OGTR's assessments, as many of the aspects of human and environment safety are common to both regulators.

The Gene Technology Ministers' Meeting has committed to implementing recommendations of the Third Review of the National Gene Technology Scheme. This includes considering adjusting the scope of gene technology regulation and introducing mechanisms to address duplication of regulatory effort at the interface with other regulatory schemes. The government supports the reduction of regulatory overlap wherever feasible, so long as appropriate management of risks is ensured. The government notes that this is consistent with the outcomes of the Third Review of the National Gene Technology Scheme.

1.4.2 Access to innovative products

Access to safe and effective pesticides and veterinary medicines is important for Australia's agricultural industry. While the government does not support the recommendation made in the Independent Review regarding implementing a licensing scheme, further consideration of potential options for a pathway for certain lower risk products will be explored.

The Australian agricultural industry requires diversity in pest and disease management tools, not only to combat resistance in pests and diseases but to support different agricultural practices and farming systems.

The Independent Review outlined that:

> Australia is a much smaller market for pesticides and veterinary medicines than North America, Europe and Asia. Because of this, Australians often miss out on timely access

> (and sometimes any access) to new pesticides and veterinary medicines and their uses, available to their overseas counterparts. This can put Australian exporters at a competitive disadvantage. It also denies Australians choice in state-of-the-art treatments or alternatives to existing products with lower risks to health, or easier-to-implement risk mitigation strategies. (DAWE 2021:152)

The Independent Review recommended:

> improving access to safe and effective pesticides and veterinary medicines not yet available in Australia but registered in credible, equivalent international regulatory systems, by creating a new licensing scheme for importers and manufacturers, which could also be accessed by grower groups and other users. (DAWE 2021:152)

The government recognises the intention of an internationally registered products pathway. However, the government considers the scope of this recommendation to be too broad and that the proposed licensing scheme would undermine the primacy of the APVMA's regulatory decisions. The APVMA already accepts international assessments for comparable products by comparable overseas regulatory authorities and includes this evidence as part of its evaluation of these products against Australian requirements. The government will consider and explore potential options for a pathway for lower risk pest and disease management tools, such as certain biopesticides, and expanded uses of products already registered in Australia and products registered for use in companion animals.

The government acknowledges that the APVMA can only evaluate applications to register products that have been lodged by an applicant. It is a matter for the agvet chemicals industry and applicants to present products for assessment to ensure a full range of product options are available to the agvet chemicals industry.

The government notes that the international registration by comparable regulators of innovative products like biopesticides, or other uses of existing Australian registered products, may in combination with any unique Australian requirements be sufficient to satisfy the APVMA of the product meeting the legislative criteria. These types of products generally represent lower or known risk categories that can readily benefit from this proposed pathway. The opportunity to assess alternative uses of existing registered agvet chemical products would allow transition from older products.

Leveraging trusted international regulatory evidence will remove potential assessment duplication, and the APVMA will be able to focus on the uniqueness of the Australia-specific components, while improving assessment timeframes. This will encourage the registration of new products in the Australian market, improving the choice of state-of-the-art treatments or alternatives to existing products.

1.4.3 Regulation of active constituents

The Independent Review suggested improvements to legislative requirements for active constituents. The department and the APVMA will explore further options to streamline the regulation of active constituents, while ensuring there are appropriate and efficient oversight mechanisms of the sources of active constituents. This will include the consideration of and continued efforts to update standards, in consultation with stakeholders.

In line with international practice, the APVMA approves each source of active constituent before it can be used in a registered product. Each approved source of active constituent is issued a unique approval number by the APVMA and is entered into the Record of Approved Active Constituents for Chemical Products. New sources of approved active constituents for agricultural chemicals must be chemically equivalent and not be of greater toxicological concern than the source first approved with that active constituent (subject to limitations on the use of data). Applicants must nominate an approved source of active constituent at the time of product registration and can seek approval for a new source as part of the product application. Following registration, holders may use any approved source of the active constituent without notifying the APVMA.

The Independent Review observed that manufacturers of chemicals could have multiple active constituent approvals associated with a single product registration, with each active constituent source product requiring a separate approval from the APVMA (DAWE 2021:200–201). The Independent Review suggested:

> The current legislative requirements are outdated and reflects the past when manufacturers often produced the active constituent and the product at the same site. The continued existence of these requirements is an example of how the regulatory system has not adapted to changes in the operational environment and leaves product manufacturers constrained in their ability to respond quickly to changes in active constituent supply or price. (DAWE 2023:201)

To resolve these issues, the Independent Review recommended that 'active constituents be considered and approved at a "substance level", independent of the site of manufacture' (DAWE 2021:202).

The department and the APVMA will explore options for streamlining regulation of active constituents and efficient ways to increase oversight by improving visibility of the use of active constituents from different approved sources. While more detailed standards for certain active constituents may bring about benefits and savings for industry (for example, data generation, reducing delays and costs associated with approvals of manufacturing sites) and reduce the APVMA's workload in the long term, this will require further consideration to ensure the risks are identified and appropriately managed and stakeholder engagement occurs where required.

The APVMA and the department will work together to ensure the continued update of standards to streamline the regulation of active constituents while effectively managing the risks to safety and efficacy.

1.4.4 Regulation of imported materials

The Independent Review outlined potential opportunities to streamline regulatory processes associated with the importation of biological pesticides and veterinary medicines. The department will explore these opportunities in further detail.

The Independent Review outlined that:

> there are improvements that can be made to better support biological-based businesses in meeting the demands of users and the expectations of the community, especially as the proportion of such products increases in the future. (DAWE 2021:187)

It also outlined that there is a:

> deregulatory opportunity to allow certain goods (or classes of goods) to be imported under alternative conditions on the basis of recognised international standards for the manufacture of high quality, safe, bulk biological materials. This deregulation would streamline import processes, including border clearance, through the publication of standard alternative conditions and reduce the burden of permit processes benefitting manufacturers, the government and users including farmers. (DAWE 2021:188)

The government notes that opportunities may exist to streamline processes. The department will explore the scope and feasibility of streamlining processes within Australia's biosecurity framework to reduce complexity and create efficiencies.

1.5 Product labelling practices

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
Nil	Nil	22, 23, 24, 25, 26, 27, 29, 41

1.5.1 Long and detailed product labels with some information not relevant to a user's needs or subject to obligations under concurrent regulatory schemes

The government acknowledges the potential opportunities presented by new technologies in product labelling. Potential opportunities to improve product labels require further consideration to ensure that essential safety information is retained for all users.

The Agvet Code requires registration holders of agvet chemicals to provide, on a physical label attached to the container, information that supports the safe use and disposal of chemicals. The label acts as the primary source of information about the product and outlines the required responses in case of an emergency.

Current product labelling practices have resulted in various challenges, including limited space for instructions in alternative languages and additional safety information. Product labels may include instructions that cover a range of commodities and pests and a diverse range of applications. This leads to complicated labels with large amounts of information, much of which 'is not relevant to an individual user's specific needs' (DAWE 2021:122). Also:

> Some stakeholders argued that registration holders should be able to include on their labels additional precautions (over and above those required by the APVMA) – such as additional personal protective equipment requirements. (DAWE 2021:123)

As product labels are the primary source of safety and use information, it is important that there is consistency across the various elements of the labels. Further, states and territories rely on approved product labels as the basis for their compliance and enforcement activities.

The government notes the importance of product labelling. Given the linkages of product labels to control-of-use matters, the development of a national labelling standard is a matter that may be considered by the ACS (see Appendix C) in addition to other national consistency topics as outlined in 1.2.1. Other product labelling matters that may be considered by the ACS include the exploration of smart labelling that is consistent with global practices; measures to clearly identify APVMA assessment elements for label content; and adoption of complementary and/or supporting electronic resources via smart labelling – for example, labels that contain a QR code that links to a website with further information. Consideration of these matters by the ACS would support the safe use and disposal of chemicals across Australia.

1.5.2 Operational practices on sources of first aid and safety directions

The Independent Review proposed the inclusion of first aid and safety directions drawn from any established Australian standard. The APVMA will retain a single source of first aid and safety directions to ensure that hazards are targeted and formulation specific.

The APVMA has primary responsibility for the *Handbook of first aid instructions, safety directions, warning statements and general safety precautions for agricultural and veterinary chemicals* (FAISD Handbook) (APVMA 2024b). The FAISD Handbook, is updated quarterly and published on the APVMA website, where it is available free of charge. The FAISD Handbook is updated using a consolidation of reports prepared by the APVMA.

The Independent Review recommended that the APVMA allow inclusion on the product label of first aid and safety directions drawn from any established Australian standard to the extent that the words would ensure the safe handling of the product (DAWE 2021:126). The Independent Review states that this will provide efficiencies by focusing 'pre-market assessment by the APVMA on those matters that are unique to pesticides and veterinary medicine' (DAWE 2021:126).

The government does not support this recommendation and will not be undertaking any further action to change the sources used to set the requirements for first aid and safety instructions on product labels. A single source of first aid and safety instructions for label directions (i.e. the FAISD Handbook) remains the preferred approach, even where statements from other recognised and regulatory sources exist. A move away from this approach would increase complexity in labelling requirements of products.

Other sources of first aid and safety directions, such as the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), may not be specifically tailored to the use of a particular product, increasing the risk of incorrect use and to the health and safety of people, animals and the environment. Safety directions are formulation specific and apply regardless of the concentrations at which the substance is scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (TGA 2024). A single entry in the 'Safety Directions' section of the FAISD Handbook applies only to that specific formulation description. Additionally, the GHS provides broad, generic information. This may result in the inclusion of broad, rather than targeted, hazards. This can

result in risks being overstated, leading to users disregarding warning statements on labels or reducing the use of chemicals where this is not warranted.

1.5.3 Barriers to including niche uses on full product labels

The Independent Review identified supplemental labels as a mechanism to reduce barriers for niche uses of agvet chemicals. The government considers that other measures will provide improved efficiencies and flexibility within the existing permit system.

The Independent Review recommended that the government introduce supplemental labels for agricultural and veterinary chemicals. This approach would provide a pathway 'enabling priority minor uses to be initially registered through a supplemental label, as opposed to issuing a permit' (DAWE 2021:176). It was assumed that efficiencies would be realised through allowing the original consideration for permit approval to be used to determine a permanent regulatory outcome, streamlining existing procedures. This would replace the need for farmers to 'hold and renew permits and avoid the APVMA needing to undertake the resource intensive permit to label transfer process' (DAWE 2021:177).

The current permit system allows for the short-term use of unregistered chemical products, or for minor uses of products contrary to label instructions. The current system places responsibility on users, as there is high reliance by farmers on the current permit system for new minor uses of agvet chemicals, particularly in small or emerging commodities where these uses do not form part of the registration process. Generally, the agvet chemicals industry may not consider minor niche uses or specialty crops for inclusion in registration, due to limited sales and the expense of developing data to support registration for niche uses.

The government does not support the introduction of supplemental labels for agricultural and veterinary chemicals, given the flexibility of existing mechanisms to address the concerns raised by the Independent Review. The government considers that the assumed efficiencies can be achieved through other measures such as improvements to permits, the APVMA's previous permit to label process, the use of international assessments, and the Improved Access to Agvet Chemicals Program (DAFF 2024) (see 1.8.1). These measures will result in improved access to new minor uses of agvet chemicals, particularly in small and/or emerging commodities.

1.6 Assessment and application pathways

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
22	Nil	14, 16, 34, 38, 39, 40

1.6.1 Ensuring regulatory effort reflects the practical risks of products

The Independent Review recommended that the regulatory scope of agvet chemicals should be framed on product risk profiles. This will be explored further in consultation with stakeholders, including other regulators, to ensure the APVMA's regulatory effort is considerate of products that have a higher risk potential for impacts on safety.

The breadth of products that fall within the agvet chemicals regulatory system means that a diverse range of risks are all subject to the same regulatory processes. The Independent Review noted that in specific instances these processes may impose unnecessary regulatory burden on some lower risk products and detract or delay safety considerations of some higher risk products (DAWE 2021:142).

Under the current legislative settings, some products that are subject to agvet chemicals regulation may be more effectively addressed through other regulatory schemes. This includes commodity gases, disinfectants, herbal extracts, and consumer goods that are used predominantly in households with little to no risk profile or personal protective equipment recommendations.

The government notes the recommendation to achieve efficiencies in the regulatory system. The department will work with the APVMA and industry to explore discrete situations and products where the full regulatory focus of the APVMA is not warranted.

As a general principle, aligning regulatory processes with consideration of risk and ensuring resources are being allocated to products with higher potential for impacts on safety contributes to a more efficient and effective agvet chemicals regulatory system. This is beneficial for the regulated industry and the APVMA.

1.6.2 Permit system improvements

The department and the APVMA will consider how the statutory criteria are applied to decision-making for permits and whether updates are warranted. This includes considering updates that may be required to ensure there is a clear distinction between permits that have been issued for emergencies and permits that have been issued for future potential emergencies. Further consideration of a licensing scheme for research purposes will be progressed for prioritisation by the ACS.

An efficient and effective permit and registration system must ensure the safety of humans, animals and the environment while providing sufficient risk-based mechanisms for ease of access. The Independent Review identified potential improvements that could be made to the current permit system to reflect the differences in risks posed by the controlled and limited use of agvet chemicals allowed through permits versus the broad-scale and generalised use allowed through registrations (DAWE 2021:173).

The Independent Review noted that the current legislative criteria for permits do not effectively or easily distinguish the application of statutory criteria in assessing a permit or the nature of an issued permit (in particular, emergency permits issued in anticipation of an event but not yet active) (DAWE 2021:173–174).

The Independent Review also highlighted that the existing criteria for the research permit PER7250 (APVMA 2004) are suitable for general small-scale research but not larger scale field trials and product evaluations, resulting in larger scale research trials requiring separate permits (DAWE 2021:175).

The government notes the recommendations. The department will consider how the statutory criteria are applied to decision-making for permits to ensure contemporary regulatory progression.

The department will continue to investigate potential updates that may be appropriate to differentiate and streamline permit approvals from product registrations.

The APVMA proactively consults with the Commonwealth, state and territory governments to ensure that current and future emergency permits are in place as needed and as appropriate. Consideration will be given to possible changes to permits or the Public Chemical Registration Information System Search (PubCRIS) (APVMA n.d.) to ensure there is a clear distinction between permits for active emergencies and permits for future emergencies.

The government is focused on ensuring strong support for biosecurity preparedness and agvet chemicals research through continuous improvements and making changes only when benefits can be realised. Therefore, the existing research permit mechanism will remain as it is, with further consideration to be given to adoption of a licensing scheme for research purposes as part of the ACS (in accordance with DAWE 2021, recommendation 19). The government notes the need to ensure that other regulatory systems (particularly food standards and poisons scheduling) are considered as part of the licensing system if adopted.

1.6.3 Mechanism to enable flexible and agile responses to new information about registered chemicals

While acknowledging the APVMA's progress on completing many of the longstanding chemical reconsiderations, the Independent Review noted further opportunities to improve associated processes and triggers. The department, with the APVMA, will explore these opportunities further, in addition to other contemporary mechanisms that provide appropriate assurance that products continue to meet the statutory criteria following their registration. Stakeholder consultation will be at the forefront of this work.

Australia is one of only a few countries (of those with a comparative agvet chemicals regulatory system) that do not have a mechanism for the systematic cyclical reconsideration of agricultural chemical products against contemporary standards. The current legal framework requires registration holders to meet safety, efficacy, trade and labelling criteria at the point of initial registration. From that point forward, the onus generally rests on the APVMA (and holders with regard to the requirement to submit relevant information where they have safety concerns, in accordance with the Agvet Code) to identify when agvet chemical products, or classes of agvet chemical products, may become a threat to safety or may have lost their efficacy, unduly prejudice trade, or no longer meet labelling criteria.

When the APVMA was established in 1993, all agvet chemical products that had been previously approved by states and territories were automatically registered and were not reassessed by the APVMA. Approximately 5,000 registered products were grandfathered into the National Registration Scheme for Agricultural and Veterinary Chemicals, containing around 600 active constituents. Noting the use of registered products as reference products, there are products registered since that time that still carry the directions for use, safety directions and other warning statements established by the states and territories before the establishment of the APVMA.

The APVMA's chemical review process relies on information from adverse experience reports, information identified by registration holders or the public, information from international decisions,

or expertise of scientific staff to identify potential sources of risk – based on their evaluations of other applications and variations – indicating that agvet chemical products, or classes of agvet chemical products, may not meet the statutory criteria. There is no general obligation placed on holders to undertake activities to identify or generate information that identifies a threat to safety or loss of efficacy, although there is an obligation for holders to submit relevant information to the APVMA if they become aware of concerns about safety or efficacy. While the APVMA does undertake chemical reviews, there are no other mechanisms in place to periodically and systematically confirm that registered agvet chemicals continue to be safe and efficacious and to meet contemporary scientific standards or enable the implementation of new risk mitigation measures if needed.

The Independent Review identified several concerns about the current chemical review process. These concerns include the responsibility assigned to the APVMA to undertake chemical reviews without a clear trigger, resulting in the perception that the process is subjective and lacking transparency. Public confidence in the rigour of the review process may be further impacted by the lack of obligation for the APVMA to publish the reasons why it considers that a chemical review is not required (DAWE 2021:93).

There have been mixed reviews from stakeholders about the timeliness of the reviews. Many chemical reviews take over a decade to complete and certain chemicals remain under review for more than 15–20 years. Further, the Independent Review notes that 'the APVMA's resource focus historically has been on timely product registration at the expense of chemical reviews' (DAWE 2021:94).

The Independent Review made several recommendations to improve both the transparency and the speed of the chemical reconsideration review process, including the implementation of legislated triggers to initiate a reconsideration, introduction of obligations that require the APVMA to publish a statement of reasons for not conducting a reconsideration, and development of clear standards that trigger chemical reconsideration with established suspension, cancellation and variation administrative processes (DAWE 2021:98).

The government notes efforts the APVMA has made to finalise longstanding chemical reconsiderations since the ministerial direction on chemical reviews issued in July 2023. The government supports the principles that underpin the related recommendations, to provide clarity around when chemical reviews are undertaken and transparency on decisions to not undertake chemical reviews. The department, with the APVMA, will undertake consultations on potential triggers for a chemical reconsideration review that could be considered by government to ensure the regulatory system can respond to emerging issues in a timely way. This will also include considering the extent to which the existing suspension, cancellation and variation processes are appropriate; and addressing transparency concerns, including the publication of chemical reviews or findings in instances when the APVMA assesses that a full review is not warranted.

The Rapid Evaluation also recommended the establishment of a cyclical registration model with associated legislative amendments that:

> would ensure that agvet chemical products have a more continuing contemporary assessment for their continued safe use, and that holders of registration are

> addressing contemporary concerns where there is emerging science, or data about health, efficacy or impacts on trade. (Matthews 2023:35)

The government acknowledges the workload challenges that have occurred internationally with periodic chemical review programs (specifically those used in the EU, Canada and the USA) and will draw on learnings from these programs to inform the design of an Australian model. Any model will be developed through a considered and consultative approach that analyses and formulates potential solutions for an appropriate, risk-based, proportionate and targeted regulatory mechanism. Matters to be considered in consultation with stakeholders will include:

- triggers to initiate a reconsideration
- transparency for when a reconsideration is not conducted
- design aspects such as registration timeframes and requirements for data generation (if and when needed)
- differences within the agvet chemicals industry that need to be taken into account (for example, differences between the agricultural chemicals and veterinary chemicals industries)
- resourcing requirements.

Any model, if implemented, would be pragmatic, practical and efficient to ensure the ongoing safety of Australia's people, animals and environment.

1.7 Product safety outcomes

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
16, 21	Nil	11, 12, 28

1.7.1 Monitoring the effectiveness of the Australian agvet chemicals regulatory system

There is an opportunity to improve monitoring of agricultural and veterinary chemicals in the food chain and the environment, ensuring the effectiveness of Australia's agvet chemicals regulatory system. The department will explore this opportunity in consultation with stakeholders, including states and territories, other regulators and government departments.

There is currently no existing comprehensive system to support monitoring the effectiveness of agvet chemicals regulation in Australia. The Independent Review noted that 'the current lack of comprehensive surveillance and monitoring arrangements undermines the credibility of the existing Australian regulatory system' (DAWE 2021:79).

The lack of monitoring of outcomes of the agvet chemicals regulatory system limits the government's ability to respond proactively to emerging issues. It is important that Australia's agvet chemicals regulatory system has 'the ability to objectively monitor performance and to ensure any areas of regulatory concern are identified for speedy investigation and response' (DAWE 2021:76). There are datasets that could be used in measuring the overall performance of Australia's agvet chemicals regulatory system. These datasets are developed through academic studies, industry programs,

international regulatory findings, and by citizen scientists. The Independent Review notes that although some of the data is available, it is disconnected and not being used to the extent it could be (DAWE 2021:77).

While Australia has a National Residue Survey monitoring system in place for agricultural export commodities and some domestic produce, the Independent Review considered 'the lack of a general system for monitoring and reporting on domestic produce to be a serious gap in Australia's current regulatory system' (DAWE 2021:81). The Independent Review also found that chemical monitoring methodology is applied inconsistently across jurisdictions and that the level of resources varies among states and territories (DAWE 2021:81).

The Rapid Evaluation noted: 'Community expectations are steadily becoming more demanding about the quality of regulation of agricultural and veterinary chemicals in the food chain and the environment' (Matthews 2023:38). There are currently limited post-market compliance checks to assess how effectively agricultural and veterinary chemical risks are being managed, and only ad hoc research into environmental impacts of chemicals (DAWE 2021:77); this includes no consistent national monitoring for the presence of agricultural (or veterinary) chemicals in waterways and soils in regions with intensive chemical use (DAWE 2021:84).

The Independent Review proposed that:

> enhanced safety (of human/animal health, the environment and trade) will be achieved through the implementation of 5 elements:
>
> - system surveillance, data mining and analysis
> - domestic produce monitoring
> - environmental monitoring
> - identifying product related concerns
> - greater transparency through public reporting of system surveillance. (DAWE 2021:75)

The government supports the consideration of a cost-effective surveillance and monitoring system that works in conjunction with chemicals surveillance and monitoring undertaken by states, territories and other relevant regulators. A surveillance and monitoring system would be expected to provide data to verify that the mitigation of risks established by the APVMA during the registration of products (or issuing of a permit) is effective; and by extension the intention of Commonwealth legislation to ensure the safety of Australia's human/animal health, the environment and trade is achieved.

The government also supports, in principle, consideration of increasing the monitoring of – and publication of findings from the monitoring of – domestic produce, water, soil and environment. However, it notes that the states and territories have responsibility for these matters.

Work has already begun in the department to explore the parameters of a surveillance and monitoring system. Key parameters to be explored include:

- how to efficiently and cost-effectively collect meaningful information about the use of agricultural and veterinary chemicals across Australia, leveraging existing data sources, programs and processes
- how to best leverage insights from similar overseas regulatory systems
- an agreed approach for the department to work with state and territory partners and other regulators to establish data sharing and reporting arrangements
- any legislation considerations.

In addition to other national consistency topics as outlined in 1.2.1, the ACS may provide an appropriate forum for consultation with state and territory governments. In formulating a system, further consultation with industry and other stakeholders (including state and territory governments; the Department of Health and Aged Care; the Department of Climate Change, Energy, the Environment and Water; and the Australian Council of Trade Unions) and regulators would be required to ensure analysis of the risks, issues and potential overlap with other regulators and existing solutions.

Given the potential complexity of a surveillance and monitoring system, a staged approach would involve consulting with stakeholders as a first step, followed by exploring the development of a minimum viable product or a proof of concept for future government consideration. This would assist with determining if larger investment is warranted for a surveillance and monitoring system. This reform work would aim to provide a mechanism that monitors agricultural and veterinary chemicals in the food chain and the environment, ensuring the effectiveness of the regulatory system.

1.7.2 Outdated label instructions

The Independent Review noted that labels may become outdated over time, with the latest label information not available to users. Requiring registration holders to review product labels will require further consideration by the department.

Australia's current agvet chemicals regulatory system does not require registration holders to ensure information on the label is correct and up to date, either periodically or when new information becomes available. This has resulted in outdated labels for products that are already in the supply chain, including labels that do not reflect changes to application rates, changes to application practices or emerging resistance. This means that users may not have access to the most current information.

The Independent Review identified a need for:

> the holder of a product registration to maintain an up-to-date understanding of the risks posed by the product, the currency of mitigation strategies for those risks, and that the product is accurately represented in terms of its use. (DAWE 2021:127)

The government notes the principles that underpin this recommendation. Compelling applicants to conduct a label review has value in ensuring holders are responsible for products in the market, and would act as a trigger for holders to check for up-to-date safety instructions that are relevant to the

formulation and use of the product and the efficacy of the product. An approach to address this issue requires further consideration as part of the process to design and implement changes to chemical reviews and related considerations (outlined in 1.6.3), and to be considered alongside smart labelling initiatives (outlined in 1.5.1). Any approaches considered would increase compliance with contemporary standards for agvet chemical use in Australia and improve agvet chemical safety outcomes.

1.8 Other regulatory processes

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
Nil	Nil	17, 37, 42, 45, 46, 47, 49

1.8.1 Improving access to newer chemistries

The department will progress further considerations regarding improving access to agvet chemicals in consultation with stakeholders. The APVMA will continue to manage its permit workload in accordance with the existing legislated timeframes.

The Independent Review identified that the small size of the Australian market can make registering an agvet chemical for use in Australia commercially unviable (DAWE 2021:21), particularly in the treatment of pests and diseases in specialty crops and livestock. Larger sectors face a similar problem when managing uncommon or emerging pests and diseases. These chemical access issues are often referred to as the 'minor use' issues. The Independent Review also identified that the APVMA relies on an informal prioritisation practice for applications, generally limited to the date the application is received (DAWE 2021:179).

The Independent Review recommends expanding the government's Improved Access to Agvet Chemicals Program (DAFF 2024) and introducing a fast-track application process for agvet chemicals that meet prescribed criteria (DAWE 2021:180).

The Improved Access to Agvet Chemicals Program has provided an average of $2 million annually since 2014–15 to Australia's agricultural rural research and development corporations (RDCs). It allows the RDCs to undertake trials and other work necessary to support applications to the APVMA for permits or label uses in small and emerging commodities, such as 'minor use' issues. Returns on government investment exceed 100:1 for the sectors involved (Eather et al. 2020). Noting this initiative expires in 2024–25, any further decisions on the program would be a matter for future consideration.

The government does not support the introduction of a fast-track application process. The APVMA is best placed to manage its workload, and the government will not mandate a prioritisation process for applications. The APVMA currently manages applications on a case-by-case basis. Where required as a result of external drivers, such as the incursion of invasive pests or supply disruptions, the APVMA can and does prioritise applications. All application/assessment processing follows the legislated timeframes.

1.8.2 Consideration of national benefits/consequences from access to a product in decisions on continued use

In accordance with the APVMA's regulatory responsibility to ensure safety, the agvet chemicals statutory criteria will continue to be required to be met in full and all decisions will remain science based.

In accordance with the Agvet Code, if the APVMA determines that a product does not meet the legislated criteria, then this is grounds to refuse an application to register a product or to suspend or cancel an existing product. The Independent Review found that some stakeholders have suggested that this is too narrow a focus and that the value created through using a product might outweigh such a concern; however, it noted that there was mixed support for introducing an additional benefits test (DAWE 2021:189). For example, if a new plant disease is impacting a major crop that could be treated by a particular product, there could be debate as to whether the treatment of the plant disease to save the crop is a greater priority compared to the need to remove that product from the Australian market because its use has been shown to kill pollinators.

The government does not support mandating measures that would diminish the safety and protection of Australia's people, animals or environment. Expanding the existing legislative criteria to consider the national benefits and market benefits of agvet chemicals during the evaluation process could diminish safety. Consideration of market benefits and the consequences of not having access to a product when proposing either to refuse an application for registration or to suspend or cancel a registration might also lead to a loss of public confidence in the regulatory system if it were perceived that market benefits/returns outweighed safety concerns or significant adverse environmental impacts.

The APVMA already considers levels of acceptable off-target risk. Mandating the consideration of market benefits would detract from the APVMA's role in ensuring safety and would result in an imbalanced and impractical framework. The safety, trade and efficacy criteria will remain balanced and must be met in full. Market advantages and benefits will not outweigh safety concerns. Assessments will continue to use science-based evidence to consistently make defensible decisions on all applications.

1.8.3 Information about the humaneness of vertebrate control tools, particularly between chemical and non-chemical options

The Independent Review recommended additional regulatory requirements to include humaneness scores on vertebrate pest control product labels. However, this sits outside the APVMA's regulatory scope. The government acknowledges that the states and territories have responsibility for animal welfare and that there are opportunities for manufacturers to provide information regarding the humaneness of the pest control products they produce.

The humaneness of a pest animal control method refers to the overall welfare impact that the method has on an individual animal. A more humane method will have less impact on welfare than a less humane method. The Independent Review notes that there are growing community expectations about good animal welfare practices, including the impacts of vertebrate pest control products on the suffering of the pest species (DAWE 2021:99).

The Independent Review suggested that Australia's agricultural and veterinary chemicals regulatory system should have greater regard to animal welfare considerations for treating pests. Animal welfare is a state and territory responsibility; however, the registration of agricultural chemicals is the responsibility of the Commonwealth and there may be capacity to consider animal welfare impacts in the regulatory system (DAWE 2021:99). There is a concern that label information does not allow people purchasing vertebrate poisons to compare products based on their relative humaneness (DAWE 2021:99).

The government does not support mandating the inclusion of humaneness scores for pest control products on the label. Regulating humaneness scores for pest control products is unrelated to the APVMA's existing regulatory scope and would introduce unnecessary and inconsequential complexity and additional regulatory burden on the APVMA. There is not a clear cost–benefit advantage to increasing regulation, as manufacturers of products can already include information on labels regarding the humaneness of the product, provided that the information does not contradict the labelling requirements under the Agvet Code or other relevant legislation. The government encourages industries that use vertebrate poisons to consider the inclusion of humaneness scores within their best practices or codes of conduct, to assist with the selection of vertebrate control tools.

The government notes that animal welfare is a state and territory responsibility, including preparing and enforcing animal welfare legislation, providing suitable institutional and legislative frameworks, implementing appropriate policies and programs, and making these readily accessible to the public. For example, the Queensland Government has prohibited the use of poisons on feral or pest animals that include the ingredients carbon disulphide and phosphorus, due to animal welfare concerns. State and territory governments also regulate non-chemical pest control methods such as trapping and provide information to users about the humaneness of different methods of pest control.

1.8.4 Balancing the promotion of innovation with facilitating access to market of lower cost generics

The department will consider opportunities to harmonise and improve legislative provisions that govern the APVMA's use of information, in consultation with stakeholders. The department will also explore removing the APVMA's mediation and arbitration provisions where there are appropriate existing state and territory mechanisms covering these matters.

The Agvet Code provides agvet chemicals innovators with periods of market exclusivity to 'protect their investment and recover their development costs' (DAWE 2021:191). Market exclusivity is ensured through legislative provisions that protect the information relied on by the APVMA to make certain decisions in certain circumstances, for a period of 3 to 15 years. During this period the APVMA cannot use the knowledge gained from the information for another purpose unless specific exemptions apply. The exclusivity period attached to an active constituent or product is based on multiple criteria including the type of information, when it is received, the kind of application it relates to, and if the information relates to an agricultural or a veterinary chemical. These provisions are complicated and inconsistent between agricultural and veterinary chemical products in similar situations.

The Independent Review acknowledged that:

> Some stakeholders would like to see longer periods of data protection to account for the significant upfront investment required to bring new pesticides and veterinary medicines, or new uses of existing pesticides and veterinary medicines, to market. Others seek shorter periods of protection since data protection effectively provides innovator chemicals companies with a monopoly on the market, which typically results in higher product prices and limits the number of comparable products available during the protection period. (DAWE 2021:192)

The Agvet Code also provides for compensation, in limited defined situations, if the APVMA uses protected information given to it in making subsequent regulatory decisions. As part of the compensation provisions, the APVMA facilitates mediation and arbitration when establishing appropriate compensation if that amount cannot be agreed between the parties. The Independent Review considers that:

> the negotiation of data access and compensation is a matter to be negotiated between companies and should not form part of the new pesticides and veterinary medicines regulatory system. The APVMA should be free to concentrate on its core business. (DAWE 2021:195)

The Independent Review recommended 'discontinuing the APVMA's role in arbitrating data access and compensation agreements between parties with similar products and uses that are under review' (DAWE 2021:196).

The government notes the recommendations, and the department will explore options to simplify and ensure consistency across the legislative provisions that limit the APVMA's use of information and remove the APVMA's arbitration and mediation provisions within the Agvet Code.

1.8.5 APVMA's role as both scientific assessor of applications and decision-maker following assessment

Timely assessment of applications will remain a priority of the APVMA. The APVMA acknowledges previous restrictions and challenges in recruitment of skilled assessors and will seek to improve its workforce surge capacity and implement performance indicators to measure surge capacity effectiveness.

Qualified and experienced assessors are critical to the execution of the APVMA's regulatory functions. The APVMA has struggled to recruit and retain sufficiently skilled assessors to meet its requirements in some areas, especially when trying to deal with workload surges.

The Independent Review outlined concerns about 'key person risks' where there is reliance on a small number of assessors with highly specialised skill sets. Further:

> The centralisation of suitable assessment skills and resources has resulted in Australia's limited chemical data assessment skill-base being largely concentrated within a single organisation. The decision to internalise environmental and health assessments, which the APVMA previously outsourced to the environment and health departments, has further concentrated these skills, leading to additional reductions in

> national chemical assessment capacity as well as impacting process efficiency. (DAWE 2021:203)

The Independent Review noted that the APVMA has the authority to use external experts via contractor arrangements, and some stakeholders have advocated for a need to expand this into a broad pre-application third-party assessment, including allowing large volumes of assessments to be outsourced to reduce costs and improve assessment timeframes (DAWE 2021:203).

While the government does not support a pre-application third-party assessment scheme, it notes the intent to ensure timely assessment of applications. Timely assessments are critical in supporting the productivity of Australia's agricultural industries, and this will be addressed through improving the arrangements for using external expert assessors and internal resourcing within the APVMA. The APVMA will maintain workforce surge capacity through the introduction of a protocol which will include appropriate performance indicators to measure its surge capacity effectiveness.

Concurrently, the government notes the efforts of the APVMA in strengthening its capacity to recruit, train and retain sufficient skilled staff. While the 2016 Order restricting the location of the APVMA was in place, the APVMA experienced challenges in filling a suite of vacancies across the agency – including, specific to this example, skilled assessors. Following the recent government decision to repeal the 2016 Order, location in Armidale is no longer a prerequisite, and recruitment can begin unconstrained within the available budget. The APVMA has started recruitment for positions in Armidale and Canberra with potential for relocation assistance and flexible working.

The people and culture improvements that are underway will support the APVMA becoming an employer of choice because of the increased employee value proposition (see 3.1.4), which will improve attraction and retention of staff. The APVMA is also engaging with the University of New England to build more interest in regulatory sciences to create a talent pipeline and succession plan for assessors while simultaneously addressing skill gaps in the employment market.

These efforts will ensure that the APVMA has sufficient workforce to undertake its assessment activities and meet its performance targets, providing Australians with access to improved products.

2 Improvement in governance of the APVMA

'Regulators require governance arrangements that ensure their effective functioning, preserve its regulatory integrity and deliver the regulatory objectives of its mandate' (OECD 2014). The Strategic Review and Rapid Evaluation identified areas for improvement in the governance of the APVMA. This chapter of the Detailed Response articulates reform work already undertaken by the APVMA to strengthen its governance. This chapter also highlights future government reforms that will support the establishment of transparent and accountable governance arrangements to challenge the APVMA's strategic management and performance issues and to improve public confidence in the legitimacy and robustness of the APVMA.

2.1 Isolation from the APS and other regulators

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
1, 2, 3, 6, 14a, 14c, 24, 25, 26, 27, 28	Nil	Nil

2.1.1 Strengthened governance of the APVMA, with appropriate oversight by the minister

The Rapid Evaluation suggested that the APVMA had become separated from the APS and the minister and recommended that the APVMA be replaced by an independent regulator within the department. This recommendation is not supported, as alternative measures to address the issues have been and continue to be implemented to improve the APVMA's governance and communication with the minister.

Alignment with APS practices, norms and standards is critical for the APVMA as a corporate Commonwealth entity. Upholding the APS Values, Employment Principles and Code of Conduct ensures staff exercise their position of trust and authority appropriately, demonstrate good public administration, and engender public confidence in their work (APSC 2022a).

The Rapid Evaluation suggested that the relocation of the APVMA to Armidale over the period of April 2017 to June 2019 impacted the performance and culture of the APVMA (Matthews 2023:14). Only 9% of staff accepted the offer to relocate, and many staff recruited following the relocation had little or no public service experience and did not have opportunities to build APS connections (Matthews 2023:14–15). This saw a reduced awareness of contemporary APS best practice and whole-of-government processes (Matthews 2023:15). 'Deficiencies in induction training or job handovers meant new staff may not have been fully aware of their obligations as an APS employee' (Matthews 2023:14).

The Rapid Evaluation found that the relocation of the APVMA to Armidale also resulted in isolation from other regulators across the APS and the department. Isolation from other APS regulators at senior levels may have contributed to the APVMA adopting behaviours that differed from regulator best practice and a 'decline in compliance and enforcement action' (Matthews 2023:16). The

APVMA's senior leaders were isolated from the department's senior executive staff (Matthews 2023:15).

The minister was not aware of any staffing issues raised at the Senate estimates hearing on 8 November 2022 (Senate Rural and Regional Affairs and Transport Legislation Committee 2022). The Strategic Review could not find reporting that had occurred to the department or the minister regarding staff complaints, issues or concerns (Clayton Utz 2023:50). The absence of complaints being appropriately escalated meant that relevant action could not be taken. It should be noted that, due to the nature of the Strategic Review, the veracity of these matters was not assessed (Clayton Utz 2023:50). While the APVMA Board has a duty under the PGPA Act to notify the minister when it becomes aware of any significant issue that may affect the APVMA, in this instance the Strategic Review noted there was 'little if any reporting of these matters to the Board' (Clayton Utz 2023:50).

The government does not support the recommendations for the creation of a new regulatory entity to replace the APVMA, as the process would carry high levels of risk and cost, requiring multiple years to implement and significant restructuring of the current legislative framework at both Commonwealth and state levels, and risking a low level of efficacy. Regulatory entity changes may not deliver benefits and could contribute to ongoing regulatory disruption and chain-of-command conflicts. Administrative changes to APVMA practices and governance (as detailed in this report) address the cultural and performance issues of the APVMA at a lower cost and with less complexity.

The identified risks and costs of implementing these recommendations include:

- onerous legislative requirements – potentially involving restructuring and redrafting of state and Commonwealth legislation, which would require in-depth and lengthy consultation and rely on multiple parliaments passing legislation
- compromised independence, and/or perceived independence, of the regulator
- staff impacts
- performance impacts.

The APVMA has made a considerable effort to reconnect with the Australian Public Service Commission (APSC) and has introduced training requirements to bring APVMA practices, norms and standards in line with the rest of the APS. Since February 2023 there has been widespread promotion of the APS Values and the APS Code of Conduct, and the development and promotion of the APVMA's own values and behaviours. The APVMA has redesigned its induction and core training modules, with annual completion required to be eligible for pay point progression.

Communication between agencies is a shared responsibility. 'A well-functioning collaborative relationship between policymakers and regulators drives better regulatory policy, practice, and performance for Australia and its people' (Department of Finance 2024a). Increasing collaboration and knowledge sharing between the APVMA and the department will provide the basis for shared responsibility for agvet chemicals policy, legislation and regulation. A Reporting and Cooperation Framework is being developed for internal use, to support collaboration and knowledge sharing between the APVMA (including the APVMA Board and CEO), the department and the minister. The framework will provide guiding principles and specify frequencies and timings for meetings between specific parties. It is intended to preserve the independence of the APVMA's scientific decisions,

while facilitating access to support and expertise from the department, and appropriate oversight from the minister. The framework will be implemented by the end of 2024.

Stewardship and risk management within the APVMA have improved. The Executive Leadership Team (ELT) of the APVMA has placed importance on coming together to steward the organisation, beyond individual line and functional responsibilities. The ELT uses a forward annual work program to ensure that enterprise risks and the APVMA's own compliance obligations are managed. In March 2023 the APVMA completed a major review of its corporate and enterprise risks to more accurately reflect its risk profile. As a result of the review, an AVPMA Board approved risk management framework is now in place and actively managed at tactical, operational and strategic levels. The APVMA has also revised its management structure, including adding a new position of Executive General Counsel to better allow the agency to manage its legal risks. The APVMA is developing a governance framework to describe all governing arrangements within the agency. This will be in place by December 2024 and will ensure that all governance processes are integrated and consistent. These reform activities make risk management a more active and explicit responsibility of the APVMA leadership and board. By creating an environment in which risks are accurately identified and responsibilities are clear, the AVPMA is more likely to achieve successful risk management.

The ministerial statement of expectations issued in September 2023 stated:

> The APVMA will maintain robust, effective and collaborative working partnerships with other Commonwealth, state and territory agencies, as well as the APVMA's counterpart regulators in overseas jurisdictions, to ensure the proper functioning of Australia's regulatory framework.

Consistent with these expectations, the APVMA is a member of key communities of practice (for example, the National Regulators Community of Practice), participates regularly in regulatory education activities and in international working groups, and has implemented work-sharing agreements with overseas regulators. The APVMA uses these forums to discuss and continually learn about improvement practices and regulatory best practice as demonstrated by Australian and international peers.

The APVMA has reinstated formal engagement with the minister to ensure compliance with the PGPA Act and establish a coherent system of governance and accountability. These formal engagements include the APVMA Board Chair meeting with the minister's office regularly and the CEO providing briefings as needed on specialist issues. Formal briefings are provided to the minister on regulatory reform activities, and after each of its ordinary meetings the APVMA Board has provided a formal written report to the minister that articulates any significant issues.

Metrics incorporated into the updated performance framework (outlined in 1.1.1) demonstrate that:

- the behaviour of APVMA staff upholds the APS Values, Employment Principles and Code of Conduct, in line with the rest of the APS
- APVMA staff are working and communicating regularly with other regulators to make continuous improvements
- APVMA is proactively managing risks to reduce the likelihood of future mismanagement

- briefings and meetings give the Minister appropriate oversight.

Improved corporate governance and management of the APVMA will result in the APVMA meeting its legislated mandate, including complying with its regulatory expectations and best practices.

2.2 Transparency of governance

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
7, 14b, 23, 33	9	7, 8, 9,10, 15

2.2.1 Enhanced ministerial guidance and increased transparency

The APVMA has implemented several measures to increase transparency in communication with the minister, following observations in the reviews that there was room for enhancement. Ministerial statements of expectations, ministerial directions and APVMA statements of intent will be made available to the public and staff to ensure the effective execution of ministerial guidance.

Ministers issue statements of expectations to provide greater clarity about government policies and objectives relevant to the regulator in line with its statutory objectives and the priorities the minister expects it to observe in conducting its operations (Department of Finance 2023e). Publishing ministerial statements of expectations provides full transparency to all interested parties, both inside and outside the APVMA. In line with Department of Finance (2023e) guidance, statements of expectations and statements of intent should be available on regulator websites and transparency.gov.au as part of a corporate plan and/or annual report.

The Rapid Evaluation observed:

> decisions by the Authority's leadership to transfer resources from compliance and enforcement to registration functions – the latter being an understandable priority for industry and emphasised by then-Minister Joyce in his guidance to the Authority. (Matthews 2023:16)

The Strategic Review suggested that the impacts of a registration timeframe oriented focus may have influenced the subsequent outcomes in compliance and enforcement: 'the APVMA's objective of timeliness may have been pursued to the detriment of other regulatory activities including investigations, monitoring, compliance and enforcement' (Clayton Utz 2023:16). The government has subsequently found that before 2023, ministerial statements of expectations and the corresponding regulator statements of intent were not made available to the public.

In September 2023 the then Minister for Agriculture, Fisheries and Forestry, Senator the Hon Murray Watt, issued a statement of expectations seeking improvements to workplace culture, governance, transparency, accountability and engagement. In line with Department of Finance guidance (Department of Finance 2023e), another ministerial statement of expectations will be issued by the end of 2024 following the appointment of the new APVMA Board Chair and CEO in July 2024, and the release of this response. This is an opportune time for the minister to provide clarity on government objectives and priorities, with a focus on capturing this Detailed Response, which concludes significant review processes that have been in progress since 2021. Following the issuance of the new

statement of expectations, the APVMA will respond with a statement of intent that outlines how it intends to meet the minister's expectations. The statement of intent will also highlight emerging risks or operational issues.

The APVMA Board and executive leadership, including the recently appointed chair and CEO, are committed to improving transparency and developing appropriate responses to ministerial statements of expectations. Focus will be placed on future statements of intent identifying and managing risks when responding to ministerial guidance.

The APVMA has taken action to improve the sharing of information with staff and stakeholders to promote understanding and effective execution of ministerial guidance. This has included publication of the September 2023 ministerial statement of expectations on the APVMA's website on 28 November 2023, along with the APVMA Board's regulator statement of intent, and the introduction of a formalised process for executive-level leaders to develop subsidiary guidance for their staff based on ministerial statements of expectations.

Other initiatives have been implemented to keep staff informed of work across the APVMA. This includes the introduction of a weekly staff briefing 'CEO downloads' by the then acting CEO in March 2023. The staff briefings will be continued by the new CEO on a fortnightly basis from July 2024. These briefings allow staff to be informed of what is going on across the agency and to ask direct questions of the CEO or other senior executive staff. The briefings occur in person and online and are recorded so that staff can access each briefing for up to 2 weeks afterwards.

These reform actions are reflected in improvements in the APVMA's 2023 and 2024 APS Census results. There were measurable increases in staff ratings for internal communications and Senior Executive Service (SES) communications, including improved engagement scores for the articulation of agency directions and priorities, and staff connection to the agency's purpose, objectives and goals.

The process in place to improve the sharing of ministerial guidance with staff and external stakeholders to promote understanding, and effective execution will result in government priorities being met and ensure the best regulatory practice by the APVMA.

2.2.2 Awareness of APVMA reform activities

The reviews noted that communication about reform activities between the APVMA, the department and the minister could be improved. The APVMA has recently implemented significant improvements in communication, including a refreshed organisational reform agenda and reporting framework which will provide awareness while maintaining the agency's regulatory independence.

Honesty and transparency are important principles of the APS Change Framework (Department of Home Affairs 2023). The Rapid Evaluation suggested 'at senior staff level [within the APVMA] … a pronounced lack of openness to externally-generated reform proposals' (Matthews 2023:14).

The APVMA leadership 'may have confused independence with isolation' (Matthews 2023:15), and 'awareness on the part of the Minister and the department of events, developments, and risks in the APVMA was reduced' (Matthews 2023:15).

The Strategic Review also identified high staff turnover as having a negative impact on required reform activity. High staff turnover 'would have inevitably resulted in a loss of corporate knowledge' which impacted organisational operations (Clayton Utz 2023:51).

It is fundamental that there is a coordinated approach to regulatory policy, practice and performance to ensure issues are resolved in a way that promotes regulatory best practice. Regulatory independence is important to ensure that regulatory decisions are made on an objective, impartial and consistent basis, which is why a well-functioning collaborative relationship between policymakers and regulators is effective in driving the reform agenda for regulatory policy, practice, and performance.

The current APVMA ELT and board have undertaken considerable work to progress critical reforms. This includes the creation of a process to agree an organisational reform agenda which is captured in the APVMA Consolidated Action Plan. It outlines reform priorities that respond to both the findings of the Strategic Review and the ministerial direction on chemical reconsideration. Reform activities undertaken to date include several key governance reforms (outlined in 2.1.1). The APVMA also published the APVMA Strategy 2030 (APVMA 2023) and associated implementation plan, which provides clear strategic direction for the agency. The Strategy 2030 will be regularly reviewed by the board to ensure it identifies and responds to emerging challenges.

The government recognises the importance of a robust, effective and collaborative working relationship between the APVMA and the department to ensure the delivery of fit-for-purpose regulation. Regular senior engagement has been established between the APVMA and the department to discuss matters of joint interest and policy development. Operational-level discussions will continue to occur consistently, with clear communication between operational and senior levels.

A formal process to brief the responsible minister on operationalising regulatory reform activities has been introduced. Since March 2023 the APVMA Board has provided a formal written report to the minister after each of its ordinary meetings that articulates any significant issues. The APVMA Board Chair and CEO also meet the minister at least twice a year.

In a ministerial direction in July 2023 and a ministerial statement of expectations in September 2023 the then Minister for Agriculture, Fisheries and Forestry, Senator the Hon Murray Watt, requested regular updates on chemical reviews and reform activities. The APVMA has provided updates in accordance with these requirements. The government supports the APVMA providing regular reports to the minister on its progress in implementing activities outlined in this Detailed Response and the reform process overall. The cadence of reporting will be discussed and agreed between the minister and the APVMA to ensure the reporting is fit for purpose and does not add an ongoing, unnecessary resource burden to the APVMA. A reporting and cooperation framework will outline the commitments made in the Detailed Response and make reporting and communication expectations explicit, as described in 2.1.1.

The APVMA, the department and the minister each have different roles and responsibilities. Ultimately, successful reform of the APVMA and the agvet chemicals regulatory system requires the APVMA, the department and the minister to each use the different levers available to them. For

example, when the APVMA shares its knowledge and experience with the department, this can be used to inform better policy design.

There will be clear delineations of responsibilities between the APVMA, its board and CEO, the minister and the department to aid more focused and productive communication and give assurance as to the APVMA's regulatory independence. The updated performance framework (outlined in 1.1.1) will incorporate metrics that assess the frequency of meetings between the APVMA and the department, the speed of responses, and employee perceptions of collaboration quality.

The Independent Review recommended the establishment of a Commissioner for Pesticides and Veterinary Medicines within the department. The government does not support this recommendation and is confident that the reforms proposed in this Detailed Response are effective alternatives. Several of the proposed responsibilities for a commissioner are, or will be following this Detailed Response, undertaken by the department, the ACS, the APVMA CEO and/or the APVMA Board. For example, the department is well placed to perform policy leadership, whole-of-system reporting and continuous improvement, and to lead forums through its established stakeholder networks and information technology (IT) infrastructure. The recommendation would add another layer of hierarchy and require legislative amendment, without adding value or benefits to the regulatory system.

The reform activities outlined here are intended to lead to a coordinated approach to agvet chemicals regulatory policy, practice and performance.

2.2.3 Board oversight, awareness and understanding of issues facing the APVMA

The Strategic Review highlighted benefits to be gained by clarifying the APVMA Board's functions and responsibilities, and by removing communication obstacles that challenged effective governance measures. Work has started to strengthen the board's role and improve relationships with the new ELT and the minister.

The APVMA Board was established in March 2022 following a recommendation in the Independent Review (DAWE 2021:66). Since its establishment, the board has experienced several issues, many related to its lack of clarity in implementation, and subsequent confusion regarding the board's authority and formal reporting requirements. The board was unable to identify the problems and risks based on the information presented 'either due to the lack of context or a lack of understanding as to the actual operations of the APVMA or the information presented' (Clayton Utz 2023:56). Deficiencies in board support processes were identified and were believed to have reduced the board members' awareness of potentially significant events, trends and developments that were in the board's areas of responsibility (Matthews 2023:14). As suggested in the Strategic Review:

> Based on the information we have reviewed it appears that the APVMA's governance model in the first year of the Board's operation was not successful in promoting Board oversight, awareness and understanding of the issues facing the APVMA. (Clayton Utz 2023:52)

The Rapid Evaluation highlights communication and cooperation issues between the board and the APVMA (Matthews 2023:14). The Rapid Evaluation notes 'the role of the board was made difficult by alleged failures on the part of senior staff to escalate significant issues involving key staffing matters, financial issues, ministerial issues and emerging risks to Board level' (Matthews 2023:13-14). As a result, it then became difficult for the board to notify the responsible minister of significant issues, as required under section 19 of the PGPA Act (Matthews 2023:13–14).

The APVMA has clarified and strengthened board governance and supporting processes in multiple ways, underpinned by a resetting of the relationships between the board and executive members. In March 2023 the APVMA appointed a board secretary with experience in public sector board secretary roles to support board functions. The APVMA has also developed a Board Skills and Composition Matrix to inform future board appointments and identify areas for professional development, and reviewed and strengthened the Board Charter and Accountable Authority Instructions to clarify the roles of the minister, the board and the CEO. The latter 2 documents will be reviewed annually.

The APVMA will continue to strengthen its governance structures, including through an update of the Internal Audit Charter to reflect changes to the Global Internal Audit Standards and to align the charter with the board and Audit and Risk Committee charters. The creation of a governance framework as an overarching document that details all governing arrangements within the APVMA will ensure that governance arrangements at all levels in the APVMA align and are consistent. This framework is due for completion in December 2024. The proposed reporting and cooperation framework (outlined in 2.1.1) will also assist in strengthening governance structures by clearly articulating the board's reporting responsibilities to the minister.

Section 27K of the Administration Act requires that 'the Minster must cause a review to be conducted of the functions and operation of the Board'. The review must be completed within 4 years of commencement of that section. Section 27K commenced on 4 March 2022; therefore, the review must be completed before 4 March 2026. The government undertook the legislated independent review in mid-2024 and will table the report in parliament once completed.

The government considers that establishing and maintaining an environment where the board is set up for success and enabled to perform its core functions is a necessary first step. The current APVMA Board structure is typical of other government statutory agency boards that are operating effectively. The recommendation in the Rapid Evaluation (Matthews 2023) to abolish the APVMA Board is not supported.

The government acknowledges the challenges faced by the board due to the nature of its implementation, subsequent changes in personnel, and the operating context. The government considers that further analysis of the composition and membership of the board is warranted to ensure the board has the skills, experience and capacity to perform the functions required of it.

Noting the steps already taken by the board, the APVMA and the department, any further actions considered should provide APVMA Board members and the ELT with a clear understanding of the delineation between the board and the ELT, their respective legislated and governance obligations, and their respective roles and responsibilities. This will be bolstered by an effective relationship between the minister, the board and the APVMA, supported by a formal reporting process for the

CEO and executive to report to the board. This will result in a more transparent, accountable and effective governance of the APVMA.

2.3 The purpose of Australia's agricultural and veterinary chemicals regulatory system

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
14d	1	1, 2, 3

2.3.1 Focus, identity, vision and leadership of the agvet chemicals regulatory system

The Independent Review and Rapid Evaluation highlighted the importance of a clear identity, vision and leadership of the agvet chemicals regulatory system. The purpose of the agvet chemicals regulatory framework is to protect and ensure the safety of Australia's people, animals and environment. The government will consider the vision statement, related objectives and principles if future legislative changes occur.

The Independent Review stated that Australia's agricultural and veterinary chemicals regulatory system 'lacks focus, a clear identity, vision and leadership' (DAWE 2021:25), making it 'difficult for producers, manufacturers, users, consumers, and the broader public to understand and engage with it, and for all the players in the system to operate in a coherent and coordinated way' (DAWE 2021:25–26). Stakeholders 'confirmed protection of human, animal, and environmental health as the primary objective' of Australia's agricultural and veterinary chemicals regulatory system (DAWE 2021:26). The Independent Review also recommended objectives and principles that would underpin Australia's agricultural and veterinary chemicals regulatory system and provide guidance on what the regulatory system should deliver (DAWE 2021:26–32).

The government supports in principle the recommendations made in the Independent Review and is committed to the underpinning and explicit purpose of regulating agvet chemicals being protecting and ensuring the safety of Australia's people, animals and environment. However, the government does not believe that legislative amendments to the vision statement or related objectives and principles would provide benefits greater than associated costs.

The government supports the department working with states and territories to explore options to address matters of national consistency (see 1.2.1). The government notes that if this work is progressed to the point where legislative changes are required, then a review of the vision statement and related objectives and principles could also be considered.

The government supports a review of the APVMA's purpose statement and any necessary changes, as per Recommendation 14d in the Rapid Evaluation (Matthews 2023:41). The new ministerial statement of expectations will also clearly articulate the government's expectation that the role and focus of the APVMA is regulating agvet chemicals for the protection and safety of Australia's people, animals and environment, and will request that the APVMA's purpose statement explicitly reflect this.

As part of its Strategy 2030 (APVMA 2023), the agency has designed a new stakeholder survey that measures a cross-section of stakeholders and public perceptions of the APVMA's overall reputation, as well as awareness and understanding of the APVMA's role. Survey data will be used in conjunction with enquiries data, website analytics and feedback, social media and media analysis, complaints, and other feedback data to assess external understanding of the APVMA's role. It will identify targeted activities to strengthen external stakeholders' and the public's understanding of and ability to engage with the APVMA.

Reform activities outlined in this Detailed Response, including the stakeholder survey, the new ministerial statement of expectations, and an updated regulatory posture statement, will assist in clarifying the APVMA's role and the objectives already existing in the current legislative framework. This will result in producers, manufacturers, users, consumers and the broader public having an accurate and contemporary understanding of the purpose of the agvet chemicals regulatory system.

3 Improvement in operations

For the APVMA to be an effective and efficient regulator, it must be a well-functioning agency. Of the 3 reviews addressed in this Detailed Response, the Independent Review only focused on regulatory reforms, whereas the Strategic Review and Rapid Evaluation had additional content that identified potential operational issues within the APVMA. This included improvements to workplace culture. The APVMA has started on a road to improvement. The government acknowledges this and identifies that there is more work to be done. The reform activities outlined in this chapter will improve processes and practices within the APVMA and support efforts to foster professional competence and attract, develop and retain the best people to manage the APVMA's regulatory responsibilities.

3.1 People and culture

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
4, 8, 9, 10, 11, 12, 13, 15, 16, 30a	7, 8	Nil

3.1.1 Impacts of relocation on public service capabilities and culture

The Rapid Evaluation acknowledged the impact that relocating the APVMA had on workplace culture. The APVMA has started implementing a program of reforms to rebuild staff capability and improve culture.

The Rapid Evaluation noted that the APVMA's move to Armidale caused a large employee separation rate, with few staff employed at the date of transfer accepting the offer to relocate, and a small number obtaining one of the few positions in the retained Canberra office (Matthews 2023:14). The Rapid Evaluation noted that corporate memory and experienced staff were lost, along with their critical skills, particularly in regulatory science and basic APS governance and management practices (Matthews 2023:14).

The Strategic Review suggested that 'significant changes to the APVMA's staff base upon relocation from Canberra to Armidale' impacted organisational operations as there was a loss of APS experience and knowledge which 'may include practical awareness of foundational public service principles' (Clayton Utz 2023:51). The Rapid Evaluation further noted that 'Armidale has a small local public sector with few job candidates having prior experience in basic APS processes' (Matthews 2023:14), making recruitment challenging. As a result, some candidates were placed into roles for which they did not have the requisite skillsets.

The 2016 Order mandated that future role vacancies be restricted by specific location conditions. The Rapid Evaluation recommended revoking the 2016 order so that the APVMA could 'recruit staff to any suitable location' (Matthews. 2023:27). As noted in the Rapid Evaluation, the 2016 Order had 'made recruiting and retaining suitably experienced staff … especially challenging' (Matthews 2023:14).

The government does not support recommendations made in the Rapid Evaluation which require the APVMA to be relocated to Canberra. There are significant risks with relocation that are not outweighed by the identified benefits (see 2.1.1). A second move would cause significant disruption

and there is no contemporary evidence to suggest that a move back to Canberra would improve current regulatory performance or benefit the APVMA's staff and culture. Considering the improvements that the new ELT has implemented since its inception, the APVMA is now solidly on the path to performance and cultural improvement. Those gains would be put at risk by a second destabilising and disruptive move.

The Minister for Finance repealed the 2016 Order, with effect from 4 June 2024. The result is that the APVMA can now recruit the required professional, technical and leadership skills unfettered by location restrictions, in line with modern workforce management practice. Additionally, the APVMA will promote its Flexible Work Policy at the point of recruitment. A flexible approach will enable the agency to attract suitably qualified staff for its roles that can be performed outside of Armidale. This is significant given that some previous recruitment drives have been unsuccessful, and some received no applicants at all. It is anticipated that the APVMA will reap the benefits of the 2016 Order being repealed, both immediately and into the future. Location restrictions have been an issue at the point of recruitment, so advertising that restrictions are no longer in place may increase the employee value proposition and attract suitably qualified candidates who were previously put off (Matthews 2023:27–28). This action alone will cause the rate of vacancies to drop and the standard of candidates to increase. Filling vacant positions with quality candidates will help the APVMA to achieve its agency work priorities.

The APVMA is working proactively to overcome the previous disconnection in communication between the board, senior managers, and non-SES staff. This work has started, and the new executive has made significant inroads to improving linkages across the agency through a variety of communication initiatives. The APVMA will maintain continuity of this work, irrespective of changes in senior executive personnel.

Communication improvements include expanding reporting pathways to convey critical HR data to the ELT. Regular reports on employee separations, flexible working arrangements, and ensuring that prompt attention is paid to APS Census results, will increase the efficacy and timeliness of response actions. This will contribute to trend identification and effectively trigger early intervention strategies which will deliver better results that align with the APVMA's people strategy.

The APVMA has recognised the need for a senior management talent pipeline for the agency and a benchmarked set of APS skills for this cohort. It has commenced an analysis of development needs using the APSC's Integrated Learning System (APSC 2021a) to address alignment and drafted a talent management program. Additionally, all new SES officers are required to complete the APS SES Orientation Program (APS Academy 2024). The government recognises and supports the APVMA initiatives to date and encourages the APVMA to access leadership programs endorsed by the APS, talent-sharing programs across the APS, and mobility as a lever for capability building.

Regular reliable reporting of data to the ELT and the board will help change the agency's HR posture from reactive to strategic and proactive. The government supports harnessing data analysis to identify potential pain points promptly so that early intervention strategies can be applied. Early intervention strategies for HR matters will allow the APVMA to resolve issues quickly, prevent escalation and maintain a productive work environment.

The APVMA will prioritise supporting staff with regular access to learning and capability-building opportunities. It will employ a variety of learning methodologies (for example, active learning, or blended learning using a combination of delivery methods such as online and face to face). Adapting delivery to suit employee needs will achieve sustained capability growth in the APVMA workforce. Additionally, investing in specific senior manager and leadership skill sets will result in a general capability uplift across multiple disciplines.

Applying these initiatives will allow the APVMA to stabilise and consolidate its skill base. The performance of the agency – meaning its ability to deliver against its core functions, make evidence-based decisions, communicate, strengthen relationships and provide a safe and supportive workplace – will be improved and no further reviews or interventions will be required.

3.1.2 Handling of misconduct allegations

The Strategic Review and Rapid Evaluation identified the need for improvements in how the APVMA handled misconduct allegations. The APVMA has implemented a schedule of foundational improvements that is delivering capability uplift in this realm. Further work will consolidate progress and contribute to effective complaint handling in the agency.

In November 2022 a line of questioning in Senate estimates brought to light 'serious allegations' (Clayton Utz 2023:3) about the internal culture of the APVMA (Senate Rural and Regional Affairs and Transport Legislation Committee 2022). Subsequent reviews of the APVMA (the Strategic Review and the Rapid Evaluation) identified that a capability uplift in communication and management of people issues, and in complaint handling and reporting, was required (Matthews 2023:13–14).

The Rapid Evaluation observed that the APVMA pursued an interpretation of independence that led to agency isolation from peer APS agencies and colleagues – 'it began to act as though independence required isolation' (Matthews 2023:18) – which resulted in behavioural standards and complaint-handling procedures that fell short of APS expectations. The Rapid Evaluation further notes that a failure to respond to issues raised by staff also contributed to shortfalls in complaint handling and management of people issues (Matthews 2023:13), resulting in an environment where 'isolated from the APS, coupled with recruitment of staff with little or no public service experience, a different culture gradually emerged, licensing different workplace behaviours and personal conduct' (Matthews 2023:15). HR records show that a formal complaint was made about once every 4 to 6 weeks for 5 years, which was a large number for an agency of the APVMA's size (Clayton Utz 2023:50).

The Strategic Review reported that 'there were allegations of instances where instead of supporting people who were trying to make a complaint, they were instead actively discouraged from making the relevant complaint' (Clayton Utz 2023:50) and that 'the allegations also suggest a consistent theme of dissatisfaction in the manner that complaints were handled or progressed' (Clayton Utz 2023:47). Additionally, the Rapid Evaluation noted 'alleged failures … to escalate significant issues involving key staffing matters' to the board (Matthews 2023:13–14).

The HR policy framework became outdated, comprising more than 40 obsolete HR policies, leading to the need to 'Review, revise and reissue the full suite of HR (people) management guidance material – some of which is now well out of date' (Matthews 2023:31).

Concerns raised included 'Poor workplace culture and evidence of demoralisation, stress, disaffection, and alienation of some staff' (Matthews 2023:13); thus, the poor workplace culture was 'costly to organisational performance and staff well-being' (Matthews 2023:16). The Strategic Review noted 'allegations about taking adverse action against employees who raised concerns about the management or the culture of the APVMA' (Clayton Utz 2023:49). Similarly, the Rapid Evaluation observed 'Possible procedural failings and lack of support for staff, in the way whistleblowers and complainants were treated' (Matthews 2023:13).

To address these deficiencies, the APVMA implemented a people strategy which describes its systematic approach to people management improvements, encompassing complaint handling and cultural enhancements. The government notes that the APVMA has addressed all outstanding HR complaints, including referral of matters to the appropriate authorities where required. The government acknowledges that the APVMA has also supported capability uplift and improved communication pathways by implementing:

- a renewed focus on the APS Values and Code of Conduct (APSC 2022a), including launching a set of APVMA-specific values and behaviours
- a new Risk Framework which communicates the APVMA's risk appetite
- a refreshed Integrity Framework which describes responsibilities and obligations for employees and managers
- public interest disclosure training and awareness, and the establishment of public interest disclosure officers to protect whistleblowers
- new workplace contact officer and mental health first aid officer networks as alternative supporting mechanisms and reporting pathways for psychosocial safety
- a restored relationship with union representatives, with regular meetings about workforce and reform activities
- a re-established Staff Consultative Committee with scheduled quarterly meetings and out-of-session meetings as required for any significant organisational change or before each new policy launch.

The government supports these initiatives and is aware that much more work remains to be done. The APVMA has developed an annual census action plan and identified several key actions, including the need to review outdated HR policies and build effective guidance materials for employees and manager decision-makers – all of which require investment.

The APVMA's employees and managers will benefit from a robust HR policy framework and effective people strategy, as the efforts of the workforce will be aligned and optimised to attract, engage, develop and retain staff. Addressing the policies and the supporting guidance material is a priority for the APVMA, as these efforts will deliver effective HR practice, grow people management capability in the workforce, demonstrate standards and expectations to staff, and send a clear message that staff wellbeing is valued. Further, actions that enhance communication with union representatives about these initiatives will improve outcomes.

The APVMA's re-established connection to its HR obligations, including the APS Values and Code of Conduct, will continue to strengthen. It is anticipated that successful implementation of these initiatives will deliver rapid, measurable improvements in the severity, incidence and handling of complaints, and that the improved communication pathways will ensure the APVMA workplace remains safe and free from psychosocial harm.

3.1.3 Career development, succession planning and talent management

The Rapid Evaluation highlighted that the APVMA's relocation had unintended consequences whereby it was detached from public sector values, conventions and best practice. Reform initiatives will address the impacts of detachment on the workforce, which affected career development, success planning and talent management.

The establishment of the APVMA in Armidale may have led to a detachment from established APS development and capability-building opportunities, and 'a consequential decline in understanding of public service values, conventions, and best practice' (Matthews 2023:16).

With the exception of some regulatory networking, the APVMA had limited or no APS inter-agency peer engagement, so there was inadequate cross-pollination of experience and ideas because of 'the corrosive sense of isolation from the APS and from the [professional] community' (Matthews 2023:29); thus development stagnated, and policy frameworks became outdated and less relevant.

The APVMA leadership team did not appear to address turnover with effective succession planning, creating 'significant gaps in its capability' (Matthews 2023:14–15). This led to the recommendation in the Strategic Review that 'strategies are put in place to maintain corporate knowledge if there is staff turnover' (Clayton Utz 2023:51).

The APVMA's learning and development function had insufficient support from the executive, which led to under-resourcing and an inability to service the needs of staff effectively, as evidenced by the recommendation to provide or augment corporate services (Matthews 2023:22).

The APVMA has recognised that it would benefit from improved relationships with the department, peer regulators and other APS stakeholders, such as the APSC, to make opportunities for development available as they arise. The government supports the APVMA fostering a closer and more effective relationship with the department which will also provide opportunities for partnered arrangements, such as linking learning management systems. By developing an agreement with the department, the APVMA may capitalise on the economies of scale that the relationship with a large agency may bring. These initiatives will reduce duplication and promote collaboration, which is a One APS goal (APSC 2021b), without compromising the APVMA's independence or appropriate delineations of responsibility.

The APVMA has drafted an updated Professional Development Assistance Policy and a Learning and Development Strategy. This is a significant step towards its goal of upskilling staff and expanding the range and diversity of learning products that are available. The APVMA will continue to expand its Instructional Material Library (IML) to support these documents. The IML operates as an easy-access single source of truth for all policies, strategies, guides and instructional materials. The government supports the expansion of the IML to inform and assist employees to upskill to a self-service standard where appropriate.

Additionally, the APVMA has started to develop a manager's 'toolbox' which will articulate the agency's requirements on management development training and timeframe expectations. This will be especially relevant for new managers or employees in technical roles who may not have had previous experience in managing people. The government supports these initiatives as they address identified manager capability gaps and will empower managers to foster high performance and engagement from their people.

The APVMA will continue to expand its position description library for all positions in the agency. This streamlines recruitment effort and provides a sound basis for development of a capability framework. A comprehensive capability framework will give the APVMA the robust data evidence it needs to succession plan effectively. It will also positively contribute to mobility planning and preparing employees for their chosen career paths. The government supports initiatives that increase career opportunities for APS employees and minimise corporate knowledge losses by capitalising on a continuous operational succession plan which will remove the threat of future skill gaps. The government recognises that the APVMA may require assistance to build a capability framework, given the specialist skills this requires, and may need to procure the skills required to finalise this work within the APVMA's existing budget.

The APVMA will proactively cultivate relationships with other APS agencies, the department and the APSC to maintain a best practice approach to skills development that is continuously improving and aligned with contemporary APS approaches. There will be a focus on development of management skills, with managers being supported to access APS-approved courses and participate in APS-wide professional peer groups as required. The government expects the APVMA to monitor capability uplift to ensure sustained improvement across the agency.

The APVMA will liaise with other regulatory agencies, using communication pathways such as professional communities of practice, to identify emerging changes in the regulatory fields that require staff development and to develop a method of benchmarking changes which is under continuous assessment.

3.1.4 Employee life cycle processes support and integration

The Strategic Review and Rapid Evaluation identified that a disconnection from APS standard practices affected multiple points along the employee life cycle. The APVMA has made substantial progress in re-establishing its sense of APS belonging, and the reform initiatives underway will cement that connection.

As an APS agency, the APVMA is required to recruit staff in line with the APS Employment Principles. From 2018 to 2023 there were 'allegations of nepotism and favouritism' (Clayton Utz 2023:49). According to allegations, some recruitment decisions were not based on merit, which conflicts the with Public Service Act 1999 section 10A, APS Employment Principles.

The APVMA did not have an effective APS induction process, and new staff 'may not have been fully aware of their obligations as an APS employee' (Matthews 2023:14); consequently APS best practice was lost (Matthews 2023:15).

The Strategic Review noted that the APVMA's HR function had 'a lack of capacity to respond and/or keep accurate records in relation to the complaint' (Clayton Utz 2023:50).

Exit interviews were considered a low priority and conducted sporadically, and there was no consistent approach to analysing interview data. 'Basic public administrative practices such as … separation practices have lapsed from best practice' (Matthews 2023:24). The Rapid Evaluation recommended that:

> Well-tested APS practices of maintaining records of decisions, with reasons, need to be restored. Records need to be readily searchable and retrievable. The reported failings in these areas need to be taken seriously and put right. (Matthews 2023:24)

Given the span of issues and problems identified in the reviews, the solutions required to bring the APVMA up to meet or exceed APS employment quality standards are multifaceted and diverse. The APVMA has started work on a recruitment policy framework which aligns all recruitment activity with APS legislative obligations and other APS guidance and policies. Building on the improvements already made – for example, revised recruitment practices which have now been assessed as exceeding APS requirements – the government expects further and sustained progress in recruitment to continue. Complaints will reduce as all future recruitment decisions will be based on merit and will be transparent, evidence based and defensible. Any challenges to recruitment decisions will be dealt with professionally, and responses will comply with the recruitment policy framework.

The APVMA has identified a suitable recruitment training course that is being rolled out across the organisation and will be a future requirement for all selection panel chairs. The APVMA proactively consulted with other small APS agencies to benchmark the content of the course for suitability and consistency. The APVMA has developed a comprehensive list of recruitment requirements for panel members and vacancy managers to accompany each recruitment process.

Probation is the first measure of a new starter's suitability and the last step in the recruitment process towards delivering a high-performing workforce. All new APS staff are subject to probation as per the Australian Public Service Commissioner's Directions 2022. The government expects the APVMA to be compliant with the directions; therefore, all APVMA staff recruited from outside the APS must pass through a robust probation process to assess their performance. To ensure an integrated approach and to support the employee life cycle, the APVMA will develop a suite of policies to support performance management and to manage underperformance.

The government supports the suite of mandatory core APS training the APVMA has already implemented. Core training refreshers have been proven to increase knowledge retention. This is pertinent to the APVMA's learning strategy, as staff who are focused on technical or operational work often deprioritise their corporate and APS obligations. Learning about values is not a set-and-forget matter; the regular refreshers will ensure seamless capability building. Mandatory training will be supported by managers, who must be held accountable for completions. The APVMA has demonstrated its commitment to core training by linking it to staff pay point progression.

The APVMA will benefit from a better understanding of its ongoing employee separation data. This data can be a timely indicator of issues gathering momentum that can be addressed by an early intervention strategy before they escalate. Achieving a future state where HR professionals are confident in conducting exit interviews and employees are willing to participate in the interviews is

one measure which will generate valuable data that the APVMA can analyse to assess if its reform program is working as intended.

To deliver the quantity and complexity of work required to restore the APVMA as a quality employer will take concerted effort from the HR and learning and development functions. A priority will be supporting specialist HR capability uplift by investing in a development program for all HR staff. The Strategic Review recognised that adequate resourcing is essential to deliver high-quality work against business-as-usual obligations and the reform program, as noted in its recommendation for 'Increasing the depth and capacity of the APVMA People Team, including by creating new positions in the team' (Clayton Utz 2023:52). HR professional development can be focused by benchmarking against the Australian HR Capability Framework (Australian HR Institute n.d.).

The government expects all new APS employees to complete probation, and all new APVMA employees to complete induction, within specified timeframes. All existing employees will complete core mandatory training and actively participate in the performance cycle. Valuable separation data will be used to inform decision-making. This integrated approach will deliver sustainable quality improvements across the employee life cycle.

3.1.5 Aligning diversity and APS Values in the workplace

The Strategic Review and Rapid Evaluation noted that the APVMA was arguably not aligned with the APS Values and Code of Conduct, which are foundational for all APS agencies. The current AVPMA leadership is implementing reforms that will better support the agency's diverse workforce, with the goal of exceeding APS, ministerial and employee expectations.

When recruiting for the newly relocated APVMA, the agency engaged staff 'with little or no public service experience' (Matthews 2023:15), and consequently 'there was reduced understanding of how to apply public service values in the myriad of different situations' (Matthews 2023:16). 'The new culture led to a sustained high volume of staff complaints' (Matthews 2023:16). The Strategic Review identified that of the 56 complaints made between 2018 and 2023, 21 were categorised as 'inappropriate behaviour' (Clayton Utz 2023:49) and that the complaints included 'matters which are arguably more personal in nature' (Clayton Utz 2023:50).

The Rapid Evaluation recommended that the APVMA's ELT 'commission an independent review of the treatment of women and diversity within the Authority' (Matthews 2023:31) as a measure to address cultural reform. While this recommendation is supported in principle, it is anticipated that the cultural reforms noted below will achieve the required outcomes without subjecting the agency to another review process.

The Rapid Evaluation also recommended that the APVMA 'Review, revise, and reissue internal grievance, complaint, and whistleblower processes' (Matthews 2023:31) as a mechanism to support improvements in complaint handling.

The APVMA has developed a Diversity and Inclusion Policy and a Reconciliation Action Plan as foundational documents to support its transition back to an inclusive workplace that values equality and diversity. The Diversity and Inclusion Policy covers a variety of diversity groups, each of which will be assessed by HR to identify the need for individual action plans. Additionally, each diversity group will be offered the opportunity to set up its own diversity network where practicable. The

APVMA will increase its APS engagement by participating in whole-of-APS diversity and inclusion activities. Diversity initiatives will assist in removing barriers to employment and advancement, and staff education will normalise inclusion practices. Members of diversity networks can support each other with their shared lived experience. People with diverse backgrounds will feel more accepted, supported and able to bring their authentic selves to work. Importantly, more staff will become allies of diverse colleagues and will be empowered to speak up if they witness unacceptable behaviours.

The APVMA will develop a specific policy posture on harassment, sexual harassment and bullying in the workplace, to reinforce the shift from previous approaches. Recent changes to the Sex Discrimination Act 1984 include a new positive duty obligation for employers. This means agencies must take reasonable and proportionate measures to eliminate, as far as possible, sexual harassment and related unlawful behaviours from occurring. Staff need educational support so that bystanders and managers are in no doubt about their obligations. The education package will include coverage of 'workplace technology facilitated sexual harassment', as this is a growing area of complaints and was a feature of previous APVMA staff complaints.

The APVMA will implement a broader range of inclusive APS recruitment pathways that attract and retain First Nations candidates. Partnering with other agencies that have established processes in place, like the APSC's SES100 initiative (APSC 2024c), will reduce duplication and increase the APVMA's collaboration with the broader APS.

The APVMA will align with the requirements of the Gender Equality Agency to deliver against the APS Gender Equality Strategy (APSC 2022b) and the Commonwealth Working for Women strategy (Department of the Prime Minister and Cabinet 2024).

RecruitAbility (APSC 2024b) is a feature of the APVMA's recruitment. The government recommends that the APVMA pursue a more robust agenda to attract and retain workers with a disability and create a working environment where employees feel safe disclosing their disability status. The APVMA will benefit from implementing a workplace adjustment policy to support manager decision-making and making access to assistive technologies consistent across all agency locations. This approach will be expanded to educate staff about people who are living with mental illness or who are neurodiverse, to ensure appropriate responses and equity of access to employment opportunities.

The APS Culturally and Linguistically Diverse Employment Strategy and Action Plan (APSC 2024a) specifically notes that 'representation drops sharply at the senior executive levels'. The APVMA is currently a strong performer in terms of culturally and linguistically diverse (CALD) employment overall. The APVMA's challenge is to ensure bias does not unfairly affect a CALD employee's opportunities for promotion, and to increase the representation of CALD employees at senior management levels. The APVMA will leverage existing APSC resources to build multicultural capability and awareness.

Actioning these recommendations signals a commitment by the APVMA's ELT to manage the culture towards even greater acceptance of diversity and celebration of difference. By embracing diversity and following a zero-tolerance protocol for racism, sexism and cultural vilification, the APVMA will improve its standing as an employer of choice and be better able to meet the needs of its diverse workforce.

As a model employer, the APS must foster respectful workplaces that are safe and inclusive. The APVMA will align its commitment to its positive duty obligations and seek professional guidance from the expertise within its HR function to ensure that it does not repeat the failings of previous years.

Measures of success for the APVMA will be seen in HR data metrics and feedback. Successful implementation of the diversity and inclusion initiatives will enable the APVMA to match or outperform the APS target metrics, and feedback on the census questions will indicate improvement trends. Education will reduce the bystander effect and promote inclusion of diverse people throughout their APVMA career with no barriers to advancement. The APVMA will ensure that implementing improvement initiatives is a sustained effort over time, and it must plan for long-term investment to achieve transformation. Cultural and behavioural change can only be achieved through multifaceted continuous improvement measures.

3.1.6 Challenges with hybrid and flexible workforce strategies

The Strategic Review and Rapid Evaluation identified people and culture challenges that the APVMA faced which coincided with a national movement to hybrid, flexible and remote working. The impacts on engagement appear to have been exacerbated in this environment. The APVMA is embracing a broad scope of reforms that will better support its workforce.

The APVMA's relocation to Armidale over the period April 2017 to June 2019 coincided with a national movement towards flexible and remote working, which included working away from the office. The Rapid Evaluation noted 'Flexible working arrangements including work-from-home and remote working intensified during the pandemic' (Matthews 2023:15), which closely followed the timing of the relocation to Armidale. 'In these circumstances building and maintaining a positive and inclusive organisational culture became more difficult' (Matthews 2023:15).

Additionally, the significant staff turnover due to the relocation caused a loss of corporate knowledge 'At the same time … the organisation had to deal urgently with significant gaps in its capability, capacity and corporate memory' (Matthews 2023:14-15). The Rapid Evaluation notes that 'negative impacts persisted, indeed grew perniciously, in the years that followed' (Matthews 2023:15).

The APVMA implemented a mitigation strategy requiring a minimum of 20% attendance in the office, which was increased to 50% in mid-2023; however, compliance was variable. The APVMA's Enterprise Agreement (APVMA 2024a) no longer permits a minimum attendance approach for groups, so the attendance quota has been removed.

The APVMA has begun a series of flexible work governance improvements to address these issues, including:

- implementing a newly developed Flexible Work Policy to encompass the diverse methods of flexible work that are available to employees. This will be supported by a suite of educational materials. It will align with the APSC's publication *All roles flexible: principles of flexible work in the APS* (APSC 2023) and the applicable clauses of the APVMA Enterprise Agreement to ensure legislative compliance
- continuing to deliver 'Constructive Conversations' workshops to continuously improve the quality of communication between all employees

- reviewing all performance management resources, educational material and guidance/instructional material to ensure that they cover how geographically separated managers and employees should conduct their performance conversations to remain aligned with best practice.

The government sees value in the APVMA harnessing data insights to better understand its workforce and respond to issues as they arise. Data analysis will remove assumptions and provide a solid evidence base for the APVMA to demonstrate success in addressing organisational culture related reforms.

The government supports the APVMA implementing a robust Flexible Work Policy framework which is well supported by educational material. This will enable managers to make decisions in line with wider APS practice and for opportunities for disagreement or a misalignment of expectations to be minimised. Ultimately complaints to HR (or the Fair Work Commission) will be minimised as a result of this work.

In addition, the government supports the APVMA focusing on communication education to assist in successfully implementing the flexible work needs of employees which align with business needs. Increasing communication skills will improve engagement, increase employees' sense of belonging, and build stronger relationships for improved team collaboration and performance.

The government anticipates that the initiatives described in this section will deliver an array of improvement measures for the Flexible Work Policy framework, both tangible and intangible. Tangible HR system data can be used to demonstrate that employees are accessing a variety of flexible work options according to their needs and the needs of the APVMA. Performance management data can be used to demonstrate sustained performance that meets expectations and productivity outcomes. In the latest annual APS census, AVPMA employees have expressed increased satisfaction. The results of the 2024 census include improved scores for the APVMA in engagement, SES leadership, communication, wellbeing, and flexible work access. Building on these early results with the recommended initiatives will contribute to future stabilisation and increased satisfaction, including against the specific APVMA cultural pulse check questions in the census. Examples of success would be an increase in suitable candidate numbers for roles and an accompanying measurable decrease in attrition and turnover.

Intangible measures of success should include improved job satisfaction and increased managerial confidence in managing the performance and wellbeing of staff members who are geographically dispersed. Improvements in the flexible work offering should contribute to an increase in the internal employee value proposition, resulting in better staff retention, and in the external employee value proposition, which will be attractive to a broader range of candidates during recruitment, thus supporting the APVMA in achieving its aim to become an employer of choice.

In a competitive job market, employees and job candidates have increasingly high expectations about access to flexible work arrangements. These improvements will help cater to the needs of the employee market, contribute to enhanced productivity, promote healthier work–life balance and foster greater job satisfaction and higher retention rates.

3.2 Financial management and procurement

Rapid Evaluation recommendations	Strategic Review recommendations	Independent Review recommendations
29, 30 [b, c, d, e, f], 31, 32	76, 7	50, 51, 52, 53, 54, 55, 56, 57, 58

3.2.1 Unsustainable APVMA cost-recovery framework

The Independent Review and Rapid Evaluation observed that the APVMA's current cost recovery is insufficient to resource its functions and responsibilities. The government will undertake analysis to determine the sustainability of the APVMA's current cost-recovery framework with the aim of the APVMA being financially sustainable.

The reform activities will achieve an evidence-based funding framework that limits the risk of capture of the APVMA by industry. Future funding of the APVMA will be determined through government processes, and industry will be consulted when new cost-recovery implementation statements are developed. Further analysis will be undertaken as to the sustainability of APVMA's current cost-recovery framework, and policy options will be developed if required.

The Australian Government's overarching Cost Recovery Policy (Department of Finance 2023b) is that, where appropriate, non-government recipients of specific government activities should be charged some or all the costs of those activities. The Cost Recovery Policy promotes consistent, transparent and accountable charging for government activities and supports the proper use of public resources (Department of Finance 2023b). The agvet chemicals industry is the primary beneficiary of the agvet chemicals regulatory process. It is a regulatory system that provides for the safe and confident use of agvet chemicals, creating a long-term demand for these products and discouraging poor behaviour that would result in an inefficient market. It is therefore appropriate that the agvet chemicals industry bears the full efficient costs of the regulatory function delivered by the APVMA.

The Rapid Evaluation observed that the APVMA's current cost recovery is insufficient to fully resource the APVMA's functions and responsibilities, forcing the APVMA to prioritise resources and limit some functions (Matthews 2023:37). For example, there had been a prioritisation of registrations and approvals, at the expense of compliance and enforcement activities (Clayton Utz 2023:13). Several factors have contributed to current financial challenges, including the fact that the APVMA did not increase fees, levies and charges between 2020 and 2023 but that its operating costs (e.g. employee and ICT expenses) increased (APVMA 2024c). The Rapid Evaluation noted that considerable pressure from industry to minimise the fees, charges and levies imposed upon it may have contributed to the limited increase in fees, levies and charges (Matthews 2023:37).

The APVMA applies the government's Cost Recovery Policy (framework) to charge non-government recipients for specific regulatory activities (Department of Finance 2023b). This includes cost-recovery fees for registration and approval of agvet chemical products, and collection of statutory levies on sales or disposals of agvet chemical products. The Independent Review found that current levels of cross-subsidisation – in which levy revenue subsidises fees – distort the market, skew decision-making, are inequitable and 'are not consistent with the general principle that individuals or

groups should be charged for the regulatory activities their businesses generate' (DAWE 2021:212). Levies currently cover 60% of APVMA fee-for-service regulatory activities (APVMA 2022b:5).

The APVMA is currently preparing a new cost-recovery implementation statement (CRIS) for 1 July 2025 to 30 June 2026, informed by a full consultation process. The APVMA is coordinating the CRIS in consultation with the department to address opportunities for broader policy reforms identified during the process. Any proposed changes to fees, levies and charges will be accompanied by clear and transparent justifications.

The government notes the recommendations made in the Rapid Evaluation and is currently undertaking a future-focused cost analysis of the APVMA's legislated functions. Following completion of this work and in parallel to the CRIS process outlined earlier, the government will undertake further analysis as to the sustainability of the APVMA's current cost-recovery framework and will develop policy options if required.

The ministerial statement of expectations issued in September 2023 stated: 'It is expected the APVMA will be efficient in its operations and demonstrate value for money for the functions it performs.' This is in line with one of the Australian Government's charging principles of efficiency, which states that all activities are expected to be delivered 'at least cost, while achieving the policy objectives and legislative functions of the Australian Government and considering the economic impact of charging for the activity' (Department of Finance 2023a). The efficient and effective use of resources will continue to be a priority for the new substantive board chair and CEO. The board, as the accountable authority, will build upon its existing work in this area as outlined in section 10 of the PGPA Act. The APVMA will measure the impacts of any efficiency mechanisms implemented and clearly communicate these to the minister and stakeholders.

The work underway aims to achieve a funding framework that provides the APVMA with financial stability and allows for the efficient and effective use of resources in accordance with the PGPA Act. This includes transparent and accurate forecasting and modelling of APVMA's cost base to deliver its legislated regulatory functions.

3.2.2 Improving procurement expertise in resolving ICT systems risks

Reviews identified several ICT issues across the APVMA and noted that limited ICT procurement expertise in the agency may have contributed to a lack of progress. Engagement of an ICT strategic adviser has been instrumental in the development of an ICT roadmap and scoping of a shared services proposal, both of which will contribute to the required improvements.

The Rapid Evaluation noted that there are several complex ICT-related issues that have compounded over time, leading to an urgent need to identify and procure replacement and upgraded solutions. These issues include inadequate internal IT infrastructure, an ageing and unsupported core business system, unacceptable cyber security risks and excessive IT expenditure per staff member (Matthews 2023:39).

The Rapid Evaluation noted 'Clayton Utz identified shortcomings in the proper management of government procurement processes. They gave particular attention to a long-running and costly, but still unsuccessful, procurement program to raise the standard of ICT services within the Authority' (Matthews 2023:13). The Rapid Evaluation went on to recommend 'Underperforming IT systems are

an enduring drag on the Authority's performance which needs to be finally resolved' (Matthews 2023:39).

The APVMA commissioned an IT functional review in August 2023 that confirmed the findings of the Strategic Review and Rapid Evaluation. As a result of the IT functional review, the APVMA has engaged a specialist cyber security firm to monitor and develop mitigations to cyber security risks, and an independent ICT strategic adviser to assist in managing ICT strategy and investment. The strategic adviser has developed and delivered an ICT Strategy and Roadmap 2023–2028 to the APVMA Executive, as well as resolving several technology, supplier and delivery issues.

The ICT Strategy and Roadmap is a future-focused, medium-term strategy to provide a clear direction for leveraging technology and digital solutions to achieve the APVMA's objectives as a regulator and improve its overall effectiveness and efficiency. The roadmap provides options for timing of initiatives to prioritise risk mitigation and decision-making principles to achieve this future state, including resourcing, governance, adaptability and security. Resourcing for the roadmap will be reviewed annually by the APVMA to ensure that there is sufficient provision to manage ICT priorities and risks into the future.

The department has completed a detailed discovery process to facilitate a potential transition of APVMA ICT support services to a shared services arrangement to reduce excessive expenses for ICT services. The government is currently considering the shared services scoping analysis to determine feasibility, timing and funding.

As the APVMA is a small agency, sharing ICT services with a large agency will provide a significant uplift in the APVMA's ICT capability, including in cost-effective ICT service delivery, on-demand advice and expertise, and support for ICT services maturity in the medium term. It will also allow the APVMA to achieve economies of scale in gaining access to ICT services that are normally only available to larger agencies. The independence of the APVMA as a regulator will be taken into account and preserved through any shared services arrangement.

Critical work is also underway to replace the APVMA's core business system. This work involves reviewing and analysing business requirements of the APVMA and providing recommendations for next steps. Once the current analysis is complete, the department and the APVMA will explore options to ensure the APVMA's core business system is fit for purpose. The department will support the APVMA with the design, procurement and implementation of the replacement core business system. Further analysis will be undertaken to understand additional digital enhancements to reduce risk and improve agency performance.

A fit-for-purpose, contemporary and resilient core business system will bring the APVMA's ongoing ICT expenditure in line with that of similar agencies and improve compliance with the Australian Government's Strategies to mitigate cyber security incidents (Australian Signals Directorate 2017).

3.2.3 Improving compliance with procurement rules

The Strategic Review identified that the APVMA's reliance on manual procurement systems, and tracking and analysis challenges, may have contributed to potential non-compliance with procurement rules. The APVMA has implemented procurement process improvements and is

currently upgrading its financial system, which will contribute to enhanced compliance with procurement legislation.

The Strategic Review identified a range of risks associated with the APVMA's procurement processes. These included an absence of robust systems for the purposes of managing and tracking procurements and minimising the risk of non-compliance with relevant requirements, a manual record-keeping system for procurement that provided limited ability to assess and improve compliance with the Commonwealth Procurement Rules (CPRs) (Department of Finance 2024b), and a lack of guidance and internal processes for staff to understand the CPRs (Clayton Utz 2023:6).

The Strategic Review identified material doubts about one of the procurements in relation to value for money; maintaining documentation commensurate with the scale, scope and risk of the procurement; ensuring the procurement was efficient, effective and economical; and ensuring that the work order for the procurement was appropriate. The review surmised that 'speed of implementation may have been prioritised to the detriment of compliance with procurement requirements' (Clayton Utz 2023:6).

The Strategic Review noted:

> The APVMA faces challenges in staff capability across key operational and business areas. The high volume of employee turnover in recent years, including immediately following the relocation of the agency from Canberra to Armidale, has likely contributed to challenges for the APVMA. The APVMA has needed to rapidly upskill staff with key corporate knowledge in relation to the Australian Public Service, the Commonwealth procurement rules, the APS Values and the APS Code of Conduct. (Clayton Utz 2023:4)

The APVMA had recruited staff 'with little or no public service experience' (Matthews 2023:15) and consequently experienced a 'decline in understanding of public service values, conventions and best practice' (Matthews 2023:16).

The APVMA has begun to improve staff compliance with CPRs in several ways. These include requiring all staff to complete 'APS Induction – Money and Resources' (APS Academy 2023) training within 4 weeks of commencement, ensuring that all procurement officers attend refresher training on procurement and contracts conducted by the Department of Finance, and requiring them to complete APSC courses in procurement and contract management.

The APVMA has completed activities that will strengthen internal governance, risk and compliance processes. A financial delegation review was undertaken, as a result of which changes to approval processes have been introduced, including making it compulsory for all contracts to be cleared by the APVMA legal team before execution. The APVMA has updated, and made available to staff, a financial delegations instrument that details all financial delegations. The APVMA is also implementing the Lighthouse IT system to streamline governance, risk and compliance processes. Lighthouse will increase transparency in the procurement process by including non-compliance reporting tools, declarations of conflicts of interest, and declarations of gifts and hospitality.

The APVMA is currently upgrading the financial system TechnologyOne (TechOne) to include an automated procurement, a contract module and a supply chain and purchasing module. These

modules will allow the APVMA to track contracts from end to end, including expenditure, approvals, payment and reporting, and the electronic creation and approval of purchase orders. The upgrades include checks and the ability to access contract data and documentation. This will ensure that APVMA staff are compliant with their financial delegations when procuring goods and services, and compliant with CPRs. Additionally, the improved end-to-end oversight provided by TechOne will allow for more agile responses when contracts are identified as not complying with their delivery parameters. The upgrade will include the provision of supporting training and instructional material. It is due to be implemented by January 2025.

The government supports the recommendation for the APVMA to rapidly upskill staff with key corporate knowledge in relation to the APS CPRs, APS Values and the APS Code of Conduct. The APVMA has demonstrated its commitment to robust procurement processes that support best practice procurement principles with the ability to track and record procurement approvals and expenditure. Reforms will continue to ensure appropriate policies and procedures for procurement are readily understood and used by staff. All APVMA staff will be aware of their responsibilities when spending public funds, in line with the CPRs, ensuring that the APVMA's resources 'are used in the most efficient, effective, ethical and economic manner' (Department of Finance 2024).

Glossary

Term	Definition
2016 Order, the	*Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*
ACS	Agvet Chemicals Subcommittee
Active / active constituent	The substance(s) in a pesticide or veterinary medicine product that are primarily responsible for a product's biological or other effects
Adverse experiences/effects	Unintended and sometimes harmful occurrences associated with the use of a pesticide or veterinary medicine
AER	Adverse experience report
AERP	Adverse Experience Reporting Program AERP is a post-registration quality assurance program established by the APVMA to help facilitate the management of agricultural and veterinary chemicals
AGSOC	Agriculture Senior Officials Committee AGSOC comprises all department heads and CEOs of Australian, state and territory and New Zealand government agencies responsible for primary industries policy issues. It also supports the Agriculture Ministers' Forum (AGMIN) in achieving its objectives.
Agvet chemicals	Agricultural and veterinary chemical products. This term also includes 'pesticides' and 'veterinary medicines'.
Agvet chemical legislation	The following group of Acts and regulations: • *Agricultural and Veterinary Chemicals (Administration) Act 1992* • Agricultural and Veterinary Chemicals (Administration) Regulations 1995 • *Agricultural and Veterinary Chemicals Act 1994* • *Agricultural and Veterinary Chemicals Regulations 1999* • *Agricultural and Veterinary Chemicals Code Act 1994* • Agricultural and Veterinary Chemicals Code Regulations 1995 • *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* • Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 • *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021*
Agvet chemicals regulatory system	Agricultural and veterinary (agvet) chemicals include a range of products developed to protect crops, livestock and domestic animals; safeguard our environment from invasive weeds and pests; and meet consumer needs for things such as household insecticides and pool and spa chemicals. They have brought long-term benefits to Australian agriculture by reducing the effects of weeds, pests and diseases on agricultural and forest production. This has led to increased productivity, better quality produce, more competitive industries and improved environmental outcomes. The Department of Agriculture, Fisheries and Forestry is responsible for international and domestic policy on agvet chemicals, and for Commonwealth agvet chemicals legislation. The National Registration Scheme for Agricultural and Veterinary Chemicals was established under Commonwealth and state and territory legislation. It ensures that these products are: • safe when exposed to humans and non-target species either through direct exposure or residues in treated food stuffs

Term	Definition
	• not a risk to the environment • effective on target species • labelled and packaged correctly. The department manages the legislation under which the National Registration Scheme for Agricultural and Veterinary Chemicals operates. This includes amending current legislation or introducing new Bills where Commonwealth, state and territory governments have agreed there is a need. The Minister for Agriculture, Fisheries and Forestry has overall policy responsibility for agvet chemicals and presents these changes to parliament. Further information regarding the agvet chemicals regulatory system is available on the department's website: Agricultural and veterinary chemicals – DAFF (agriculture.gov.au)
Agvet Code	Agricultural and Veterinary Chemicals Code as set out in the schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* The Agvet Code makes provision for the evaluation, registration and control of agvet chemical products and for related matters
Applied law	A cooperative legislative scheme in which one jurisdiction enacts a 'model' law which is then 'picked up' or 'applied' by another jurisdiction or group of jurisdictions
Approved active	An approved active is an active constituent approved for use in Australia
Approved label	The particulars listed on the label of agricultural chemicals or veterinary chemical products that are approved by the APVMA
APS	Australian Public Service
APSC	Australian Public Service Commission
APVMA	Australian Pesticides and Veterinary Medicines Authority – the Australian agvet chemicals regulator
Authorisation	An approval, registration, licence or permit
Biological product/control	A product/method that controls pests such as insects, mites, weeds and plant diseases using other organisms
board, the	The APVMA Board – a group of non-APS employees and the APVMA CEO who are appointed by the minister. The board is the governing body and accountable authority of the agency and is responsible for ensuring the proper, efficient and effective performance of the APVMA functions and determining the objectives, strategies and policies of the APVMA.
CALD	Culturally and linguistically diverse – a diversity subset
CEO	Chief executive officer – a person with the highest employment level ranking in an organisation
Chemical review	See 'Reconsideration'
Community of practice	A group of people with a common interest, such as a profession, who come together to share knowledge and foster productive relationships within a culture of learning
Companion animal	An animal kept as a pet and not used for production of food, fibre or hide
Compounding/ compounded products	Compounding involves the small-scale manufacture of a medication – generally by a veterinarian or pharmacist – to fill a void where no registered product is available with the suitable active constituent, dose or form (e.g., tablet versus paste)
Consumer products	Goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption

Term	Definition
Control-of-use	The regulation of how agricultural or veterinary chemicals can be used. State and territory governments have responsibility for controlling the use of agricultural and veterinary chemicals.
Co-regulation / co-regulatory system	A system whereby industry develops and administers its own arrangement – to demonstrate compliance, quality assurance etc. – but government provides legislative backing to enable the arrangements to be enforced
CREs	Conditional required elements – the elements of the label that are fixed
CPRs	Commonwealth Procurement Rules
CRIS	Cost-recovery implementation statement – a document that sets the fees and charges to be paid by industry for regulatory activities.
DAFF	Department of Agriculture, Fisheries and Forestry – from July 2022 to present
Data protection	Limiting the use of information, including its use in connection with an application for authorisation of another product, or for variation of the relevant conditions of authorisation of another product
DAWE	Department of Agriculture, Water and the Environment – from February 2020 to July 2022
Delay costs	The foregone profits resulting from longer waiting times to access a market
Department, the	Department of Agriculture, Fisheries and Forestry (see also 'DAFF' and 'DAWE')
DPI	Department of Primary Industries
Efficacy	The ability of a product to produce its claimed effects
Enterprise Agreement	Australian Pesticides and Veterinary Medicines Authority Enterprise Agreement 2024–27
ELT	Executive leadership team – senior management body composed of staff members at the Senior Executive Service employment level
Employee value proposition	The unique balance of rewards and values that an employer offers the employee (internal for existing employees and external for job candidates)
Exemptions	A measure to provide that a provision in legislation does not apply, either with or without conditions
Flexible work	A work attendance arrangement that is different to standard working hours and not classed as shiftwork. See also 'hybrid work', 'remote work' and 'working away from the office'.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GMOs	Genetically modified organisms
HACCUT	Harmonised Agvet Chemicals Control of Use Task group
Hazard	A situation or thing that has the potential to cause harm
HGP	Hormonal growth promotant
Holder	The person or entity listed as having legal responsibility for a product registration issued by either the APVMA or a comparable overseas regulator
HR	Human resources
Hybrid work	A work attendance arrangement that typically uses more than one location as the base for work. Commonly, hybrid arrangements use an agency location and the employee's home address. See also 'flexible work', 'remote work' and 'working away from the office'.
IGA	Inter-governmental agreement on agricultural and veterinary (agvet) chemicals

Term	Definition
IML	Instructional Material Library – an intranet site holding copies of all policies, guides, work instructions, operating procedures, and other instructional material
Levies	Amounts paid by registration holders based on volume of registered agricultural chemicals and veterinary chemical product sales
Licence	The authority to manufacture veterinary chemicals not listed in section 59 of the Agricultural and Veterinary Chemicals Code Regulations 1995
Limits on use of information	See 'Data protection'
Minister, the	Minister for Agriculture, Fisheries and Forestry
Minister Watt	Senator the Hon Murray Watt, Minister for Agriculture, Fisheries and Forestry 2022–2024
Minister Joyce	The Hon Barnaby Joyce MP, Member for New England, Minister for Agriculture and Water Resources 2015–2017
Minor use	A use of a product or constituent that does not produce sufficient economic return to make it worthwhile for an applicant to seek registration on their own
Neurodiverse person	A person whose brain works differently, meaning they experience and interact with the world in a non-typical way. Often used in the context of autism spectrum disorder, conditions such as attention deficit hyperactivity disorder, or learning disabilities
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
Panel	Independent Review Panel – the group of individuals appointed by the former Minister for Agriculture to undertake the review of the agvet chemicals framework
Permit	An authorisation allowing for the legal use of agricultural chemicals and veterinary chemicals that would otherwise be unlawful – e.g. a permit for the limited use of unregistered agricultural chemicals or veterinary chemical products
Prescription	A written instruction provided by a veterinarian to allow the dispensing of a veterinary medicine, including compounding
Pest	An animal, plant or other biological entity that injuriously affects the physical condition, worth or utility of another animal, plant, or thing, or the use or enjoyment of a place
Pesticide	A substance or preparation for destroying pests, usually by being poisonous to them, especially in agricultural use, such as herbicides, fungicides, acaricides; or in domestic use for killing mosquitos, flies, cockroaches etc. Subset of 'Agvet chemicals'.
Poisons scheduling	Poison schedules provide a means of classifying poisons to identify the degree of control to exercise over their availability to the public. Scheduling is undertaken by the TGA.
Post-market (regulation, compliance, information)	Undertaken after a product is registered by the APVMA
Pre-market (assessment, regulation)	Undertaken before a product is registered by the APVMA
Produce monitoring	Testing for agricultural or veterinary chemicals residues in food commodities
Products, Permits, Licences, Actives	The APVMA's internal application management system, record of approved active constituents, and register of chemical products and relevant APVMA files for labels
Protected information	See 'Data protection'

Term	Definition
PubCRIS	Public Chemical Registration Information System – a public-facing database for registered products, approved active constituent and permits. It contains the product name, product category, host and pest information and, in most cases, a product label (or list of relevant label particulars).
QA	Quality assurance
QR code	Quick response code – an array of black and white squares or pixels set in a grid that can be scanned with a smartphone to link to information, usually a website
RAE	Regulatory assessed elements – the elements of a label that are assessed and approved by the APVMA
Reconsideration	The formal process of reviewing agricultural chemicals or veterinary chemicals where new information suggests a change in the risks to human health, the environment, animal or crop safety, and trade
Record, the	Record of Approved Active Constituents for Chemical Products, kept under section 17 of the Agricultural and Veterinary Chemicals Code Act 1994
RecruitAbility	A scheme which aims to attract and develop applicants with disability and also facilitate cultural changes in selection panels and agency recruitment
Reference product	A registered agricultural chemical or veterinary chemical product referred to in an application for another product because information for that registered product is relevant to the application
Registered product	An agricultural chemical or veterinary chemical product contained in the Register of Agricultural and Veterinary Chemical Products. May also be referred to as registered chemicals or registered agvet chemicals and other similar variations.
Remote work	A work attendance arrangement that is 100% worked from a location that is not the role's designated site. Typically, the location will be another agency's site or the employee's home location. See also 'flexible work', 'hybrid work', and 'working away from the office'.
Residue	Any components, derivatives, metabolites or degradation products of agricultural chemicals or veterinary chemicals remaining in a commodity
Resistance	The decreased susceptibility of a pest or disease agent to a product that was previously effective at controlling that pest or disease agent
Restricted chemical product	A highly hazardous product which may only be supplied to authorised persons. Restricted chemical products are declared by the APVMA under the Agvet Code.
Risk	The possibility that harm (including death, injury or illness) might occur due to exposure to a hazard
Risk assessment	A risk assessment of an agvet product considers both the hazards posed by the product and the likely exposure of humans, animals and the environment to these hazards
Scheduling	The process by which medicines and poisons are classified, controlling how they are made available to the public
SES	Senior Executive Service
Statutory criteria	The list of criteria that the APVMA must be satisfied are met before approving an application. The statutory criteria include: • safety criteria • trade criteria • efficacy criteria • labelling criteria.
Statutory office holder	A person who holds a position to which duties and functions are specifically assigned in legislation

Term	Definition
TGA	Therapeutic Goods Administration – the regulatory body for therapeutic goods in Australia. It is a division of the Australian Department of Health.
Timeframe performance	The proportion of applications determined within the period required for the application
Turnover	The percentage of employees who leave an organisation during a given time period
Use pattern	The combination of all factors involved in the use of a formulated agvet chemical product
Veterinarian	A person qualified to treat diseased or injured animals
Veterinary medicine	A medicine that is administered for the prevention and treatment of animal diseases or the treatment of injured animals. A subset of 'Agvet chemicals'.
Working away from the office	A work attendance arrangement that allows work to be conducted from a location other than the role's designated site for part of the working week. Typically, this is the employee's home address. See also 'flexible work', 'hybrid work' and 'remote work'.
Workplace technology facilitated sexual harassment	Unwelcome sexual conduct using digital technologies, perpetrated in a workplace context – within and beyond the physical location of the workplace, and during or after working hours

References

AFP 2022, Australian Government Investigations Standards, Australian Federal Police, Canberra, accessed 29 July 2024.

APS Academy 2023, APS Induction – Money and Resources, Australian Public Service Academy, Canberra, accessed 29 July 2024.

APS Academy 2024, SES Orientation Program, Australian Public Service Academy, Canberra, accessed 29 July 2024.

APSC 2021a, Integrated Leadership System, Australian Public Service Commission, Canberra, accessed 29 July 2024.

APSC 2021b, One APS, Australian Public Service Commission, Canberra, accessed 29 July 2024.

APSC 2022a, APS Values and Code of Conduct in practice, Australian Public Service Commission, Canberra, accessed 29 July 2024.

APSC 2022b, Realising the benefits for all – APS Gender Equality Strategy 2021–26, Australian Public Service Commission, Canberra, accessed 29 July 2024.

APSC 2023, All roles flexible: principles of flexible work in the APS, Australian Public Service Commission, Canberra, accessed 29 July 2024.

APSC 2024a, APS Culturally and Linguistically Diverse Employment Strategy and Action Plan, Australian Public Service Commission, Canberra, accessed 29 July 2024.

APSC 2024b, RecruitAbility, Australian Public Service Commission, Canberra, accessed 29 July 2024.

APSC2024c, SES100, Australian Public Service Commission, Canberra, accessed 29 July 2024.

APVMA n.d., Public Chemical Registration Information System search, Australian Pesticides and Veterinary Medicines Authority, Armidale, New South Wales, accessed 29 July 2024.

APVMA 2004, Permit to allow the conduct of small-scale trials with agvet chemicals, Australian Pesticides and Veterinary Medicines Authority, Armidale, New South Wales, accessed 29 July 2024.

APVMA 2022a, Adverse Experience Reporting Program, Australian Pesticides and Veterinary Medicines Authority, Armidale, New South Wales, accessed 29 July 2024.

APVMA 2022b, Cost Recovery Implementation Statement (CRIS), Australian Pesticides and Veterinary Medicines Authority, Armidale, New South Wales, accessed 29 July 2024.

APVMA 2023, APVMA Strategy 2030, Australian Pesticides and Veterinary Medicines Authority, Armidale, New South Wales, accessed 29 July 2024.

APVMA 2024a, APVMA Enterprise Agreement 2024–27, Australian Pesticides and Veterinary Medicines Authority, Armidale, New South Wales, accessed 29 July 2024.

APVMA 2024b, Handbook of first aid instructions, safety directions, warning statements and general safety precautions for agricultural and veterinary chemicals, Australian Pesticides and Veterinary Medicines Authority, Armidale, New South Wales, accessed 29 July 2024.

APVMA 2024c, 2024 cost recovery review, Australian Pesticides and Veterinary Medicines Authority, Armidale, New South Wales, accessed 29 July 2024.

Australian Centre for Evaluation 2021, Commonwealth Evaluation Policy, The Treasury, Canberra, accessed 29 July 2024.

Australian HR Institute n.d., The Australian HR Capability Framework, Australian HR Institute, Melbourne, accessed 29 July 2024.

Australian Signals Directorate 2017, Strategies to mitigate cyber security incidents, Australian Signals Directorate, Canberra, accessed 29 July 2024.

Clayton Utz 2023, Australian Pesticides and Veterinary Medicines Authority Strategic Review report, Clayton Utz, Canberra, accessed 29 July 2024.

DAFF 2024, Improved access to agricultural and veterinary chemicals program, Department of Agriculture, Fisheries and Forestry, Canberra, accessed 29 July 2024.

DAWE 2021, Final report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia, Department of Agriculture, Water and the Environment, Canberra, accessed 29 July 2024.

Department of Finance 2023a, Australian Government Charging Policy, Department of Finance, Canberra, accessed 29 July 2024.

Department of Finance 2023b, Australian Government Cost Recovery Policy, Department of Finance, Canberra, accessed 29 July 2024.

Department of Finance 2023c, Evaluation in the Commonwealth (RMG 130), Department of Finance, Canberra, accessed 29 July 2024.

Department of Finance 2023d, Progressing Australia's regulatory reform agenda, Department of Finance, Canberra, accessed 29 July 2024.

Department of Finance 2023e, Regulator Performance (RMG 128), Department of Finance, Canberra, accessed 29 July 2024.

Department of Finance 2024a, Regulator Policy, Practice and Performance Framework, Department of Finance, accessed 12 August 2024.

Department of Finance 2024b, Commonwealth Procurement Rules, Department of Finance, Canberra, accessed 29 July 2024. Department of Home Affairs 2023, APS Change Framework, Department of Home Affairs, Canberra, accessed 29 July 2024.

Department of the Prime Minister and Cabinet 2023, Regulatory impact analysis guide for ministers' meetings and national standard setting bodies, Department of the Prime Minister and Cabinet, Canberra, accessed 29 July 2024.

Department of the Prime Minister and Cabinet 2024, Working for Women: a strategy for gender equality, Department of the Prime Minister and Cabinet, Canberra, accessed 29 July 2024.

DISR 2021, APS framework for engagement and participation, Department of Industry, Science and Resources, Canberra, accessed 29 July 2024.

Eather J, Addai D, Hafi A & Gomboso J 2020, Benefits of increased access to minor use chemicals, ABARES research report to client prepared for the Department of Agriculture, Water and the Environment, Agvet Chemicals Branch, Canberra, February.

Matthews K 2023, Final report: future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority (APVMA), Department of Agriculture, Fisheries and Forestry, Canberra, accessed 29 July 2024.

OECD 2014, The governance of regulators: OECD best practice principles for regulatory policy, OECD Publishing, Paris, DOI: 10.1787/9789264209015-en.

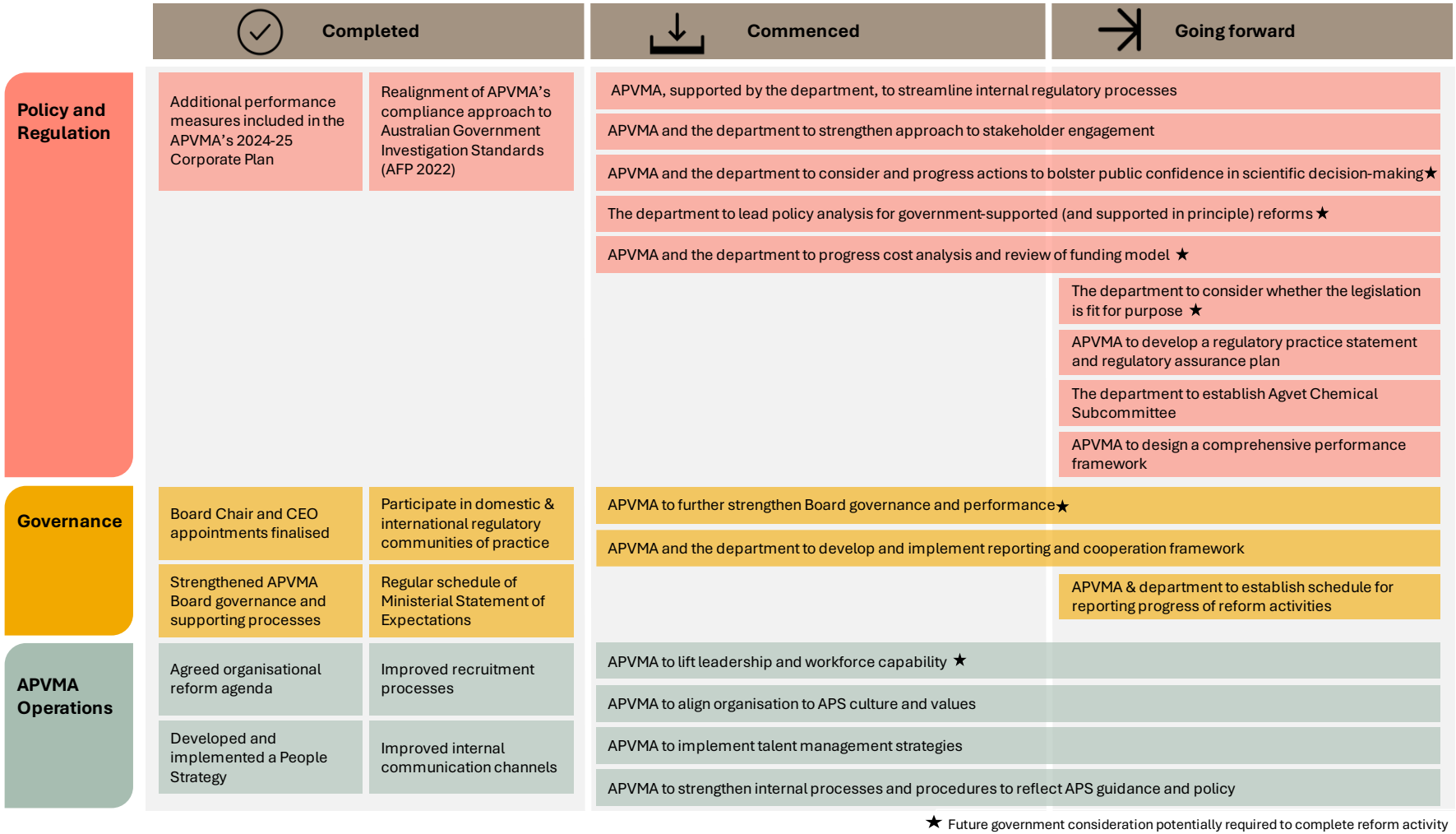
OECD 2017, Creating a culture of independence: practical guidance against undue influence – the governance of regulators, OECD Publishing, Paris, DOI: 10.1787/9789264274198-en.

OECD 2021, OECD Regulatory Policy Outlook 2021, OECD Publishing, Paris, DOI: 10.1787/38b0fdb1-en.

Senate Rural and Regional Affairs and Transport Legislation Committee 2022, Estimates: Final, Official Committee Hansard, Canberra, 8 November, pages 49–51, accessed 29 July 2024.

TGA 2024, The Poisons Standard, Therapeutic Goods Administration, Canberra, accessed 29 July 2024.

Appendix A: Reform roadmap



★ Future government consideration potentially required to complete reform activity

Appendix B: Recommendation tables

Table 1 Final report – future structure and governance arrangements for the APVMA

Theme	Recommendation	Government response	Report section
A new regulatory entity	1) The CEO of the APVMA become a statutory office holder and be re-designated the Australian Pesticides and Veterinary Medicines Regulator (the 'APVMR').	Not supported	2.1.1
	2) An 'Office of the APVMR' be created to support the APVMR officeholder.	Not supported	2.1.1
	3) Most current staff of the APVMA should transfer to the Office of the APVMR.	Not supported	2.1.1
	4) The Office of the APVMR be headquartered in Canberra and maintained with a discrete identity within the Department of Agriculture, Fisheries and Forestry.	Not supported	3.1.1
	5) The independence of the APVMR in science-based regulatory decision-making be protected in legislation.	Not supported	
	6) The future relationship between the APVMR and the Secretary of the department be detailed and made transparent through a publicly available exchange of letters between the Secretary and the APVMR along the lines of Attachment C to this report.	Not supported	2.1.1
	7) The APVMA Board be abolished.	Not supported	
A program of organisational reform	8) The transfer of the Authority to Canberra be progressive and take full account of the needs and preferences of staff, subject to cost-effective operational requirements.	Not supported	3.1.1
	9) The APVMR and the departmental executive should jointly develop a Transition and Relocation Plan to ensure a successful and welcoming transfer of current APVMA staff to their new placements within the Office of the APVMR, within the department.	Not supported	3.1.1
	10) A modest appropriation-funded relocation package should be made available to facilitate the relocation process and to minimise impacts on its operations.	Not supported	3.1.1
	11) The Location of Corporate Commonwealth Entities Order 2016 (the 'GPO') should be revoked.	Supported and implemented	3.1.1
	12) A package of internally managed governance, leadership and management reforms be undertaken to lift the Authority's performance in the areas of workplace culture, regulatory performance, and staff understanding of the necessary reforms (details in Chapter 3, and Table 1A – Internally managed governance improvements).	Supported	See **Table 1A** 1.1.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.1.5, 3.1.6
	13) The APVMR be explicitly required to actively build positive linkages with the portfolio, other regulators, and the wider Australian Public Service.	Supported – as it applies to the APVMA	3.1.3
	14) A package of external governance reforms be implemented, including:	-	-
	a) the governance changes accepted by Government from the present report, specified in Section 3, Feature	Not supported – as it relates to R1–7,	See **Table 1B** 2.1.1

Theme	Recommendation	Government response	Report section
	Box 1: "Recommended future governance arrangements".	which are not supported	
	b) a revised Statement of Expectations from the Minister, including the Minister's expectation that the APVMR will actively seek to advance the endorsed reforms from the 2021 systemic review.	Supported – as it applies to the APVMA	2.2.1
	c) a consolidation and streamlining of the four pieces of legislation currently governing the work of the Authority.	Not supported – as it relates to R1–7, which are not supported	2.1.1
	d) a revised mission (purpose) statement, nested within the vision statement for the Australian regulatory system as a whole.	Supported – as it applies to the APVMA	2.3.1
	15) The APVMR consult with staff and unions about implementation of the reform and change processes which may affect them, consistent with APSC Circular, 22/08, dated 6 October 2022 which describes consultation obligations.	Supported – as it applies to the APVMA	3.1.2
Broadening the scope of regulatory activities	16) The APVMR be made responsible under the revised legislation for ensuring balanced discharge of all functions in the new Act, including sufficient attention to compliance and enforcement, chemical review, stakeholder consultation, and contributing to an agvet chemicals surveillance and monitoring system to be developed by the Department of Agriculture, Fisheries and Forestry.	Partially supported Not supported – as it relates to R1–7, which are not supported Supported for APVMA regulatory functions as described in the Minister's Statement of Expectations and Ministerial Direction	1.1.1, 1.1.2, 1.3.1, 1.7.1, 3.1.2
	17) The APVMR implement measures to further strengthen the quality and integrity of scientific decision-making, including arrangements to provide assurance about the regulator's scientific methods and practices, and arrangements to improve coherence of APVMR methodologies with the methodologies used by other Australian Government agencies.	Supported – as it applies to the APVMA	1.1.1, 1.1.3
Changed relationships with stakeholders	18) The abolition and redesign of current APVMA stakeholder consultation machinery and processes, to provide more balanced access for stakeholder groups in addition to industry.	Supported in principle	1.3.1
	19) The development of more balanced performance indicators, including environmental, public health, compliance, stakeholder engagement, and staff-related indicators, to complement current indicators relating to product registration statutory timeframes.	Supported in principle	1.1.1
	20) The development of guidance material and training for staff about the appropriate posture and conduct of professional regulators in their dealings with stakeholders.	Supported in principle	1.3.1
	21) Implementing a scheme that publishes foundational health and safety data and ensures APVMR access to all information on a product's risks.	Supported in principle	1.1.3, 1.7.1
	22) Work commences on designing a cyclical registration model for implementation by the future APVMR.	Supported in principle	1.6.3

Theme	Recommendation	Government response	Report section
Clearer relationships with related entities	23) Routine publication of future Statements of Expectations from the Minister.	Supported and implemented	2.2.1
	24) Publication of a transparent statement of agreed working arrangements between the APVMR and the Secretary, with emphasis on the independence of the APVMR's decision making, and autonomy in outsourcing services, or not.	Not supported – as it relates to R1–7, which are not supported	2.1.1
	25) Specification of the APVMR's independent right to communicate directly with the Minister, lodge its own annual report with the Minister each year, and independently release its own performance reports.	Not supported – as it relates to R1–7, which are not supported	2.1.1
	26) Specification that the APVMR will be accountable to the Secretary under the PGPA Act, to the Secretary under the Public Service Act, and to the Minister for all powers and functions under the APVMR legislation.	Not supported – as it relates to R1–7, which are not supported	2.1.1
Transparent arrangements for the appointment of the APVMR	27) The APVMR be appointed by the Governor General, based on transparent selection criteria, specific to the APVMR position, following a selection process endorsed by the Australian Public Service Commissioner.	Not supported – as it relates to R1–7, which are not supported	2.1.1
	28) A substantive appointment be made as a matter of urgency, and that the appointee and future appointees have relevant regulatory experience.	Not supported – as it relates to R1–7, which are not supported	2.1.1
Transitional and continuing funding arrangements	29) The APVMR continue to be largely funded through cost recovery arrangements, except for the limited purposes identified in Section 5 of this report.	Noted	3.2.1
	30) The APVMR bring forward an assertive, fully costed, new CRIS proposal, sufficient to adequately resource the APVMR's full range of operations when complemented by the specific-purpose appropriation funding below:	-	-
	a) appropriation funding to facilitate the relocation of the agency from Armidale.	Not supported – as it relates to R1–7, which are not supported	3.1.1
	b) supplementary (50%) appropriation funding to assist the restoration and maintenance of capability in compliance and enforcement.	Noted	3.2.1
	c) supplementary (50%) appropriation funding to assist catch-up, maintenance, and reform of the chemical review program.	Noted	3.2.1
	d) supplementary appropriation funding to meet the cost of government support activities, including funding to progress the reform process now to be triggered by the Government.	Noted	3.2.1
	e) supplementary appropriation funding to redress cyber security risks, and to finalise the IT upgrade commenced at the time of relocation to Armidale, but never satisfactorily completed.	Noted	3.2.1, 3.2.2
	f) appropriation funding to support the introduction of new arrangements to assure the quality of science decision-making.	Noted	3.2.1

Theme	Recommendation	Government response	Report section
	31) Appropriation funding to the Department of Agriculture, Fisheries and Forestry to sustain public confidence in Australia's overall regulatory system through the establishment of an integrated data surveillance and monitoring system, with the APVMR to receive funding to support its contribution to this system.	Noted	3.2.1
	32) The APVMR administer its own Special Account or equivalent arrangement, and that funds and staff funded from the Account only be able to be used for the purposes and legislative functions of the APVMR legislation.	Not supported – as it relates to R1–7, which are not supported	3.2.1
Next steps	33) Following Government consideration of this report, the Department of Agriculture, Fisheries and Forestry and the APVMR provide quarterly reports to the Minister on implementation progress on each recommendation and the reform process overall.	Supported as it applies to the APVMA	2.2.2

Table 1A Recommendation 12 – internally managed governance improvements

Theme	Point	Government response	Report
Measures to address culture	Develop a Relocation Transition Plan in consultation with the department which ensures a welcoming re-location and speedy and efficient access for staff to available departmental services and resources.	Not supported – as it relates to R1–7, which are not supported	3.1.1
	Review, revise, and reissue internal grievance, complaint, and whistle-blower processes.	Supported	3.1.2
	Review, revise, and reissue staff/union consultation arrangements, including the Staff Consultative Committee.	Supported	3.1.2
	Issue guidance on the proper conduct of staff selection processes consistent with APSC guidance and APS best practice. Require the Chair of all selection committees to vouch that the guidance has been followed.	Supported	3.1.4
	Review, revise, and reissue the full suite of HR (people) management guidance material – some of which is now well out of date.	Supported	3.1.2
	Commission an independent review of the treatment of women and diversity within the Authority.	Supported	3.1.5
	Review, revise, and reissue the agency's Reconciliation Action Plan.	Supported	3.1.5
	Develop a Training Plan, which defines mandated APVMR induction training, as well as targeted training on people management, performance management, whole of government procurement processes, and APS values and Code of Conduct.	Supported as it applies to the APVMA	3.1.2, 3.1.4, 3.2.3
	Source targeted and tailored training in good regulatory practice for SES and executive staff in particular, and relevant non-executive staff.	Supported	3.1.1
	Mandate APSC leadership training for incoming SES officers within six months of their appointment.	Supported	3.1.1

Theme	Point	Government response	Report
	Continue staff surveys to provide feedback from staff on cultural and performance issues that may require management attention. Reinforce confidentiality arrangements.	Supported	3.1.2, 3.1.5, 3.1.6
Measures to address performance	Abolish and redesign stakeholder consultative arrangements to ensure more balanced access for stakeholder groups in addition to industry.	Supported	1.3.1
	Develop and implement a new set of performance indicators, covering the full range of functions of the Authority, and including indicators of staff satisfaction, and organisational culture	Supported	1.1.1
	Develop and implement a new standard format and framework for regular reporting to stakeholders and the Minister on performance	Supported	2.1.1, 1.1.1
	Review, revise, and re-issue guidance on best practice staff performance management.	Supported	3.1.4, 3.1.6
	Review, revise, and re-issue the Authority's risk map and risk management assurance arrangements	Supported	2.1.1
Measures to improve staff understanding of expectations	Make available to all staff, the Minister's Statement of Expectations. Encourage executive level leaders of internal teams to develop subsidiary guidance for their staff.	Supported	2.2.1
	Review, revise, and reissue the Authority's vision and mission statements, taking account of the lessons of the Clayton Utz and current review.	Supported	2.3.1
	In consultation with the department, develop a document describing the respective roles of the various players within Australia's national agvet chemical regulatory system, including the APVMR, the Minister, the Secretary, the department, the states and territories, industry, other regulators, etc.	Supported as it applies to the APVMA	2.1.1, 2.2.3
	Revise the Authority's regular survey of stakeholders to provide more meaningful external feedback, including from a wider range of interested stakeholders on a more balanced range of performance parameters.	Supported	1.3.1, 2.3.1

Table 1B Recommendation 14a – recommended future governance arrangements

Theme	Point	Government response	Report
Establish a new entity	The CEO will become a statutory officeholder and be re-designated the Australian Pesticides and Veterinary Medicines Regulator (the 'APVMR').	Not supported	2.1.1
	An 'Office of the APVMR' will be created to support the APVMR office holder.	Not supported	2.1.1
	Most current staff of the APVMA will transfer to the Office of the APVMR.	Not supported	2.1.1
	All staff will continue to be employed under the Public Service Act	Not applicable – no change	N/A
	The Office of the APVMR will be located in Canberra and maintained as a discrete entity within the Department of	Not supported	2.1.1

Theme	Point	Government response	Report
Re-locate to Canberra	Agriculture Fisheries and Forestry, with its identity and operational independence preserved.		
	Transfer of positions from Armidale will be progressive and take full account of the needs and preferences of staff, subject to operational requirements.	Not supported	2.1.1, 3.1.1
	Interim or longer term remote working arrangements will be utilised where operational requirements permit. However, within the framework of APS conditions of service, attendance at the office will be encouraged at least to levels sufficient to build a more positive corporate culture	Supported (to the extent permitted under the Enterprise Agreement)	3.1.6
	All positions will be reviewed initially, and again upon vacancy, by the APVMR personally to identify their optimum location.	Not supported (APVMA location flexibility permitted unless excluded for operational reasons)	3.1.6
Introduce a new appointment process	The APVMR will be appointed by the Governor General on the advice of the Minister, based on transparent selection criteria specific to the APVMR position, and following a selection process endorsed by the Australian Public Service Commissioner.	Not supported as it relates to the APVMR	2.1.1
Guarantee independence in decision-making	Legislation will guarantee the independence of the APVMR in science and regulatory decision making.	Not applicable	N/A
	The APVMR will have the independent right to communicate directly with the Minister, as required.	Not applicable	N/A
	The APVMR will have the independent right to lodge its own annual report with the Minister each year, for tabling in the Parliament.	Not applicable	N/A
	The APVMR will independently release its own performance reports.	Not applicable	N/A
Re-define accountability arrangements	The Board will be abolished and the Secretary of the Department of Agriculture, Fisheries and Forestry will take its place as the accountable authority under the PGPA Act. The Secretary may delegate to the APVMR the authority to spend money and undertake other PGPA Act functions.	Not supported as it relates to the APVMR	2.1.1
	The APVMR will be accountable to the Secretary under the PGPA Act, to the Secretary under the Public Service Act, and to the Minister for all powers and functions under the consolidated new APVMR legislation.	Not supported as it relates to the APVMR	2.1.1
Re-define responsibilities	The APVMR office holder will be responsible for the performance and conduct of all staff of the Office of the APVMR (including compliance with the APS values and code of conduct, and the maintenance of a positive workplace culture). If required, the Secretary will provide support for the APVMR in these functions.	Not supported as it relates to the APVMR	2.1.1
	The APVMR will be required to inform the Secretary of significant issues affecting or involving the APVMR, to enable Ministers to be kept informed, as required under the PGPA Act.	Not supported as it relates to the APVMR	2.1.1
	The APVMR will be responsible for developing and providing balanced consultation access for all stakeholder groups in addition to industry groups, while preserving the proper, arms-length posture of a professional industry regulator.	Supported as it relates to the APVMA	1.3.1

Theme	Point	Government response	Report
	The APVMR will be responsible under statute for ensuring balanced discharge of all functions under the legislation, including sufficient attention in future to compliance and enforcement and chemical review.	Supported as it relates to the APVMA	1.1.2, 1.6.3
	The APVMR will be tasked with playing a constructive role in the implementation of any longer-term systemic reforms flowing from the Government's consideration of the Final Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia, 2021.	Supported as it relates to the APVMA	See Independent Review references
	The Minister's expectations of the APVMR will be made transparent to all parties through the publication of the Minister's occasional Letter of Expectations.	Supported as it relates to the APVMA	2.2.1
Settle the relationship between the APVMR and the Department	The Secretary of the department will be responsible for making effective and enduring arrangements for the APVMR to access information, advice, and senior executive counsel, on broader developments in public administration, good APS practice, government policy, and legal requirements.	Not applicable as it relates to the APVMR	N/A
	The APVMR will be empowered to enter into voluntary agreements with the Secretary or others, for the provision or augmentation of corporate services e.g., HR, IT, finance, property, legal services, travel services, etc. For the avoidance of doubt, the APVMR will have discretion to retain all, any, or part of any such services in-house.	Not applicable as it relates to the APVMR	N/A
	It is currently envisaged that core compliance and enforcement functions will increasingly be sourced from inside the Office of the APVMR. In-house capacity will need to be grown.	Supported as it related to the APVMA	1.1.1
	As members of the APS in the Department of Agriculture, Fisheries and Forestry, all staff members will have the same access to information flows, employment opportunities, training, diversity networks, and personal development opportunities as any other departmental officer.	Supported in principle as it relates to the APVMA under One APS	3.1.3, 3.1.5
	The operational relationship between the APVMR and the Secretary, including their respective responsibilities, will be made transparent to all parties through the publication of an agreed written statement.	Not applicable as it relates to the APVMR	N/A
Settle arrangements for Budgets	The Office of the APVMR will have, and administer, its own Special Account or equivalent. The APVMR will be the officer responsible and accountable for the Account. Funds from the Special Account, and staff funded from the Special Account, will only be able to be used for the purposes and legislated functions of the APVMR.	Not applicable as it relates to the APVMR	N/A
	Legislation will require that budgetary and other resources be allocated across all functions of the APVMR, sufficient to discharge responsibilities adequately in each area, including compliance and enforcement and chemical review.	Not applicable as it relates to the APVMR	N/A
Revise the legislation	The four separate Acts currently governing the operations of the APVMA will be reviewed, revised and consolidated.	Supported in principle	Section 1

Theme	Point	Government response	Report
	Recommended reforms accepted by the Government from this [Rapid Evaluation] report will be given legislative effect where required. Other reforms which may be adopted by the Government from the 2021 regulatory system systemic review [Independent Review] will also be taken up in the legislative consolidation process.	Partially supported	Multiple sections of report

Table 2 APVMA Strategic Review Report

Theme	Recommendation	Government response	Report section
Regulatory Performance	1) APVMA's overall regulatory posture requires examination and re-evaluation	Supported	1.1.2, 2.3.1
	2) There are capacity building opportunities for the APMVA in relation to compliance and enforcement	Supported	1.1.1, 1.1.2
Financial Management and Performance	3) The APVMA timeframe performance targets need to align with realistic regulatory best practice	Supported	1.1.1
	4) The APVMA approach to engaging with industry should be re-evaluated as a matter of priority.	Supported	1.3.1
Operations	5) Investigate the underlying causes of the delays affecting the Chemical Review Program	Supported	1.1.1
	6) Further investigation in relation to compliance with the Commonwealth Procurement Rules	Supported	3.2.2, 3.2.3
	7) The APVMA needs to rapidly upskill staff with key corporate knowledge in relation to the Australian Public Service, the Commonwealth Procurement Rules, the APS Values and the APS Code of Conduct	Supported	3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.1.5, 3.1.6, 3.2.3
	8) The Board and the APVMA should continue to progress the [reform] initiatives already implemented and should continue to act and implement strategies to ensure that the APVMA is a safe and respectable workplace.	Supported	3.1.2, 3.1.4, 3.1.5, 3.1.6,
	9) The APVMA's governance structure, including relationship between the CEO and the Board, should be clarified.	Supported	2.2.3

Table 3 Independent review of the pesticides and veterinary medicines regulatory system in Australia

Theme	Recommendation	Government response	Report section
A new vision, objectives and principles for the future regulatory system	1) The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system: "A trusted and nationally consistent regulatory system for the responsible and safe use of effective pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to new products and uses."	Noted	2.3.1
	2) The Panel recommends that the future pesticides and veterinary medicines regulatory system is guided by the following 6 equally weighted objectives: • protect human health and wellbeing	Noted	2.3.1

Theme	Recommendation	Government response	Report section
	• protect animal health and welfare • protect the environment • support primary industries • protect Australia's trade • contribute to biosecurity preparedness.		
	3) The Panel recommends that the following principles should govern the design and implementation of the new regulatory system (8 principles): • The regulatory system should be based on risk, not on hazard alone. • Processes and decisions should be objective, independent and science based. • Regulatory decisions should be transparent, and decision-makers should be responsive to all stakeholders, including the community, users, and the regulated industry. • Risk management measures should be reviewed as new information becomes available. • The system should be efficient, and outcomes focused by making use of contemporary and fit-for-purpose regulatory practices. • The system should achieve a single nationally consistent model with shared responsibility for managing the risks associated with the manufacture, import, export, supply, use, and disposal for regulated products. • The system should be adaptive to new technologies, practices, and knowledge. • The regulatory system should support a resilient supply chain.	Noted	2.3.1
Establishing a truly nationally consistent regulatory system	4) The Panel recommends that the Australian Government works with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. If agreement cannot be reached within 12 months, the Commonwealth should use its constitutional reach to implement a single national approach.	Noted	1.2.1
	5) The Panel recommends that the Department of Agriculture, Water and the Environment have responsibility for policy and legislation for control-of-use as well as associated licensing activities. The Panel also recommends that 'on the ground' control-of-use functions continue to be delivered by the states and territories, but now with the national guidelines, with increased resources made available through the Commonwealth providing an additional $5 million per annum conditional funding across all states and territories.	Noted	1.2.1
	6) The Panel recommends that the need for, and the scope, role, and form of a new IGA (intergovernmental agreement) are considered as part of this review's implementation. The Panel also recommends the existing IGA be extended until a new IGA is formed. • Any future IGA should:	Noted	1.2.1

Theme	Recommendation	Government response	Report section
	• provide that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail • require any jurisdiction that departs from the IGA approach to provide a public reason for such departure • mandate minimum resource levels for regulating control-of-use compliance and enforcement activities, to effectively meet assurance obligations and require publication of those resource levels • require regular input by each jurisdiction for the purpose of public reporting against performance indicators for the entire regulatory system, supported by clear targets or goals • require regular publication (or input to the Department of Agriculture, Water and the Environment's reporting) of performance against these indicators and targets or goals.		
	7) The Panel recommends the establishment of a position in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines. The Commissioner will have responsibility for: • strong and independent policy leadership and responsibility to recommend and drive continuous improvement • reporting on whole-of-system impacts and outcomes through biennial reports based on whole-of-system performance measures • whole-of-system surveillance and monitoring, drawing on data from a range of sources • ongoing open engagement with stakeholders • establishing and leading Stakeholder and Whole of System Forums • establishing a domestic produce monitoring program.	Not supported	2.2.2
	8) The Panel recommends that the Commissioner advise Government and the public on the performance of the regulatory system as a whole by establishing a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should also establish health-risk indicators for Australia. The Commissioner would be responsible for producing a biennial report of whole-of-system performance and make this report publicly available. The Commissioner should report publicly on the progress of the reforms in its first year, with system wide reporting on performance measures commencing 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact. Reporting should be informative and educational and include the results of domestic produce residue monitoring and environmental monitoring as well as adverse experience reports, providing the community with assurance that pesticides and veterinary medicines are being used safely, or in cases of exceedances, that response action is being taken. The data must be	Not supported	2.2.2

Theme	Recommendation	Government response	Report section
	deidentified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.		
	9) The Panel recommends the establishment of a 5 member, skills-based board (including the CEO of the APVMA as an ex officio member) for the APVMA to strengthen its governance arrangements, provide the necessary oversight to support it in managing operational, financial and performance matters, and drive the reform agenda.	Supported and implemented in 2022	2.2.3
	10) The Panel recommends that the Commissioner have responsibility for convening and hosting 2 formal and one ad-hoc consultation mechanisms to consider and offer advice to ministers and the Department of Agriculture, Water and the Environment on the impacts and other consequences of policies, laws and other initiatives that affect, or are affected by, the use of pesticide and veterinary medicine products. These mechanisms are: • a Stakeholder Forum • a Whole of System Forum • Expert Advisory Panels (as needed).	Not supported	1.3.1, 2.2.2
Protecting the health and safety of people, animals and the environment	11) The Panel recommends that the Commissioner develop a cost-effective, integrated national data surveillance system fit for the needs of a 30-year future. The Commissioner should also develop arrangements to curate relevant information to enhance data accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and system response purposes. The Commissioner's biennial report should report on trends identified in system surveillance data. The surveillance system should: • Collate and analyse information from multiple data sources which may include annual pesticides and veterinary medicines sales and volume data, industry quality assurance programs, users' records, published literature, changes in market expectations, decisions by overseas regulators, and intelligence or reports from professional bodies and academic institutions. • Incorporate residue detections from monitoring of domestic produce, environmental monitoring data and adverse experience reports to support a more comprehensive surveillance system.	Supported in principle – noting the Commissioner related elements are not supported	1.7.1
	12) The Panel recommends increased whole-of-system monitoring by government of pesticides and veterinary medicines in produce and the environment. Domestic produce monitoring • Establishment of a comprehensive, cost-effective, and authoritative Government-led national domestic produce monitoring system. The scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise. • A domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residue Survey, primary producers, the community and state Final Report of the	Noted	1.7.1

Theme	Recommendation	Government response	Report section
	Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia 224 and territory governments to ensure it aligns with the whole-of-system surveillance scheme. Water and soil monitoring • Monitoring water, waterway sediment and soil samples to detect levels of pesticides, parasiticides and antimicrobial drugs in the environment. The testing program should be scalable and targeted, based on risk. • Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy Environmental monitoring • Development of a government funded, risk based, Environmental Monitoring Plan to identify areas of priority for monitoring taking account of the 13 major water catchments and key agricultural zones (for soils) across Australia. Further, the Panel recommends the collection and testing of samples be done on a seasonal basis to take account of differing cropping, weather patterns and pesticide patterns		
	13) The Panel recommends that adverse experience reporting (AER) be consolidated, improved, and better utilised: • The structure and reporting process required when reporting adverse experiences should be detailed in legislation for both pesticides and veterinary medicines. • The Department of Agriculture, Water and the Environment develops and maintains a single national portal for AERs under the single national law for control-of-use. The Department of Agriculture, Water and the Environment should collate reports to establish a system wide 'pharmacovigilance' approach. • The AER national portal would automatically refer AERs to the appropriate authority when they are received, thus acting as a single point of contact and automated AER referral system, while also providing for a national database of AERs. • The APVMA and state and territory regulators would be provided with tailored access to the adverse experience report dataset and should publicly report on adverse experience reports that fall under their jurisdiction.	Noted	1.2.2
	14) The Panel recommends the transparency and responsiveness of the chemical review process be improved. Reviews should be initiated through one of 3 mechanisms: as the result of a well-defined, legislated trigger (such as a relevant international decision); at the discretion of the APVMA; or on referral from the Commissioner. If the APVMA is required to commence a review into substances on the basis of the trigger, it would be required to publicly disclose that the review is commencing. However, the trigger should not result in repeated near	Noted	1.6.3

Theme	Recommendation	Government response	Report section
	identical reviews within a 3-year period, unless APVMA chooses to initiate a review within this time. Where an international decision would trigger a chemical review but the APVMA considers the matter is not relevant to the Australian circumstance, the APVMA would not be required to carry out the review. However, in such a case the APVMA would be required to publish, within 6 months of the trigger occurring, a statement of reasons for not conducting the review		
	15) The Panel recommends the Commissioner have responsibility for referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program. Similarly, the Commissioner should be able to refer substances imported under the international licensing scheme to the Department of Agriculture, Water and the Environment for investigation. To refer a chemical to the APVMA or Department, the Commissioner would need to be satisfied that there are sufficient reasons to consider a review and would need to provide those reasons to the APVMA or Department when making the referral. If the APVMA or Department chooses not to initiate a chemical review or investigation based on a referral from the Commissioner, it should be required to publish a statement of reasons for not conducting the chemical review or investigation within 3 months of the referral being made.	Not supported	2.2.2
	16) The Panel recommends that the chemical review process rely on established suspension, cancellation, and variation administrative processes. This approach will streamline regulation and rely on processes established for other administrative actions by the APVMA.	Noted	1.6.3
	17) The Panel recommends that a humaneness score for vertebrate pest control products, based on the model developed and used by the NSW DPI Vertebrate Pest Research Unit, and adopted by the Australian Animal Welfare Strategy, be presented on the label so that users can make an informed decision regarding the humaneness of a vertebrate pest control product.	Not supported	1.8.3
Ensuring Responsible Use	18) The Panel recommends (concurrent with the recommendations for achieving nationally consistent control-of-use) that general product obligations should apply to dealings with pesticides and veterinary medicines to formalise and acknowledge responsibilities of all users across the life cycle of a product from design to disposal. These should enhance current existing industry processes, including codes of practice, work health and safety risk management plans, spray diaries, animal treatment records, industry QA, and stewardship schemes and be consistent with existing management practices to minimise the regulatory burden in meeting these obligations. Final Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia 226 The general product obligations should be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and	Noted	1.2.1

Theme	Recommendation	Government response	Report section
	veterinary medicine products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harm to health, safety and trade, and actions to demonstrate compliance through suitable analysis, systems and record keeping.		
	19) The Panel recommends the Department of Agriculture, Water and the Environment develop a single national legislative framework to accommodate all licences, throughout the product life cycle. The single national licensing framework should enable specific, targeted licensing schemes to be created to regulate specific activities irrespective of whether they relate to supply or use activities. All licences for individual schemes created under the national licensing framework would, with the exception of good manufacturing practice and HGP licensing, be issued by the Department of Agriculture, Water and the Environment, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. Licences should be issued to businesses where possible, rather than individuals, with businesses responsible for undertaking due diligence to ensure their operators hold the accredited education, training, competencies, or other relevant qualifications. Such licences, where relevant, would incorporate mandatory licence conditions that allow for the recognition of suitably rigorous industry quality assurance schemes.	Noted	1.2.1
	20) The Panel recommends that all businesses who apply pesticides commercially (be it agricultural or domestic) are responsible for ensuring operators complete accredited education, training, competencies or other relevant qualifications in chemical use and application techniques, including handling, storage, risk assessment and management, end-of-life cycle disposal and recycling, regardless of whether the activity is subject to licensing.	Noted	1.2.1
	21) The Panel recommends that the Department of Agriculture, Water and the Environment completes the work of HACCUT to establish suitably rigorous training standards for restricted chemical products and Schedule 7 poisons and builds on it to develop a comprehensive set of publicly available national training and competency standards for dealing with pesticides. Competency standards should be established for roles introduced through other recommendations in this review, including the issuing of special use licences. These include: • accredited assessors who undertake third-party assessment work for the APVMA • government auditors engaged to ensuring compliance with licensing requirements under veterinary manufacturing standards, access to internationally registered products and other nationally consistent licensing schemes. Where similar industry-based accreditations or other qualifications exist or are developed, these may also be	Noted	1.2.1

Theme	Recommendation	Government response	Report section
	recognised as meeting the requirements for the qualification or licence, subject to review by the Department of Agriculture, Water and the Environment. The Department of Agriculture, Water and the Environment. should also establish standing liaison arrangements with the ASQA and industry associations responsible for industry-based accreditations.		
	22) The Panel recommends the Department of Agriculture, Water and the Environment, in consultation with relevant stakeholders and consistent with other standard setting approaches, establish the labelling standard under the single national law framework.	Noted	1.5.1
	23) The Panel recommends essential information that relates to safety, first aid, disposal, or use restrictions remain affixed to the product container, but that consideration is given to how it could be enhanced through more comprehensive smart label content.	Noted	1.5.2
	24) The Panel recommends that legislation to facilitate the use of smart labelling and machine-readable labelling be developed. The legislation should allow for progressive implementation of these technologies as telecommunication connectivity improves. Further, labels should not be prevented from including access to complementary and supporting electronic resources (such as links to a copy of the label, safety data sheet, instructional videos, educational material, and label instructions presented visually or in alternate languages).	Noted	1.5.1
	25) The Panel recommends that the label content, i.e., the information constituting the label for control-of-use matters, is divided into 2 categories: regulatory assessed elements (RAEs) and conditional required elements (CREs). The Panel recommends that CREs be those elements that are fixed and do not change as a result of assessment and would not form part of the APVMA's pre-market assessment. CREs would be required to be included on the label by product registration conditions and therefore be subject to post-market compliance. RAEs would then represent those elements for which the expert pre-market consideration of the APVMA is required. RAEs may be communicated, to the extent provided by the labelling standard, through means other than being affixed to the container.	Not supported	1.5.1
	26) The Panel recommends that the APVMA, supported by legislation to the extent necessary, allows the inclusion of first aid and safety directions drawn from any Australian established standard to the extent they would ensure the safe handling of the product. The Panel considers this wording could, at the discretion of the applicant, be drawn from existing standards including APVMA first aid and safety directions, the Poisons Standard, or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).	Not supported	1.5.2
	27) The Panel recommends manufacturers should be permitted (and indeed, should be encouraged) to include additional safety information on product labels, provided	Noted	1.5.1

Theme	Recommendation	Government response	Report section
	it is not inconsistent with the regulatory assessed label elements.		
	28) The Panel recommends that every 5 years, at a minimum, the registration holder conducts its own review of label content to ensure the information on the label remains current and correct – noting that emerging scientific evidence or consumer concerns could also trigger review of the label at any time.	Noted	1.7.2
	29) The Panel recommends that when regulators are determining compliance with responsible stewardship and control-of-use requirements, they should only consider compliance with the regulatory assessed label elements and not against the content on the label not assessed by the APVMA.	Noted	1.5.1
	30) The Panel recommends strengthening good disposal practices (in line with good agricultural practice) by: • encouraging industry QA schemes to include requirements and guidance on good disposal practices as part of being deemed to meet general product obligations (see Section 4.1) • responsible and sustainable disposal practices being considered as a condition for relevant licences • publication of a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs or do not have equivalent programs in place, addressing container management, recycling, and disposal.	Noted	1.2.1
	31) The Panel recommends that compounded veterinary products fall within the scope of the future regulatory system but are exempt from registration where they comply with the prescription protocol. In developing the protocol, the Panel recommends: • registered products be considered first, and compounded products are only prescribed where no suitable or available regulatory assessed products exist • the prescription protocol is finalised and implemented under the single national law for control-of-use • the APVMA works with the Australian Veterinary Association, Pharmacy Board of Australia and leading veterinary compounding pharmacies to ensure one or more suitable manufacturing standards are established to enable said exemption.	Noted	1.2.1
	32) The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.	Noted	1.2.1
	33) The Panel recommends establishing a national rule under the single national law for control-of-use that sets out the requirements for:	Noted	1.2.1

Theme	Recommendation	Government response	Report section
	• a pesticide product's responsible use, including off-label use, and the records that must be kept establishing responsible use • a veterinary medicine's responsible use, including a prescription protocol that applies to all animal use, and the records that must be kept establishing responsible use.		
Improving access and choice in pesticide and veterinary medicine tools	34) The Panel recommends efficiencies for the future regulatory system including: • new definitions for pesticides and veterinary medicines that exclude product classes or uses that are expected to be low risk as they have low hazard or low exposure or are effectively and suitably regulated by other regulators (as outlined in Annex 5) • establishment of exemption pathways which remove pre-market regulation for certain low regulatory concern products • development of standards by the Department of Agriculture, Water and the Environment enabling the exemption pathways, utilising input from industry and public consultation • establishment of a Products Requiring Pre-market Assessment (PRPA) list.	Noted	1.6.1
	35) In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or the OGTR) becomes the decision-maker for an application. Depending on the category of 'substance' and the risks it presents, it may be excluded from the scope of APVMA regulation. In other cases, the regulator making the decision could seek the other's advice when assessing an application and notify it, if and when the application is approved.	Noted	1.4.1
	36) The Panel recommends establishing a licensing scheme to allow for safe and effective pesticides and veterinary medicines registered by equivalent international regulatory systems but not available in Australia, to be supplied and used in Australia. • In support of this scheme, the Panel recommends: • that there be an instrument setting out international regulators determined to be equivalent, and that this be regularly reviewed for currency • that the Department of Agriculture, Water and the Environment, in consultation with the APVMA determine equivalent regulators • establishment of a list of prohibited chemistries and classes of products and uses that would not be allowed under licence • that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation. The Panel recommends that licence holders: • be required to make available all uses approved by an equivalent international regulator, except where the pest, disease, crop or animal is not present in Australia, or a specific grower/producer group only	Not supported	1.4.2

Theme	Recommendation	Government response	Report section
	wants to bring in uses associated with their industry sector and within their control • develop, submit for approval, and implement a risk management plan detailing practices for assessing and controlling risks associated with internationally registered products, with specific consideration of unique Australian circumstances • be subject to regular audits to ensure they are complying with the approved risk management plan and other licence conditions • be required to make risk management plans, with exceptions for confidential commercial information or other trade secrets, publicly available to ensure the community has confidence that the full range of risks have been identified and are being managed • cannot supply a product under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active • provide information on request confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions.		
	37) The Panel recommends expanding support by Government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing industries' access to tools for pest and disease management.	Noted	1.8.1
	38) The Panel recommends establishing specific criteria to grant an emergency, research, or minor use permit, as long as the use of the product would not jeopardise safety or trade and is reasonably expected to be efficacious	Noted	1.6.2
	39) The Panel recommends expanding the authorising of emergency use permits in advance of the emergency through establishing 2 categories within the public listing of permits for 'active-emergency permits' and 'future-emergency permits'. Future-emergency permits would include details of the trigger to transition from the 'future' to 'active' permit category and vice versa.	Noted	1.6.2
	40) The Panel recommends building national research capacity through the adoption of a licensing scheme that authorises entities to undertake research relating to pesticides and veterinary medicines. The licence is to include a condition that a risk management plan has been approved, supported by research quality and safety management systems, and regular independent assurance checks including audits.	Noted	1.6.2
	41) The Panel recommends the APVMA be empowered to approve a priority need (use) via a supplemental label if it determines that further confirmatory data is necessary. Uses on the supplemental label will transfer to a permanent label following the provision and assessment of any confirmatory data, if and where required. • Supplemental labels will not form part of the primary approved label attached to the product container and will be approved for a fixed time only. • The option to place a use on a supplemental label should be provided only for the priority pest, disease,	Not supported	1.5.3

Theme	Recommendation	Government response	Report section
	and animal health needs identified by producers and veterinarians. • The APVMA will identify the information necessary to confirm or refine the original decision as a condition of the supplemental label approval. • A workplan will be a required condition to ensure delivery of the required information before expiration of the supplemental label.		
	42) The Panel recommends: • a 'fast track' application process for pesticides and veterinary medicines that meet prescribed criteria (including, but not only, introduction of a new active constituent, use on a crop group, alternatives to chemicals under review, specialised areas classed as minor uses, reduced environmental risks, increased environmental benefits, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs. • criteria for prioritisation be drafted by the Department of Agriculture, Water and the Environment, and determined by the Minister.	Not supported	1.8.1
	43) The Panel recommends: • the APVMA provide nationally consistent use patterns for pesticides and veterinary medicines as the default arrangement with targeted controls implemented only where warranted • targeted controls be based primarily on climatic regions, with other regional divisions able to be used where the risk factors to be managed do not align with climatic regions.	Noted	1.2.1
	44) The Panel recommends amendments to the Biosecurity (Conditionally Non-prohibited Goods) Determination 2021 to expand alternative conditions for imports of biological pesticides and veterinary medicines. The Panel also recommends the overall pesticides and veterinary medicines regulatory system performance indicators include measuring biologically-based products by quantifying their number and growth over time.	Noted	1.4.4
	45) The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product when proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.	Not supported	1.8.2
	46) The Panel recommends that the limits on the regulator's use of information should be the minimum needed to encourage new uses or chemicals without needlessly impeding flow-on innovation, competition, and access to alternative chemical products. • Equivalent protection periods should be provided for pesticides and veterinary medicines. – 10 years for registration of a new product with a new active constituent or approval of a new active constituent	Noted	1.8.4

Theme	Recommendation	Government response	Report section
	– 5 years for information relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent, issue a research permit, provided in support of a chemical review, or where information contradicts information in the Record or Register. • The same arrangements should apply irrespective of how the information has been provided to the regulator (e.g., associated with a registration application or a chemical review). • These periods should only be further extended as an incentive to bringing priority uses to Australia, as per the measure in the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019 currently before Parliament. • These limitation periods should not prevent the regulator using information where there is a public interest reason to do so.		
	47) The Panel recommends discontinuing the APVMA's role in arbitrating data access and compensation agreements between parties with similar products and uses that are under review. Negotiation of data access and compensation is best left as a matter to negotiate between companies.	Noted	1.8.4
Contributing to supply chain resilience	48) The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture. The APVMA should: • establish a standard for each active constituent prior to its inclusion in products • ensure due regard is given to matters of commercial confidentiality and intellectual property protection in development of these standards • apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard including in products.	Noted	1.4.3
	49) The Panel recommends the establishment, within 18 months of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA. The model for this scheme should be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.	Not supported	1.8.5
Funding of the Regulatory system	50) The Panel recommends changes to the existing levy on product sales including: • that the levy be continued but at a reduced rate with each component of the levy being charged only to those that receive the corresponding service • where regulatory effort for an activity reflects the volume or value of products sold, the component of the levy should be based on a volume or value of	Not supported	3.2.1

Theme	Recommendation	Government response	Report section
	product sales and may be tiered. In other cases, the component of the levy should ideally be a flat charge.		
	51) The Panel recommends changes to assessment charging structures including: • the introduction of hourly charging for highly variable regulatory activities and flat rates for activities with little variation • that the costs for registration applications be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis • the assessment of applications for accreditation, together with the costs to maintain this accreditation, be 100% recovered from the accredited parties • that the full costs for advice given by the APVMA in relation to an application for registration should be recovered, by fees, charged on an hourly basis, with the first hour's advice provided 'free of charge'.	Not supported	3.2.1
	52) The Panel recommends 100% cost recovery for issuing and maintaining licences via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.	Noted	3.2.1
	53) The Panel recommends that where Government audits are routine and predictable the costs of this service be incorporated into the fees for the parent program for example, via licence fees. Where the cost of the audit is highly variable, for example veterinary medicines manufacturing audits, the cost should be recovered on a full hourly fee-for-service basis.	Not supported	3.2.1
	54) The Panel recommends changes to the APVMA's permit charging structure including: • maintaining a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines • minor use permit applications should attract a discounted application fee with the balance of costs recovered via the levy on product sales payable by the holder • emergency use permit applications should be fully recovered as a component of the levy.	Noted	3.2.1
	55) The Panel recommends that the costs of chemical reviews and APVMA compliance and enforcement activities be recovered entirely from industry via a component of the levy on product sales.	Noted	3.2.1
	56) The Panel recommends that the cost of general control-of-use compliance and enforcement activities should continue to be funded by states and territories under their current finding arrangements. However, wherever possible or, where the beneficiary is clearly identifiable, such as a licensed operator, a fee-for-service approach would be used. The Panel also recommends an additional Commonwealth Government contribution of $5 million per annum to support the increase in post market compliance and enforcement activities.	Noted	3.2.1

Theme	Recommendation	Government response	Report section
	57) The Panel recommends public funding for the costs of: • data mining and analysis for system surveillance and monitoring • environmental monitoring • domestic produce monitoring.	Noted	3.2.1
	58) The Panel recommends that the activities of the Commissioner such as reporting on progress in the transformation process, system surveillance and monitoring, and the cost of stakeholder consultation should be Government funded.	Not supported	3.2.1

Appendix C: Agvet Chemicals Subcommittee

The Australian Government will work with states and territory governments to establish the Agvet Chemicals Subcommittee (ACS) under the stewardship of the Agriculture Senior Officials Committee. The ACS will be the key senior executive forum for agvet chemical policy leadership between the Australian Government and state and territory governments. The Independent Review made recommendations related to agvet chemical control-of-use regulatory reforms. The primary purpose of the ACS will be to reform agvet chemical control-of-use functions.

The government acknowledges the previous efforts over several decades to harmonise state and territory agvet chemical control-of-use functions within the existing legislative frameworks. Despite the considerable efforts to-date, effective national consistency remains a key goal for stakeholders of Australia's agvet chemicals regulatory system.

The Australian Government will work through the ACS to consider and explore options to achieve national consistency for the agvet chemicals legislative framework.