

Preliminary government response to *Final Report on Future Structure and Governance Arrangements for the Australian Pesticides and Veterinary Medicines Authority (APVMA)*

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent statutory authority responsible for the regulation of agricultural chemicals and veterinary medicines in Australia.

The purpose of the Rapid Evaluation

The Final Report on Future Structure and Governance Arrangements for the Australian Pesticides and Veterinary Medicines Authority (APVMA) (Rapid Evaluation) was commissioned by the government following an independent review by the law firm Clayton Utz. Clayton Utz identified very serious matters that suggested a high risk of systemic administration and governance problems, including suggestions of potential industry capture, that may have contributed to the APVMA not performing its full regulatory responsibilities. Both reports note the relocation of the APVMA to Armidale disrupted and exacerbated issues with the organisational culture, staff capability, performance of the APVMA while also presenting new recruitment challenges.

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 organisational culture shortcomings of the APVMA.

The government's commitment to an independent, capable, and high-performing APVMA

An effective APVMA supports Australia's thriving agricultural industry and makes a vital contribution to the protection of Australia's people, our environment and economy through access to less harmful and more targeted chemistries and tailoring pesticide use.

The government is committed to ensuring the APVMA is a capable, high performing agency operating independently of government supported by robust governance, a sustainable funding base, fit for purpose performance indicators and stakeholder engagement processes and a healthy workplace culture.

Taking immediate action on key recommendations

The government is releasing the Rapid Evaluation and taking immediate action on key recommendations. The government supports the APVMA as an independent statutory authority and does not support abolishing either the APVMA or its Board (Recommendations 1-7).

The government rejects the recommendation to relocate the APVMA back to Canberra although the government does support the recommendation to repeal the Government Policy Order (GPO) dictating the location of the APVMA (Recommendation 11). This will allow the APVMA Board and CEO to make decisions on staff and office locations that best suit the authority's operational needs. Repealing the GPO will bring the APVMA into line with other Commonwealth agencies and APS

standards by enabling the agency to make decisions on staff and office locations that best suit their operational needs and will assist in recruitment efforts.

These immediate actions enshrine APVMA's independence and provide certainty to stakeholders and assurance to staff on the APVMA's future.

Action already underway in response to findings

The APVMA has already taken steps to address the findings raised in recent reviews. The APVMA is making progress in line with a Ministerial Direction issued to expedite eight long-running chemical reconsiderations and a Ministerial Statement of Expectations requiring improvements to workplace culture, governance, transparency, accountability and engagement.

With new interim leadership, there is clear strategic direction outlined in the APVMA Strategy 2030, relationships between the Board and CEO are clarified with the updated Board Charter and improved engagement with their employees. The government commends the APVMA for the work it has done so far in addressing the findings of recent reviews and improve its operations. We can already see progress in rebuilding the APVMA.

Further consideration and engagement will occur

The Rapid Evaluation makes a number of recommendations – for example, concerning improvements to the quality and integrity of scientific decision making, the development of more balanced performance indicators, and adjustments to the APVMA's funding base – that are inherently more complex and require further consideration and engagement.

This preliminary response indicates whether the government supports, supports in principle, partially supports, or does not support each of the 33 recommendations.

A detailed response will be issued by the government in mid-2024 and will address each recommendation in greater detail, as well as addressing issues identified in earlier reports regarding the APVMA. The detailed response will comprehensively outline 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. The purpose of the detailed response is to demonstrate the government's commitment that the high performance and operational stability of the APVMA is restored and sustained into the future.

Recommendations of the Final Report on Future Structure and Governance Arrangements for the Australian Pesticides and Veterinary Medicines Authority (APVMA)

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').
- 2. An 'Office of the APVMR' be created to support the APVMR officeholder.
- 3. Most current staff of the APVMA should transfer to the Office of the APVMR.
- 4. The Office of the APVMR be headquartered in Canberra and maintained with a discrete identity within the Department of Agriculture, Fisheries and Forestry.
- 5. The independence of the APVMR in science-based regulatory decision-making be protected in legislation.
- 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.
- 7. The APVMA Board be abolished.

Government Response

This suite of recommendations is not supported.

The government has determined these recommendations involve significant risks and effort that outweigh identified benefits. The government considers abolishing the APVMA and creating the APVMR in DAFF creates a risk to the organisational independence of the agvet chemical regulator.

The government does not consider there is a clear case that the abolition of the APVMA as an independent statutory authority will improve regulatory performance. The extensive legislative and related administrative changes required to relocate the APVMA as a statutory office within DAFF's Canberra headquarters would entail significant disruption to both the APVMA and DAFF. It is acknowledged that DAFF has experienced several machinery of government changes and further disruptions would hinder current reform processes underway in both the APVMA and the department.

Additional actions to improve and support the regulatory performance of the APVMA will be outlined in the detailed response to the Rapid Evaluation report in mid-2024.

The government does not support recommendations $\mathbf{1} - \mathbf{7}$.

- 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.
- 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.
- 10. A modest appropriation-funded relocation package should be made available to facilitate the relocation process and to minimise impacts on its operations.
- 11. The Location of Corporate Commonwealth Entities Order 2016 (the 'GPO') should be revoked.
- 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 Section 3, "Package 2 Internally managed governance improvements").
- 13. The APVMR be explicitly required to actively build positive linkages with the portfolio, other regulators, and the wider Australian Public Service.
- 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 Box 1: "Recommended future governance arrangements"
 - 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

This suite of recommendations is partially supported.

The government rejects the recommendation to relocate the APVMA back to Canberra (Rec 8). The government supports revocation of the Government Policy Order (GPO) dictating the location of the APVMA (Rec 11). Repealing the GPO will bring the APVMA into line with other Commonwealth agencies and APS standards by enabling the agency to make decisions on staff and office locations that best suit their operational needs. Future decisions regarding the location and recruitment of APVMA staff, including remaining in Armidale, will be for the APVMA Board and CEO.

The government supports recommendations **12**, **13**, **14(b)** and **(d)**, and **15** as they apply to the APVMA. The Minister issued a Ministerial Statement of Expectations on 12 September 2023 that outlined expected internally managed reforms in the APVMA's workplace culture and governance; and, independence, transparency, and accountability. The APVMA has developed an action plan for the program of reforms requested in the Ministerial Statement of Expectations. The detailed response to the Rapid Evaluation will identify additional actions to give effect to these recommendations.

The government does not support recommendations 8, 9, 10 and 14 (a) and (c) as they relate to recommendations 1-7 which are not supported.

- a consolidation and streamlining of the four pieces of legislation currently governing the work of the Authority
- d) a revised mission (purpose) statement, nested within the vision statement for the Australian regulatory system as a whole.
- 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.

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.
- 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.

Government Response

This suite of recommendations is partially supported.

The government supports recommendation **17** as applied to the APVMA. Steps to identify measures to strengthen the quality and integrity of scientific decision-making of the APVMA will be outlined in the detailed response to the Rapid Evaluation report in mid-2024. The measures will assure the Australian public and our trading partners that APVMA is meeting their compliance and enforcement aims in line with Government Regulatory Good Practice Principles.

Recommendation **16** is not supported as it relates to recommendations **1** – **7** which are not supported. However, the government supports the balanced and timely discharge of the full range of the APVMA's regulatory functions including new registrations, chemical reviews, monitoring, compliance and enforcement, as set forth in the Ministerial Statement of Expectations, and as will be further outlined in the detailed response issued in mid-2024.

Changed Relationship 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.
- 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.
- 20. The development of guidance material and training for staff about the appropriate posture and conduct of professional regulators in their dealings with stakeholders.
- 21. Implementing a scheme that publishes foundational health and safety data and ensures APVMR access to all information on a product's risks.
- 22. Work commence on designing a cyclical registration model for implementation by the future APVMR.

Government Response

This suite of recommendations is supported in principle.

The government supports in principle recommendations 18 and 20. In line with the Ministerial Statement of Expectations issued on 12 September 2023, the APVMA is updating their Stakeholder and Engagement Management Plan, guidance material, and training on best practice engagement with stakeholders. The department is working with the APVMA so that the amended plan, guidance material, and training provides more balanced access for stakeholder groups and industry.

The government supports in principle recommendation **19**. The detailed response to the Rapid Evaluation in mid-2024 will outline the approach to develop best practice performance indicators.

The government supports in principle recommendations **21** and **22**. The detailed response will outline the steps for analysis and policy development involving consultation with stakeholders to address these recommendations.

Clearer Relationship with Related Entities

- 23. Routine publication of future Statements of Expectations from the Minister
- 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

Government Response

This suite of recommendations is partially supported.

The government supports recommendation **23** and its implementation according to existing government policy for best practice under the *Public Governance, Performance and*

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	

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

Accountability Act 2013 as described in the Regulator Performance Guide (RMG 128) administered by the Department of Finance.

The government does not support recommendations **24, 25** and **26** as they relate to recommendations **1-7** which are not supported. These recommendations are not necessary because the government supports retaining the APVMA as an independent statutory authority, with its existing independence preserved.

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
- 28. A substantive appointment be made as a matter of urgency, and that the appointee and future appointees have relevant regulatory experience

Government Response

This suite of recommendations is not supported.

The government does not support recommendations **27** and **28** as they relate to recommendations **1-7** which are not supported.

The APVMA Board is currently undertaking a merit-based selection process for a CEO in line with the government's merit and transparency policy.

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
- 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:

Government Response

This suite of recommendations is noted.

The government notes recommendations 29 and 30 (b) – (f). The department is analysing APVMA's funding mix to ensure that the agency is adequately resourced to undertake the full range of operations. The analysis will consider the Australian

- a) appropriation funding to facilitate the relocation of the agency from Armidale
- b) supplementary (50%) appropriation funding to assist the restoration and maintenance of capability in compliance and enforcement
- c) supplementary (50%) appropriation funding to assist catch-up, maintenance, and reform of the chemical review program
- 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
- 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
- f) appropriation funding to support the introduction of new arrangements to assure the quality of science decision-making.
- 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.
- 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.

Government Charging Framework. APVMA is updating their Cost Recovery Implementation Statement (CRIS).

The updated CRIS and any subsequent proposals for appropriation funding will be presented for government decision.

The government notes recommendation **31**. The department will undertake detailed analysis and develop a considered position on the establishment of an integrated data surveillance and monitoring system. Timing for this policy work will be outlined in the detailed response to the Rapid Evaluation in mid-2024.

The government does not support recommendations 30(a) and 32 as they relate to recommendations 1-7 which are not supported.

Next Steps	Government Response
33. Following Government consideration of this report, DAFF and the APVMR provide quarterly reports to the Minister on implementation progress on each recommendation and the reform process overall.	This recommendation is supported as applied to the APVMA. The Minister issued a Ministerial Statement of Expectations on 12 September 2023 that set out requirements for regular updates against reform activities to improve the APVMA workplace culture and governance arrangements. A Ministerial Direction was issued on 13 July 2023 to progress the determination of chemical reconsiderations requirements with a request for updates every three months. The APVMA has provided updates against these requirements. The department will develop a Reporting and Cooperation Framework as part of the detailed response that will specify a
	reporting routine of the reform process.