## **Final report**

Future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority (APVMA)

Ken Matthews, AO

20 October 2023

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#### Letter of transmittal

20 October 2023

Senator the Hon Murray Watt Minister for Agriculture, Fisheries and Forestry Parliament House, Canberra, ACT 2600

Dear Minister,

I am pleased to submit to you my report on the future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority (APVMA).

You commissioned the report following some disturbing findings of a Strategic Review of the APVMA by Clayton Utz in July 2023 and a prior investigation by Ms Mary Brennan of allegations raised during Senate Estimates hearings in November 2022.

In brief, my report finds that change and reform to the APVMA is necessary. My report recommends significant adjustments to the Authority's governance arrangements. The changes are designed to lift the Authority's performance and restore a positive workplace culture. The changes will enable the Authority to resume its previous position and high reputation among professional regulatory authorities within the Australian Government.

My recommendations comprise two packages – an externally-initiated package of governance reforms to be decided by the Government, complemented by a package of internally-driven management improvements to be pursued by the new leadership of the Authority.

Consistent with your terms of reference for my review, I have also sought to nest the Authority-specific reforms to the APVMA within the context of the wider systemic reforms recommended in the 2021 whole-of-regulatory-system review already before the government.

By considering the two reports together, the Government would have the opportunity to launch a serious piece of overdue microeconomic reform in the agriculture sector, which will have enduring benefits for many years into the future. Taking both reports together would also enable the government to build public confidence in the rigour of Australia's arrangements for the regulation of agricultural and veterinary chemicals at a time when community concerns about the presence of chemicals in the environment and our food supply continue to increase.

In preparing my report, I have had the benefit of helpful support from the department. However, I want to make clear that my recommendations have been independently formulated. I take full responsibility for them.

I commend the report to you.

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Yours sincerely,

Ken Matthews AO

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### **Executive summary**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator of agricultural and veterinary (agvet) chemicals. The APVMA has two offices, the main office in Armidale NSW and a smaller satellite office in Canberra.

In Senate Estimates hearings on 8 November 2022, serious allegations were raised about the conduct of certain APVMA senior staff. Investigations were conducted by Ms Mary Brennan and subsequently, Clayton Utz. Clayton Utz found alleged examples of potential noncompliance with Commonwealth procurement and financial rules, high staff turnover and workplace complaints, and an apparent lack of balance across the full range of the APVMA's regulatory responsibilities. It identified a potential risk of industry capture of the regulator.

The Minister for Agriculture, Fisheries and Forestry then commissioned me to conduct an independent, rapid evaluation of the Clayton Utz findings and to advise on future governance arrangements for the APVMA.

In reviewing the performance and culture of the APVMA over the period under review (2019 - 2022), there are at least five areas of concern:

- 1) Alleged shortfalls in leadership and management within the APVMA
- 2) Performance impacts on the APVMA from the relocation to Armidale
- 3) Alleged shortfalls from Australian Public Service standards and best practice
- 4) Alleged shortfalls by the APVMA from best practice as a government regulator
- 5) Alleged deficiencies in stakeholder management by the APVMA.

My examination of these five areas of concern suggests that the Authority lost sight of its fundamental identity as a professional regulator. Its operations became unbalanced among its several functions. Its dealings with stakeholders became inequitable.

Its separation from the remainder of the APS increased – it began to act as though independence required isolation. Its understanding and application of the APS values and Code of Conduct began to fall away.

Its separation from the community of other Australian Government professional regulators intensified. Consequently, its regulatory practices diverged from counterpart regulators over time.

The ethical and human values of its corporate culture began to degrade. Staff complaints and dissatisfaction increased to high levels.

These concerns suggest a previously respected and highly motivated organisation which had lost its way. In the words of a senior level close observer at the time, "the agency lacked leadership knowledge of regulator and APS best practice. It had become an isolated island of paralysed decision making, and had lost confidence as a regulator."

Many of the issues identified by Clayton Utz and the current review are now being addressed by the new leadership team. This report seeks to identify a package of governance and structural changes to support the APVMA's current improvement efforts, and to ensure that the alleged past failures never recur.

Notwithstanding the efforts of the Authority's current leadership team, I have concluded that significant reform of governance arrangements is required. The recommended reforms comprise two packages: a package of externally initiated governance reforms; and a package of internally managed governance improvements.

#### **Recommended Externally Initiated Management Reforms**

The CEO of the APVMA would be made a statutory office holder, appointed by the Governor General. The Officeholder would be re-designated the Australian Pesticides and Veterinary Medicines Regulator ('the APVMR').

There would be a phased transfer of the Authority from Armidale to Canberra to join the Agriculture department. The discrete identity of the Authority would be preserved in legislation. Most current staff would become members of the 'Office of the APVMR' and become departmental employees.

The independence of science-based regulatory decisions by the APVMR would be guaranteed in legislation. Governance, management. and professional linkages from the Office of the APVMR into the department and the wider Australian Public Service would be rebuilt, leveraging the benefits of its new Canberra base.

The APVMR would 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.

The Board would be abolished and the Secretary of the Department of Agriculture, Fisheries and Forestry would 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.

The APVMR would 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.

The Office of the APVMR would administer its own Special Account or equivalent. Funds from the Special Account, and staff funded from the Special Account, would only be able to be used for the purposes and legislated functions of the APVMR.

Legislation would 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.

The four separate Acts currently governing the operations of the APVMA would be reviewed, revised and consolidated.

The Authority's name would be changed to the Australian Pesticides and Veterinary Medicines Regulator (APVMR), reinforcing to staff and stakeholders its core role as a regulator.

The reform package would enable the Authority to more readily tap into good APS practice in staff management and leadership. It would enable the APVMR to access information, advice, and senior executive counsel from the Secretary and other senior officers of the department. It would provide the opportunity for the APVMR at their discretion, to source departmental services in support of its operations.

For all these reasons, establishing the APVMR headquarters in Canberra is an essential prerequisite of the governance, leadership, and management reforms which are now required of the Authority.

Ultimately however, the recommendation to return the Authority to Canberra was not based on a choice between geographic locations, but rather on <a href="https://example.com/how-best-to-achieve-the-necessary-operational-and-cultural-reforms-now-required-of-the-Authority">https://example.com/how-best-to-achieve-the-necessary-operational-and-cultural-reforms-now-required-of-the-Authority</a>.

These reforms would enable a robust re-connection between the Authority and the Australian Public Service. They should reverse the sense of isolation, which in recent years has gradually taken root in the Authority. They would also enable more ready access to professional, technical, experienced, and senior leadership staff.

The Armidale office will reduce in size over time through natural attrition. Taking advantage of the opportunities for remote work not previously available, it should be possible in 2023 to design a prudent, graduated re-location process which reasonably sustains the Authority's operations, and minimises impacts on most staff and the Armidale community.

A modest appropriation-funded relocation package is recommended to facilitate the process and to minimise impacts on operations.

The Agriculture portfolio continues to be the most appropriate portfolio home for the Authority, because it covers a larger span of relevant regulated domain. It certainly covers the largest economic and land use interests in the regulation of pesticides and veterinary chemicals, that is, the agriculture sector.

Certain stakeholder groups will express concern that the independence of the APVMR may be compromised by its linkages into the department. These concerns can be answered by legislative guarantees of independence of decision-making, together with transparent administrative arrangements within the department to ensure a discrete identity and operational autonomy in the Regulator's work.

#### **Internally Managed Reforms**

The recommended package of externally imposed governance improvements would be complemented by a package of management improvement initiatives managed within the Authority itself.

The recommended internally managed reforms include: measures to address culture, measures to lift regulatory performance, and measures to ensure staff understanding of expectations.

#### **Confidence Building Measures**

The terms of reference for my review also asked me to consider any other actions the Government should take to ensure or restore confidence in Australia's agvet chemical regulatory system.

Recommendations include:

- Measures to further strengthen the quality and integrity of scientific decisions
- Measures to improve the Authority's regulatory performance indicators
- Measures to enhance transparency.

Finally, public confidence can be maintained by positioning the recommended reforms to the APVMA in the wider context of reforms already recommended to Australia's regulatory system as a whole. The Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia, 2021 has made many additional, complementary recommendations aimed at improving the performance of Australia's agvet chemical regulatory system as a whole and specifically building public confidence and trust in Australian regulatory processes.

It is recommended that the Government consider the present report on the APVMA alongside the wider, whole-of-regulatory-system report. Taken together, there is an opportunity to launch a long-overdue process of microeconomic reform to lift the performance of, and public confidence in, the national agvet chemical regulatory system as a whole.

#### **Costings**

The agvet chemicals industry currently funds around 95% of the APVMA's \$43m annual budget through fees, charges and levies.

This general approach is appropriate for the future APVMR and should continue. However, the Government's charging framework also provides for deviations from full cost recovery to achieve other sound policy outcomes, if required. On this basis I recommend limited appropriation funding in four areas: part funding of compliance and enforcement; surveillance and monitoring; funding for government support activities; and a one-off investment in IT.

## Section 1: Background to the evaluation

#### What is the APVMA?

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator of agricultural and veterinary (agvet) chemicals. For an agvet chemical to be legally manufactured, imported, supplied, sold or used in Australia, it must be authorised by the APVMA.

The APVMA's authorisation process involves scientifically evaluating the safety and effectiveness of a product in order to preserve the health and safety of people, animals and the environment, and protect Australia's trade.

The APVMA has two offices, the main office in Armidale NSW and a smaller satellite office in Canberra. As at 30 June 2023 the APVMA comprised 203 staff, of which 150 positions (144 actual staff) were located in Armidale.

The APVMA is a cost recovered agency with a 2022-23 budget of \$47.07 million. Ninety-five percent of its budget comes from fees or levies on the industry that it regulates.

#### The need for a rapid evaluation

In Senate Estimates hearings on 8 November 2022, serious allegations were raised about the conduct of certain APVMA senior staff.

The Minister for Agriculture, Fisheries and Forestry, as the responsible minister, immediately commissioned an investigation into the allegations specifically, and the culture of the organisation more generally. That investigation was conducted by Ms Mary Brennan.

Ms Brennan's investigation identified further serious allegations concerning the APVMA's culture and operations. Ms Brennan's interim report was received by the Minister on 8 February 2023. The Minister referred a number of matters to the APSC and the NSW Police.

Given the gravity of the issues reported by Ms Brennan, the APVMA Board commissioned a more detailed review by Clayton Utz to examine the APVMA's allocation of regulatory priorities, its capability to carry out the full scope of regulatory functions, and its operations.

Clayton Utz found alleged examples of potential noncompliance with Commonwealth procurement and financial rules, high staff turnover and workplace complaints, and an apparent lack of balance across the full range of the Authority's regulatory responsibilities. It identified a potential risk of industry capture of the regulator. The report focused on the period 2019 - 2022.

The Clayton Utz report was received in July 2023. As he released the report, the Minister said that he had commissioned me to conduct an independent, rapid evaluation of the Clayton Utz findings and deliver advice on the future structure and governance arrangements for the APVMA. The Minister requested the report by 30 September 2023. The Minister subsequently agreed to my request for an extension of time to 27 October.

#### Scope of this report

Under the Terms of Reference (Attachment A), I was asked to consider the findings of the Clayton Utz report and any other relevant information, including recommendations from the 2021 Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia and the regulator's cost recovery and funding information. (Note: I chaired the panel that produced the 2021 report.)

The Terms of Reference invite recommendations on:

- the regulator's future governance, operational structure (including physical location) and legislative framework
- any further urgent actions the Government should take to ensure confidence in Australia's agvet chemical regulatory system
- the regulator's funding framework, including options that uphold the existing polluter and beneficiary pays principle.

I was asked to have regard for how the regulator can better balance regulatory outcomes that maximise the national public health benefit rather than industry preferences, and how governance, cultural and legislative recommendations will impact on the future of the regulator's regulatory arrangements.

#### Factors guiding the recommendations

In the course of my review I met with APVMA staff on three occasions to invite their input and to hear their concerns. In those consultations, I made a number of commitments about the character of my report. I said I was aiming to:

- Maintain the Authority's independence in regulatory decision-making
- Maintain a discrete identity for the regulator
- Assemble a meaningful reform package, i.e., a package sufficient to redress, and be seen to redress, reported management, cultural, and operational issues of concern and re-build public confidence and respect for the Authority
- Recommend a sufficient budget for the necessary reforms and for the ongoing work of the Authority.
- Ensure staff and union views about the necessary change process were taken into account.

I put my view to staff that the APVMA was a fundamentally good and previously respected organisation that in recent years had lost its way. I said I recognised that under its new management many positive steps have been taken to improve the organisation. I said that I recognised the hidden transitional costs of many public sector restructuring and reorganisation processes. I said that for all these reasons, I thought it was important not to 'bulldoze' the current organisation, and instead, to seek to build on the past strengths of the Authority, and the current first steps it is taking towards reform. My recommended package later in this report seeks to do that.

My report seeks also to nest the recommended reforms to the APVMA within the wider set of whole-of-regulatory-system reforms recommended in the 2021 report currently before the government. Taken together, the two reports provide an opportunity for the Government to launch a substantial

and valuable microeconomic reform process to build a much-improved agvet chemical regulatory system for the decades ahead.

## Section 2: APVMA Performance - What are the issues of concern?

In reviewing the performance and culture of the APVMA over recent years, there are at least five areas of concern. Many were alleged in the Brennan review, others in the Clayton Utz review and evidence of others has been seen in my present evaluation.

#### The areas of concern are as follows:

- 1) Alleged shortfalls in leadership and management within the APVMA.
- 2) Performance impacts on the APVMA from the relocation to Armidale.
- 3) Alleged shortfalls from Australian Public Service standards and best practice.
- 4) Alleged shortfalls by the APVMA from best practice as a government regulator.
- 5) Alleged deficiencies in stakeholder management by the APVMA.

## Alleged shortfalls in leadership and management within the APVMA

The Brennan and Clayton Utz reviews reported allegations of serious cases of misconduct, including, but not only, by senior staff, and failure to take firm and rapid action in response to those allegations. The reports noted a high number of workplace complaints, and staff dissatisfaction with the way complaints had been handled within the Authority. Unsurprisingly, the APVMA saw a sustained high level of staff turnover during this period.

#### Reported concerns included:

- Possible procedural failings and lack of support for staff, in the way whistleblowers and complainants were treated.
- Perceptions that certain complaints continued unaddressed, or unresolved, for extended periods.
- Staff scepticism about the integrity of certain staff selection, promotion, and separation processes.
- Poor workplace culture and evidence of demoralisation, stress, disaffection, and alienation of some staff.
- Ethical concerns about allegedly favoured treatment of certain industry stakeholders.

Additionally, 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.

The reviews also questioned the effectiveness of the APVMA Board. Clayton Utz reported that 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. As a result, it became difficult for the Board to report, if necessary, to ministers as required under section 19 of the *Public Governance, Performance and Accountability Act 2013 (PGPA Act)* i.e., to notify the responsible Minister as soon as practicable after the accountable authority becomes aware of any significant issue that has affected the entity.

For its part, the Acting Board Chair has confirmed to me that the Board did not have a clear understanding of its responsibilities and legislatively prescribed role to provide effective oversight. He also communicated the Board's belief that deficient Board support processes had had the effect of reducing Board members' awareness of potentially significant events, trends and developments in the Board's areas of responsibility.

There were reports of resistance at senior staff level to the Board and other monitoring and review processes and a pronounced lack of openness to externally-generated reform proposals.

Despite clear legislation, it appears there was a lack of understanding from the outset of the proper respective roles of the CEO and the Board. This may have been a consequence of the lack of experience in public sector governance matters of some senior leaders.

**Comment**: All of the above (the alleged misconduct, alleged procedural failings, alleged governance shortcomings, and alleged resistance to review and reform) thus comprise the first set of issues that can potentially be remedied by governance improvements. Recommended changes to governance arrangements are made later in this report.

#### Performance impacts on the APVMA from the relocation to Armidale

The enforced move to Armidale over the period April 2017 to June 2019, has had serious impacts on the performance and culture of the APVMA in the years since.

Only 9% of staff employed at the date of transfer accepted the offer to relocate. Although a number of key staff were able to continue to work from the satellite office in Canberra, there was a disproportionate loss of the scarce but critical regulatory scientist staff cohort. Many administrative staff with knowledge of basic APS governance and management practices were also lost. This meant that standard government processes such as procurement and staff selection became less familiar over time.

To add to this, Armidale has a small local public service sector with few job candidates having prior experience in basic APS processes such as procurement, contract management and human resource management. This made recruiting and retaining suitably experienced staff for these functions in Armidale especially challenging, with many positions remaining unfilled, or filled with junior staff on higher duties arrangements, perpetuating the inexperience problem. Deficiencies in induction training or job handovers meant new staff may not have been fully aware of their obligations as an APS employee at the APVMA.

Shortly after the announcement of the relocation, the then-CEO resigned. The new CEO's period of service was not long and a third CEO commenced. Consequently, there was senior executive and leadership turnover at a critical time. The eventual SES team had had little significant regulatory or regulatory policy experience. At the same time, below Executive level, the organisation had to deal

urgently with significant gaps in its capability, capacity and corporate memory. With the focus of the leadership team on re-locating the APVMA as quickly as possible, there was a reduction in oversight and support for staff, which may have impacted on the Authority's performance and on the well-being of staff.

Isolation of the Authority from the wider APS began to develop and isolation of the APVMA SES from their SES departmental colleagues was reinforced. Senior staff rarely engaged with the SES from the portfolio department and as a result there was less exposure to contemporary leadership, management, and public administration best practices.

Isolation from the APS community of regulators was also heightened. APS conventions guiding a professional regulator's proper relationship with the industry it regulates became obscured.

Flexible working arrangements including work-from-home and remote working intensified during the pandemic, meaning face-to-face workplace contact significantly reduced not long after the Authority's full transition to Armidale. A minimum requirement of 20% attendance in the office was introduced and remained in place until the interim leadership changes of February 2023. In these circumstances building and maintaining a positive and inclusive organisational culture became more difficult.

Given the geographic separation, the difference in APS experience of the Canberra-based office compared with the Armidale office, and the growing sense of organisational isolation, awareness on the part of the Minister and the department of events, developments, and risks in the APVMA was reduced. Certain emerging problems went unreported and unnoticed, and ultimately unmanaged.

**Comment**: The transfer to Armidale had serious impacts on the performance and culture of the Authority - although it was by no means the only contributing factor. The impacts were highly visible in the early stages of the transfer. However, negative impacts persisted, indeed grew perniciously, in the years that followed. There is little doubt that the re-location reduced the effectiveness of the Authority's governance and management arrangements in place at the time.

There are lessons about how to design governance arrangements to capitalise on the Authority's location, and about how to structure any re-location process. These lessons need to be taken into account in the governance improvements recommended later in this report.

#### Alleged shortfalls from APS standards and best practice

As noted above, the growing sense of isolation of the Authority from the wider APS gradually reduced the Authority's awareness of contemporary APS best practice, and standard whole of government processes.

This was not only a result of the move to Armidale. The recruitment of staff with little or no APS experience exacerbated the problem, while at the same time the APVMA's former leadership may have confused independence with isolation - the former being a critical and legitimate element of APVMA operations, the latter being an operational risk factor.

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. Knowledge and direct experience of the APS values and code of conduct was less pervasive among

the leadership group, new recruits and locally recruited staff. There was a consequential decline in understanding of public service values, conventions, and best practice. In particular, there was reduced understanding of how to apply public service values in the myriad of different situations involving industry/regulator contacts, staff/staff interactions, and public administration processes.

The new culture led to a sustained high volume of staff complaints. Clayton Utz reported that the high turnover of staff and poor culture directly affected the APVMA's day to day operations.

For example, Clayton Utz reported a failure to follow the normal Government procurement rules and evidence of weak procurement project management. It reported deficiencies in procurement tracking systems and a lack of guidance for staff on procurement requirements. It saw evidence of poor documentation of procurement decisions and a lack of written supporting justification.

**Comment**: The degradation of the APVMA's workplace culture and gradual divergence of APVMA practices from APS norms were costly to organisational performance and staff well-being. The right governance arrangements can foster a positive and high-performing culture. The right governance arrangements can also embed and promote public sector processes which have developed over many years to minimise risk and protect the interests of the taxpayer. Recommendations to develop better arrangements for the APVMA in the future are provided later in this report.

## Alleged shortfalls from best practice as a government regulator

The APVMA's isolation from the APS and from professional colleagues in other regulatory agencies, particularly at agency leadership level, may have led to the APVMA failing to maintain the proper and transparent relationship between a regulator and the industry it regulates.

In its well-intentioned efforts to satisfy industry demands for timely registration of agvet chemical products, the Authority may have lost sight of its fundamental identity – that is, a robust, independent regulator of industry on behalf of the community at large.

For their part, industry stakeholders may also have lost sight of the fundamental identity of the Authority – they became protective of the Authority and its practices, and increasingly regarded and treated the Authority as a service provider accountable to them for its performance.

Isolation from other APS professional regulators especially at senior levels may also have contributed to the decline in compliance and enforcement action, a core function of any regulatory agency. Clayton Utz reported significant evidence that the APVMA favoured education and warnings over compliance action and had a low-risk appetite for compliance and enforcement action. This was associated with 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.

As a regulator, the APVMA has a range of legislated compliance and enforcement powers available for its use. As the Authority tasked with regulating agvet chemicals entering the Australian market, it is the public's expectation that the APVMA uses these powers to take action that is appropriate and proportionate to any instances of non-compliance. Failure to do so may jeopardise health, safety and

trade, and risk the reputation of the Authority, the Australian agvet chemicals industries, and the social licence of Australia's agricultural sector.

Maintaining a proper balance among the statutory functions of a regulator, is an important general principle throughout the community of APS regulators. In contrast, in the APVMA, the regulator began to rely on a narrow set of performance indicators, including disproportionate attention to agvet chemical product registrations, assessment, and approvals timeframes. These were the performance indicators of most interest to industry stakeholders and the performance indicators highlighted by former Ministers as the key measure of success or failure.

A core function of the Authority, the Chemical Review program – a process to determine whether a previously registered agvet chemical is still safe to use based on more recent information – also continued to languish. This was exacerbated by the gradual shift of resources to the agvet chemical product registration process. The Chemical Review program was most recently run by eight staff; the registration management team comprised 89 staff.

The alarming backlog of chemicals under review has been known for a long time, and was identified as an issue in the 2021 independent review of the agvet chemicals regulatory system. The Clayton Utz report reported the apparent slow progress with concern, noting that some chemicals had been under review for more than 17 years without resolution. (The Minister for Agriculture has since given a formal direction that these reviews are to be prioritised, better resourced and finalised as soon as possible.)

Such examples were evidence to Clayton Utz of the risk of capture of the regulator by the industry. Disproportionate concern about the interests and preferences of industry stakeholders is clearly not consistent with good government regulatory practice.

**Comment**: Good governance arrangements can build guardrails to minimise the risk of industry capture. Governance arrangements to require, or encourage, the right balance in the posture and work of the APVMA are recommended later in this report.

## Alleged deficiencies in stakeholder management by the APVMA

In addition to the above, a lack of balance began to emerge in consultation arrangements with stakeholders. In its treatment of stakeholders, the APVMA failed to respond to the steadily more demanding expectations about safety, environment, and transparency of process from stakeholders other than industry.

Access for industry was prioritised; access for public health and environmental groups continued to languish or be absent. Authority-led forums, such as the Agvet Users Forum and Consultative Forum, were established to provide an opportunity for industry and agvet chemical product users to engage directly with the regulator. However, there were no equivalent consultation mechanisms for public health and environmental groups. The proper even-handed and arms-length posture of a professional industry regulator was not maintained.

Clayton Utz reported disturbing staff allegations about favoured access and treatment of certain industry stakeholders. Such allegations are not indicative of a sound regulatory posture and suggest a lack of balance in the Authority's engagement with some stakeholders to the exclusion of others.

#### In short...

Over the period under review, the organisation began to lose sight of its fundamental identity as a professional regulator. Its operations became unbalanced among its several functions. Its dealings with, and access for, stakeholders became inequitable.

Its separation from the remainder of the APS increased, particularly at Authority leadership level – it began to act as though independence required isolation. Its knowledge, understanding, and application, of the APS values and Code of Conduct began to fall away.

Its separation from the community of other Australian Government professional regulators intensified. Consequently, its regulatory practices diverged from counterpart regulators over time.

The ethical and human values of its corporate culture began to degrade. Staff complaints and dissatisfaction increased to high levels.

These concerns are indicative of a previously respected and highly motivated organisation which had lost its way. In the words of a senior level close observer at the time, "the agency lacked leadership knowledge of regulator and APS best practice. It had become an isolated island of paralysed decision making, and had lost confidence as a regulator."

#### What is the view of staff and the union?

Members of APVMA staff have put their views – both in a series of all-staff and staff/union meetings, and in separate private submissions to me following the meetings. Most staff also completed an informal survey as input to this review.

Based on the meetings and submissions, most staff vigorously reject allegations that the integrity of their science based regulatory advice has been compromised. Some staff members concede that the culture of the organisation had been toxic, although many say that this did not apply to their local team, and that overall culture is now much improved. Many staff say that a return to Canberra would be costly and distressing to them and disruptive to APVMA operations. A minority see merit in a return to Canberra, both to improve organisational culture, enable them to perform their duties more effectively, and to redress lack of APS experience and exposure. Most staff argue that the Authority is already lacking sufficient staff and budget to do its job well, even now. Some staff say that the organisation is suffering change and review fatigue. Many say that the new APVMA leadership team is doing a good job in responding to identified problems. Many staff argue that if a move is essential, it will be important to retain the APVMA's independent identity, avoid a sudden Big Bang move, maximise the utilisation of remote working arrangements, retain a 'branch office' presence in Armidale, treat affected staff fairly, and learn the lessons from the last enforced relocation.

<u>Based on the informal staff survey</u>, a considerable majority of staff were concerned by the Clayton Utz findings about their organisation, and most think that changes are therefore required to improve governance, culture, and structure. Many staff acknowledge that, under the Authority's new

leadership, positive changes are already in train. Most staff see stronger connections with the wider APS as a good thing, but many see such connections as already in place. The strongest message from the staff survey was concern about a potential relocation to Canberra. Some 43% of staff would seek a remote working arrangement in that event, and about one in five staff indicated they would seek alternative employment.

#### Where to from here?

It is important to note that many of the issues identified by Clayton Utz and the current review are now being addressed by the new leadership team and progress has been made to get the organisation back on track. Certainly, some of the issues can be addressed by changes to internal governance, management and leadership practices. However, other governance reforms will require external decisions beyond the authority of internal agency leadership.

Those external governance reforms need to be seen in a whole-of-system context. The 2021 review of the agricultural and veterinary chemicals regulatory system as a whole includes many systemic reforms, which can improve the performance and culture of the APVMA, given its central role in the overall regulatory system.

The remainder of this report seeks to identify a package of governance and structural changes to support the APVMA's current reform and improvement efforts, and to ensure that the alleged past failures never recur.

# Section 3: Future governance arrangements to deal with the issues of concern

The issues of concern identified in Section 2 require significant reform of governance arrangements. The <u>recommended reforms</u> comprise two packages: a package of externally imposed governance reforms; and a package of internally managed governance improvements.

#### Package 1 – externally imposed governance improvements

The CEO of the APVMA would be made a statutory office holder, appointed by the Governor General. The Officeholder would be re-designated the Australian Pesticides and Veterinary Medicines Regulator ('the APVMR').

There would be a phased transfer of the Authority from Armidale to Canberra to join the Agriculture department. The discrete identity of the Authority would be preserved in legislation. Most current staff would become members of the 'Office of the APVMR' and become departmental employees.

The independence of science-based regulatory decisions by the APVMR would be guaranteed in legislation. Governance, management and professional linkages from the Office of the APVMR into the department and the wider Australian Public Service would be rebuilt, leveraging the benefits of its new Canberra base.

These arrangements would be similar to the Office of the Gene Technology Regulator (OGTR) which works within the Department of Health and Aged Care. A number of comparable overseas regulators have similar governance arrangements within government departments.

More details of the recommended arrangement are in Feature Box 1, following.

#### Feature Box 1: Recommended future governance arrangements

#### Establish a new entity

- The CEO will become a statutory officeholder, and be re-designated the Australian Pesticides and Veterinary Medicines Regulator (the 'APVMR').
- An 'Office of the APVMR' will be created to support the APVMR office holder.
- Most current staff of the APVMA will transfer to the Office of the APVMR.
- All staff will continue to be employed under the Public Service Act.

#### Re-locate to Canberra

The Office of the APVMR will be located in Canberra and maintained as a discrete entity within the
Department of 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.
- 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.
- All positions will be reviewed initially, and again upon vacancy, by the APVMR personally to identify their optimum location.

#### 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.

#### Guarantee independence in decision-making

- Legislation will guarantee the independence of the APVMR in science and regulatory decision making.

  Recommended areas to be reserved by statute for independent decision-making are listed at Attachment B.
- The APVMR will have the independent right to communicate directly with the Minister, as required.
- The APVMR will have the independent right to lodge its own annual report with the Minister each year, for tabling in the Parliament.
- The APVMR will independently release its own performance reports.

#### 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.
- 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.

#### 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.
- 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.
- 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.
- 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.
- 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.

• 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.

#### 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.
- 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.
- 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.
- 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.
- 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. An illustrative example is at Attachment C to this report.

#### 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.
- 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.

#### Revise the legislation

- The four separate Acts currently governing the operations of the APVMA will be reviewed, revised and consolidated.
- Recommended reforms accepted by the Government from this report will be given legislative effect where
  required. Other reforms which may be adopted by the Government from the 2021 regulatory system
  systemic review will also be taken up in the legislative consolidation process.

#### **Basis for the recommendations**

Establishing the APVMR as a statutory office holder within the department is a proportionate response to the seriousness of the issues and allegations covered in the Clayton Utz report. It provides governance arrangements to reduce the Authority's organisational isolation while adding operational and cultural support mechanisms.

This package retains the critical requirement for independence in science-based regulatory decisions, while reducing the Authority's previous organisational and geographic isolation from broader developments in public administration, best regulatory practice, government policy, and changing legal requirements.

Changing the Authority's name to the Australian Pesticides and Veterinary Medicines Regulator (APVMR), reinforces to staff and stakeholders its core role as a regulator, while respecting the Authority's previous proud historical identity.

The package will enable the Authority to more readily tap into good APS practice in staff management and leadership, and strategies for building a positive, ethical and people-centred corporate culture. It enables the APVMR to access information, advice, and senior executive counsel from the Secretary and other senior officers of the department. It provides the opportunity for the APVMR at their discretion, to source departmental services in support of its operations.

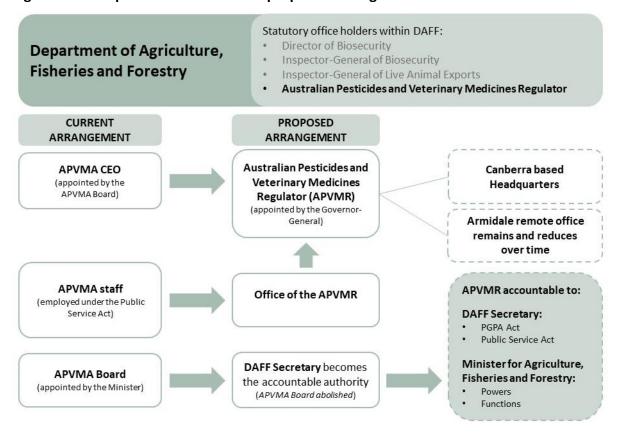
For all these reasons, establishing the APVMR headquarters in Canberra is an essential prerequisite of the governance, leadership, and management reforms which are now required of the Authority and to ensure that it re-builds its culture as a safe and respectful workplace.

Employment in a larger department provides benefits for staff in career development opportunities, peer engagement, support through diversity networks and professional diversity in roles.

The package also provides further opportunities to advance more comprehensive systemic reforms foreshadowed in the 2021 report, Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia.

Establishing the APVMR as a statutory office holder conforms with the latest guidelines provided by the Department of Finance on the appropriate structural model for different types of Australian Government Bodies and is more aligned with the models adopted for other comparable regulators (e.g., the OGTR, TGA and ACIS).

Figure 1: A comparison of current and proposed arrangements of the APVMA



#### Why should the Authority return to Canberra?

In the course of this rapid evaluation, the issue of whether or not the Authority should return to Canberra has attracted a great deal of attention.

It is important to recognise that some staff of the Authority have strong personal, family, career, and financial interests in this decision. Similarly, the Armidale community has a keen interest in the outcome. Strong representations have been made to keep the Authority in Armidale by the Mayor on behalf of the community. Many staff members have expressed concern and disappointment at the prospect of a reversal of a previous Government decision on which they thought they could rely.

An informal staff survey of September 2023, indicated that a significant proportion (43%) of staff would seek a remote working arrangement if a return to Canberra were to be decided. Around 20% indicated that they would seek alternative employment. (Around 90% of then-staff declined the original move to Armidale.)

These staff and community interests are absolutely legitimate, and for at least these reasons, the recommendation to return the agency to Canberra has not been made lightly. For these reasons also, a relocation package to manage the impacts of the change is recommended.

Ultimately however, the recommendation to return the Authority to Canberra was not based on a choice between geographic locations, but rather on <a href="https://example.com/how-best-to-achieve-the-necessary-operational-and-cultural-reforms-now-required-of-the-Authority">https://example.com/how-best-to-achieve-the-necessary-operational-and-cultural-reforms-now-required-of-the-Authority</a>.

Those reforms require a robust re-connection between the Authority and the Australian Public Service. They require reversal of the sense of isolation, which in recent years has gradually taken root in the Authority. Aspects of performance and culture, such as unbalanced relationships with stakeholders and tolerance of poor conduct, need to be quickly brought into line with APS norms and standards.

The reforms also require closer linkages to counterpart regulators in Australia. They require strengthening of professional networks. They would benefit from readier exposure to counterpart organisations' operational models and practices.

The reforms will require catching up, and staying up-to-date with changes in Public Service and public administration best practice. They will require continuing awareness of the high standards of conduct the public expects of public servants. The necessary work on the Authority's workplace culture and people management practices will be easier when there are alternative models in close proximity, to consider and adopt if suitable.

Partly as a consequence of the APVMA's isolation, basic public administration practices such as: publicly defensible procurement; rigorous project management; and high integrity staff selection, promotion, and separation practices have lapsed from best practice. 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.

To deliver on all these cultural and operational reform requirements, there would be advantage in a location at the centre of the APS. Canberra is that location. But while location in Canberra will help, it

will not by itself deliver the reforms which are necessary. It is commitment to reform, rather than commitment to a location that will count most.

Other relevant factors favouring a return to Canberra, include more ready access to professional, technical, experienced, and senior leadership staff, and the opportunity to source necessary corporate and support services from outside the organisation, if the APVMR so chooses.

Delivering nationally consistent regulation will often benefit from location in the national capital. Investigations and inspections of premises usually based in capital cities across Australia will be more easily delivered than from Armidale. This will be particularly important if the compliance and enforcement program is strengthened, as recommended.

Similarly, liaison with international counterparts and best practice sharing, can be facilitated by a national capital location.

Finally, it should be noted that the then Government's own benefit / cost study prior to the original move to Armidale showed a negative national benefit in making the move. It should be noted also that of the Authority's 211 average staffing level (ASL), 49 are already based in Canberra and of the 160 Armidale-based positions, six are currently vacant.

#### How best to manage the relocation process

The process of returning the Authority to Canberra, needs to be managed prudently and conservatively to minimise the risk of loss of staff and operational capability as occurred in 2017 - 2019. The process should not be rushed.

The overriding objective should be to minimise the impact of the transfer on the Authority's overall operational capability, while taking full account of the interests of staff.

The process should commence with the formal transfer of the CEO and key senior executive positions to Canberra. There should be a publicly declared commencement date for the new office location.

For all other positions, there should be a position-by-position process to identify the optimum geographic location: Canberra; Armidale; either; or other remote location. The APVMR personally should be the decision-maker about each position.

Subject always to operational requirements, staff preferences should be taken fully into account, including utilising reasonable, but cost-effective remote working arrangements. Where operational requirements permit, notice periods for the transfer of a specific position could be negotiated with the incumbent staff member.

The optimum location for all positions should be reviewed again on vacancy, with the default position that the position will eventually return to Canberra. As previously, the decision maker for each position should be the APVMR personally.

Compared to 2017, technologies and practices to enable remote working are now more readily available. The Authority can continue to operate in two locations (Armidale and Canberra), for an extended transition period, with the Canberra office being the headquarters. Work models to continue certain operations from Armidale are now more feasible, even when the headquarters move.

However, it needs to be made clear that the ultimate outcome will be a Canberra base for the great majority of staff, with remote working arrangements (including from Armidale) authorised only when operationally justified.

The Armidale office will reduce in size over time through natural attrition. Taking advantage of the opportunities for remote work not previously available, it should be possible in 2023 to design a prudent, graduated re-location process which reasonably sustains the Authority's operations, and minimises impacts on most staff and the Armidale community.

To improve staff understanding and buy-in, it will be important that staff and unions are properly consulted in the implementation of these changes. Australian Public Service Commission Circular 2022/08 dated 6 October 2022 describes the responsibility of government agencies to consult their employees on change processes potentially affecting them.

The APVMR and the departmental executive should jointly develop a Transition and Relocation Plan (in line with relevant procedures and policies) to guide the transfer of current APVMA staff to their new placements within the Office of the APVMR, within the department. The plan should ensure that staff have access to all necessary information and are welcomed and fully supported throughout the process. Induction processes to introduce incoming staff to departmental services should be made available.

While the impacts of relocation should be manageable, a modest appropriation-funded relocation package is recommended to facilitate the process and to minimise impacts on operations. Appropriation funding is appropriate in this case given that the costs of relocation derive from a government policy directive and are not a direct consequence of the existence and operation of the regulated industry itself.

The package should be available to:

- assist retention of key staff
- meet the costs of redundancies for affected staff who choose not to move
- assist with staff re-location costs and specialist advice e.g., financial advice and counselling
- meet make-good and fit-out property costs
- assist in reducing the impact on public facing operations during the relocation period.

A similar package was made available by the then-Government in 2017.

This should reduce the level of any short-term disruption to the Authority's work caused by the relocation. In the longer-term, a settled operational base in Canberra should reduce costs to industry as a result of reduced travel and reduced operational and management overhead costs.

The 'Location of Corporate Commonwealth Entities' Order

The original move to Armidale from Canberra was triggered by a legal instrument issued by the Minister for Finance under the PGPA Act - the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016 (the 'GPO').

It is recommended that the Order be revoked as soon as practicable. Revocation is recommended regardless of whether the recommendation to establish the APVMR in Canberra is accepted. Revocation would enable the APVMR to recruit staff to any suitable location, attracting a broader range of applicants. Revocation would also enable the executive team to manage its office and staffing location to maximise operational performance.

#### Why retain the Authority in the Agriculture portfolio?

An important question when settling future governance arrangements for a Government agency is the threshold decision about which portfolio is the most suitable home.

For the agvet chemical regulator, the Health portfolio is sometimes suggested, given the important public health responsibilities of the Authority. However, the Health portfolio covers only part of the regulated domain, that is, public health, but not the environment, natural resource management, international trade, animal welfare, and the largest group of agvet chemical product users - Australian farmers.

Similarly, the Environment portfolio covers an important part of the regulated domain, but not the major part.

The Agriculture portfolio continues to be the most appropriate portfolio home for the Authority, because it covers a larger span of relevant regulated domain. It certainly covers the largest economic and land use interests in the regulation of pesticides and veterinary chemicals, that is, the agriculture sector.

The Agriculture portfolio also has strong interests in international trade and market access, including a network of representatives in key Australian agricultural export markets around the world. The Agriculture portfolio also has well-established regulation capabilities in related areas, including biosecurity, animal welfare aspects of trade, and plant and animal disease management.

For all these reasons, it is recommended that the APVMR continue to be located within the Agriculture portfolio.

## Within the Agriculture portfolio, why bring the Authority into the department?

Many other Commonwealth regulators operate successfully, and with full public confidence, as part of a mainstream government department, e.g., the Therapeutic Goods Administration (TGA) and the Office of the Gene Technology Regulator (OGTR), both of which operate within the Department of Health and Aged Care. The critical requirement is to have demonstrable independence in regulatory decisions.

There is no reason that a statutory office holder such as the APVMR within a department would have less independence in respect of science-based regulatory decisions than the APVMA has now.

In recent years, the APVMA has been isolated geographically and organisationally from the parent APS. The benefits of this separation have been unclear at best, while there is little doubt the separation contributed to the performance problems identified in the Clayton Utz review.

By bringing the Authority into the department, APVMR executive staff will have more ready access to senior advice and counsel on leadership, management, organisational, and people management issues from senior and experienced colleagues.

Opportunities for recruitment and retention of staff will be improved by more ready access to the wider pool of departmental and other APS employees.

Arrangements can and should be made for the discrete identity of the agvet chemical regulator to be preserved, while still located within a departmental structure. (A minor, but important point here would be to maintain a separate and identifiable APVMR email address for staff members of the Office of the APVMR.)

Arrangements can and should be made to separate the policy advising part of the department from the APVMR regulator, although sensible informal collaboration should be encouraged. The latter has been missing until recently, to the disadvantage of both parties.

Certain stakeholder groups will express concern that the independence of the APVMR may be compromised by its linkages into the department. These concerns can be answered by legislative guarantees of independence of decision-making, together with transparent administrative arrangements within the department to ensure a discrete identity and operational autonomy in the Regulator's work (see Attachment C).

There will be scope for efficiency gains if the APVMR chooses to outsource some of its corporate services to the parent department. The chances of process failures in the future, such as those reported by Clayton Utz to have occurred in procurement and IT management in the past, will reduce.

Finally, it should be noted that the Authority's status since 1993 as a Corporate Commonwealth Entity may be inconsistent with current Department of Finance guidance on the appropriate form of a statutory regulatory body. Creation of the recommended APVMR statutory officeholder, supported by an Office of the APVMR within the Department of Agriculture, Fisheries and Forestry, would be consistent with current guidance.

For all these reasons, it is recommended that the APVMR and its supporting Office be located within the Department of Agriculture, Fisheries and Forestry. It is recommended also that the discrete identity of the regulator be valued and preserved while putting in place arrangements to preserve decision making independence, and reap full operational and cultural benefits from the regulator's placement within the department.

More detailed guidance on the recommended future relationship between the Secretary and the APVMR is at Attachment C to this report.

#### Other governance arrangements considered

In formulating the recommendation above regarding the most appropriate governance arrangements for the agvet chemical regulator, the following alternative models were considered.

Option 1: The status quo

One option is to make no change to the APVMA's governance arrangements or physical location. The APVMA's new leadership team has made many positive changes to the Authority and is already driving it in the right direction.

Retaining the status quo would eliminate any risk of disrupting the new leadership's improvements and drive, and it would ease the concerns of staff and the Armidale community relating to a relocation of the APVMA. It is likely some industry stakeholders would be in favour of this approach and there would be no disruption to the APVMA's operations.

However, this approach would be uncertain as it relies heavily on having the right people in the right leadership roles at the right time for a sustained period to drive improvements to the APVMA's governance, operations and culture. It would also require close oversight from the Minister to ensure the Board is rectifying the issues and allegations highlighted in the Clayton Utz report.

Additionally, there would be no evident Government response to the serious allegations and deficiencies highlighted in the Clayton Utz report. Staff would see no reason to persist in improving the behaviours, practices and culture of the organisation. The risk of similar, or even worse conduct and performance problems emerging in the future, would continue unchecked.

Difficulties would continue in maintaining proper relationships between a regulator and the industry it regulates. Challenges would remain in attracting and retaining staff and nurturing a positive workplace culture embracing the APS values and APS code of conduct. Isolation from APS best practice would continue.

#### Option 2: Re-location of the APVMA 'as is' to Canberra

A second option is to move the APVMA to Canberra with no change to its governance arrangements. This could be achieved either promptly, or through a progressive re-location process.

A prompt transfer of the APVMA from Armidale to Canberra would address the challenges the APVMA is facing recruiting suitably qualified staff to the Armidale location (though in the short term there could be a greater number of vacancies to fill). It would immediately reduce the sense of isolation from the APS that has contributed to the erosion of the APVMA's culture and performance since its relocation from Canberra.

However, this approach would be likely to result in a drop in the APVMA's performance with an abrupt disruption to the lives of staff as well as unexpected disruption to the community and businesses of Armidale.

Rather than a prompt transfer of APVMA from Armidale to Canberra, a phased progressive approach was therefore considered. In this approach the executive staff would move in the first instance, vacancies would be advertised as Canberra based and over time, remaining staff would transfer to Canberra as capability builds. This approach would be less disruptive to staff, the APVMA's performance and the community of Armidale.

It would also reduce the corrosive sense of isolation from the APS and from the community of professional government regulators that has gradually come to characterise the Authority since its move. Although it would be seen as a response of sorts to the serious problems highlighted in the

Clayton Utz report, it would not be seen as a comprehensive response - and perhaps a missed opportunity to find an enduring 'fix' to the problems.

Changing the Authority's location without tackling the deeper problems of the Authority's governance and relationships with other arms of government would have no guarantee of success.

Option 3: Establish agvet chemical regulatory functions within a department

The APVMA could be abolished as an independent statutory authority and its functions reestablished within the Department of Agriculture, Fisheries and Forestry.

This governance arrangement would establish the Secretary of the department as the accountable authority for the purposes of the PGPA Act and as well the delegate for all the regulatory powers and functions under the relevant agricultural and veterinary chemical legislation. The Secretary could delegate, as appropriate, these functions to departmental staff.

This governance arrangement would be similar to that of the Therapeutic Goods Administration which is a part of the Health Products Regulation Group within the Department of Health and Aged Care.

In this approach the Secretary of the department would establish a group or division to carry out the regulatory functions as delegated by the Secretary. Existing APVMA staff would be transferred to the new division, augmented with existing departmental resources and services.

While this governance arrangement mirrors many of the benefits and reasons set out in my recommended governance arrangement, it does not enshrine independence of science-based regulatory decisions in the same manner. Although legislation could address this, it is likely there would be a perception of the Secretary and their delegates being subject to political interference or the opportunity for such interference in regulatory decisions.

In addition, the discrete identity of a regulator of pesticides and veterinary medicines would be difficult to maintain. Public facing operations could become obscured in the wider departmental public presence. There would be a cost to staff morale and staff identification with the agency.

It is for these reasons that I do not recommend this governance arrangement.

#### Package 2 – internally managed governance improvements.

The recommended package of externally initiated governance improvements (Feature Box 1) should be complemented by a package of governance and management improvement initiatives managed within the Authority itself. Already, the new management has initiated some commendable improvements to the culture and operations of the Authority. It is recommended that the internal reform package build on these initiatives, as well as broadening the range of management and leadership improvements as described below.

In light of the Clayton Utz findings, the following management improvement measures are recommended to be carried forward by the APVMR Executive Leadership Team. Some sequencing and phasing will be necessary to avoid management congestion. Some initiatives will be able to be progressed in conjunction with the department.

#### 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.
- Review, revise, and reissue internal grievance, complaint, and whistleblower processes.
- Review, revise, and reissue staff/union consultation arrangements, including the Staff Consultative Committee.
- 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.
- Review, revise, and reissue the full suite of HR (people) management guidance material some of which is now well out of date.
- Commission an independent review of the treatment of women and diversity within the Authority.
- Review, revise, and reissue the agency's Reconciliation Action Plan.
- 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.
- Source targeted and tailored training in good regulatory practice for SES and executive staff in particular, and relevant non-executive staff.
- Mandate APSC leadership training for incoming SES officers within six months of their appointment.
- Continue staff surveys to provide feedback from staff on cultural and performance issues that may require management attention. Reinforce confidentiality arrangements.

#### Measures to address performance

- Abolish and redesign stakeholder consultative arrangements to ensure more balanced access for stakeholder groups in addition to industry.
- 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.
- Develop and implement a new standard format and framework for regular reporting to stakeholders and the Minister on performance.
- Review, revise, and re-issue guidance on best practice staff performance management.
- Review, revise, and re-issue the Authority's risk map and risk management assurance arrangements.

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.
- Review, revise, and reissue the Authority's vision and mission statements, taking account of the lessons of the Clayton Utz and current review.
- 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.
- 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.

It would be essential to develop an Implementation Plan specifically for the reforms flowing from this report, including regular reports to the Minister on progress. To encourage staff buy-in, it would be desirable also to make the reports available to staff. Achievable timeframes for delivery of the various reforms will need to be set.

# Section 4: Other measures to restore or maintain public confidence in Australia's regulatory arrangements

The terms of reference for my review asked me to consider any other actions the Government should take to ensure or restore confidence in Australia's agvet chemical regulatory system.

It is of concern that the disturbing findings presented in the Clayton Utz report may have compromised trust and public confidence in Australia's agvet chemical regulatory system, and the safety of Australian produce.

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, and many of the governance reforms to the APVMA proposed earlier in this report are designed at least in part, to sustain community confidence in the regulator and the regulatory system.

However, there is more that can be done. Below are proposals to:

- Further strengthen the quality and integrity of scientific decisions
- Improve the agency's regulatory performance indicators
- Enhance transparency.

#### Further strengthen the quality and integrity of scientific decisions

If the regulator's decisions are to be trusted by the public and our trading partners, they must be transparent and be supported by quality evidence. Desirably, the methodologies for assessing the evidence would be consistent - as far as practicable - with those employed across the Australian Government in similar fields, such as human health, worker safety, environmental impacts, and food standards.

The Clayton Utz report suggested a disconnect exists between the agvet chemical regulator's approach to science assurance and that of other APS science-based regulators. Any such disconnect may be a symptom of the regulator's isolation from the APS, including from other regulators with similar roles.

For their part, many professional staff point to their ad hoc involvement in communities of regulatory practice and similar activities. However, such involvement seems to have been incidental, rather than integral, to the work of the Authority in recent years. It needs to be strengthened and made mainstream.

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.

The Authority previously had a Chief Regulatory Scientist with responsibility for ensuring the quality of science decisions. This role was discontinued by previous management. To restore emphasis on the quality of science decisions, I propose that the APVMR should as soon as practical establish a Principal Scientist (PS) position that is functionally separate from the Authority's roles in registration, review of chemicals and compliance. The position should report directly to the APVMR, and lead the Authority's engagement with counterpart agencies across the Australian regulatory and government sphere.

- The PS should establish a quality assurance program that tests the quality of scientific decision making across the full suite of regulatory functions. The findings of this program should form part of the annual report and be incorporated in the regulator's performance indicators.
- The PS should convene an Expert Advisory Panel (EAP), (recommendation 10 of the 2021 independent review) to benchmark the APVMR's science approach against current and emerging international approaches.

Even in advance of the appointment of the PS, the Authority should seek to re-open engagement with relevant departments such as the Department of Health, the Department of the Environment, and Safe Work Australia to review and advise on APVMR risk assessment and mitigation methods, tools and models. Of course, there will always be unique aspects of pesticides and veterinary medicines that will require specific science methodologies.

#### **Enhance the Authority's regulatory performance indicators**

In recent years the APVMA has used registration timeframes as its principal performance measure, and given much less attention to its other regulatory functions when measuring its performance. Industry and government both accepted this approach, which inevitably led to an overemphasis on timely registrations, while other functions became under resourced.

I propose the Government, consistent with the Department of Finance's Regulator Performance Guidance (RMG 128), establish a new, broader framework against which the Regulator is to report its performance. The measures should at least include indicators along the following lines:

- Average time difference between actual and target timeframes (statutory or operational) for all activities.
- Indicators of compliance and enforcement activity to ensure human or environmental health, or to address trade.
- Indicators of progress in the chemical review program.
- Indicators of resource commitment (including staff numbers) to the various statutory functions
   separated into operational/assessment resources and resources for support services.
- Indicators of stakeholder engagement activities, across the full range of stakeholder groups.
- The findings of science quality programs including all benchmarking processes.

• Indicators of staff commitment, satisfaction, and welfare including staff retention and vacancy rates, and findings of the APS staff census and internal staff surveys.

The new set of performance indicators should be developed in close consultation with the policy area of the department. The performance indicators should be complemented by new arrangements for publication. I recommend that the APVMR statutory office holder should release the indicators on each occasion, together with commentary on the it's progress. Any release event should be designed to engage a wide range of stakeholders, in addition to industry.

#### Increased public confidence through improved transparency measures

There is an opportunity to improve public confidence in regulatory decisions by improving public access to the data and information relied upon by the Regulator in its work. Similarly, an opportunity exists to improve transparency by requiring information on the volumes of agvet chemical (products) supplied within Australia. These approaches are already being developed by comparable regulators (such as in Canada, EU, and US). This will, of course, require careful balancing of intellectual property rights and commercial in confidence information, with public interest objectives.

The Government should establish a scheme that requires the APVMR to publish information it relied on to be satisfied about the health and safety of a chemical product. In delivering this improved transparency, the scheme should ensure that the intellectual property of chemical product proponents is not compromised. The Government should establish requirements on proponents of chemical products to supply the regulator with details of all information (including trials) relating to safety, efficacy, or trade impacts they hold for the chemical product. (For clarity this need not include information solely related to marketing or promotion of the product.)

The Australian scheme's design should broadly reflect the approaches now being developed in comparable jurisdictions overseas. Comparable regulators recognise that it is only through comprehensive access to all available information about a product's risk that the most rigorous regulatory decisions can be made. To minimise impacts, both measures should be applied at the time of application only.

#### Cyclical Registration Model

The Government and the community expect that the APVMR would have mechanisms to enable flexible and agile responses to new information about registered chemicals. The establishment of a 'cyclical registration model' would complement and modernise the APVMA/APVMR existing mechanisms. A cyclical registration mechanism 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.

I recommend that work commence on designing a cyclical registration model for implementation by the future APVMR and that provision for such a model be made in the legislative amendments to the agvet chemical legislation following Government decisions on this review.

#### Positioning these reforms in a wider context

Finally, public confidence can be maintained by positioning the recommended reforms to the APVMA in the wider context of reforms already recommended to Australia's regulatory system as a whole.

The Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia, 2021 has made many additional, complementary recommendations aimed at improving the performance of Australia's regulatory system as a whole and specifically building public confidence and trust in Australia's regulatory processes.

Governance reforms to the APVMA will certainly improve the performance of the Authority, but the APVMA is only a part, albeit a central part, of the complete Australian regulatory system. The APVMA sits and works alongside many other players that interact with pesticides or veterinary medicines all along the chain from design through to manufacture, distribution, use and disposal. These include: the states and territories; industry; the research community; non-government service providers; and other relevant regulators.

Improving outcomes of the regulatory system as a whole will require reforms and change to practices in all of these groups. It is recommended that the Government consider the present report alongside the wider, whole-of-system report. Taken together, there is an opportunity to launch a long-overdue process of microeconomic reform to lift the performance of, and public confidence in, the national agvet chemical regulatory system as a whole.

### **Section 5: Costings**

The Australian Government Charging Framework is the whole of government policy that relates to cost recovery. This framework states that where an industry creates the demand for government activity then it should generally be charged for the cost of delivering that activity. In the case of the APVMA, the existence of the agricultural and veterinary chemicals industry creates the need for government regulatory oversight. Accordingly, the industry currently funds around 95% of the APVMA's \$43m annual budget through fees, charges and levies.

This general approach is appropriate for the future APVMR and should continue. However, the Government's charging framework also provides for deviations from full cost recovery to achieve other sound policy outcomes, if required. It is therefore for consideration whether any of the APVMA's performance and cultural issues of concern could be ameliorated by adjustments to cost recovery arrangements.

The Clayton Utz Review and some stakeholders other than industry, have suggested that the current cost recovery funding model may have unduly influenced the Authority's relationship with stakeholders – causing an unbalanced focus on industry interests and preferences. Clayton Utz suggested that the steady rundown in resources dedicated to compliance and enforcement and chemical reviews in recent years may be evidence of that.

Clayton Utz and others have expressed concern about the risk of 'capture of the regulator' by industry. While this is vigorously contested by the Authority's professional staff, the perception is undoubtably corrosive to public confidence. Partly for this reason I am proposing certain limited adjustments to past cost recovery arrangements.

#### **Inadequate Resource Base**

Over recent years, there has certainly been considerable (understandable) pressure on the APVMA from industry to minimise the fees, charges, and levies imposed upon them. This may have contributed to a succession of inadequate increases to the APVMA's resource base through the regular CRIS (Cost Recovery Implementation Statement) process. The resulting resource base gradually became insufficient to fully resource all the required regulatory activities. Creating a resource-poor regulator has in turn required the regulator to choose which of its legislated responsibilities to prioritise (rather than fully delivering on all its statutory responsibilities).

The solution to this is for the Authority to now bring forward an assertive, fully costed, new CRIS proposal, which will adequately resource the APVMR's full range of operations. I recommend accordingly.

However, the question remains about whether there is a case for additional appropriation funding to deliver Government policy objectives and requirements beyond direct regulatory activities.

#### **Compliance and Enforcement**

Although there are examples among other Commonwealth regulators of full appropriation funding for compliance and enforcement and similar activities, I do not recommend that in this case.

Rather, my recommendation is that the currently under-resourced compliance and enforcement, and chemical reconsideration activities should receive part-funding (50%). Cost shifting from industry charges to Government appropriation would need to be avoided. Joint funding in this way would enable a speedy necessary catch up in both these areas and rebuild public confidence that the strong community interest in robust compliance, enforcement and review, is being supported by direct government funding into the future on behalf of the community beneficiaries.

The indicative annual cost to Government of a 50% share of compliance and enforcement and chemical reconsideration would be \$4.2m.

#### Surveillance and monitoring

Restoring public confidence could also be assisted by appropriation funding for surveillance and monitoring. Community expectations are steadily becoming more demanding about the quality of regulation of agricultural and veterinary chemicals in the food chain and the environment. However, it is not well understood publicly that current arrangements for surveillance and monitoring of the presence, and environmental and public health impacts, of those chemicals are not well developed.

There are real risks of public alarm triggered by unexpected chemical detections and consequential public criticism of the longstanding unaddressed deficiencies in national surveillance capacity. The APVMR will need to work with a range of other agencies to develop more satisfactory national monitoring arrangements, including reforming the current Adverse Experience Reporting (AER) arrangements. Accordingly, I recommend appropriation funding for the Department of Agriculture, Fisheries and Forestry to commence the necessary work on developing an adequate national monitoring and surveillance system into the future, together with specific appropriation funding for the APVMR to contribute its part.

The indicative cost to Government of initial system design work would be \$600,000. Additional funding would be required in future years to build and maintain the system.

#### **Funding for Government Support Activities**

A further recommended area for appropriation funding comprises government support functions. These are the functions less directly related to regulating the agricultural and veterinary chemicals industry. Examples include input into government policy development, reporting, including through annual reports, and appearing at Senate Estimates, hearings, and liaison with the states and territories over general agvet chemical operational issues.

Importantly over the next few years, these sorts of demands on the APVMA will increase if a serious reform transformation process is launched affecting the APVMA as a central player in the wider agvet chemical regulatory system. If reforms are to be triggered by Government, it will be important that they be resourced sufficiently to be developed and implemented without delay.

Similarly, some of the APVMA's international engagement is undertaken as part of being a responsible Authority of the Australian Government – such as helping regulators in neighbouring countries improve their regulatory practices.

The estimated cost to Government if government support activities were to be funded would be around \$3.1m p.a. in years 1 and 2, reducing to less than \$2m as the reform program was bedded down.

#### **IT Improvements**

Finally, Clayton Utz was highly critical of the APVMA's performance in procurement, project management, and IT services. It was concerned about record keeping, document retrieval, finance management, and the day to day operational difficulties and risks experienced by staff members through inadequate internal IT, information management, and finance systems. The Authority recently scored 0/8 for its cyber safety security rating.

The APVMA had been tackling the IT services issue without success for years. IT expenditure per staff member per annum is around \$60,000 - almost six times the Department of Finance indicative rate. However, the standard of service continues to be well below typical APS levels. The new management team has begun to introduce some discipline, but much remains to be done.

Underperforming IT systems are an enduring drag on the Authority's performance which needs to be finally resolved. I therefore recommend budget support for IT improvements (including dealing with current cyber security risks). I suggest that this needs to be a closely supervised one-time expenditure to urgently get the necessary IT, information management, and finance systems up to an acceptable standard to meet staff operational needs.

The costs to Government cannot at this stage be estimated; the task needs to be scoped and a request for tender issued.

#### Section 6: Recommendations

Details of the governance recommendations are in Section 3, Feature Box 1: "Recommended future governance arrangements". Major elements are listed below.

A New Regulatory Entity

#### I recommend that:

- 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

A Program of Organisational Reform

#### I recommend that:

- 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
- 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
- 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
- c) 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

#### I recommend that:

- 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

Changed Relationships with Stakeholders

#### I recommend:

- 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

Clearer Relationships with Related Entities

#### I recommend:

- 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
- 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

Transparent Arrangements for the Appointment of the APVMR

#### I recommend that:

- 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

Transitional and Continuing Funding Arrangements

#### I recommend that:

- 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:
  - 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
  - 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
  - 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

Next Steps

#### I recommend that:

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.

#### Attachment A

## Terms of Reference: Rapid evaluation of the Australian Pesticides and Veterinary Medicines Authority (APVMA) review findings and provision of advice on structure and governance

The APVMA Board, at the Minister for Agriculture's request, commissioned the Clayton Utz review into the operations of the APVMA. The Clayton Utz review identified significant deficiencies in the APVMA's governance, operational capability, and culture.

The Government has agreed to an evaluation of the Clayton Utz review findings to deliver advice on future structure and governance arrangements for the APVMA.

The evaluation will:

#### 1) Consider:

- a) the findings of the Clayton Utz review into the APVMA
- b) any other relevant information, including recommendations from the Independent Review of the pesticides and veterinary medicines regulatory system in Australia (the Matthews review) and APVMA cost recovery and funding information.

#### 2) make recommendations on:

- a) any further urgent actions the Government should take to ensure confidence in Australia's chemical regulatory system
- b) the APVMA's future governance, operational structure (including location) and legislative framework
- c) the APVMA's funding framework, including options that uphold the existing polluter and beneficiary pays principle

#### 3) Have regard to:

- a) how the APVMA can better balance regulatory outcomes that maximise the national public health benefit rather than industry preferences
- b) how governance, cultural and legislative recommendations will impact on the future of the APVMA's regulatory arrangements.

In undertaking the evaluation, input may be sought from across the Australian government where required.

The evaluation will provide recommendations to the Minister for Agriculture, Fisheries and Forestry, by no later than 30 September 2023. A single report will be provided, including a version deidentified for privacy purposes (if required), prior to publication.

The report will be prepared in accordance with the requirements of the Australian Government Guide to Policy Impact Analysis.

#### Attachment B

## Guidance on decision-making by the APVMR to be given statutory independence

Decisions by the APVMR to be guaranteed independence by legislation include decisions relating to the approval, registration or permitting of active constituents, products and labels; decisions relating to issuing licences, decisions on the suspension, cancellation of approvals, registrations, labels or permits for active constituents or product; and the conditions that would apply to an approval, registration, permit or licence.

Functions of the APVMA in the current legislation where independence in future legislation would need to be preserved, are as follows:

- to assess the suitability for supply in Australia of active constituents for proposed or existing chemical products
- to assess the suitability for supply in Australia proposed or existing chemical products, including proposed or existing labels for containers for chemical products
- to evaluate the effects of the use of chemical products in the States and participating Territories
- to exchange information relating to chemical products and their use with overseas and international bodies having functions similar to the APVMA's functions
- when requested by the Minister, or on its own initiative, to report to or advise the Minister on any matter relating to chemical products or arising in the course of the performance of its functions
- to decide to investigate or enforce compliance with legislation.

#### Attachment C

## Guidance on the operational relationship between the APVMR and the departmental secretary

The APVMR is an independent statutory office holder within the Agriculture, Fisheries and Forestry department. The APVMR is supported by the Office of the APVMR, also within the department.

The Secretary is responsible for making enduring arrangements for the APVMR to access information, advice and senior executive counsel on broader developments in good APS practice, government policy, and legal requirements.

The Secretary will make arrangements to maintain the discrete identity of the Office of the APVMR.

The Secretary and the APVMR may enter into voluntary agreements to provide or augment property, ICT, finance and other corporate services to the APVMR.

The Secretary of the department has no role in the science-based regulatory decision-making of the APVMR.

The Secretary will ensure that there is appropriate organisational separation between the APVMR and the policy area of the department. Appropriate collaboration will be encouraged without compromise to the prerogatives of either group.

The APVMR is responsible for ensuring the conduct of staff of the Office of the APVMR conforms with the APS values and Code of Conduct. If required, the Secretary will arrange support for the APVMR in this role.

Within the department's financial arrangements, the APVMR will be responsible for its own Special Account. Funds and staff funded from the Special Account will not be available for purposes other than the proper functions nominated in the APVMR Act.

The APVMR is responsible for timely reporting to the Minister and the Secretary significant events, developments and risks.

Reports by the APVMR to the Minister will be made available to the Secretary.

The above arrangements will be detailed and made transparent through a publicly available exchange of letters between the Secretary and the APVMR.