Australian Pesticides and Veterinary Medicines Authority

Strategic Review Report - July 2023

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IMPORTANT NOTICE

Any statement of opinion or conclusion made in this Report is based on the documentation that has been provided and is not a conclusive statement or assertion of fact.

Contents

1. Executive summary

1.1.1 The Australian Pesticides and Veterinary Medicines Authority (**APVMA**) is the independent statutory authority responsible for the regulation of agricultural chemicals and veterinary medicines in Australia. This Report is a strategic review of the APVMA's allocation of regulatory priorities, its capability to carry out the full scope of its regulatory functions and its operations.

1.1.2 This report was commissioned by the Board of the APVMA (**Board**) at the request of the Minister, in response to serious allegations raised during the Senate Estimates Hearing for the Rural and Regional Affairs and Transport Legislation Committee in November 2022, and further serious allegations raised during the independent review undertaken by Ms Mary Brennan between December 2022 and February 2023 (**Brennan Review**). This report focuses on material relating to the period 2019 - 2022.

1.1.3 Based on the current material, we draw the following findings to the Board's immediate attention.

The APVMA's overall regulatory posture requires examination and re-evaluation.

The material reviewed as part of this report does not indicate any instances where agvet chemical products have been registered inappropriately. However, we are concerned about the impact of the APVMA's key regulatory priorities and how the allocation of those priorities may have otherwise impacted its approach to regulation. In particular, we are concerned that the APVMA's focus on timeframes for registrations, assessments and approvals has prioritised regulatory performance in relation to registrations, assessments and approvals over regulatory performance in relation to monitoring, compliance and enforcement.

There are capacity building opportunities for the APVMA in relation to compliance and enforcement.

The material reviewed indicates an educational approach to enforcement and a reticence to pursue alternative, and more significant, enforcement measures. We accept that an educational approach to enforcement may be appropriate for minor contraventions and note that the APVMA appears confident and capable to respond to alleged contraventions through educational measures, such as the use of formal warnings. However, educational measures will not always be appropriate, particularly where an alleged contravention is serious. The material reviewed indicates one instance where the APVMA elected to proceed with educative enforcement measures, despite referral for criminal prosecution or civil penalty proceedings having been recommended as appropriate enforcement measures for that alleged contravention. The material reviewed for the purposes of this report does not reveal a motivation for the decision not to proceed with criminal prosecution or civil penalty proceedings in that instance.

The Board should assess how the APVMA can build and diversify its compliance and enforcement capabilities to ensure that the APVMA is equipped to respond appropriately to serious contraventions in the future.

The APVMA's current timeframe performance targets do not align with realistic regulatory best practice.

While we do not suggest that any agvet chemical products have been registered inappropriately, we are concerned that setting targets of 100% for timeframe compliance and making timeframes the key driver and performance metric for registrations, assessments and approvals is not realistic, and does not reflect regulatory best practice or resourcing. This issue is interlinked with the APVMA's operational challenges as aiming for 100% timeframe compliance inevitably impacts the capacity and workload for the APVMA's staff.

The APVMA's approach to regulation appears to align with industry interests.

There are instances where the APVMA's level of engagement with industry stakeholders should be carefully examined. Accepting that part of being a regulator is engaging with and

working with industry, the information reviewed includes instances where the APVMA's approach appears focused on assisting industry. Alignment with industry interests also appears to be embedded into the APVMA's regulatory priorities and culture. The APVMA's emphasis on timely registrations, assessments and approvals over monitoring, compliance and enforcement is a prioritisation that, on one view, best serves industry interests. While this review does not purport to provide an explanation for this perception, we do recommend that the APVMA's approach to engaging with industry be re-evaluated as a matter of priority.

A majority of the APVMA's ongoing chemical reviews have been in progress for nearly two decades.

One of the APVMA's core monitoring programs - the Chemical Review Program - is experiencing significant and protracted delays in finalising its review of registered agvet chemicals. Of the 10 ongoing chemical reviews, eight have been in progress for over 15 years or more, with seven ongoing for nearly 20 years. While this report does not draw conclusions with respect to the effects of these chemicals or seek to pre-empt the outcome of ongoing reviews, the underlying causes of the delays affecting the Chemical Review Program should be investigated as a matter of priority as such delays are not an acceptable regulatory outcome.

There appear to be deficiencies in the APVMA's current capacity in relation to financial management around procurements.

The material reviewed indicated a baseline knowledge and awareness of the Commonwealth procurement requirements and a knowledge of the need to comply with these requirements. However, the material also reflected deficiencies in both the level of staff knowledge and awareness of procurement requirements and in the systems used by the APVMA to manage procurements. We are particularly concerned that these deficiencies may have led to non-compliance with the Commonwealth Procurement Rules for one particular key service contract procurement. We recommend that the Board consider further investigation in relation to compliance for this procurement.

Staff turnover may have impacted capability across key operational and business areas.

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

The APVMA has an unacceptable volume of personnel related complaints for an agency of its size - including allegations of serious misconduct.

The seriousness of the complaints and allegations made by current and former APVMA staff is also cause for concern and further attention by the Board. Both the seriousness of the allegations, the concentration of the allegations and the wide-ranging nature of the allegations requires immediate further assessment by the Board. The Board and the APVMA should also continue to progress the initiatives already implemented, and should continue to act and implement strategies to ensure that the APVMA is a safe and respectful workplace.

The APVMA's governance structure, including the relationship between the CEO and the Board, should be clarified.

The role of the Board and the Board's relationship with the CEO should be clarified to promote effective oversight and strategic governance of the APVMA going forward. In particular, it may be prudent to:

- outline in detail the role of the Board in the context of the administration of the APVMA;
- review, revise and clarify guidance about the relationship between the Board and the CEO, including by implementing formal reporting and briefing guidance from the CEO to the Board; and

- expand the number of Board members to facilitate the inclusion of additional skill sets.

A summary of findings in relation to key issues is set out below at 1.3.

1.2 Scope of this report

1.2.1 This Strategic Review Report (**Report**) was undertaken by way of desktop review and analysis.

1.2.2 The Report focuses on the following key issues:

(a) regulatory performance (section 3);

(b) financial management and procurement (section 4); and

(c) operations, organisational and governance issues (section 5).

1.2.3 **This Report is based on the period until February 2023, with a particular focus on the period between 2019 - 2022.**

1.2.4 Accordingly, and unless otherwise stated, references to the APVMA and the members of the APVMA executive in this Report refer to the personnel occupying those substantive positions during the relevant period.

1.2.5 In this respect, we note that an interim CEO was appointed in February 2023 and confirm that matters since that time are not within the scope of this Report, other than to the extent necessary to provide context or clarity in relation to specific issues.

1.3 Summary of findings in relation to key issues

1.3.1 A summary of the key findings and takeaways in relation to each issue is set out below.

Summary of key findings and takeaways

Regulatory performance

- During the period 2019 - 2022, the APVMA's focus in undertaking regulatory activities were achieving timeframes for registrations and assessments and industry stakeholder engagement. This is captured by the APVMA's own goal-setting, which include 100% targets for timeframe compliance. Compliance targets of 100% are unrealistic, do not reflect best regulator practice and may contribute to a reduction in regulatory performance.
- During the period 2019 - 2022, the APVMA's level of activity in relation to compliance and enforcement activities declined.
- The compliance and enforcement activities that were taken indicate that the APVMA adopted a low risk profile approach.
- There are instances where this low risk profile approach arguably did not align with the severity of the non-compliance being addressed.
- It appears that the APVMA has limited capacity to progress ongoing monitoring activities, with the most notable example being the protracted progression of its Chemical Review Program. In particular, it is concerning that a number of chemical reviews have been ongoing for over 20 years.
- Having regard to best practice principles for government regulators, it appears that during the period 2019 - 2022, the APVMA's approach to regulation did not

Summary of key findings and takeaways

achieve an appropriate balance across all regulatory performance principles and potentially demonstrated a skew towards collaboration and engagement with stakeholders. The APVMA's approach to issuing infringement notices either indicates a reticence to penalise industry or a lack of capability to appropriately investigate, prepare and issue infringement notices.

- Potential factors that may influence the APVMA's regulatory posture include the implementation of recommendations from previous reviews, the APVMA's relationship with industry, the APVMA's funding model and the APVMA's organisational structure. The APVMA appears reticent to take compliance and enforcement action against industry.

Financial management and procurement

- There is a need for capacity building among APVMA staff at all levels to promote applied awareness of procurement requirements.
- Based on the materials provided to us, there appears to be an absence of robust systems for the purposes of managing and tracking procurements and minimising the risk of noncompliance with relevant requirements. There also appears to have been a lack of guidance and internal processes for staff to understand how to comply with procurement requirements.
- We have material doubts as to whether one of the select procurements reviewed for the purposes of this Report complied with Commonwealth procurement requirements, including in relation to value for money, maintaining documentation commensurate with the scale, scope and risk of the procurement, ensuring the procurement is efficient, effective and economical and that the work order for the procurement was appropriate. In relation to this procurement, speed of implementation may have been prioritised to the detriment of compliance with procurement requirements.
- There appears to be significant limitations on the APVMA's case management systems which may be impacting compliance with procurement requirements and is likely limiting the APVMA's capacity to prepare or maintain sufficient documentation to achieve or demonstrate compliance with relevant procurement requirements and detect non-compliance with procurement requirements.
- The APVMA's manual record keeping systems for procurements also limits its ability to assess and improve its procurement performance.

Operations

- During the period 2019 - 2022, the APVMA received a significant number of personnel related complaints. The volume of complaints is of high concern having regard to the size of the agency. The allegations also suggest a consistent theme of dissatisfaction in the manner that complaints were handled or progressed.
- It should be noted that a number of the allegations and complaints made by staff were very serious. We understand that, where appropriate, allegations have been referred to the relevant authorities for further investigation.
- Significant and recent changes to the APVMA's staff profile following the relocation of the office to Armidale in 2019, has most likely impacted corporate knowledge, workload, and work capacity as well as changes to its governance structure (with the Board having been introduced in early 2022). We understand only a small proportion of previous APVMA staff moved from Canberra to Armidale and it may be inferred that the new staff and lack of previous APS knowledge and experience impacted the operations of the APVMA.

Summary of key findings and takeaways

- The current governance structure, and in particular, the relationship between the CEO and the Board, needs to be carefully examined and more clearly defined.
- This lack of clear delineation of roles was probably a factor in the APVMA's leadership failing to escalate serious issues which would normally require the Board's strategic oversight.
- Robust reporting and strategic frameworks, including a clear charter of the Board's roles and responsibilities, may enhance the way that the APVMA identifies and responds to significant challenges in the future.
- Greater reporting between the APVMA and the Department and Minister would allow for the APVMA to greater integrate into the overall APS and executive framework and policy settings.

2. Background

2.1 The APVMA

2.1.1 The APVMA is an independent statutory authority and body corporate established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cth) (**Administration Act**). It is a Commonwealth entity within the portfolio of the Minister for Agriculture, Fisheries and Forestry.

2.1.2 As the national regulator of agricultural and veterinary chemical products in Australia, the APVMA operates in partnership with State and Territory governments to administer laws relating to the regulation and control of such chemicals up to the point of retail sale. These functions are addressed in further detail in Section 3 and the Appendix of this Report.

2.1.3 In addition to the powers and functions conferred by the Administration Act, the APVMA also administers the Agvet Code pursuant to the *Agricultural and Veterinary Chemicals Act 1994* (Cth) (**AVC Act**) and *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (**Agvet Code Act**), and the levying of agricultural and veterinary products under the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Cth) (collectively the **AVC legislation**).[1]

2.1.4 The APVMA performs a range of regulatory functions under the AVC legislation. There are three broad categories by reference to which these functions may be described:

(a) **Assessment functions** – including suitability assessments for the supply of chemical (and constituent) products and other chemical safety reviews;

(b) **Advisory and consultation functions** – including in relation to the development of industry standards and guidelines, and the management and control of chemical products and their constituents; and

(c) **Investigatory and enforcement functions** – including monitoring and compliance activities, and enforcement action (ranging from issuing warnings and enforceable directions to the suspension or cancellation of statutory approvals).

2.1.5 The key activities undertaken by the APVMA in performing each of these functions (and the powers conferred on it to do so) are detailed in the table at the Appendix.

2.2 Context underlying this review

The November Senate Estimates Hearing

2.2.1 On 8 November 2022, the Senate Rural and Regional Affairs and Transport Legislation Committee convened a hearing in Canberra (**November Senate Estimates Hearing**). The then CEO attended the November Senate Estimates Hearing on behalf of the APVMA.

2.2.2 At the November Senate Estimates Hearing, Senator Whish-Wilson asked the CEO a question about *'an incident that occurred at a staff Christmas party in 2021, in which a senior male staff member allegedly urinated on other staff members*'.[2] The CEO stated in response that she was *'not aware of it in that context… I am aware of an incident that occurred in a private*

[1] While the APVMA receives some funding through government appropriations, it is a cost-recovered agency with the majority of its income sourced from industry levies, fees and charges (which comprised $41.570 million of the APVMA's total income of $43.657 million in the 2021-2022 financial year).

[2] Hansard transcript (Tuesday, 8 November 2022) Rural and Regional Affairs and Transport Legislation Committee, page 49.

capacity - not at a work function'.[3] During the remainder of the questioning for this hearing, the CEO stated that she had been made aware of the matter but that *'there was no official complaint made*'.[4]

2.2.3 At the conclusion of the November Senate Estimates Hearing, the Minister described the allegations put to the CEO by Senator Whish-Wilson as '*obviously very concerning*' noting that he had not previously been aware of the allegations and would seek an urgent briefing from the Department.[5]

The Brennan Review

2.2.4 On 23 November 2022, the Minister appointed an independent reviewer, Mary Brennan, to undertake an external review into the workplace culture of the APVMA (**Brennan Review**). As part of her external review, Ms Brennan spoke with current and former APVMA employees. On 8 February 2023, Ms Brennan provided an interim report to the Minister (**Interim Report**).

2.2.5 Having regard to the seriousness of additional allegations reported in the Interim Report, the Minister discontinued the Brennan Review and referred the allegations to the Australian Public Service Commissioner and the relevant policing authorities.

2.2.6 These referred matters are not the subject of this review and we make no comment or conclusion in relation to those matters.

Request for the current report

2.2.7 Following the discontinuation of the Brennan Review, the Minister also requested that the Board immediately consider and provide a report to the Minister addressing the following issues, including:

(a) issues raised regarding the APVMA's regulatory performance, including allegations of fee anomalies, and relationships with industry and compliance with statutory timelines being prioritised over the safe registration of chemical products;

(b) a review of the issues raised in relation to the financial management of the agency, including the potential misuse of public resources in a significant IT procurement; and

(c) a review of the issues raised in relation to the administration and operation of the agency more generally, including any Code of Conduct investigations as appropriate.

2.2.8 The present Report has been prepared in response to the Minister's request to the Board. The present review focuses on the first two issues as listed above. In relation to the third issue, this Report considers the current administration and operations of the APVMA but is not a workplace culture report or workplace relations report.

2.2.9 The present review runs in parallel to the matters referred to other authorities and mentioned at 2.2.5 above.

[3] Hansard transcript (Tuesday, 8 November 2022) Rural and Regional Affairs and Transport Legislation Committee, page 50.

[4] Hansard transcript (Tuesday, 8 November 2022) Rural and Regional Affairs and Transport Legislation Committee, page 50.

[5] Hansard transcript (Tuesday, 8 November 2022) Rural and Regional Affairs and Transport Legislation Committee, page 51.

2.3 Approach and scope of the Report

2.3.1 This Report has been prepared in accordance with the following stages:

1	**Scoping and requests for information**	• Requests for documents falling within the scope of the matters to be addressed in the Report were made. • Relevant publicly available documents were also reviewed for the purposes of preparing this Report.
2	**Desktop review**	• A desktop review of the documents provided was undertaken. • This includes documents provided by the APVMA, as well as other documents and information provided to us in the course of the review, including by APVMA employees and the Board.
3	**Report preparation**	• This Report and the accompanying recommendations have been prepared.

2.3.2 We have not conducted interviews with staff of the APVMA for the purposes of this review.

2.3.3 The current executive of the APVMA has been fully supportive in attempting to provide us with all relevant information and documentation.

2.3.4 The information that the APVMA has provided as part of this review has been limited to the information that it has been able to collect using its document management platform and other case management systems. We have also been provided with a limited and unsorted selection of other hard-copy documents comprising APVMA correspondence and file notes.

2.3.5 Given the volume of documents held by the APVMA and its system limitations, we prepared specific requests for information based on the matters raised in the Minister's letter initiating this review. We understand the information provided has been at times filtered for relevance.

2.3.6 Based on the information that was provided, we prepared supplementary requests to target additional relevant information. While some of this information was provided in response to the supplementary requests, we understand there is still additional relevant information which has not been provided - noting the known limitations associated with the APVMA's current document management platform as detailed below. Given this, the documentary material we have been able to review from the APVMA is not comprehensive.

2.3.7 We note that we have also had regard to publicly available material in completing this review.

2.3.8 We understand that the document management platform used by the APVMA is heavily reliant on manual user filing and does not have any automated filing functionality. Further, we understand that there is an inherent limitation as to the amount of relevant information that can be extracted from the APVMA's document management platform.

3. Regulatory performance

Summary of key findings and takeaways

- During the period 2019 - 2022, the APVMA's focus in undertaking regulatory activities were achieving timeframes for registrations and assessments and industry stakeholder engagement. This is captured by the APVMA's own goal-setting, which include 100% targets for timeframe compliance. Compliance targets of 100% are unrealistic, do not reflect best regulator practice and may contribute to a reduction in regulatory performance.
- During the period 2019 - 2022, the APVMA's level of activity in relation to compliance and enforcement activities declined.
- The compliance and enforcement activities that were taken indicate that the APVMA adopted a low risk profile approach.
- There are instances where this low risk profile approach arguably did not align with the severity of the non-compliance being addressed as discussed later in this section.
- It appears that the APVMA has limited capacity to progress ongoing monitoring activities, with the most notable example being the protracted progression of its Chemical Review Program. In particular, it is concerning that a number of chemical reviews have been ongoing for over 20 years.
- Having regard to best practice principles for government regulators, it appears that during the period 2019 - 2022, the APVMA's approach to regulation did not achieve an appropriate balance across all regulatory performance principles and potentially demonstrated a skew towards collaboration and engagement with stakeholders. The APVMA's approach to issuing infringement notices either indicates a reticence to penalise industry or a lack of capability to appropriately investigate, prepare and issue infringement notices.
- Potential factors that may influence the APVMA's regulatory posture include the implementation of recommendations from previous reviews, the APVMA's relationship with industry, the APVMA's funding model and the APVMA's organisational structure. The APVMA appears reticent to take compliance and enforcement action against industry.

3.1 Introduction and approach to assessing regulation

Scope

3.1.1 The Minister requested the Board to report on allegations relating to the APVMA's regulatory performance, including regarding fee anomalies, relationships with industry and compliance with statutory timelines being prioritised over the safe registration of agvet chemical products.

Approach to examining the APVMA's regulatory performance

3.1.2 In examining the APVMA's regulatory performance, we have considered open-source material and the APVMA's own published statistics that indicate how the APVMA undertakes its regulatory activities, including the frequency of its regulatory activities and its approach to regulation as described in its strategic material, including the Statements of Expectation and Intent, the most recent of which were exchanged between then Minister David Littleproud MP and the APVMA in March 2022. The APVMA's strategic approach to regulation, as captured in its public facing documents and its own performance measures, is considered in section 3.3.

3.1.3 To further contextualise this material, which provides a high-level indication of the APVMA's regulatory performance, we have also identified case studies for each category of regulatory

activity. These case studies provide insight into the manner in which the APVMA has undertaken its regulatory functions in recent years.

3.1.4 These case studies also provide illustrative examples of the matters that should be addressed as a priority when considering the future strategic direction of the APVMA from a regulatory performance perspective.

Approach to assessing the APVMA's regulatory performance

3.1.5 We have considered the APVMA's approach to regulation having regard to the Commonwealth's Resource Management Guide 128 (**RMG128**) for regulatory performance. It is in the context of the principles set out in RMG128 that we have examined specifically the APVMA's regulatory posture and approach to registrations, assessments and approvals, and monitoring and compliance activities.

3.1.6 The RMG128[6] sets out a best practice guide for regulators and three core principles that should inform the manner in which Commonwealth regulatory functions are performed, those being:

> **Principle 1: Continuous improvement and building trust** (in terms of performance, capability and culture, developing organisational values that support best practice, utilising internal and external accountability processes, and harmonising activities with other regulators);
>
> **Principle 2: Risk-based and data driven** (monitoring and proportionate managing of risks, maintaining essential safeguards and compliance strategies, and choosing efficient and cost-effective regulatory actions); and
>
> **Principle 3: Collaboration and engagement** (transparency in communication and decision-making, regular and timely engagement with stakeholders via a range of meaningful consultation mechanisms, and accessibility of information).

3.2 Key observations and findings

3.2.1 We have set out in detail our analysis of the APVMA's regulatory performance at section 3.6, and section 3.7.

3.2.2 We make the following key observations about the APVMA's regulatory performance:

(a) the APVMA's primary regulatory priorities appear to be to meet timeframes for registrations, assessments and approvals and industry stakeholder engagement. This position is reflected in the APVMA's public facing communications, its performance metrics, internal communications and industry engagement and registration and assessment statistics;

(b) the APVMA is less active in relation to enforcement activities. When the APVMA does engage in enforcement related activities, the APVMA appears to favour education letters and formal warnings over compliance action and appears to have a low risk appetite for compliance action more generally;

(c) the APVMA's assessment, investigations and monitoring statistics suggest that in general, the APVMA is not overly active in the enforcement space and there are material concerns arising from the decision making processes of the APVMA in relation to regulatory compliance and the regulatory capture of the APVMA;

[6] Department of Finance, *Resource Management Guide 128: Regulator Performance* https://www.finance.gov.au/government/managing-commonwealth-resources/regulator-performance-rmg-128.

(d) the protracted progression of the APVMA's Chemical Review Program indicates that the monitoring aspect of the APVMA's regulatory activities is not a priority when compared with registrations, assessments and approvals. There are concerns that this has resulted in some chemicals remaining in products in Australia where they have been banned in other jurisdictions;

(e) overall, the APVMA's approach to regulation, coupled with its engagement with specific stakeholders in certain instances has a high risk of regulatory capture by industry; and

(f) potential factors that may influence the APVMA's regulatory posture include recommendations from previous reviews, the APVMA's relationship with industry, and the APVMA's organisational structure.

3.2.3 Putting these observations in the context of the principles set out in RMG128, we make the following findings about the APVMA's regulatory performance:

(a) in relation to Principle 1 (continuous improvement), the information about the manner in which the APVMA has carried out its regulatory activities between the period 2019 - 2022 suggests that the APVMA resources for monitoring may be limited and that the APVMA has a very low risk appetite in relation to undertaking compliance and enforcement activities;

(b) in relation to Principle 2 (risk based and data driven), the information available indicates that the APVMA approaches its monitoring, compliance and enforcement activities with a low-risk appetite, insofar as the quantum and frequency of these activities is low. This raises a concern that the action being taken by the APVMA is not proportionately managing compliance risks. However, the timeframe compliance targets and completion for registrations, assessments and approvals could, on one view, indicate a higher risk tolerance for the registration of agvet chemical products; and

(c) in relation to Principle 3 (collaboration and engagement), it is clear that the APVMA is highly engaged with its stakeholders. The material we have reviewed indicates that transparency, communication and engagement with stakeholders is a regulatory priority for the APVMA, at a public, organisational and executive level. The nature of the APVMA's stakeholder relationships arguably inform and contextualise its regulatory approach in other areas, and in particular its lack of compliance and enforcement action. The issue is that prioritising stakeholder relationships may result in a reduction in compliance activity where that activity would otherwise be appropriate.

3.3 The APVMA's regulatory posture

3.3.1 We consider that the APVMA's own self-described regulatory posture is critical to understanding and contextualising its regulatory performance.

3.3.2 In order to understand the APVMA's regulatory posture, we have considered its annual reports, other public facing documents such as its annual compliance plan, and its communications with industry as set out in its quarterly newsletters. This publicly available material indicates that the APVMA considers that its primary regulatory priorities are timeliness and collaboration with industry. Further, this material indicates that the APVMA's focus lies with registration, assessments and approvals for agvet chemical products, and appears publicly to be less focused on matters related to monitoring, compliance and enforcement activities.

3.3.3 In its 2021 - 2022 Annual Report, the APVMA opened its section on regulatory performance with the following statement:

> *In 2021-22, the APVMA has remained focused on ensuring Australians are provided with timely access to safe and effective agricultural and veterinary chemical products that support agricultural productivity and improved animal health*.
>
> *This year we maintained our strong timeframe performance, completing 97% of applications for pesticides, veterinary medicines and permits within statutory timeframes*.[7]

3.3.4 The APVMA's 2021 - 2022 strategic priorities are described as delivery, engagement, reform and foundation.[8] In its annual report, the APVMA sets out a series of activities for each strategic priority. The APVMA measures its performance against the activities for each strategic priority by way of identified performance measures. Timeframe compliance is consistently communicated across publicly published materials as one of the APVMA's regulatory performance measures. Four of the APVMA's self-imposed six key performance measures in relation to regulation are related to timeliness or compliance with statutory timeframes.[9]

3.3.5 The APVMA's 2022-2023 Compliance Plan describes its approach to regulation as being informed by intelligence led delivery, collaborative engagement, and a continuous improvement approach to reform.[10] Our assessment is that the Compliance Plan reflects an education and engagement based approach to regulation rather than an investigation and enforcement based approach.

3.3.6 In the year 2021-2022, the APVMA set a target of 100% compliance for the following activities falling under the strategic priority of "delivery":[11]

(a) 100% of applications to be finalised within legislative timeframes for risk based assessment and registration of pesticides and veterinary chemicals;

(b) 100% of audits conducted to the Australian Good Manufacturing Practice Code closed within 3 months of receipt;

(c) 100% of reconsiderations completed in accordance with the Chemical Review Program Plan; and

(d) 100% of Annual Compliance Plan activities completed in accordance with the Annual Compliance Plan.

3.3.7 100% compliance targets may detract regulators from most efficiently using their resources to manage risks and maximise regulatory opportunities.

3.3.8 These kinds of targets are inconsistent with risk-based regulation practice, which requires an evidence-based means of targeting the use of resources and prioritising attention to the highest risks in accordance with a transparent, systematic and defensible framework.[12] Risk-based regulation requires regulators '*focus on risks not rules*'.[13] A published case study of one Australian regulator found that genuinely responding to complex problems with

[7] 2021-2022 Annual Report, page 4.

[8] 2021-2022 Annual Report, page 28.

[9] APVMA Annual Report 2021-2022, page 98, Figure 1.

[10] APVMA 2022-23 Compliance Plan.

[11] APVMA Annual Report 2021-2022, pp 28-33.

[12] Julia Black and Robert Baldwin, 'Really Responsive Risk-Based Regulation' (2010) 32(2) *Law and Policy* 181, 181.

[13] Ibid, 184.

appropriate solutions based on minimising risk could be hampered where staff felt '*pressured to act quickly*'.[14]

3.3.9 Best practice regulation requires regulators to focus on cases offering strategic opportunities to create public value.[15] Regulatory culture that is too focused on procedures and timelines for performance can hinder regulators from adopting a responsive posture or focusing on opportunities for systemic change.[16] Regulatory commentators have relevantly observed that overemphasis on '*key performance indicators (KPIs) and risk-reduction metrics can be highly dangerous things. They have a place but must be kept in their place*'.[17]

3.3.10 While the 100% compliance target indicates the APVMA's strong commitment to these aspects of its performance, allocating target percentages of 100% may not reflect the most effective or appropriate regulatory approach, particularly when dealing with complex and technical subject matter.

3.4 Registrations, assessments and approvals

3.4.1 Registrations, assessments and approvals of agvet chemical products form a large and critical part of the APVMA's regulatory remit. All agvet chemical products sold in Australia must be registered by the APVMA. As part of the registration process, the APVMA is required to assess the potential effects of agvet chemical products on the health and safety of people, animals, crops and the environment. The APVMA will then consider whether any particular restrictions should be placed on the manner in which is the agvet chemical product is used. Once an agvet chemical product is registered by the APVMA, it is approved for the purposes and the uses stated on its label.

3.4.2 Applications may also be made for permits allowing agvet chemical products to be used in a manner that is not permitted by the label.

3.4.3 Registrations, assessments and approvals are a critical part of the APVMA's regulatory role because an inability to register a particular agvet chemical product may have trade and retail impacts. The corollary of this is that this aspect of the APVMA's regulatory functions requires a high level of interface and engagement with industry stakeholders, including manufacturers and suppliers.[18]

How does the APVMA describe its approach to registrations and assessments?

3.4.4 The APVMA's public facing materials include resources for applicants seeking to register or vary regulated products and actives, as well as statistics in relation to the APVMA's regulatory performance for each quarter.

3.4.5 Significant attention in the APVMA's public facing materials is focused on emphasising the importance of timeliness in processing registrations and assessments. Communications in relation to timeframe performance has increased since 2020. For example, since 2020, the APVMA has published quarterly regulatory newsletters on its website, which relevantly

[14] Bridget Malcolm and Mieke van der Bijl-Brower, *Developing a Systemic Design Practice to Support an Australian Government Regulatory Agency* (Paper delivered to Relating Systems Thinking and Design Symposium, 13-15 October 2016, Toronto), 8: http://openresearch.ocadu.ca/id/eprint/1915/.

[15] John Braithwaite, 'Responsive Excellent' in C Coglianese (ed) *Achieving Regulatory Excellence* (Brookings Institution Press, 2017) 23.

[16] Ibid 27.

[17] Ibid 32.

[18] The APVMA regulates the use of agvet chemicals up until the point of sale, after which regulation is undertaken by the States and Territories. See: APVMA website, Agvet chemical regulation.

includes a summary of the APVMA's registration and assessment timeframes for each quarter.[19]

3.4.6 The APVMA's published statistics indicate that the APVMA has, in recent years, significantly improved its compliance with statutory timeframes. The APVMA publishes quarterly performance reports with statistics in relation to its timeframe compliance for applications and the number of applications in progress for the reporting period.[20] A comparison of the quarterly reports for the July - September quarter from 2017 to 2022 suggests an increase in timeframe performance, particularly from 2020 onwards.[21]

Quarterly performance report	Overall timeframe performance
July - September 2017	**58%**
July - September 2018	**86%**
December 2019	**87%**
July - September 2020	**94%**
July - September 2021	**94.7%**
July - September 2022	**96.9%**

3.4.7 The APVMA has not to our knowledge published any other data concerning quality, challenges, compliance, enforcement or risk management - the inference being that this data subset was not a focus or concern for the APVMA.

3.4.8 The APVMA's public-facing approach to prioritising timeframes for registrations and assessments appears to have flowed through to its internal discussions and its discussions with stakeholders. The material we have reviewed indicates that timeframe compliance was a frequent theme in discussions both within the APVMA and in the APVMA's discussions with its external stakeholders.

Potential impacts of a timeframe-oriented focus

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

3.4.10 In particular, we note the following allegations raised in the material reviewed for this Report. While the list below describes the allegations as made, given the general nature of the allegations and the scope of the review undertaken for the purposes of this Report, it is not possible to assess the veracity of each allegation:

(a) the APVMA expedited the approval of registrations for certain agvet chemical products, including where staff processing registrations were at times directed to approve certain chemical agvet chemical products;

[19] See: APVMA website, Newsletters.

[20] See: APVMA website, Performance statistics.

[21] See: APVMA website, Performance statistics and archives.

(b) employees were directed to undertake work specifically to assist particular industry stakeholders in relation to specific agvet chemical product registrations;

(c) senior APVMA staff appeared to advocate internally for the registration of particular agvet chemical products from particular companies (including where APVMA staff were former employees of those companies);

(d) progress for outstanding applications was permitted to plateau after the relevant statutory timeframe for determination of the application had passed. As we understand it, the inference arising out of this allegation is that where an application was not be completed before the statutory deadline, it would not be prioritised after the deadline had passed because completion of the application would no longer positively contribute to the key performance indicator for timeframe compliance; and

(e) concerns from staff that Australia may be missing out on the newest chemicals because international companies feel they cannot trust the registration system. This is of course an allegation that is worthy of further review and investigation.

Registrations and assessments case study: Changes to labelling for 2,4-D products

3.4.11 In particular, the 2,4-D case study captures an instance where the APVMA made a decision at the conclusion of a lengthy chemical review process and gave holders less than 24 hours to implement the decision.

3.4.12 This case study illustrates the impact of the APVMA's impractical approach to timeframe management in regulatory decision-making.

Cancellation and suspension of 2,4-D product labels

3.4.13 2,4-D is used as a herbicide and a weed killer, targeting broadleaf weeds. Weedkillers containing 2,4-D are regularly used in agricultural settings in Australia, including in relation to crops grown for human consumption.

3.4.14 A summary of the relevant key milestones in the APVMA's regulatory decision-making process in relation to the cancellation and suspension of 2,4-D product labels is as follows:

Date	Milestone and descriptions
2003	**Chemical review of 2,4-D begins** In 2003, the APVMA began its reconsideration of 2,4-D as part of the Chemical Review Program, due to concerns about the impact of 2,4-D on human health (including occupational health and safety) and the environment (including impacts on waterways and non-target animals and plants).[22]
24 October 2019	**Proposed regulatory decision for 2,4-D is published** On 24 October 2019, the APVMA published its proposed regulatory decisions with respect to the reconsideration of 2,4-D. This relevantly included an attachment identifying 2,4-D product labels that were proposed to be affirmed and varied by the final regulatory decision.[23]
3 September 2020	**Chemical review of 2,4-D is finalised and published**

[22] APVMA website, 2,4-D.

[23] APVMA Special Gazette, 24 October 2019.

Date	Milestone and descriptions
	On 3 September 2020, the APVMA completed its chemical review of 2,4-D (**2,4-D Decision**). This decision included as an attachment a list of labels that were proposed to be affirmed and varied.[24] This decision cancelled the registration and label of only a single product.
30 September 2020	**Cancellation and suspension of 2,4-D labels** On 30 September 2020, the APVMA published a further Special Gazette notice in relation to approved labels for 2,4-D products (**2,4-D Notice**).[25] This notice immediately cancelled or suspended previously approved labels for registered 2,4-D products - including products listed in the 2,4-D Decision, made earlier that month, as being affirmed and varied. The 2,4-D Notice issued on 30 September 2020 accordingly reflected a change in position from the APVMA as to the registration status of product labels for over 230 products.[26] Additionally, the 2,4-D Notice prescribed requirements that came into effect on 1 October 2020 - the very next day after the 2,4-D Notice - for suppliers of 2,4-D products to immediately update supply instructions for all affected 2,4-D products sold. The 2,4-D Notice provided holders with a 12 month buffer period to update existing affected 2,4-D product labels.

3.4.15 The material we have reviewed indicates that industry representatives were not provided with prior notice of the APVMA's decision to cancel or suspend the affected 2,4-D products.

3.4.16 As a result of the decision, holders were required to make new applications in relation to affected 2,4-D products and/or product labels, and suppliers had to immediately provide copies of the updated supply instructions with less than 24 hours' notice. The documentation that we have reviewed does not appear to provide an explanation as to why this change was communicated with less than 24 hours' notice for implementation.

3.4.17 In our view, it is concerning that a regulator would make a decision with such broad ranging impact on holders, manufacturers and suppliers with a notice period of less than 24 hours to implement certain mandatory requirements flowing from that decision. This is particularly the case in circumstances where the decision made on 30 September 2020 reflected a change in position from that communicated in October 2019 and 3 September 2020.

3.4.18 Regulatory best practice should have seen greater forewarning provided to those impacted by the decision in circumstances where the most recent communication from the APVMA on 3 September 2020 indicated that existing product labels would be affirmed and varied and had not listed any product labels for cancellation or variation.

Registrations and assessments case study: item 25 assessment

3.4.19 The APVMA also dedicated its resources to assisting holders to expedite applications for permits and changes to labelling requirements. Employees of the APVMA at the time of this decision later commented that the push to expedite these applications was inappropriate.

[24] APVMA Special Gazette, Thursday 3 September 2020 - see Attachment 2.

[25] APVMA Special Gazette, Wednesday, 30 September 2020.

[26] Specifically, labels were cancelled for 195 products and labels were suspended for 38 products.

3.4.20 This case study relates to the apparent dedication of APVMA resources to assist a company (referred to as Company A) to expedite an application.

Background: item 25 assessment

- The APVMA published a proposed regulatory decision in relation to an agvet chemical. This relevantly included the proposed introduction of restrictions to products containing this agvet chemical (**affected products**).
- Company A raised concerns about the proposed restrictions and requested that the APVMA commence an item 25 technical assessment to consider an independent assessment obtained by Company A.
- Company A argued that having regard to the conclusions in the independent assessment, there was a basis for the APVMA to not impose all of the proposed restrictions initially contained in the proposed regulatory decision.
- Internal email correspondence shows that during this item 25 assessment, the APVMA approached Company A to obtain Company A's views - as a member of industry - about how the revised proposed restrictions could be presented. It also appears that as a result of this exchange, Company A sought input from other industry stakeholders to report back to the APVMA as to industry's feedback about the proposed restrictions.
- The APVMA completed the item 25 assessment. The completed assessment indicates that the APVMA accepted, in part, Company A's position and the independent assessment provided in support of its position. The assessment also appears to adopt the format of the revised proposed restrictions with Company A's input.
- The material we have reviewed also includes references from APVMA employees that made observations which appear to relate to the level of assistance provided to Company A, including that the research being undertaken by APVMA employees appeared to be for the purposes of supporting Company A's position in advocating for changes to the proposed restrictions.
- The material we have reviewed also indicates that this item 25 assessment was prioritised and expedited. One purpose for this was presumably to minimise the potential adverse commercial impacts on Company A.

3.4.21 This case study is not in and of itself demonstrative of any impropriety by the APVMA with respect to the assistance that it provided to Company A. In this respect, we note that an item 25 assessment is a specific type of technical pre-application assistance that potential applicants can seek from the APVMA prior to making an application in relation to an agvet chemical product.

3.4.22 However, we do consider that this case study raises the following issues with respect to the approach of the APVMA to its regulatory function:

(a) it appears to us, based on the material we have reviewed, that senior members of the APVMA's leadership at the time were involved in assisting Company A to identify an item 25 assessment as a pathway through which to bring about changes to the proposed regulatory decision;

(b) the actions of APVMA staff in actively consulting with Company A, and through Company A, other members of industry, as to proposed changes to the restrictions raises concerns about whether the APVMA was, in this instance, adopting an evidence-based approach to undertaking the item 25 assessment; and

(c) to the extent that the allegations raised by employees in relation to the assistance provided to Company A as part of this case study are accurate, it is also concerning if staff of the APVMA approached the item 25 assessment with a view to supporting Company A's position, rather than undertaking an independent and evidence-based approach to the technical assessment.

What could these case studies indicate about registrations, assessments and approvals?

3.4.23 The APVMA made the 2,4-D product labelling decision with significant implications for industry and provided less than 24 hours' notice to holders whose products would be affected by the decision. It is not clear to us why this notice period was so limited but note that it appears it would have been clear to the APVMA that the immediate change to labelling requirements and new supply instructions was going to be very difficult for industry to comply with.

3.4.24 In this instance, the lack of a buffer period allowing for holders and suppliers to get across the new labelling requirements appears to have resulted in backlash from industry which the APVMA then felt compelled to respond to by way of assisting industry. Making significant regulatory decisions in this way is not, in our view, best practice regulation.

3.4.25 In terms of what these case studies indicate about registrations, assessments and approvals:

(a) the labelling decision shows a lack of best practice from the APVMA with respect to timing and transparency for a decision with a wide-ranging industry impact; and

(b) the item 25 assessment:

(i) is indicative of an industry focused approach to undertaking assessments; and

(ii) raised concerns about the overall approach of the APVMA - that is, whether it was approaching the assessment independently or with a focus on facilitating an outcome for industry.

3.5 Monitoring, compliance and enforcement

3.5.1 After an agvet chemical product is registered in Australia, the APVMA can continue to monitor that agvet chemical product. The purpose of ongoing monitoring is, among other things, to maintain the safe and effective use of agvet chemicals, including having regard to their potential impacts on human, animal and plant health and environmental impacts.

3.5.2 One of the APVMA's key monitoring initiatives is its Chemical Review Program. The purpose of chemical reviews is to determine whether registered agvet chemicals are still safe to use, based on the latest information (including scientific research) from both Australian and international sources. Monitoring may result in changes to existing production registrations or requirements - for example, additional conditions on the use of a particular agvet chemical product or the imposition of further limitations on the circumstances in which a registered agvet chemical product may be used, or changes to the labelling requirements for a particular registered agvet chemical product.

3.5.3 Additionally, once an agvet chemical product is registered, individuals, companies or organisations responsible for a registered agvet chemical product or active constituent must continue to comply with the relevant requirements with respect to labelling, advertising, manufacturing, importing, selling or supplying that registered agvet chemical product or active constituent.

3.5.4 Pursuant to Division 9A of the Agvet Code, the APVMA can exercise statutory powers to address non-compliance with those statutory obligations. Non-compliance action is taken at the discretion of the APVMA and can range from educational measures (for example, warning letters) for minor contraventions to criminal prosecution for the most serious categories of

contravention. The APVMA may decide to take compliance and enforcement action after investigating allegations of non-compliance, which can be reported to the APVMA by the industry and by members of the community.

3.5.5 The proper and consistent exercise of these powers is, in our view, clearly critical to the APVMA carrying out its functions as a regulator. Quality assurance through monitoring as part of the Chemical Review Program is critical to ensure that registered agvet chemical products are safe for use in Australia. Effective compliance and enforcement action is necessary to deter non-compliance at all levels of industry, including manufacturers, importers and distributors.

How does the APVMA describe its approach to enforcement activities?

3.5.6 The APVMA states that it monitors compliance with the Agvet Code by monitoring marketed product labels, undertaking compliance campaigns, and completing audits.[27] The APVMA also publishes its compliance statistics (described in more detail further below).

3.5.7 The APVMA has published an Annual Compliance Plan in relation to its enforcement activities. All three items in the Annual Compliance Plan for 2021-2022 were directed towards education.[28]

3.5.8 In 2021, the APVMA also published Enforcement Guidelines describing its approach to regulatory enforcement.[29] We observe that this document is explanatory in nature and sets out each of the possible enforcement pathways that the APVMA can use and the circumstances where it may consider using them.

3.5.9 Based on material that we have reviewed that describes the APVMA's internal compliance culture, it appears that there has been a very low risk appetite for compliance action. While it does not appear that this is an official internal risk setting with respect to compliance and enforcement activities, it may be indicative of a broader compliance culture that has a very low risk tolerance. This type of compliance culture would appear to be consistent with the APVMA's compliance statistics (considered in detail below).

3.5.10 Additionally, a number of concerns were raised in the material reviewed for this Report regarding the APVMA's enforcement and compliance function, including:

(a) that the APVMA had a practice of "discounting" infringement notices;

(b) when it became clear that the practice of discounting was not legal, the APVMA did not issue any infringement notices for a period of time because the penalty amount was seen as being too high;

(c) that there had been a failure to take appropriate and proportionate regulatory action in relation to non-compliance; and

(d) in general, a lack of priority afforded to the enforcement and regulatory activities of the APVMA.

How does the APVMA undertake enforcement activities?

3.5.11 The material we have been provided supports a conclusion that the APVMA does not appear to approach enforcement or compliance through penalties as a core part of its business.

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[27] APVMA website, 'How we monitor compliance'.

[28] APVMA Annual report 2021-2022, page 32.

[29] See: Enforcement Guidelines, current to 5 January 2022; first published in 2021.

3.5.12 We note for completeness that the APVMA can also regulate risks associated with agvet chemical products through control measures on agvet chemical products, which included cancelling or suspending registrations, approvals or permits; imposing registration or permit conditions; restricting access to a chemical; or requiring certain information to be communicated on a product label.[30] In preparing this Report, we have distinguished control measures (set out in Part 4 of Schedule 1 of the Agvet Code) from the APVMA's enforcement powers (set out in Part 9A of Schedule 1 of the Agvet Code).

3.5.13 It was difficult to obtain information about the APVMA's enforcement caseload. Comprehensive statistics were available for the period 1 July 2019 to 3 April 2020. The difficulty in obtaining statistics seems to stem from a lack of proper systems to track active cases. We understand from information submitted as part of this review that the APVMA uses a MS Teams page to track cases. It is essential that the APVMA is able to report on its enforcement activities and a proper system for recording and tracking matters should be implemented as a priority.

3.5.14 The table below, shows how cases were resolved during the period 1 July 2019 to 3 April 2020:

Outcomes of Closed Cases	No. of Cases
Administrative Action	1
Administrative Action Completed	3
Formal warning issued	3
Infringement Notice	2
Insufficient information available	1
Insufficient information to proceed	1
Low Priority	8
Negotiated compliance: Claims withdrawn	3
Negotiated compliance: Education	4
Negotiated compliance: Published notice withdrawn	2
Negotiated compliance: Unregistered product withdrawn	3
No Offence	21
Recall Action	8
Recall actions completed	1
Referred for ABF	3
Referred to ABF for disposal of unregistered product	18

[30] See: Risk analysis framework.

Outcomes of Closed Cases	No. of Cases
Referred to another agency	2
Voluntary compliance completed	4
Total number of cases[31]	**88**

3.5.15 In other words, infringement notices (the most serious enforcement action apparently undertaken in the period) were issued in respect of less than 2.5% of closed matters. For more than 97% of enforcement matters, the matter appears to have been dealt with by negotiation or other administrative action. These statistics appear to indicate that the APVMA's approach to regulation is as a facilitative/educative regulator.

3.5.16 These statistics may not be surprising if the majority of the issues being considered were trivial or technical non-compliance issues. However, the material we have been provided does not suggest that to be the case. Of the closed matters, more than 50% were assessed as being medium or high risk. For example, one matter classed as high risk was in relation to advertising or supplying an unregistered product. That matter was resolved by issuing a formal warning.

3.5.17 These matters suggest that the APVMA has failed to take appropriate and proportionate regulatory action in relation to non-compliance assessed as medium or high risk. It would be necessary to examine each matter to make a conclusive finding about this, but one inference that could be drawn from these statistics is that the APVMA typically favours regulatory action by way of informal warnings rather than more serious penalties, such as infringement notices, criminal prosecutions or civil penalty proceedings. We observe that regulatory best practice would not support avoiding serious compliance action where the relevant alleged contravention warrants a strong regulatory response.

3.5.18 One of the specific allegations raised in the material we have reviewed related to a practice of "discounting" the amount of infringement notices. The information we have been provided suggests that this practice was common in 2018-2019 but appears to have been discontinued after that time. To this end, we note that none of the infringement notices that were issued within the period 17 May 2018 to 10 September 2019 were for the amount specified in the legislation.

3.5.19 According to the information we were provided, no infringement notices were then issued until 20 February 2020. The infringement notices issued since that date, and their ultimate outcome, is set out below:

Offence	Outcome
Section 89 of the Agricultural and Veterinary Chemicals Code Act 1994	Paid
Reg 48(1)	Paid
Reg 53(2)	Withdrawn - representations made by the company
Reg 48(1)	Withdrawn - administrative error (date of contravention)

[31] We note that the total number of cases resolved cannot be reconciled with the number of cases reported as being finalised in the same period (which is 75). Other than further reinforcing the difficulties with the APVMA's reporting on enforcement matters, nothing turns on this issue.

Offence	Outcome
Reg 51(2)	Withdrawn - administrative error (date of contravention)
Section 105 (1) of the Agricultural and Veterinary Chemicals Code Act 1994	Paid
Section 105 (1) of the Agricultural and Veterinary Chemicals Code Act 1994	Paid
Section 78 (1) of the Agricultural and Veterinary Chemicals Code Act 1994	Withdrawn & enforceable undertaking entered
Section 80 (1) of the Agricultural and Veterinary Chemicals Code Act 1994	Withdrawn & formal warning issued
Section 69B(1)(ii) of the Agricultural and Veterinary Chemicals (Administration) Act 1992	Paid
Section 88 (2) of the Agricultural and Veterinary Chemicals Code Act 1994	Paid

3.5.20 The table above shows that of the 11 infringement notices issued, 5 (or about 45%) were subsequently withdrawn.

3.5.21 This material leads us to an inference that the APVMA:

(a) may not have taken appropriate and proportionate regulatory action in relation to matters involving medium or high risk;

(b) does not make sufficient use of the regulatory tools available to it, and in particular, does make sufficient use of infringement notices; and

(c) too readily agrees to withdraw infringement notices that it does issue.

Recent statistics in relation to the APVMA's monitoring and compliance activities

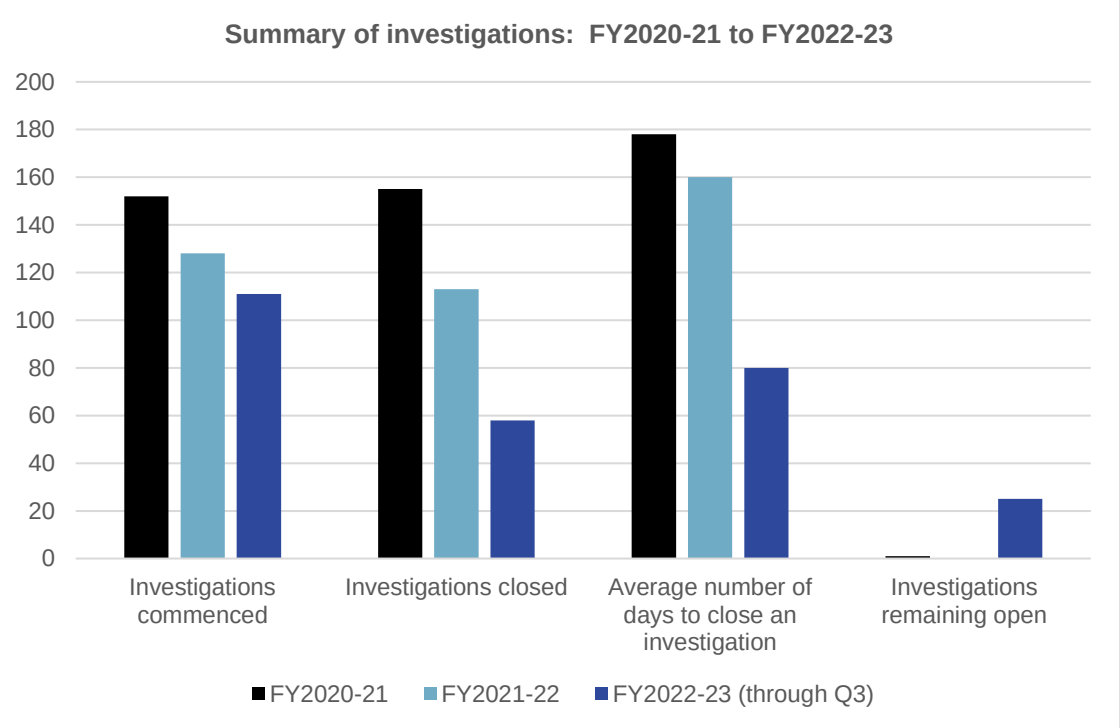
3.5.22 More recent compliance statistics also suggest a clear preference for enforcement by way of education and engagement over infringement notices, enforceable undertakings, civil proceedings and prosecutions.[32] Indeed, it should be noted that no civil penalty proceedings or prosecutions have been commenced by the APVMA to date.

3.5.23 The APVMA's own published statistics appear to indicate a downward trend in compliance activities since FY2020-2021 continuing through to FY2022-2023.

[32] See: APVMA website, Performance statistics.

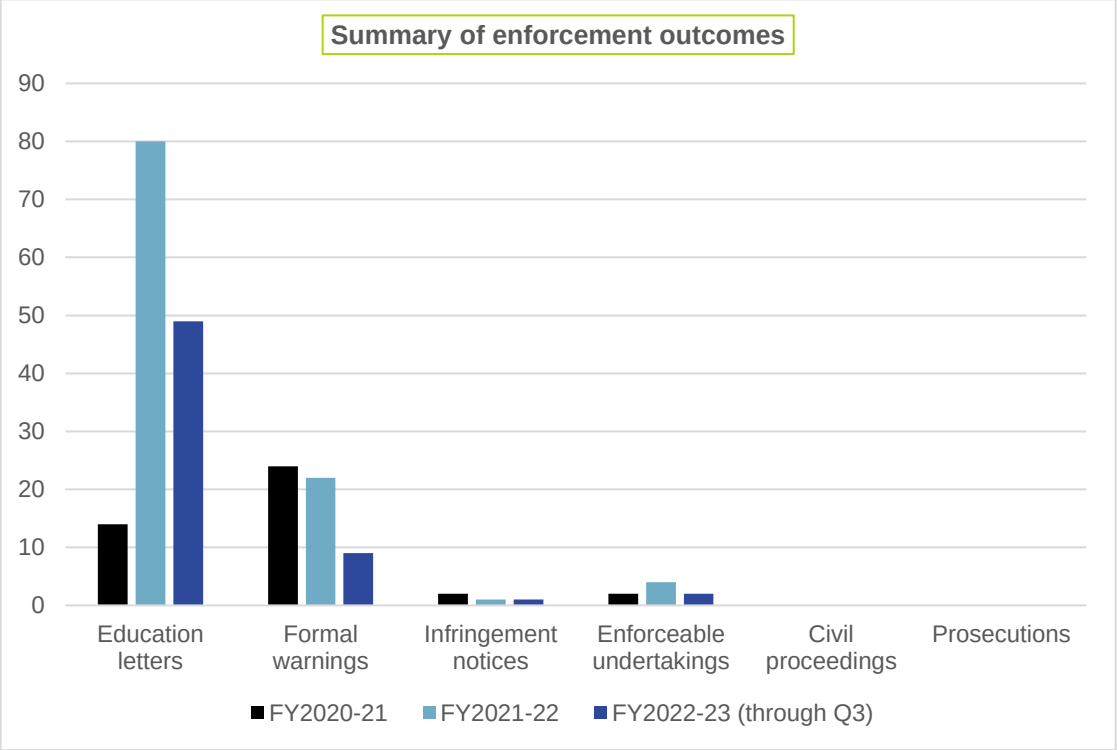
3.5.24 The graphs below show the APVMA's compliance statistics for the period FY2020-2021 - FY2022-2023.[33]

Summary of investigations	FY2020-21	FY2021-22	FY2022-23 (through Q3)
Investigations commenced	152	128	111
Investigations closed	155	113	58
Average number of days to close an investigation	178	160	80
Investigations remaining open	1	0	25



Summary of enforcement outcomes	FY2020-21	FY2021-22	FY2022-23 (through Q3)
Education letters	14	80	49
Formal warnings	24	22	9
Infringement notices	2	1	1
Enforceable undertakings	2	4	2
Civil proceedings	0	0	0
Prosecutions	0	0	0

[33] These graphs have been prepared based on the Compliance Statistics published by the APVMA on its website: Assessment, Investigation and Monitoring.



3.5.25 The above data leads to the following propositions:

(a) there has been an overall drop in regulatory compliance activity - it is not clear to us as to why this is the case;

(b) there has been a very significant increase in sending "education letters" rather than the undertaking of more formal regulatory action - again, we can only assume that this focus on education was part of the regulatory posture of the APVMA to not take a contentious approach to issues with industry participants; and

(c) there was an apparent unwillingness to utilise all regulatory levers available.

3.5.26 The majority of formal warnings issued during the period FY2020-21-FY2022-23 were issued in relation to supplying or selling agricultural or veterinary chemical products rather than the industry manufacturers, where the recipient of the warning:

(a) supplied the product in contravention of the conditions of its registration; or

(b) where the relevant product was not registered under the Agvet Code.[34]

3.5.27 The list of infringement notices published for the period from March 2020 onwards included fines for failing to comply with requirements of a recall notice, failing to comply with importation requirements, failing to provide records, providing false or misleading information and for publishing notices that offer to sell unregistered chemical products.[35]

[34] The APVMA can issue a formal warning pursuant to s 145J of the Agvet Code for a contravention of the Agvet Code.

[35] APVMA website, Assessment, Investigation and Monitoring.

3.5.28 The following sections detail particular case studies that highlight the approach of the APVMA to monitoring and compliance regulatory activities.

Monitoring case study: Chemical Review Program

Summary

The Chemical Review Program is one of the APVMA's key regulatory monitoring activities. The Chemical Review Program was established in 1995.[36] The purpose of the Chemical Review Program is for the APVMA to undertake a review of a registered active constituent where scientific information obtained after registration suggests the existence of previously unknown risks to human health, animal or crop safety, the environment or trade, or suggests that the product is not effective.[37]

A large proportion of the chemicals subject to review as part of the Chemical Review Program have been under review for a protracted period of time, with some reviews ongoing for nearly 20 years.

While measures were introduced to encourage shorter completion timeframes for chemical reviews in 2014 (imposing a maximum statutory timeframe of 57 months for the most complex categories of review),[38] these measures were not retrospective, and at present it appears that limited progress has been made in relation to finalising ongoing chemical reviews.

3.5.29 We understand that there are presently 10 categories of chemicals subject to ongoing review as part of the Chemical Review Program.[39] Of these, eight of the reviews have been ongoing for 15 years or more, with seven ongoing for nearly 20 years (**legacy reviews**). The longest-running review has been ongoing since December 1996.

3.5.30 The APVMA's website suggests that it anticipates that final regulatory decisions will be made in relation to each of the in-progress chemical reviews by July 2025. We have some doubts about this statement given that a previous proposed regulatory decision timeline from October 2021 suggests that all proposed regulatory decisions would be completed by the end of 2023.

What could the Chemical Review Program tell us about monitoring?

3.5.31 The legacy chemical reviews account for 80% of the Chemical Review Program. The information available to us suggests that there are significant delays and limited progress in relation to the outstanding chemical reviews. This is particularly concerning for the legacy reviews.

3.5.32 The information that we have reviewed in relation to the Chemical Review Program case study has comprised of publicly available information and additional information confirmed by the APVMA. Given that the Chemical Review Program is a key component of the APVMA's regulatory monitoring function, we consider that the pace of the Chemical Review Program is not acceptable.

[36] APVMA website: Chemical review process.

[37] APVMA website: Chemical review process.

[38] APVMA website: Chemical review process.

[39] APVMA website: Listing of chemical reviews. We note that there are 25 listed entries marked as 'in progress' but that there are certain chemicals falling within the scope of one chemical review (eg. anticoagulant rodenticides and neonicotinoids).

3.5.33 The reasons for this outcome may be that the APVMA:

(a) has not placed the necessary importance on the review program; and/or

(b) has not focussed on the program; and/or

(c) requires additional resourcing to continue to progress the outstanding reviews, and in particular, the legacy reviews that were commenced between 15 and 27 years ago.

Compliance case study: Company B

3.5.34 This case study concerns the APVMA's regulatory decision-making for alleged breaches of the Agvet Code relating to an agvet chemical product. In our view, this case study raises concerns about the APVMA's capability and willingness to undertake investigations and compliance measures.

Background: Compliance case study - Company B

Investigation

- The APVMA undertook an investigation into Company B in relation to a range of alleged contraventions of the Agvet Code.
- The investigation into Company B resulted in the preparation of at least nine evidence matrices for various potential contraventions. An APVMA staff member indicated that their estimate of the total number of potential contraventions as being over 20. It was not possible to conclusively verify this estimate based on the records reviewed for the purposes of this report.

Compliance action

- As a result of its investigation, the APVMA sent Company B an education letter. The APVMA's compliance team records include a statement that 'the present facts indicate that an enforcement outcome of an infringement notice would be appropriate' and proceeded to also issue Company B with three infringement notices.
- All three of these infringement notices were eventually withdrawn. Two infringement notices were withdrawn on the basis that they were invalid because they had been dated and issued one day after the expiry of the statutory timeframe (despite the notices being ready for issue prior to the expiry of that statutory timeframe). The third infringement notice was withdrawn after Company B contended that it had been invalidly issued. The APVMA appears to have made the decision to withdraw the third infringement notice on the basis that its own records could not support continuing to press the infringement notice.
- Internal APVMA records show that a further contravention by Company B was not pressed after the APVMA was contacted by an officer from Company B. The records in relation to this discussion suggest that Company B proposed to the APMVA's compliance officer that Company B be 'educated first' and offered to provide feedback on some of the APVMA's template forms. It appears that Company B did proceed to provide that feedback, the APVMA revised its forms, and compliance action in relation to this contravention was not pressed.

Internal APVMA views

- Internal APVMA records include statements from senior members of the regulatory team to the effect that no further enforcement action would be undertaken without briefing to the APVMA executive.
- One view expressed by a staff member of the APVMA was that there was a reluctance within the APVMA to issue infringement notices to Company B

Background: Compliance case study - Company B

because the APVMA did not want to invite the perception that they were 'picking on' Company B.

What could the Company B case study tell us about enforcement?

3.5.35 It is an undesirable outcome that the attempted regulatory action in this case resulted in the withdrawal of all three infringement notices issued in relation to contraventions that were assessed by the APVMA as being serious enough to warrant enforcement action.

3.5.36 We make the following observations about this case study:

(a) the instances of the three withdrawn infringement notices, and in particular the two instances where infringement notices were incorrectly dated one day outside the statutory timeframe, raise concerns that there were deficiencies in the APVMA's internal investigation processes such that key dates for enforcement action were missed;

(b) the openness of the APVMA to changing its approach based on a suggestion by Company B as an alternative to the APVMA taking enforcement action against Company B is, in our view, not a best practice regulatory response. This is because it either suggests that the APVMA was willing to adopt a more lenient approach on the basis of a suggestion from Company B or that the APVMA had not undertaken sufficient investigative action to support the proposed enforcement action prior to approaching Company B with its proposal to take enforcement action; and

(c) the information we have reviewed does not provide an explanation for why the APVMA issued only three infringement notices despite APVMA staff expressing the view that there may have been were over 20 potential alleged contraventions.

Compliance case study: Company C

3.5.37 The material that we have reviewed as part of this case study suggests that the APVMA did not take enforcement measures that were proportional to the alleged contravening conduct. Having regard to the seriousness of the alleged contravening conduct, the APVMA did not exercise its regulatory functions in a manner that was appropriate in the circumstances.

Background: Compliance case study - Company C

- Company C was the supplier of an agvet chemical product (**Product X**). Product X was relevantly used on crops intended for human consumption.
- The APVMA commenced an investigation after it became aware of allegations that certain batches of Product X were contaminated during manufacturing. These allegations were brought to the APVMA's attention through adverse experience reports and do not appear to have been drawn to the APVMA's attention by Company C. As a result of the contamination, growers that had used Product X alleged that they experienced significant crop loss.
- The investigation included the review of documentary material, witness interviews and requests to Company C for additional information in relation to the alleged contravention. This included information suggesting that Company C were aware of the contamination three months prior to the contamination being brought to the APVMA's attention.
- APVMA staff whose comments were reviewed as part of this review stated, in relation to the facts giving rise to this case study, that there were factors that, in

Background: Compliance case study - Company C

their view, warranted a very strong regulatory response that was different to the action that was taken. The documents we have reviewed indicates that this view was consistent with internal and external recommendations made as to the appropriate level of enforcement action for the alleged contraventions in this case.

- The internal documents produced by the APVMA indicate that the AVPMA executive ultimately decided to take enforcement action in the form of a formal warning letter to Company C.
- The APVMA's internal documents indicate that it took the APVMA's executive over 6 months to make a decision in relation to the decision brief addressing proposed enforcement action against Company C as a result of the alleged contraventions.
- The documents produced by the APVMA indicate that the decision to issue a formal warning was made following the expiry of the statutory referral period for a brief to the Commonwealth Director of Public Prosecutions (**CDPP**) for potential prosecution.
- APVMA staff also expressed the opinion that one possible explanation for the decision to take enforcement action by way of a warning letter for what appeared to be a significant and serious contravention was the that the APVMA wanted to avoid prosecuting Company C.

Regulatory framework: the APVMA's enforcement powers

3.5.38 In its Enforcement Guidelines, the APVMA identifies seven general categories of enforcement actions which are available to it, being:[40]

(a) formal warnings;

(b) infringement notices;

(c) administrative notices and orders made under legislation;

(d) proceedings for court orders provided for under legislation;

(e) enforceable undertakings;

(f) prosecution; and

(g) suspension or cancellation of approval, registration, permit, licence or authority.

3.5.39 The Enforcement Guidelines go on to state that the choice of enforcement action in each matter will be determined by reference to the seriousness of the contravention and the desired outcome in the circumstances of that matter, but that, as a guide:[41]

(a) warning letters are generally reserved for low or minor contraventions;

(b) infringement notices for minor contraventions;

[40] See: APVMA Enforcement Guidelines, page 12.

[41] Ibid.

(c) administrative notices and orders (with the exception of cancellation of approvals, registrations, licences or permits) for moderate to serious contraventions;

(d) enforceable undertakings are considered to be an alternative enforcement action for moderate contraventions; and

(e) court orders, prosecutions and cancellations of approvals, registrations, permits or licences are generally reserved for major or serious contraventions of legislation.

3.5.40 We have also examined an internal APVMA instruction document which provides consistent guidance on the enforcement options that are available for contraventions by reference to their 'risk level'. Relevantly, the document identifies the following types of enforcement action as being generally appropriate against each level of risk:

(a) high/very high risk: criminal prosecution, civil penalty proceedings;

(b) high/medium risk: enforceable undertakings, infringement notice, injunction, enforceable direction, cancellation/suspension/recall;

(c) low risk: formal warning; and

(d) very low risk: advisory letter.

3.5.41 The instruction document relevantly describes the decision-making process for resolving contraventions following compliance enquiries or investigations as follows:

> *The Case Officer may consult with superiors and colleagues to determine the best method of case resolution. All recommendations to resolve contraventions should be supported by a Case Decision Record that recommends appropriate enforcement response(s) proportionate to the matter. It must be clearly documented why the recommended option is recommended above all other available options.*
>
> *Where otherwise available enforcement actions are not being recommended, it is good administrative practice to document why such measures are not recommended. This provides a sound record of the decision making process and helps to inform robust decisions that stand up to future reviews.*
>
> *The Case Decision Record should be reviewed by the officer's supervisor before being provided to the Director, Compliance, for approval.*
>
> *Recommendations for use of punitive enforcement actions will include preparation of a briefing for the Enforcement Committee to ensure executive oversight and awareness ...*
>
> *Once agreement is reached on the path for resolution of the contravention, the Case Officer must record the decision on the Compliance case file and take appropriate action to put the agreed recommendations into effect ...*

3.5.42 Unlike other enforcement options, the commencement of proceedings is identified as requiring "*Executive (delegate) approval*" (where referral for criminal prosecution is proposed) or "*Delegate approval*" (in the case of civil penalty proceedings).

3.5.43 Consistently, the Enforcement Guidelines only indicate that the referral of a brief to the CDPP specifically is a matter for executive decision-making. The Enforcement Guidelines state that '*the decision to refer for consideration of criminal proceedings is generally made by the*

APVMA Chief Executive Officer or General Counsel' based on the circumstances of the alleged offending and consideration of whether prosecution is in the public interest.[42]

3.5.44 Based on the documents we have reviewed it is not possible to conclude whether the APVMA's executive team deliberately delayed the progression of the referral to CDPP or otherwise acted so as to avoid prosecuting Company C.

3.5.45 **However**, the material before us suggests:

(a) it does not appear to have been contested that Product X was contaminated and resulted in crop loss;

(b) an internal APVMA investigation was completed in relation to Product X and revealed that Company C became aware of a potential contamination some three months prior to notifying the APVMA;

(c) a recommendation was made to the APVMVA executive to refer the matter to the CDPP for potential prosecution of Company C's alleged contravention of the Agvet Code. A significant period of time later, the APVMA executive rejected this proposed course of action shortly before the statutory limitation period expired having required additional briefing materials and advice before arriving at the final decision to only issue a formal warning;

(d) considerable periods of time passed between different internal actions for the management of the case, including an apparent failure to align legal and non-legal workstreams to ensure that information could be provided promptly and in completeness for decision-making purposes;

(e) a recommendation was made to the APVMVA executive that it was appropriate to commence civil penalty proceedings against Company C for the alleged contravention and that, alternatively, an enforceable undertaking should be considered given the seriousness of Company C's conduct and culpability; and

(f) despite this advice, and internal assessments of the matter as being of a high/serious risk level, the only enforcement action ultimately taken against Company C was the issuing of a formal warning.

3.5.46 It is our view that Company C's conduct in this case presented an appropriate case for enforcement action in the form of criminal or civil proceedings to be taken.

3.5.47 The material we have reviewed suggests that Company C were aware of the potential contamination some three months before the contaminated Product X was recalled, but chose not to disclose relevant information to the APVMA in a timely manner as it was required to under the Agvet Code. While the contamination was not caused by Company C (having seemingly occurred at the manufacturing stage), Company C's subsequent conduct in not promptly passing all relevant information on to the APVMA is, in our view, clearly on the serious end of the scale when considering the types of activities that fall within the APVMA's regulatory purview.

3.5.48 It is not satisfactory that a regulatory body in this position elected to take enforcement action reserved for the most minor of contraventions in circumstances where Company C's conduct, on the information available, appeared to be at the upper end of seriousness.

3.5.49 This case study raises the following issues:

(a) the APVMA's executive team appeared reluctant or reticent to undertake major regulatory action - consistently wanting reassurance that the action was

[42] See: APVMA Enforcement Guidelines, pages 19-20.

appropriate. Even when this advice confirmed the appropriateness of undertaking such action, no such action was taken;

(b) why there were material delays in considering regulatory action in the first place and why action was not taken against other involved companies;

(c) an apparent a lack of awareness about the use of enforcement activity to deter non-compliance by holders. Based on the information available to us, this lack of awareness appears to extend both to when enforcement action ought to be taken, and how to effectively undertake that enforcement action; and

(d) the material we have reviewed about this case (including decision briefs and minutes) contain little if any indication as to any motive(s) which informed each stage of decision-making or the reasons underlying the APVMA's decisions:

(i) to not refer the investigation to the CDPP (including whether this was informed by the short timeframe within which the decision had to be made or reliance on advice); or

(ii) to not pursue civil penalty proceedings or an enforceable undertaking contrary to the recommendations consistently expressed in advice; or

(iii) that a formal warning was the most appropriate enforcement option, or why this required the approval the APVMA's executive.

3.6 Comments from case studies

3.6.1 The APVMA's primary focus area of regulation is in collaboration and engagement with stakeholders - particularly industry stakeholders. While stakeholder engagement is acknowledged in Principle 1 (continuous improvement and building trust) and Principle 3 (collaboration and engagement) of the best practice guide for Commonwealth regulators RMG128, we consider that the level of priority afforded to industry interests may have resulted in continuous improvement, collaboration and engagement efforts being focused on maintaining industry stakeholder satisfaction, impacting the APVMA's ability to undertake regulatory activities in a more risk based and data driven manner (Principle 2 of RMG128).

3.6.2 The material we have reviewed in relation to registrations and assessments indicates that the APVMA's executive team from 1 January 2018 to 11 February 2023 were highly engaged with industry. This includes:

(a) regular meetings with industry, including where industry members are recorded as offering opinions on how the APVMA should undertake its regulatory activities and non-public requests for industry input as to the content of draft regulations affecting the regulation of agvet chemicals;

(b) consultation with industry in relation to the APVMA's regulatory approach;

(c) working with industry to develop training materials for all phases of the product development process, seasonal timeframes and the operations of the supply chain, to inform APVMA staff of the ramifications and timing of their decisions; and

(d) allegations (as discussed in relation to the Company A case study) that APVMA staff were directed to undertake research for Company A to assist Company A with a prospective application for registration.

3.6.3 Of course, there will be instances where it is entirely appropriate for regulators to consult with industry stakeholders, however care should be taken to ensure that the regulator maintains an appropriate level of independence from the entities that it regulates.

3.6.4 In this respect, there are aspects of the case studies that indicate an approach to regulation that arguably risks good compliance outcomes. We note as follows:

(a) the APVMA's practice of regularly discounting infringement notices during 2018-2019, and the statistics for the period 2020 - 2022 indicating the withdrawal of 45% of infringement notices issued, and the withdrawing of infringement notices in the Company B case study. These practices in relation to infringement notices suggest the APVMA viewed penalties imposed on industry constituents as being open to leniency or to be used for the purposes of negotiation. This approach is not consistent with best practice principles for government regulators, and, when considered over time, gives the impression that the APVMA is prioritising a collaborative and engaged relationship with industry above consistent enforcement outcomes;[43]

(b) the regulatory priorities that the APVMA has itself identified are consistent with industry interests but may not result in good regulatory outcomes. Industry is the beneficiary of a 100% compliance target for the timeliness of registrations and approvals. While regulators should not be criticised for prioritising timeliness in its regulatory activities, or indeed working with industry, we consider that the material we have reviewed suggests that timeliness is clearly prioritised for registrations and assessments over monitoring, compliance and enforcement. The case study in relation to the delays faced by the Chemical Review Program indicate that the APVMA's targets in relation to timeliness are not replicated across all regulatory areas;

(c) the perception that the APVMA prioritises industry interests in its approach to regulation was raised by multiple staff members from different business areas within the APVMA whose comments have been considered as part of this report;

(d) the APVMA's published information and statistics in relation to monitoring, compliance and enforcement indicate at the outset that there is either a lack of appetite or a lack of capability in undertaking its monitoring, compliance and enforcement functions against industry. This is apparent from the Chemical Review Program as well as the Company B and Company C case studies;

(e) the protracted nature of the Chemical Review Program illustrates the challenges that the APVMA faces in relation to resourcing and progressing this aspect of its regulatory activities. Chemical reviews are, by their nature, complex and technical, and require significant consultation and review of a large volume of material. In acknowledging these challenges, we are concerned that the slow progress to finalise ongoing chemical reviews - with at least eight ongoing reviews having been in progress for over 15 years - is a vulnerability that needs to be addressed when assessing the APVMA's regulatory performance. In particular, if the APVMA intends to maintain a position as a benchmark for regulation of agvet chemicals internationally, the progress of the chemical reviews needs to increase;

(f) the APVMA has not exercised its compliance and enforcement powers in relation to civil penalty proceedings or prosecutions. We accept that it is of course open to regulators to adopt a regulatory approach that is primarily educative. However, even an educative approach should not, in our view, wholly exclude the use of a regulator's enforcement powers where the seriousness of an alleged contravention clearly warrants the exercise of those powers. The material and contextual information we have reviewed as part of this report suggests that industry relationships and low enforcement capacity within the APVMA may also be factors

[43] As noted in the Company B case study, it is not possible for us to determine, based on the material that we have reviewed, whether infringement notices were withdrawn on the basis that the recipients made further representations or provided additional contextual information to the APVMA. For completeness, we note that if this were the case, this could indicate a need for further capacity building with respect to investigations and enforcement and determining the appropriate stage at which to issue an infringement notice.

that have contributed to an enforcement approach that favours education over penalties;

(g) it is possible that the high engagement with industry priorities contributed to a proportionally higher allocation of APVMA resources towards assessments and registrations (which are more business critical regulatory decisions for industry) over monitoring and enforcement (which could be said to pose potential adverse consequences for industry); and[44]

(h) multiple APVMA staff referred to the APVMA executive stating that 99% certainty of non-compliance was required by staff prior to undertaking enforcement action. We understand that the APVMA executive have denied this characterisation of the threshold for taking enforcement and compliance action. Regardless of whether this allegation is accurate, the fact that the allegation was made and was raised by APVMA staff in the material reviewed for this Report suggests the need for a regulatory culture reset at the APVMA to clarify the thresholds for taking enforcement and compliance action, and to build confidence and capacity for staff in those business units to assist with undertaking those regulatory responsibilities. This is something that is recognised by Principle 1 of RMG128, which states that regulators should '*actively build staff capability, including ensuring staff have relevant knowledge of the regulatory craft and the industry they regulate, and have the capacity and are empowered to identify and implement improved practices*'.[45] The need for staff to feel confident confronting regulatory risks is also addressed by Principle 2 of RMG128, which states that regulators should '*focus on risk culture, build staff understanding of regulator's approach to risk and how it flows to day-to-day decision-making*'.[46]

3.6.5 The approach to funding the APVMA through the collection of levies, fees and charges (representing 89% of its revenue) from industry may also result in a perceived conflict with the APVMA's interest as a regulator of the industry.

3.6.6 While we accept that there are a variety of different approaches to regulation that may be taken by regulators, including approaches that focus on education rather than enforcement, we consider that the APVMA's current approach to regulation creates vulnerabilities with respect to:

(a) the perception that the APVMA is not responding to serious instances of non-compliance;

(b) the perception that the APVMA is prioritising stakeholder engagement and timeliness in registrations and assessments in a manner than compromises the quantum and quality of other regulatory activities, and in particular, monitoring, compliance and enforcement; and

(c) the perception that the APVMA lacks the internal capability and risk appetite to respond to serious non-compliance where that non-compliance does occur.

3.7 Influencing factors and areas for future examination

3.7.1 Identifying potential influences on the APVMA's current regulatory posture are relevant to considerations about the APVMA's future potential regulatory approach.

[44] See: APVMA website, Assessment, Investigation and Monitoring.

[45] RMG128, Principle 1: Continuous improvement and building trust - best practice advice.

[46] RMG128, Principle 2: Risk based and data driven - best practice advice.

3.7.2 We have identified the following factors that may influence the APVMA's regulatory performance.

(a) implementing recommendations from previous reviews into the APVMA, including the 2021 Independent Review of the Pesticides and Veterinary Medicines System in Australia (**Systems Report**);

(b) the APVMA's relationship with industry, and its approach to engagement with industry, including how this is influenced by the APVMA's funding model; and

(c) the APVMA's then organisational structure, including how regulatory functions are allocated across different business units, the strategic oversight by the Board, staff resourcing, and infrastructure resourcing and capability.

3.7.3 As has been discussed, the APVMA consistently indicates that its key priorities are improving registration and assessment timeframes and being engaged with industry. This is apparent from the APVMA's own descriptions of its regulatory priorities and the metrics it applies to measure regulatory performance. It could also be inferred from the statistics we have reviewed in relation to the improvement in timeframes for registrations and assessments, which has improved, while the number of investigations appears to have decreased, and the Chemical Review Program remains affected by delays.

3.7.4 We note that recommendations in relation to timeframe compliance and engagement with industry featured heavily in the Systems Report.[47] The Systems Report was a public facing document prepared following extensive stakeholder consultation (including extensive consultation with industry). The Systems Report recommended a 'contemporary regulatory system', and suggested, in essence, that the APVMA develop a more collaborative approach to regulation with industry. The Systems Report included recommendations for the APVMA to move towards regulating industry with an outcomes-based focus (rather than process focused), to regulate with an approach that '*take[s] advantage of industry's best practice*' and for '*clear channels to be put in place to enable industry to propose improvements to regulatory arrangements to maintain dynamism in the regulatory system and to reduce the need for once-a-decade regulatory overhauls as has been the case over decades past*'.[48]

3.7.5 It appears that the APVMA's prioritisation of timeframe compliance and engagement with industry in its regulatory approach arises from concerns raised in previous reviews about a lack of compliance with statutory timeframes, and a lack of transparent performance indicators in relation to timeframe compliance.

3.7.6 We do not disagree with these concerns, and importantly nor do we suggest that the APVMA should become adversarial in its dealings with industry, however we do believe that the APVMA needs to find a middle ground that provides confidence to industry, stakeholders and the public as to the fairness, transparency and robustness of the agvet regulatory framework and its implementation.

[47] Final Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia by Ken Matthews AO, Dr Anne Astin AM PSM, Dr Mary Corbett and Dr Craig Suann, completed in May 2021.

[48] Systems Report, page 33.

4. Financial management and procurement

Summary of key findings and takeaways

- There is a need for capacity building among APVMA staff at all levels to promote applied awareness of procurement requirements.
- Based on the materials provided to us, there appears to be an absence of robust systems for the purposes of managing and tracking procurements and minimising the risk of noncompliance with relevant requirements. There also appears to have been a lack of guidance and internal processes for staff to understand how to comply with procurement requirements.
- We have material doubts as to whether one of the select procurements reviewed for the purposes of this Report complied with Commonwealth procurement requirements, including in relation to value for money, maintaining documentation commensurate with the scale, scope and risk of the procurement, ensuring the procurement is efficient, effective and economical and that the work order for the procurement was appropriate. In relation to this procurement, speed of implementation may have been prioritised to the detriment of compliance with procurement requirements.
- There appears to be significant limitations on the APVMA's case management systems which may be impacting compliance with procurement requirements and is likely limiting the APVMA's capacity to prepare or maintain sufficient documentation to achieve or demonstrate compliance with relevant procurement requirements and detect non-compliance with procurement requirements.
- The APVMA's manual record keeping systems for procurements also limits its ability to assess and improve its procurement performance.

4.1 Introduction, scope and approach of our review

4.1.1 Given that the Australian National Audit Office (the **ANAO**) carries out regular financial audits of the APVMA, our review is primarily focused on potential issues arising in respect of the APVMA's procurement of goods and services since 2018.

4.1.2 In preparing this Report we have had regard to select procurements for key services.

4.1.3 Whilst we have considered these select procurements in detail below we have also provided comments on general procurement and financial management matters.

4.2 What are the key requirements for the APVMA?

4.2.1 The financial management of the APVMA is primarily governed by the PGPA Act and the *Public Governance, Performance and Accountability Rule 2014* (Cth) (together, the **Finance Law**).

4.2.2 The Finance Law allows for the publication of Resource Management Guides (**RMGs**) by the Department of Finance which provide guidance to Commonwealth entities on applicable accounting and finance and finance requirements (such as RMG 110 and RMG 113). In particular, these resources help Commonwealth entities comply with accounting standards set by the Australian Accounting Standards Board.

Financial management requirements

4.2.3 The Board, as the accountable authority of the APVMA, has an overarching duty to govern the APVMA in a way that promotes the proper use and management of public resources for which it is responsible for and promotes its financial sustainability.[49]

4.2.4 The Board is also under a general duty to keep the Minister and Finance Minister informed of the APVMA's activities, including by:[50]

(a) providing the relevant Ministers with reports, documents, and information as they require; and

(b) importantly - notifying the relevant Ministers as soon as practicable after the Board makes a significant decision or where the Board becomes aware of any significant issue that may affect or has affected the APVMA.

4.2.5 The Finance Law imposes general financial reporting and auditing requirements on the Board, including:

(a) causing accounts and records to be kept that properly record and explain the APVMA's transactions and financial position;[51]

(b) preparing annual financial statements for the APVMA for each reporting period in accordance with the PGPA (Financial Reporting) Rule 2015, where each statement is to be provided to the ANAO;[52]

(c) allowing the annual audit of the APVMA by the ANAO, where each resulting audit report is provided to the APVMA and the Minister;[53]

(d) ensuring that the APVMA has an audit committee;[54] and

(e) preparing an annual report setting out the APVMA's activities in accordance with section 61 of the Administration Act, where each report is made publicly available.[55]

4.2.6 In relation to the auditing of the APVMA, it is noted that the APVMA has an Audit and Risk Committee which must include at least three external persons who have appropriate skills to assist with performing the Audit and Risk Committee's functions.[56] The Audit and Risk Committee provides written advice to the Board on its views regarding the financial management and risk of the APVMA.

4.2.7 The Finance Law also provides for obligations in relation to the use and management of public resources.[57] Relevantly, the Finance Law requires officials to record all commitments of

[49] PGPA Act s 15.

[50] PGPA Act s 19.

[51] PGPA Act s 41.

[52] PGPA Act s 42.

[53] PGPA Act s 43.

[54] PGPA Act s 45.

[55] PGPA Act s 46; Administration Act s 61(e).

[56] PGPA Act s 45; PGPA Rule s 17; APVMA Audit and Risk Committee Charter.

[57] Part 2-4 of the PGPA Act.

relevant money and those commitments must be consistent with any delegation or authorisation that allows the commitment by the official.[58] We note that we have not been provided copies of any of the internal delegations or authorisations relating to procurement matters.

Procurement

4.2.8 The Commonwealth Procurement Rules (**CPRs**), which are established under the Finance Law, set out the requirements that apply to the process of acquiring goods or services by relevant Commonwealth entities.

4.2.9 The CPRs apply to the APVMA as a corporate Commonwealth entity in accordance with rule 30 of the *Public Governance, Performance and Accountability Rule 2014* (Cth) (the **PGPA Rule**). All persons who are in or form part of the APVMA, such as employees, must comply with the CPRs.

4.2.10 As set out in the foreword to the CPRs, "*The Commonwealth Procurement Rules are the keystone of the Government's procurement policy framework… Achieving value for money is the core principle of the Commonwealth Procurement Rules as it is critical to ensuring that public resources are used in the most effective manner*."

4.2.11 Division 1 of the CPRs must be complied with regardless of the value of the procurement. The core rule of the CPRs is included in Division 1 and requires the APVMA official responsible for the procurement to ensure that the procurement achieves a value for money outcome. As part of the value for money objective:

(a) each procurement should:[59]

(i) encourage competition and be non-discriminatory;

(ii) use public resources in an efficient, effective, economical and ethical manner (including recognising and dealing with conflicts of interest) and facilitate accountable and transparent decision making; and

(iii) encourage appropriate engagement with risk and be commensurate with the scale and scope of the business requirement;

(b) relevantly, an official must consider the quality of the goods and services, the supplier's relevant experience and performance history and whole of life costs (which includes costs of additional features procured after the initial procurement);[60] and

(c) the expected value of a procurement must be estimated before a decision on the procurement method is made - this is to ensure that Division 2 requirements are complied with upfront where applicable. The expected value of the procurement includes options, extensions, renewals or other mechanisms that may be executed over the life of the procurement.[61]

[58] PGPA Rule s 18.

[59] CPRs r 4.4 and 6.6.

[60] CPRs r 4.5.

[61] CPRs r 9.

4.2.12 Further, officials of the APVMA must maintain a level of documentation commensurate with the scale, scope and risk of the procurement.[62] This includes maintaining documentation on the process that was followed for the procurement, how value for money was considered and achieved and the relevant decisions and the basis of those decisions.[63]

4.2.13 Where the expected value of a procurement exceeds the threshold specified in rule 9.7 of the CPRs, the rules in Division 2 apply to the procurement unless:

(a) an exemption set out in Appendix A of the CPRs applies; or

(b) the procurement is carried out in accordance with an existing standing offer.[64]

4.2.14 There are rules within the CPRs that prohibit the APVMA from avoiding the application of the CPRs, including that a procurement must not be divided into separate parts to avoid exceeding a procurement threshold and that the APVMA must not use options or modify an awarded contract so as to avoid the requirements of Division 2.[65]

4.2.15 The core purpose of Division 2 is to set out tendering requirements for procurements that exceed the relevant procurement thresholds. Division 2 also sets out the process and form requirements for tenders.

4.2.16 The two forms of tender under Division 2 are limited tender and an open approach to market, where limited tendering is only available in specified situations.[66]

4.2.17 Where a contract is awarded through limited tender, the official must prepare and appropriately file a written report detailing the procurement, justifying the use of the limited tender and demonstrating the achievement of the value for money requirement.[67]

4.2.18 Where a limited tender is not available, the procurement must be undertaken by inviting all potential suppliers to participate in the procurement and inviting submissions.

4.2.19 Additional guidance on compliance with the CPRs is provided in the policies of the Accountable Authority Instructions (**AAIs**) and Resource Management Guide 411 (Grants, Procurement and other financial arrangements) (**RMG 411**).

4.2.20 Paragraph 22 of RMG 411 relevantly confirms that any procurement continues beyond the awarding of the contract and includes the "delivery of and payment for the goods and services and, where relevant, the ongoing management of the contract and consideration of disposal of goods". The AAIs similarly provide that a variation to a procurement must comply with the CPRs.

4.2.21 While the CPRs do not apply to the extent that an official applies measures determined by the Board to be necessary for specified reasons,[68] we are not aware of the Board making any such determination in relation to the APVMA.

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[62] CPRs r 7.2.

[63] CPRs r 7.3.

[64] CPRs r 9.12.

[65] CPRs r 9.5 and 10.36.

[66] CPRs r 10.3.

[67] CPRs r 10.5.

[68] CPRs r 2.6.

4.3 Does the APVMA achieve compliance with relevant requirements?

4.3.1 On the basis of the materials we have reviewed, the APVMA has been able to demonstrate a baseline knowledge and application of procurement requirements. We have also identified deficiencies in the APVMA's past management of procurements, exemplified by the key services contract (discussed in the case study below).

4.3.2 Areas for potential improvement include:

(a) changes to embed a culture not only of the need to comply but how compliance with procurement requirements must be achieved, recorded and reviewed;

(b) attempting to replace the public service corporate knowledge that was potentially lost as part of the relocation to Armidale, where we understand less than 15 of approximately 140 full time employees stayed with the APVMA; and

(c) investing in the APVMA's capability with respect to financial management and procurement - particularly by improving the APVMA's case management and information systems.

4.3.3 We have not been provided with procurement documentation that we would expect to find for an agency similar to APVMA, including:

(a) copies of documentation demonstrating that the APVMA has complied with relevant procurement requirements in accordance with the CPRs (as opposed to documents that assert compliance and do not provide any transparent information that would allow a person to verify the asserted compliance). In particular, there appeared relatively few documents which detailed assessments of value for money for procurements, explaining the basis of procurement decisions or otherwise recording procurement processes. The APVMA's contract register (which appears to be a manual spreadsheet) provides high-level information, but importantly, does not detail the reasoning to support the information that is included. Further, it appears that the level of detail that has been included in the register has significantly decreased over time since the original entries in the register from 2018 - 2019;

(b) correspondence, templates and advice (including legal advice) regarding the satisfaction of requirements in the CPRs and whether a particular procurement achieves value for money or requires an open approach to market. In practice, such documentation may take the form of checklists, written reports and broader cost benefit analysis. Importantly, if this type of documentation did exist, the APVMA was unable to provide it for review in a timely or accessible fashion;

(c) any documentation detailing when limited tenders or standing offers have been used instead of an approach to open market or when Appendix A exemptions under the CPRs have been relied upon. It would clearly be prudent to maintain such records going forward; and

(d) any internal procurement policies, including in relation to the processes for identifying procurement risks, other than to the extent the procurement policy has been incorporated in the relevant AAIs.

4.3.4 While such documentation may exist on the APVMA's internal database, the fact that these documents have not been provided to us suggests that they are not readily available or cannot be easily located.

4.3.5 In this respect, we note that the correspondence and briefs we have been provided do not appear to attach or refer to prepared documentation of the type referred to above. The absence of such documentation, including the lack of a register where such documentation is kept, creates an impression of non-compliance with the CPRs.

4.3.6 Further, the lack of such documentation raises a concern that the APVMA may not undertake regular or ad hoc reviews of its procurement performance - which would be an important step in improving performance.

4.3.7 In this respect, the APVMA's procurements appear to be manually tracked and updated in an electronic spreadsheet. Where this is the APVMA's primary method for managing procurements, this approach is at risk of giving rise to inadvertent non-compliances as well as impeding the effective delivery of procured goods and services - such as a result of:

(a) a failure to manually incorporate new information into the spreadsheet;

(b) limited system capabilities to track and compare information in the register (which can also drain available resources away from other procurement matters as a manual review is required); and

(c) potential inconsistencies in the approach to recording information in the register. Such inconsistencies may give rise to an impression that information in the spreadsheet is unreliable and would require additional manual confirmation from APVMA personnel (which would further drain available resources). For example, a potential non-compliance with the CPRs was identified in relation to a procurement of particular expert services. The non-compliance appears to relate to an absence of evaluation criteria and assessment stage in tender documents as required by rule 7.12 of the CPRs. While it appears that the relevant non-compliance was rectified before the relevant contract was awarded, the fact that the non-compliance was only discovered inadvertently and was not provided to us in response to our original requests is consistent with a view that there may be other unidentified non-compliances with procurement requirements within the APVMA.

4.3.8 The absence of key procurement documentation in combination with the material that has been provided to us (as detailed in the case study below), indicates that some executive-level personnel of the APVMA may not have had a detailed appreciation of the intent of the CPRs and the importance of their application to the APVMA in its capacity as a corporate Commonwealth entity. This view is consistent with our findings following the review of select key challenging procurements.

Procurement case study: Key Services Contract

4.3.9 In undertaking this review, we have focused on the APVMA's procurement of a key services contract entered into under a work order with a contractor (the **Work Order**). Under the Work Order, the head contractor engaged subcontractors to carry out relevant services for the APVMA.

4.3.10 The procurement process for the Work Order raises a range of concerns about the procurement compliance and awareness within the APVMA. The APVMA was keen to progress the delivery of the services the subject of the Work Order. However, in doing so, it appears that critical procurement requirements were not met.

4.3.11 In particular, it is of concern that the total value of the Work Order for the relevant services increased very significantly without a final work product having been produced. It is also of concern that despite the relevant services under the Work Order being a significant work product for the APVMA, the procurement was carried out iteratively, by way of numerous change orders to an existing umbrella work order for the delivery of the relevant services.

4.3.12 There is a significant amount of background in relation to this complex procurement. We have set out a summary of the key factual matters relevant to this case study below.

Background

Observations on the services procured under the Work Order

From the materials provided to us, it appears that:

- the initial procurement for the Work Order may have been undertaken via a standing offer under an existing panel arrangement. It is not clear whether an initial open market procurement was undertaken for this Work Order, or whether the APVMA relied on the existence of the panel as a way to expedite the process. We were not provided with any original value for money assessment as referred to in later correspondence and material by the APVMA;
- following the entering into of the initial Work Order various additional (although associated) services were subsequently incorporated under the Work Order by the APVMA and there were various purposes for the undertaking of the services under the Work Order;
- the APVMA had made representations to industry that the services the subject of the Work Order would be undertaken within a certain timeframe;
- there were ongoing issues with the undertaking and implementation of the services and that resulted in significant delays and cost overruns;
- the implementation of the services may have been complicated by the establishment of a new main office in Armidale and the relocation of the office in Canberra. We note that the original Work Order was the subject of a change order which procured additional services for the Canberra relocation;
- a significant number of change orders to the original Work Order have been proposed which, for those that were approved, have in aggregate quadrupled the original contract value (as at 20 February 2023). As at 20 February 2023 not all services were complete and the APVMA had in its view not received any significant deliverable of value which addressed the original objectives for entering into the Work Order;
- where additional services were incorporated under the existing Work Order with the contractor, on at least one occasion this option appeared to be selected as it was the most expedient option. While we have not been provided the materials setting out the different options for undertaking this procurement, there is a concern that the APVMA may have preferred expedience over compliance;
- members of the then executive of the APVMA also made representations to industry, who were interested in the successful delivery of the relevant services, that the delivery of the services was progressing well. However, at this stage the project was significantly late, over budget and subject to serious allegations of non-performance;
- 8 months later a member of the then executive of the APVMA raised issues with the contractor in relation to the delayed progress and cost overruns for the services. The contractor responded in detail to the issues raised by the APVMA, which appeared to lead to the preparation of a Deed setting out the parties' understanding and treatment of the matters the subject of the Work Order (the **Deed**);
- although the services had not been completed, the original Work Order was set to expire unless the APVMA exercised its extension option;
- the APVMA and the contractor executed the Deed to extend the Work Order;
- in negotiating and entering into the Deed reliance appears to have been placed on the APVMA having undertaken some earlier value for money assessment

Background

such that no further assessment was required (and where this necessitated that there be no material departures in the scope of the services included as part of the Deed) and that the procurement was low risk as the Work Order had contemplated an extension of the term. Given the circumstances, it is difficult to reconcile any "low risk" categorisation of any part of this procurement;

- in this respect, the APVMA's risk register ranked the risk associated with a failure to suitably implement the services at the highest level (i.e. "extreme");
- the progression of the services was discussed in Board meetings. However, the extent to which issues were considered is not clear given there is little detail on this topic in the meetings' minutes;
- it is not clear at what stage (if any) the Minister or the Finance Minister were notified of the issues with the implementation of the services (noting the "extreme" internal rating attributed by the APVMA), including in accordance with the notification requirements under the PGPA Act;
- aside from the coversheet of the Work Order, we have not been provided any documents that relate to the undertaking of a tender process for the services; and
- as at the date of this Report we understand from the APVMA that it had limited options to address the issues associated with this procurement and has been required to extend the Work Order again, for additional cost, without a deliverable having been completed. To ensure some relevant services were delivered for the benefit of the industry and to mitigate the risk of a potential claim from the contractor this was seen as the least worst option, even where there were serious questions concerning the performance of the contract.

What could the key services procurement case study indicate about Finance Law compliance?

4.3.13 The information that we have reviewed in preparing this Report suggests that the key services procurement was not, in our view, an acceptable procurement.

4.3.14 While we have not received material allowing us to confirm that the original services were procured under the relevant standing offer or the basis of the original value for money assessment (this being an issue in itself), it appears that the procurement of additional services may not have complied with key procurement requirements. Indeed we note:

(a) there would have been an expectation on the APVMA to reassess the project or approach the open market at some point, or engage in another standing offer process (noting there were a significant number of other suppliers which were available to be used by the APVMA under existing panel arrangements) for the additional services given the significant change in the scope of the original Work Order and the issues that had arisen. The change in scope is evident in the number and value of the iterative increases to the contract and is acknowledged in various correspondence between the APVMA and the contractor;

(b) it is unclear from the materials provided whether the APVMA sought tenders for the additional services or relied upon an exception or exemption under the CPRs. As noted for general procurement matters, the APVMA does not maintain a register for exemptions relied upon during procurements;

(c) even if an exception or exemption could have applied, it is unclear to us how the APVMA would have demonstrated that an additional procurement of the relevant services from the existing contractor would represent value for money, or would be

efficient, effective, economical and ethical - given the project and contractor issues described above;

(d) there is significant doubt that compliance reviews were undertaken (or appropriately prioritised) for the procurement of certain services, including in relation to the Deed noting that the APVMA Procurement Team appeared to not sign-off on the procurement on the basis that the relevant spending proposal had "already been signed and approved by the [relevant member of the APVMA executive] so any further consideration by the procurement team is considered to be redundant" - this of course means that no advice was taken from the procurement team before deciding to complete the Deed which recommitted the APVMA to the procurement and significant additional spend; and

(e) the above concerns arise particularly in relation to the extension and variation of services under the Deed, but also arise more generally in relation to the repeated variations to the Work Order carried out prior to the date of the Deed.

4.3.15 This case study also illustrates the need for additional resourcing for record-keeping within the APVMA. Although we requested all documents relating to the procurement, we have not been provided documentation that is commensurate with the scale, scope and risk of the procurement, as required by the CPRs. Given the value and risk of the procurement (including as attributed to it by the APVMA), we would expect there to be considerably more numerous and sophisticated documentation setting out the reasoning behind procurement decisions and any risks arising in relation to Finance Law compliance. As noted above for general procurement matters, the absence of such documentation suggests that it is not readily available, cannot be easily located or was otherwise not prepared in the first instance.

4.3.16 There is a risk the expedient completion of the relevant services, and potentially other associated services, may have been prioritised to the detriment of ensuring compliance with the CPRs and AAIs. In particular, there are concerns arising from internal correspondence that compliance with procurement requirements for the Deed was only a matter considered after the Deed was substantially prepared for execution (which may create pressure to affirm that the requirements are satisfied).

4.3.17 There is also a risk the executive team of the APVMA may not have transparently or promptly communicated the Finance Law compliance risks to the Board, the Audit and Risk Committee, the Minister and the Finance Minister. Given the "extreme rating" attributed by the APVMA to the implementation of the services the subject of the Work Order, we would expect that this matter would have been notified to the Minister and the Finance Minister in accordance with the PGPA Act.

4.3.18 Similarly, we have not been provided documentation between relevant members of the APVMA executive and the Board that communicates the risks arising in relation to the management of the services procurement in a way that is commensurate to its risk to the APVMA. If these risks were properly communicated to the Board, they do not appear to have been detailed as such in the minutes.

4.4 Compliance with other Finance Law: other matters

4.4.1 As noted at the beginning of this section 4, the ANAO prepares regular reports based on detailed audits of the financial management of the APVMA.

4.4.2 The reports authored by the ANAO indicate that the risks identified during the audits are typically "moderate" or "lower risk" and nonrecurring. Where the ANAO had suggested a recommendation to address an identified risk, it appears from the materials provided that the APVMA's Audit and Risk Committee sought to implement those recommendations.

4.4.3 While we have not been provided with materials allowing us to independently confirm the extent to which these recommendations have been implemented, the fact that the same issues

were not identified in subsequent ANAO reports suggests that issues were rectified once identified.

4.4.4 One of the ANAO reports dated August 2022 (for the year ending 30 June 2022) identified the ability of the APVMA's management to override financial controls as an area of potential '*higher risk*'. We understand that:

(a) the risk only arose in the context of asset value estimations for the APVMA (which are discussed in the relevant ANAO report); and

(b) the matter has since been resolved as evidenced by a supporting statement from the relevant APVMA executive member dated 31 August 2022.

4.4.5 As a result, and noting the ANAO undertakes regular financial auditing of the APVMA, we have no additional comments on the accounting and financials of the APVMA for the purposes of this review.

5. Operations

Summary of key findings and takeaways

- During the period 2019 - 2022, the APVMA received a significant number of personnel related complaints. The volume of complaints is of high concern having regard to the size of the agency. The allegations also suggest a consistent theme of dissatisfaction in the manner that complaints were handled or progressed.
- It should be noted that a number of the allegations and complaints made by staff were very serious. We understand that, where appropriate, allegations have been referred to the relevant authorities for further investigation.
- Significant and recent changes to the APVMA's staff profile following the relocation of the office to Armidale in 2019, has most likely impacted corporate knowledge, workload, and work capacity as well as changes to its governance structure (with the Board having been introduced in early 2022). We understand only a small proportion of previous APVMA staff moved from Canberra to Armidale and it may be inferred that the new staff and lack of previous APS knowledge and experience impacted the operations of the APVMA.
- The current governance structure, and in particular, the relationship between the CEO and the Board, needs to be carefully examined and more clearly defined.
- This lack of clear delineation of roles was probably a factor in the APVMA's leadership failing to escalate serious issues which would normally require the Board's strategic oversight.
- Robust reporting and strategic frameworks, including a clear charter of the Board's roles and responsibilities, may enhance the way that the APVMA identifies and responds to significant challenges in the future.
- Greater reporting between the APVMA and the Department and Minister would allow for the APVMA to greater integrate into the overall APS and executive framework and policy settings.

5.1 Introduction, scope and key issues

5.1.1 The Minister has requested the Board report on issues raised in relation to the administration and operation of the agency more generally. We consider that there are two key components to be addressed in examining this issue:

(a) personnel and operational matters; and

(b) governance matters, in this case, the APVMA's current governance structure, including the role of the Board, the role of the CEO and the impact of the relationship between the substantive CEO and the Board between March 2022 and March 2023.

5.1.2 In preparing this Report, we have reviewed what we understand to be all recorded personnel complaints raised between 1 January 2018 to 11 February 2023.

5.1.3 It is beyond the scope of this Report to investigate allegations, to determine whether allegations may constitute a breach of the Code of Conduct or to make any findings about particular allegations in relation to staff members. It is also beyond this review to make recommendations regarding workplace culture. These matters are both being investigated and reviewed in different forums.

5.1.4 However, we have considered what the volume and seriousness of the allegations might indicate about the APVMA's operations more generally.

5.1.5 This part of the Report has also been undertaken by way of a desktop review of documentary material. This means that we have not:

(a) conducted interviews with any staff members; or

(b) conducted any form of investigation (including a desktop investigation) in relation to particular incidents or allegations contained in the material we have reviewed; or

(c) undertaken any qualitative assessment of the matters raised in the materials and cannot comment on the veracity of these matters or the steps the Board (or any other relevant party) may wish to take to address any matters.

5.1.6 Additionally, at the time of writing, referrals have been made to the Australian Public Service Commissioner and policing authorities. This Report makes no findings or recommendations in relation to the allegations that precipitated the Australian Public Service Commissioner's ongoing investigations or in relation to the overall workplace culture of the APVMA.

5.2 Personnel and operational matters

5.2.1 It is relevant to understand the size of the APVMA as an agency during 2019 - 2022 to put into context the personnel and operational matters facing the agency.

5.2.2 The APVMA has offices at two locations in Australia: one in Armidale and the other Canberra.

5.2.3 As at 30 June 2022, the APVMA employed a total of 197 ongoing and 32 non-ongoing APS employees.[69]

5.2.4 Across all APVMA staff as at 30 June 2022, there were:[70]

(a) 154 ongoing employees and 30 non-ongoing employees in the Armidale office;

(b) 43 ongoing employees and 2 non-ongoing employees in the Canberra office; and

(c) a total of 158 staff with flexible working arrangements in place.

5.2.5 At the outset, we note that the APVMA is comparatively a smaller Commonwealth agency. This context is important to understand the impact of complaints and disputes within the agency which we consider would be more likely to impact more staff on a day-to-day basis when the size of the agency is smaller, and where the resources of the agency to respond to complaints is also likely to be smaller.

Summary of staff complaints, issues and concerns

5.2.6 We sought access to information from the APVMA regarding complaints, issues and concerns raised by staff. We were provided with a number of documents from the APVMA's document management system from 2018-2023. We were able to identify 56 complaints. With the information available to us, it is not possible to say whether the complaints are all unrelated or whether some complaints are related to the same underlying conduct.

5.2.7 The complaints we have identified range from what may be described as relatively trivial workplace grievances to alleged misconduct which is very serious in nature. We have

[69] APVMA, *Annual Report 2021-22* (Annual Report, 21 October 2022), p 10.

[70] Ibid, pp 15-17.

categorised the complaints into six categories. Below, we describe each of the six categories and give an example of the types of complaints which fall into each category.

Summary of staff complaints, issues and concerns: 2018 - 2023

(a) **Conflicts of interest in recruitment** - 2 complaints

This category includes allegations of nepotism and favouritism.

(b) **Inappropriate use of technology** - 3 complaints

This category includes allegations unauthorised publication of official information on social media.

(c) **Mental health concerns** - 9 complaints

This category includes allegations about unsafe work practices (due to excessive work demands).

(d) **Poor culture and management** - 9 complaints

This category includes allegations about conflict between managers.

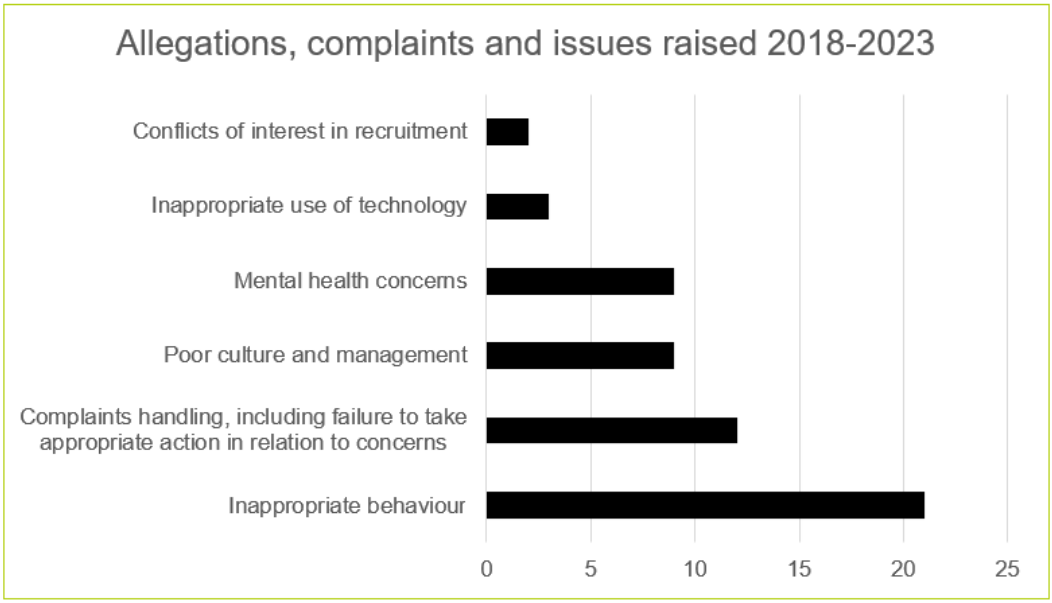
(e) **Complaints handling, including failure to take appropriate action** - 12 complaints

This category includes allegations about taking adverse action against employees who raised concerns about the management or the culture of the APVMA.

(f) **Inappropriate behaviour** - 21 complaints

This category includes allegations regarding inappropriate behaviour in the workplace.

The number of complaints in each category is also shown in the diagram below.



5.2.8 Based on the material that we have reviewed, the complaints appear to cover the entire organisation and are made by and about employees at all levels within the APVMA (from junior staff to executive level staff), and employees that are both longstanding and who had commenced recently. The seriousness of the complaints also ranges significantly from complaints on the lower end of seriousness (such as complaints about fire warden duties) to allegations of serious misconduct.

5.2.9 The broad subject matter of the complaints includes matters which are arguably more personal in nature, although which appear to filter into the work environment and affect the ability of staff to perform their role, and complaints in relation to matters that fall within the scope of the employee's position within the APVMA (such as disputes over professional responsibilities).

5.2.10 There are also a significant number of complaints that refer to serious impacts for the persons involved, including numerous instances of employees having to take periods of stress leave or feeling unable to attend work due to mental health concerns. Despite this, the manner in which complaints appear to have been handled and documented indicates:

(a) a lack of response to the complaint; or

(b) a lack of record keeping; or

(c) a lack of capacity to respond and/or keep accurate records in relation to the complaint.

What does this suggest about the operations of the APVMA?

5.2.11 Due to the nature of this review, we have not assessed the veracity of any of these matters. However, the points that need to be emphasised as a result of the mere making of the complaints are as follows:

(a) there were clearly cultural issues with the organisation given that on average there was a formal complaint about once every 4-6 weeks for 5 years;

(b) some of the complaints were very serious but there appears to have little if any reporting of these matters to the Board. There was no reporting that we could find of any kind of these matters to either the Department or the Minister meaning that matters were not escalated and relevant action could not be taken;

(c) some of the more serious complaints involved individuals that were either in the APVMA executive, or who were direct reports to the then APVMA executive;

(d) conversely, in some instances the making of a complaint and the response to it seemed potentially disproportionate;

(e) there were allegations of instances where instead of supporting people who were trying to make a complaint, they were instead actively discouraged from making the relevant complaint; and

(f) there were serious mental health matters that were raised for a number of employees.

5.2.12 It is apparent from the number of complaints that the APVMA has a very large number of what may be described as personnel and organisational issues for an agency of its size.

5.2.13 We suggest, having regard to the other information reviewed for the purposes of this Report, that the organisational operations of the APVMA has likely been significantly impacted by:

(a) frequent and recent changes to the staff profile, including staff resourcing levels for critical business areas in the regulatory and scientific areas. This includes the

significant changes to the APVMA's staff base upon the relocation from Canberra to Armidale in 2019;

(b) rapid staff turnover and high levels of staff departure, including at supervisor levels (with particularly high staff turnover reported in relation to EL2 positions);

(c) the volume of complaints with respect to inappropriate behaviour in the workplace; and

(d) employee concerns about poor culture within the APVMA and a limited response from those in management to the poor culture within the APVMA.

5.2.14 The APVMA has undergone a significant amount of organisational change in a relatively short period. The APVMA has been subject to repeated internal and external reviews with respect to its strategic direction and has as recently as early 2022 undergone a significant change to its governance structure, with the addition of the Board.

5.2.15 The relocation of the APVMA's main office to Armidale perhaps also fundamentally changed the APVMA - if for no other reason than the APVMA had a very significant turnover of staff, including a change in CEO, associated with the relocation. This turnover of staff would have inevitably resulted in a loss of corporate knowledge, a loss of corporate culture and a loss of experience and knowledge of what it is to work within the APS. This may include practical awareness of foundational public service principles, such as the need to adhere to the APS Values.

5.2.16 In reflecting on the impact of significant organisational change on the APVMA's operations, it is appropriate that for any future organisational changes, strategies are put in place to:

(a) maintain corporate knowledge if there is staff turnover;

(b) ensure that there are strong links to the Department and the wider public service so that there is a clear appreciation of the accountability and behavioural requirements expected of the APS; and

(c) ensure that communication, transparency and consultation channels with existing APVMA staff are prioritised as a central part of the plan in developing and implementing change at an organisational and structural level.

5.2.17 The information we have reviewed does indicate that the APVMA is working to implement ongoing and upcoming initiatives designed to bolster the operations and enhance the workplace culture of the APVMA. These initiatives should continue to be progressed as a matter of urgency, and it may be that additional workplace culture advice is required to deal with the issues over time.

5.2.18 Among others the initiatives being progressed include:

(a) developing and implementing new workplace policies and procedures including the People and Culture Plan, the Workplace Respect Program and the Contact Officer Network;

(b) developing a bespoke work health and safety management system designed for the APVMA, including policies which promote a flexible and agile workforce;

(c) introducing annual compulsory training in relation to bullying, harassment and inappropriate behaviour in the workplace;

(d) engaging with APVMA staff in relation to what they want to see in their workplace, including by conducting a workplace culture improvement project (the Culture Pulse Check Project). One of the Board's key commitments arising out of this project is a

quarterly report on the progress in implementing the APVMA Culture Pulse Check Roadmap;

(e) increasing the depth and capacity of the APVMA People Team, including by creating new positions in the team;

(f) identifying and providing the contact details of APVMA staff who are authorised to receive Public Interest Disclosures, with their contact details made readily available to staff on the intranet;

(g) developing a Behavioural Standards Policy that will incorporate the APS Values and embed them into relevant business processes;

(h) assisting staff to develop practical skills on how to deliver and receive feedback;

(i) facilitate 'Values in Action for Managers' workshops, establish 'Values Team Agreements' and organise team building workshops;

(j) implement a Leadership Development Program and develop the APVMA Leadership Capability Framework to articulate clear leadership expectations in line with the APS Capability Framework;

(k) undertake targeted business critical roles recruitment campaigns bi-annually, tied to successful planning and a talent program;

(l) conduct a review of organisational capabilities, including completion of a gap analysis between current and future workplace requirements;

(m) implementing measures to increase staff engagement and collaboration, including by encouraging employees to increase the days that they are working from the office (noting that until March 2023, a significant number of APVMA staff were on almost full-time remote working arrangements);

(n) create a better link between capability and performance through a revised approach to performance management;

(o) implement resources and guidance materials to support new managers' transition into leadership roles;

(p) promote prevention and early intervention strategies to manage organisational and workplace issues; and

(q) develop and implement diversity, inclusion and accessibility strategies.

5.2.19 As the above work is either ongoing or in the process of implementation, it is not possible for this Report to assess the effectiveness of these policies or initiatives. These initiatives do appear to be well placed to respond to the concerns of staff and the operational and organisational issues we have identified in this Report.

5.3 Governance

5.3.1 This review has considered, in relation to the administration and organisation of the APVMA more generally, the governance relationship between the role of the CEO and the role of the Board.

5.3.2 Based on the information we have reviewed it appears that the APVMA's governance model in the first year of the Board's operation was not successful in promoting Board oversight, awareness and understanding of the issues facing the APVMA. It is possible that this was due to a combination of the APVMA's senior executive during this period not drawing appropriate

matters to the Board's attention as well as the Board not having a sufficiently clear mandate or formal reporting requirements in relation to the operational issues of the APVMA.

5.3.3 In the section that follows, we have considered the current organisational structure of the APVMA and information available about the relationship between the substantive CEO and the Board from the period March 2022 (being when the Board was introduced into the governance structure of the APVMA) to March 2023.

Organisational structure of the APVMA

The Board

5.3.4 The Board of the APVMA was only recently established on 4 March 2022 by the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021* (Cth) (**Improvements Act**). Membership of the Board consists of the Chair, the CEO, and three other members.

5.3.5 The Board was established following repeated reviews the APVMA's governance and performance.[71] Perhaps the most relevant recent review that included the APVMA in its scope was the comprehensive review of the regulatory framework for agvet chemicals in Australia, announced by the former Minister for Agriculture in September 2019. This comprehensive review concluded with the publication and release of the Systems Report.

5.3.6 Shortly after this review was announced, the government at the time introduced the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019* (Cth). This Bill relevantly recommended the introduction of the Board.

5.3.7 The Systems Report was the result of this review and was completed in May 2021. The Systems Report relevantly include a recommendation that a Board be introduced into the governance structure. Specifically, the Systems Report stated that "*all responsibility for strategic leadership, governance, staff management, and day-to-day operations currently resides with the APVMA's CEO*",[72] and commented that this was an unusual arrangement, given 90% of Commonwealth corporate entities have a Board. The Systems Report also observed that the APVMA's CEO model creates potential vulnerability as the CEO's attention is divided between attending to external regulatory functions and internal management and governance.[73] The Systems Report recommended that the Board should '*not be involved in day-to-day management and operational activities of the regulator, nor should it impact or influence the scientific integrity of regulatory risk assessment*'.[74] Instead, the Systems Report characterised the role of the Board as supporting the APVMA in managing operational, financial and performance matters, and to drive a reform agenda.

5.3.8 Under the Administration Act, the Board's functions are to ensure the proper, efficient and effective performance of the APVMA's functions and to determine its strategic and policy direction. As the entity's accountable authority for the purposes of the PGPA Act, the Board is also subject to various statutory duties under the PGPA Act in relation to its financial, risk and audit oversight of the APVMA the performance of which is not subject to any Ministerial direction under s 27G of the Administration Act.

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[71] A history of this scrutiny, including multiple audit reports, is set out in the Senate Rural and Regional Affairs and Transport Standing Committee's 2019 report: Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

[72] Systems Report, 64.

[73] Systems Report, 64-65.

[74] Systems Report, 64-65.

5.3.9 A statutorily mandated review into the functions and operation of the Board is to be completed by no later than 4 March 2026.[75]

The CEO

5.3.10 The CEO of the APVMA is appointed on a full-time basis by the Board in consultation with the Minister. The CEO is an ex-officio member of the Board and serves as the head of the APVMA's executive team as well as the APVMA Head for the purposes of the *Public Service Act 1999* (Cth).

5.3.11 Under s 32 of the Administration Act, the CEO is responsible for the day-to-day management and decision-making of the APVMA and may exercise any of its powers and perform any of its functions. However, in doing so, the CEO must act in accordance with the objectives, strategies and polices determined by the Board, and comply with any written directions given by the Board in relation to the performance of the CEO's duties under the Administration Act.[76]

5.3.12 It is relevant that the role of the CEO changed with the introduction of a Board into the APVMA's governance structure. Notably, the introduction of the Board also came with a requirement for the CEO to report to the Board and be accountable to the Board (including with respect to the CEO's appointment). While the CEO remains responsible for the day-to-day operations of the APVMA, it appears that the changes to the APVMA's governance structure in 2019, that came into effect in 2022, were designed to carve out the broader strategic agenda for the Board to develop and progress, with the CEO to continue to have oversight over the APVMA's day-to-day operations, albeit with strategic oversight from the Board.

5.3.13 This is reflected in the Explanatory Memorandum to the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019* (Cth) which relevantly stated that "*[t]he functions of the Board will complement, but not duplicate the duties of the CEO… this split of responsibilities will ensure the Board provides the appropriate level of oversight, but will prevent it from getting involved in the day-to-day decision-making of the APVMA*".[77]

5.3.14 For completeness, we note that the Minister has general executive oversight over, and is accountable to Parliament and the public for, the APVMA.[78] In discharging those duties, the Minister is vested with specific (delegable)[79] powers and functions under the AVC legislation, including:

(a) giving written directions to the APVMA (or the Board) concerning the performance of its functions or exercise of its powers;[80]

[75] Administration Act s 27K.

[76] Administration Act, s 32.

[77] Systems Report, 71.

[78] See also PGPA Act s 19(1) which requires the Board of the APVMA to keep the Minister informed of certain matters in relation to its activities and decisions.

[79] Administration Act s 71.

[80] Ibid ss 10, 27G.

(b) approving the APVMA's annual corporate plan[81] and facilitating certain contractual and administrative arrangements involving the APVMA and the Commonwealth or with a Minister or government of a State;[82] and

(c) review and decision-making responsibility in relation to applications for reconsideration of certain permit decisions,[83] and the granting of permission (which may also be provided by authorised officers) to import, export, manufacture, or deal with otherwise prohibited chemicals.[84]

5.3.15 The Secretary of the Department has policy oversight of the legislation administered by the APVMA. In addition to the general roles and responsibilities set out in s 57 of the *Public Service Act 1999* (Cth), the Secretary also has specific responsibilities under the AVC legislation in relation to the record keeping and document management.[85]

The relationship between the CEO and the Board

5.3.16 The CEO is the person responsible for the day-to-day operations of the APVMA, and reports to the Board in that capacity. In contrast, the purpose of the Board is to provide strategic oversight and additional guidance for the APVMA and for the CEO.

5.3.17 However, the Administration Act does not identify the specific matters over which the Board ought to have oversight (if any) in the context of the day-to-day operations and administration of the APVMA.

5.3.18 The information that we have reviewed indicates that in the first year of the Board's operation (from March 2022 to February 2023) efforts were made for the Board to be regularly updated in relation to matters relevant to the underlying organisational strategy for the APVMA. Records of meeting minutes demonstrate that Board meetings were well-attended by senior members of the APVMA across various business areas (including People and Governance, ICT Services, Compliance, Reform, Finance and Legal) in addition to the APVMA's senior leadership.

5.3.19 We further understand that the Chair of the Board and the substantive CEO met on a more informal but weekly basis, also with a view to maintaining ongoing oversight by the Board of matters relevant to the APVMA's broader strategy.

5.3.20 The Board has raised significant concerns relating to the information it was provided by management of the APVMA. The provision of information to the Board is critical for the Board to be able to perform its functions and discharge its obligations. The Board has noted that it was not, in its opinion, kept informed of (and may have been inadvertently mislead in respect of):

(a) staffing matters - including complaints and incident reporting. We note that the Board was not aware of the staffing matters raised by Senator Whish-Wilson until the relevant Senate Estimates Hearing. The Board, Department and Minister only became aware of those allegations at the hearing itself;

(b) the financial performance of the APVMA; and

[81] Ibid s 51.

[82] Ibid ss 9, 58, 75(1), 76.

[83] *Agricultural and Veterinary Chemicals (Administration) Regulations 1995*, Part 3 Div 3.9.

[84] Ibid, regs 3.55, 3.110, 3.210, 3.185.

[85] See, e.g. Administration Act ss 27E-27F, 27H; Collection of Levy Act s 35.

(c) procurement matters.

5.3.21 However, we do note that the Board meeting minutes we have been provided to review record briefings from People and Governance, project updates on the significant procurements, briefings from the Chief Financial Officer and financial statements, review and Board approval of draft portfolio budget statements and annual performance statements, and regular updates from the Compliance and Risk areas. Of course, we cannot comment on whether the Board was fully briefed as a result - it may be that either the information provided to the Board was presented in a manner such that the Board was not able to identify the problems and risks based on the information presented, or the Board was not in a position - either due to the lack of context or a lack of understanding as to the actual operations of the APVMA or the information presented - to identify, understand and appreciate the significant strategic challenges that faced the APVMA during this period.

5.3.22 This is a significant issue as the Board is not in a position to comply with its statutory obligations unless and until it is provided with all relevant information from management. From a governance perspective the Board needs to be held accountable for its decisions in relation to the APVMA, but this accountability can only be established where the Board is able to review all information that allows it to govern the APVMA.

5.3.23 However, and of course, where the Board is of the view, or is otherwise concerned, that it has not received sufficient information to discharge its functions or obligations it is critical that the Board takes all reasonable steps to ensure that it procures such information.

5.3.24 Focusing specifically on the allegations of serious misconduct that were first raised during the November 2022 Senate Estimates hearing, which we accept the Board did not discuss at any Board meetings, it is concerning that the APVMA's executive team failed to provide any information in relation to the misconduct and other issues to the Board for a period of over a year (on the basis that we understand the incident raised during the November Senate Estimates Hearing took place in approximately September 2021, and the hearing took place in November 2022).

5.3.25 In this respect, it remains unclear from our review of the limited material provided to us, whether the executive team of the APVMA (including the substantive CEO) had knowledge of *all* of the relevant workplace issues which had been raised - however, that leads to one of two conclusions:

(a) the executive team knew about the number and types of complaints being made but failed to inform the Board of this; or

(b) the executive team did not know about the number and types of complaints being made.

Governance: matters for further consideration

5.3.26 Given the above, in respect of the Board's role going forward, consideration should be given to the following:

(a) Arrange for detailed governance education programs to be delivered to the Board, with a focus on Board responsibilities under the Administration Act, the applicable Workplace Health and Safety legislation and in relation to procurement matters.

(b) Consider implementing separate and formalised reporting mechanisms as between the Board and the CEO, and the Board and other executive officers. This is to ensure that the Board is informed of all relevant matters and so that compliance matters are independent from other business and operational functions of the APVMA.

(c) Review and implement more formal reporting mechanisms as between the Chair, the Board and the Secretary of the Department, consistent with the Administration Act.

(d) Outline in detail the role of the Board and those matters consistent with the Administration Act in respect of which it needs detailed information and briefings.

(e) Clarify those matters which the CEO alone is responsible for, as opposed to those in respect of which guidance is expected from the Board.

(f) Expand the number of the Board to facilitate the inclusion of additional skill sets.

6. Glossary

Term	Definition
AAIs	Accountable Authority Instructions
Administration Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
Agvet Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
ANAO	Australian National Audit Office
APS	Australian Public Service
APS Values	Means those values set out in section 10 of the *Public Service Act 1999* (Cth)
APSC	Australian Public Service Commission
APVMA	Australian Pesticides and Veterinary Medicines Authority
AVC legislation	Collectively, and as applicable, the AVC Act, Agvet Code Act and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Cth)
AVC Act	*Agricultural and Veterinary Chemicals Act 1994*
Board	Board of the APVMA
Brennan Review	Independent review into the workplace culture of the APVMA, commissioned by the Senator Murray Watt
CDPP	Commonwealth Director of Public Prosecution
CEO	Chief Executive Officer of the APVMA
Code of Conduct	The Australian Public Service Code of Conduct, as set out in s 13 of the *Public Service Act 1999* (Cth)
CPRs	Commonwealth Procurement Rules
Department	Department of Agriculture, Fisheries and Forestry
Finance Law	Collectively, the PGPA Act and the PGPA Rule
Improvements Act	*Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act* 2021 (Cth)
Interim Report	The interim report prepared by Ms Brennan in relation to the Brennan Review, provided to Senator Murray Watt on 8 February 2023
Minister	Minister for Agriculture
November Senate Estimates Hearing	Senate Rural and Regional Affairs and Transport Legislation Committee hearing in Canberra on 8 November 2022

Term	Definition
PGPA Act	*Public Governance, Performance and Accountability Act 2013* (Cth)
PGPA Rule	*Public Governance, Performance and Accountability Rule 2014* (Cth)
Public Service Act	*Public Service Act 1999* (Cth)
RMG 411	Commonwealth Resource Management Guide 411 (Grants, Procurement and other financial arrangements)
RMG 128	Commonwealth Resource Management Guide 128 (Regulator Performance)
Secretary	Secretary of the Department of Agriculture, Fisheries and Forestry
Systems Report	2021 Independent Review of the Pesticides and Veterinary Medicines System in Australia

7. Appendix: APVMA Functions

Function	Key activities
Assessment	
Assessing the suitability for supply in Australia of active constituents for proposed or existing chemical products, chemical products and labels for containers for chemical products.[86]	To perform this function, the Agvet Code confers powers on the APVMA to: • approve active constituents for proposed or existing chemical products; [87] • register chemical products; [88] • approve labels for containers for chemical products; [89] and • issue permits[90] and licences,[91] for the use, handling and manufacture of chemicals. Permits may authorise the use of unregistered chemicals for limited purposes. The APVMA can impose conditions on approvals or registrations, and can reconsider, vary, suspend or cancel approvals and registrations.
Evaluating the effects of using chemical products in states and territories.[92]	The APVMA maintains a Chemical Review Program Plan (for the purpose of reconsidering the approval of an active constituent, product registration or a product or the approval of a label).[93] The APVMA conducts chemical reviews to assess that products that have been available to the market are still safe to use, having regard to concerns raised in relation to health, safety and efficacy.
Collecting, interpreting, disseminating and publishing information relating to chemical products and their use.[94]	The APVMA: • maintains an Adverse Experiences Reporting Program to collect and assess reports of adverse experiences resulting from the use of an agvet chemical, including lack of efficacy, or harm to human, crop, animal or environmental health;[95]

[86] Administration Act s 7(1A)(a).

[87] Agvet Code, Pt 2, Div 2.

[88] Ibid.

[89] Ibid.

[90] Ibid Pt 7.

[91] Ibid ss 122-127.

[92] Administration Act s 7(1A)(d).

[93] 'Chemical Review', *APVMA* (Web Page, 2020) https://apvma.gov.au/node/10816.
[94] Ibid s 7(1A)(g).

[95] 'Adverse Experience Reporting Program', *APVMA* (Web Page, 2022) https://apvma.gov.au/node/86336.

Function	Key activities
	• collects information from registration, approval or permit holders where they become aware of new information in relation to an agvet chemical product;[96] • conducts educational campaigns including, in 2021 - 2022, in relation to importing chemicals and requirements for scheduled drugs and poisons;[97] and • provides public information via its website on the correct use of agvet chemicals.
Advice, consultation and administration	
Providing information to Commonwealth and state and territory governments and authorities about approved active constituents, chemical products and labels for chemical products, and cooperating with governments on matters relating to management and control of chemical products.[98]	The APVMA participates in the Harmonised Agvet Chemicals Control of Use Task Group with representatives from state and territory regulatory agencies (who are responsible for the use of Agvet chemicals after the point of sale) to consult with those regulators and to share APVMA activities. [99]
Keeping records and statistics of approvals, registrations granted and permits and licences issued.[100]	The APVMA keeps records including: • a Record of Approved Active Constituents for Chemical Products;[101] • a Register of Agricultural and Veterinary Chemical Products;[102] • files including information about all approved chemical labels;[103] • a Record of Permits identifying permits by their distinguishing number and stating their conditions;[104] and • in relation to licenses, the APVMA publishes particulars in the Gazette after a license is issued,[105] and from time

[96] Agvet Code s 161; 'Holders to Notify the APVMA of New Information', *APVMA* (Web Page, 2022) https://apvma.gov.au/node/10826.

[97] APVMA, *Annual Report 2021-22* (Annual Report, 21 October 2022) 32.

[98] Administration Act s 7(1A)(b).

[99] APVMA, *Annual Report 2021-22* (Annual Report, 21 October 2022) 49.

[100] Administration Act s 7(1A)(c).

[101] Agvet Code s 17.

[102] Ibid s 18.

[103] Ibid s 21(c).

[104] Ibid ss 113-114.

[105] Ibid s 123(5).

Function	Key activities
	to time publishes a list of manufacturers holding licenses.[106]
Cooperating with the Commonwealth and state and territory governments and authorities to facilitate a consistent approach to assessing and controlling agricultural and veterinary chemicals[107] and encouraging and facilitating the introduction of uniform national procedures for control of the use of chemical products.[108]	The APVMA participates in an Interagency Regulators Forum, Jurisdictional Spray Drift Working Group, Registration Liaison Forum and the Harmonised Agvet Chemicals Control of Use Task Group with Commonwealth and state/territory regulators, along with the Regulatory Science Network with Commonwealth chemical regulators to facilitate interagency cooperation. [109]
Developing, in cooperation with Commonwealth and state and territory governments and authorities, codes of practice, standards and guidelines, and recommend precautions be taken in relation to the manufacture, import and export, sale, handling, possession, use, storage and disposal of chemical products.[110]	The APVMA produces a range guidance materials and standards including: • the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 which specifies purity standards for active constituents; • health-based acceptable daily intakes for agvet chemicals;[111] • a Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for agvet chemicals;[112] • maximum residue levels for agvet chemicals, mandatory withholding periods between the last administration of agvet chemicals and the slaughter or collection of animals or crops for human consumption, and advisory intervals between last administration and export of livestock for slaughter;[113] and • the Australian Code of Good Manufacturing Practice for veterinary chemical products.[114]

[106] Ibid s 128.

[107] Administration Act s 7(1A)(e).

[108] Ibid s 7(1A)(k).

[109] APVMA, *Annual Report 2021-22* (Annual Report, 21 October 2022) 48-49.

[110] Administration Act s 7(1A)(f).

[111] 'Acceptable Daily Intakes for Agricultural and Veterinary Chemicals', *APVMA* (Web Page, 2023) https://apvma.gov.au/node/26596.

[112] 'FAISD Handbook', *APVMA* (Web Page, 2023) https://apvma.gov.au/node/26586.

[113] For an overview of these limits and guidance, see 'Pesticides and Veterinary Residues', *APVMA* (Web Page, 2022) https://apvma.gov.au/node/10806.

[114] APVMA, *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products* (Code of Practice, 2007).

Function	Key activities
Encouraging and facilitating the use of results generated from testing and evaluating chemical products.[115]	The APVMA compiles a list of acute reference doses (maximum safe doses) for agvet chemicals, drawn directly from the conclusions of scientific studies.[116]
Exchanging information relating to chemical products with overseas and international bodies with similar functions to the APVMA.[117]	In the 2021-2022 financial year, the APVMA participated in 34 international forums as an observer, participant, presenter, board member or delegation lead; and attended meetings with 11 regulators or groups of regulators.[118]
Reporting to and advising the Minister on any matter relating to chemical products or arising in the course of performing its functions, when requested by the Minister or of its own initiative.[119]	Various.
Monitoring, investigations and enforcement	
Funding and cooperating in a program designed to ensure that active constituents, chemical products and labels comply with the Agvet codes and Agvet regulations.[120]	The APVMA undertakes a range of compliance and enforcement activities designed to ensure that products comply with agvet legislation including: • issuing stop supply and recall notices for defective or non-compliant products under Pt 6 of the Agvet Code, investigations and action for defective or non-compliant agricultural and veterinary chemicals or labels; • conducting investigations and taking enforcement action in alignment with existing policies and guidelines and publishing the outcomes of these investigations. To conduct investigations, the APVMA may issue notices requiring a person to attend, given information or produce documents or things,[121] obtain and execute monitoring warrants[122] and investigation warrants.[123] The

[115] Administration Act s 7(1A)(h).

[116] 'Acute Reference Doses for Agricultural and Veterinary Chemicals', *APVMA* (Web Page, 2023) https://apvma.gov.au/node/26591.

[117] Administration Act s 7(1A)(i).

[118] APVMA, *Annual Report 2021-22* (Annual Report, 21 October 2022) 50-53.

[119] Administration Act s 7(1A)(j).

[120] Administration Act s 7(1A)(l).

[121] Agvet Code s 130.

[122] Agvet Code ss 131A, 143.

[123] Agvet Code ss 132, 132A-C, 143A.

Function	Key activities
	APVMA may also obtain civil penalty orders[124] or apply for injunctions; and[125] • compliance activities to ensure the continued safety and efficacy of registered products, and to address the risk associated with unregistered products, including issuing formal warnings,[126] infringement notices,[127] enforceable directions,[128] and cancelling or suspending permits, approvals and registrations.[129]

[124] Agvet Code s 145A.

[125] Agvet Code s 145F.

[126] Agvet Code s 145J; Administration Act s 69EO.

[127] Agvet Code s 145DA.

[128] Agvet Code s 145H(5)

[129] Agvet Code ss 34N, 118, 119.