

Chapter 2

Performance of the APVMA

2.1 Over the past decade, the APVMA has been the subject of considerable review, and legislative and regulatory intervention. While the work of the authority came into sharp focus following the November 2016 relocation announcement, concerns about various aspects of the APVMA's performance, including the timeliness of assessments and need for risk-management frameworks, preceded the relocation announcement.

2.2 A number of submitters suggested the relocation to Armidale was an additional burden imposed on an authority already facing considerable challenges. The argument was put to the Committee that, by exacerbating existing concerns and causing a loss of scientific expertise, the relocation has jeopardised the authority's ability to effectively and efficiently regulate Australian pesticides and veterinary medicines. It was also argued that the authority's international reputation was at stake, with flow-on effects to Australia's international trade. In addition, it was suggested the relocation occurred at a time of growing complexity in regulatory assessments.

2.3 This chapter considers the regulatory performance issues identified prior to the authority's move to Armidale. It also contemplates the consequences of the relocation on the APVMA's performance, including evidence that raised concerns the authority may experience significant delays in regaining the necessary scientific and technical expertise required to perform its regulatory functions effectively and efficiently. The chapter also considers the impact of any such delays, particularly on farmers and their need for timely access to necessary chemicals.

Previously identified issues in relation to regulatory performance

2.4 Since 2006, a number of reviews have been conducted into the APVMA and a range of regulatory and legislative measures that have been implemented.

Australian National Audit Office 2006 audit report

2.5 A 2006 Australian National Audit Office (ANAO) report examined whether the APVMA was performing its key regulatory functions effectively, with a focus on the delivery of regulation; timeliness of assessments; use of external scientific advice; quality monitoring; and the authority's cost recovery framework.¹

2.6 The ANAO made a number of findings and recommendations, including:

- the authority needed to better manage the risk of actual or perceived conflict of interest;
- the APVMA was not meeting legislative obligations to finalise all applications within statutory timeframes and there were no adequate systems

1 Australian National Audit Office (ANAO), *Regulation of Pesticides and Veterinary Medicines*, Audit Report No. 14, 2006–2007, p. 14.

and processes to provide assurance that the time recorded to measure performance was reliable or reflected actual performance;

- a more contestable approach to obtaining scientific advice from Australian government agencies should be considered, which might lead to greater efficiencies in the allocation of resources; and
- manufacturers' compliance with quality standards required improvement.²

Productivity Commission review 2008

2.7 A 2008 Productivity Commission review also identified issues with the efficiency and timeliness of APVMA assessments. It recommended the costs of chemical assessments be made commensurate with the risks of the chemicals concerned. The Productivity Commission also suggested the authority's priorities be directed to the 'most efficient management of aggregate risks of all agvet products'.³ Further, it stated:

The efficiency of APVMA assessments could be further improved by rectifying the currently dysfunctional arrangements for registering low regulatory concern products and through greater use of international assessment data.⁴

Department of Agriculture review 2010

2.8 In 2010, the Government directed the then Department of Agriculture, Fisheries and Forestry (DAFF) to consult with the agvet chemical industry to develop measures to improve the efficiency and effectiveness of regulatory arrangements. This resulted in the publication of a report by DAFF titled, *Better Regulation of Agricultural and Veterinary Chemicals*.⁵ According to the Productivity Commission, DAFF's findings in relation to the APVMA were that:

- its processes were inflexible and lacked clarity;
- a one-size-fits-all, rather than a risk-based approach for applications was used; and
- unnecessary data requirements were sometimes imposed on applicants.⁶

2 Australian National Audit Office (ANAO), *Regulation of Pesticides and Veterinary Medicines*, Audit Report No. 14, 2006–2007, pp. 15–20.

3 Productivity Commission, *Chemicals and Plastics Regulation*, July 2008, pp. 199, 206.

4 Productivity Commission, *Chemicals and Plastics Regulation*, July 2008, p. 199.

5 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, pp. 16–17.

6 Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 294; Australian Government, *Better Regulation of Agricultural and Veterinary Chemicals: Regulation Impact Statement*, November 2011.

Agricultural and Veterinary Chemicals Legislation Amendment Act 2013

2.9 The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (2013 Amendment Act) was designed to address some of the issues identified in the DAFF, ANAO and Productivity Commission reviews, in particular issues concerning the authority's efficiency and effectiveness.⁷ It was intended that the Amendment Act would also bring about a significant modernisation of the APVMA's regulatory activities.⁸

2.10 Under the 2013 Amendment Act, the APVMA was required to undertake a number of reforms from 1 July 2014, including:

- new regulatory guidance to industry under reformed legislative arrangements;
- a structured, upfront pre-application assistance scheme for applicants;
- a system to electronically receive all applications online;
- stricter preliminary assessment arrangements focussing on basic application requirements and restricting the ability of the applicant to rectify a defect in an application during this phase of assessment;
- revised maximum assessment timeframes based on the type of application being made, including increased time for assessment of certain product and chemical applications;
- additional requirements for the review of registered products and chemicals, and statutory timeframes for completing chemical reviews; and
- procedural, technical and transitional arrangements, including limiting acceptance of additional material from applicants and introducing requirements to provide notices of certain proposed decisions to applicants.⁹

2.11 The legislation also included two provisions that would give the APVMA the ability to better target its resources by:

- allowing the APVMA to implement a risk-based regulatory framework to direct resources towards areas of high risk; and
- introducing a new range of enforcement powers to permit a more graduated response to non-compliance.¹⁰

7 Paula Pyburne, *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012*, *Bills Digest No. 89*, 2012–13, Parliamentary Library, Canberra, 2013, pp. 8–11.

8 Paula Pyburne, *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*, *Bills Digest No. 78*, 2017–18, Parliamentary Library, Canberra, 2018, p. 4.

9 Paula Pyburne, *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*, *Bills Digest No. 78*, 2017–18, Parliamentary Library, Canberra, 2018, p. 4; Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, p. 17.

10 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, p. 17.

2.12 The 2013 Amendment Act included the introduction of a mandatory scheme for re-approval and re-registration of registered products. This provision was repealed by the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*.¹¹

Audit report of the 2013 Amendment Act reforms

2.13 A 2017 ANAO audit of the 2013 Amendment Act reforms produced mixed findings, noting the full scope of the reforms had yet to be implemented. In particular, the ANAO found the risk-based regulatory framework and upgrades to internal IT systems to support the achievement of legislative objectives had not been implemented. It also noted the APVMA was not in a position to determine the extent to which the reform objectives had been met due to the absence of a robust set of performance measures.¹²

2.14 Further, the ANAO reported that ongoing assessment of agvet product and chemical applications was not supported by fit-for-purpose workflow management systems or a robust quality control framework.¹³

2.15 With regard to the workflow management system, the ANAO found a number of shortcomings in the system had contributed to assessment delays. In particular:

- the existing internal system portal did not include sufficient information on the progress of assessments to support effective monitoring, tracking of assessment progress was fragmented, assessors had to review standalone spreadsheets to confirm the status of applications and track the progress of assessments, and assessment staff could not directly transfer records and data; and
- the existing external system portal did not provide sufficient information to applicants to track the progress of their applications, and the APVMA responded to applicant queries with general information on the assessment but no estimates of likely completion timeframes.¹⁴

2.16 The ANAO warned that the 'the absence of a fit-for-purpose internal quality framework' had limited the APVMA's ability to provide 'assurance that assessments are undertaken in accordance with legislative requirements and are appropriately evidenced'.¹⁵

11 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, p. 17.

12 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, p. 8.

13 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, p. 8.

14 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, pp. 27, 30–32.

15 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, p. 32.

2.17 With regard to quality control, the ANAO found whilst some assessment areas within the APVMA undertook peer review of technical assessment decisions, there was no integration or documentation of quality peer review processes across assessment streams. Although the regulator had begun work on an internal quality control framework in 2014–15, the ANAO noted the work was suspended in December 2016 with the intention it be restarted in early 2017. The ANAO recommended the implementation of a quality framework to which the APVMA agreed.¹⁶

2.18 However, the APVMA's *Annual Report 2017–18* noted work on the internal quality framework would not be implemented until after the organisation completed its move to Armidale.¹⁷ Thereafter, in May 2018, the APVMA released its *Digital Strategy 2018–2022*, which acknowledged continuing workflow management issues in both the internal portal and external portal:

The internal portal supports the processing of client applications across multiple business areas. The external portal provides agvet information to clients and stakeholders as well as the functionality to lodge and manage their applications. However, the ICT systems that support these portals are fragmented, most workflows are not automated and there is no integrated single repository of information to effectively extract and manage data for business reporting or analytics.

As a result, business areas are continuously required to obtain data from both portals to perform their work activities. This process is performed manually by staff developing off-system access databases and spreadsheets to manage and store information relating to client applications—leading to increased staff effort and time taken to perform their work activities.

A client application may also require input from multiple scientific teams across the business to perform assessments and approvals but not all business areas have visibility or access to data that is being stored by individuals. This is again contributing to increased staff effort to find data sources, and remove or cleanse duplicate data. Investment in the APVMA's digital strategy will automate workflows and unlock opportunities for incremental productivity gains in scientific assessment and registration areas and application management.¹⁸

2.19 The *Digital Strategy 2018–2022* contains no clear indication of a timeframe for significant improvement, though the APVMA stated the Government had provided funding over three years from mid-2018 for its implementation.¹⁹ The strategy

16 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, pp. 32–33.

17 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, p. 53.

18 Australian Pesticides and Veterinary Medicines Authority, *Digital Strategy 2018–2022*, p. 9.

19 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 5, 27.

identifies workflow management as a 'future state' to be achieved through a 'multi-stage, multi-year stabilisation, modernisation, and transformation journey'.²⁰

Agricultural Competitiveness White Paper 2015

2.20 Whilst the reforms instituted by the 2013 Amendment Act were being implemented, in 2015 the Government released the *Agricultural Competitiveness White Paper* (the white paper). The white paper called for streamlining the regulation of agvet chemicals to improve access to products to enable greater competitiveness.²¹

2.21 The white paper suggested that Australian agvet chemical regulation imposes a 'large regulatory burden' and explained that:

It is often disproportionate to the risks these products pose. This slows access to newer and better products and increases chemical cost. Australian producers often cannot access the chemicals they need to improve their competitiveness and manage resistance. Overseas producers can gain an advantage in accessing new chemicals well before their Australian counterparts.²²

2.22 In the white paper, the Government signalled its intention for the APVMA to:

- limit pre-market assessments of low- and medium-risk products;
- recognise assessments from accredited third party suppliers and trusted chemical regulators;
- examine risks different in the Australian market where products are available in trusted overseas countries, for instance different human health requirements, agricultural practices, environmental assets; and
- explore opportunities with states and territories to improve post-market compliance and national control of chemical use.²³

Productivity Commission regulation report 2017

2.23 In 2017, the Productivity Commission released its report on the *Regulation of Australian Agriculture*, recommending the removal of unnecessary barriers to accessing agvet chemicals.²⁴ Despite previous reviews and reforms, the Productivity Commission identified problems in relation to regulation, including unnecessarily lengthy, complex and duplicative registration procedures.²⁵

20 Australian Pesticides and Veterinary Medicines Authority, *Digital Strategy 2018–2022*, p. 17.

21 Department of Agriculture and Water Resources, *Submission 9*, p. 10.

22 Australian Government, *Agricultural Competitiveness White Paper*, 2015, p. 37.

23 Australian Government, *Agricultural Competitiveness White Paper*, 2015, pp. 37–38.

24 Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 291.

25 Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 291.

2.24 The Productivity Commission also recommended the APVMA increase its use of international assessments and decisions for products already registered by trusted comparable regulators overseas.²⁶

2.25 The Government recently responded to this report, stating there had been a legal direction to the APVMA from the Chief Executive Officer that required staff to maximise the use of international assessments supplied with an application in order to improve the efficiency and timeliness of assessments.²⁷ This matter is discussed further in chapter 3.

Operational Efficiency Bill 2017

2.26 More recently, the Government introduced new legislation aimed at improving the APVMA's efficiency. The Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 aims to amend various statutes relating to agvet chemical products to bring about a number of changes. The new legislation is designed to:

- simplify reporting requirements for annual returns;
- increase the ability of the APVMA to manage errors in an application at the preliminary assessment stage;
- enable the APVMA to grant part of a variation application under clause 27 of the Agvet Code;
- enable a person to apply to vary the relevant particulars or conditions of a label approval that is suspended, to the extent that the variation relates to the grounds for suspension;
- establish civil pecuniary penalties for contraventions of provisions relating to providing false or misleading information;
- amend the notification requirements in clause 8E of the Agvet Code, relating to food standards;
- amend the definition of expiry date in the Agvet Code to mean the date after which a chemical product 'must not' be used; and
- make minor and technical amendments including the repeal of redundant provisions.²⁸

2.27 Later government amendments to the bill introduced in the Senate sought to establish a governance board for the regulator that would:

26 Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 291.

27 Australian Government, *Productivity Commission Inquiry into the Regulation of Australian Agriculture: Australian Government Response*, January 2019, p. 11.

28 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2017*, 15 November 2017, p. 1; Department of Agriculture and Water Resources, *Submission 9*, p. 10.

- ensure the proper, efficient and effective performance of the APVMA's functions;
- determine objectives, strategies and policies to be followed by the APVMA; and
- do anything incidental to or conducive to the performance of the functions referred to above.²⁹

Streamlining Regulation Bill 2018

2.28 Further legislative amendment has been proposed by the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, which includes provisions aimed at simplifying a number of the APVMA's processes, including—but not limited to—approval and registration processes, voluntary recalls, computerised decision-making and accreditation of assessors.³⁰

2.29 This bill is currently subject to a separate inquiry by the Rural and Regional Affairs and Transport Legislation Committee.³¹

History of the relocation to Armidale and identification of risks

2.30 In June 2016, in response to an election commitment to create centres of excellence in agriculture, the Government announced that 'within the first year of re-election, the Coalition will proceed with the relocation of the APVMA to Armidale, New South Wales'.³²

2.31 On 23 November 2016, the Minister for Finance, Senator the Hon Mathias Cormann made the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*. It specified the location of the APVMA was to be in a regional community—not within 150 kilometres by road of Canberra or the capital city of a state, and within 10 kilometres by road of the main campus of a regional university—previously announced as Armidale.³³

29 Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017, Revised JC512. See also: Supplementary Explanatory Memorandum, and Revised Supplementary Memorandum, https://www.apvma.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=r6004 (accessed 21 January 2019).

30 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 1; Department of Agriculture and Water Resources, *Submission 9*, pp. 10–11.

31 On 29 November 2018, the Senate moved that the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 be referred to the Senate Rural and Regional Affairs and Transport Legislation Committee for inquiry and report by 11 February 2019. *Journals of the Senate*, No. 133, 29 November 2018, p. 4322.

32 The Coalition's Policy for a Stronger Agriculture Sector, June 2016, p. [7], quoted in Senate Finance and Public Administration References Committee, *Operation, Effectiveness, and Consequences of the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*, June 2017, p. 3.

33 Senate Finance and Public Administration References Committee, *Operation, Effectiveness, and Consequences of the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*, June 2017, p. 3.

2.32 Prior to the government announcement, Ernst and Young had conducted a cost, benefit and risk analysis, which concluded that the 'strategic and operational benefits of having the APVMA operate out of Armidale appear to be limited'.³⁴

2.33 The Ernst and Young report identified a number of risks associated with the relocation:

- the APVMA may be unable to relocate, or recruit and replace key APVMA executive, management and technical assessment staff;
- during transition and in the short term, the APVMA may not be able to sustain its rate of effort for registration of new agricultural and veterinary chemical products;
- the APVMA may be unable to maintain and grow its capability in the medium term; and
- the APVMA may have reduced access to stakeholders.³⁵

2.34 The most significant risk identified by the Ernst and Young report was the loss and replacement of staff. This concern had been raised earlier as a risk by the then APVMA Chief Executive Officer (CEO), Ms Kareena Arthy. In 2015 in a letter to then Minister for Agriculture and Water Resources, the Hon Barnaby Joyce MP, Ms Arthy stated:

It is highly questionable whether recruitment of the scale needed to get the APVMA back to full strength in terms of scientific capability would be possible in a capital city let alone a regional centre. Finding a minimum of 55–60 scientists with sufficient attributes or experience either in the region or willing to move to the regional location would be difficult and would take time...it could be years before capability is restored.³⁶

2.35 Evidence received by the Committee indicated that there was little industry support for the relocation of the APVMA. National Farmers' Federation members voted against the relocation in June 2015 and issued a statement:

Many of the 170 staff at the APVMA are highly technical, specialist regulatory scientists whose expertise cannot be easily replaced if they choose to accept a redundancy package. This loss of capacity could add years to approval timeframes which are already failing to meet statutory

34 Senate Finance and Public Administration References Committee, *Operation, Effectiveness, and Consequences of the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities)* Order 2016, June 2017, p. 10.

35 Senate Finance and Public Administration References Committee, *Operation, Effectiveness, and Consequences of the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities)* Order 2016, June 2017, p. 17.

36 Letter from Ms Kareena Arthy (APVMA CEO) to the Hon. Barnaby Joyce MP, 31 July 2015, p. 3, quoted in Senate Finance and Public Administration References Committee, *Operation, Effectiveness, and Consequences of the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities)* Order 2016, June 2017, p. 17.

requirements. The farm sector has a lot to lose if new chemical technologies are stuck in the approval process and can't get to market.³⁷

2.36 The loss of staff and expertise as a consequence of the proposed move was again foreshadowed by the CEO in December 2016 in a letter to industry stakeholders who were advised of staff departures and the loss of 50 per cent of the agency's chemical residues team. According to Chemistry Australia, the letter said the APVMA had 'exhausted all avenues to bring new people in or identify suitably qualified external assessors to address the immediate issues'. Further, the APVMA was understaffed in the pesticides, health assessment, environment and chemical review areas as a consequence of staff leave arrangements, departures, and difficulties recruiting suitably skilled and experienced people.³⁸

Announcement of the satellite Canberra office

2.37 In mid-2018, Dr Chris Parker, CEO of the APVMA, announced that the APVMA would maintain a satellite office in Canberra. Dr Parker advised that on 28 June 2018, prior to making the news public, he had informed the Minister for Agriculture and Water Resources, the Finance Minister, and DAWR of the decision.³⁹

2.38 In explaining his decision to maintain a satellite office, Dr Parker stated:

Our existing plans for teleworking, an enhanced reliance on external scientific assessors and recruitment into Armidale have not reduced our relocation risks to an acceptable level and more must be done...Retaining the knowledge and expertise of our scientists is essential to the effective operations of the APVMA and accommodating these staff in a Canberra office further supports the APVMA to deliver its statutory obligations.⁴⁰

2.39 At Senate Estimates in October 2018, Dr Parker indicated he had received legal advice concerning the validity of his decision, given that the November 2016

37 National Farmers' Federation, *NFF Raises Concerns Over Agency Relocations*, 19 June 2015, <https://www.nff.org.au/read/4989/nff-raises-concerns-over-agency-relocations.html> (accessed 9 January 2019). See also: NSW Farmers' Association, *Submission 8*, p. 13; National Farmers' Federation, *Submission 27*, p. [3]; Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, p. 58.

38 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, answers to questions on notice, 7 December 2018 (received 20 December 2018).

39 Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Estimates Hansard*, 23 October 2018, p. 103.

40 Brett Worthington, 'Quarter of APVMA Staff Will Remain in Canberra, After Barnaby Joyce Shifted Agency to Armidale', *ABC News*, 1 July 2018, <https://www.abc.net.au/news/2018-07-02/apvma-allows-some-staff-to-remain-in-canberra/9930670> (accessed 9 January 2019).

Order required the APVMA to be located in a regional community. This legal advice was subsequently provided.⁴¹ It stated:

The APVMA is to relocate its regulatory and corporate operations to Armidale, New South Wales. There is nothing to preclude the APVMA from also operating an office in Canberra to the extent that it is necessary to perform its legislative functions, providing in doing so it does not unnecessarily frustrate the policy objective set out in the order made under section 22(1) of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).⁴²

Current implications

Loss of experienced staff

2.40 In November 2017, Dr Parker expressed the view that the relocation to Armidale had 'disrupted our operations, and the departure of staff has impacted on our productivity and brought many underlying historical faults to the surface'. He concluded that the relocation is a 'challenge and there are risks that we continue to manage'.⁴³

2.41 This view was supported by the Secretary of DAWR, Mr Daryl Quinlivan, who stated:

I think what did become clear to us was that there were quite a number of underlying problems in the authority, and as often happens with an organisation, they're not that evident until the organisation's put under stress. It's clear that the relocation did do that. It did place the authority under stress, and so deficiencies in the organisation's financial structure, IT systems and so on became more evident.⁴⁴

41 The APVMA provided this legal advice as additional information to the Rural and Regional Affairs and Transport Legislation Committee arising from the Senate Estimates hearing on 23 October 2018. See: Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, Letter to the Chair and Legal Advice Pertaining to the Maintenance of a Canberra Satellite Office of the APVMA, additional information received 26 October 2018. The legal advice was also tabled to the Rural and Regional Affairs and Transport References Committee. See: Australian Pesticides and Veterinary Medicines Authority, *Correspondence from Dr Chris Parker, CEO, APVMA to Senator Barry O'Sullivan, Chair, RRAT Legislation Committee dated 26 October 2018 – re 'Legal advice pertaining to the maintenance of a Canberra Satellite Office of the APVMA'* (tabled 20 November 2018).

42 Australian Pesticides and Veterinary Medicines Authority, *Correspondence from Dr Chris Parker, CEO, APVMA to Senator Barry O'Sullivan, Chair, RRAT Legislation Committee dated 26 October 2018 – re 'Legal advice pertaining to the maintenance of a Canberra Satellite Office of the APVMA'*, (tabled 20 November 2018), p. [2].

43 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, pp. 8–9; Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 20 November 2018, p. 2.

44 Mr Daryl Quinlivan, Secretary, Department of Agriculture and Water Resources, *Estimates Hansard*, 23 October 2018, p. 106.

2.42 Particular concern was raised throughout the inquiry about the loss of experienced specialist scientists. Of a total of approximately 190 staffing positions in the APVMA, 90 are for regulatory scientists. In terms of filling the scientists' positions, as of November 2018, the authority had:

- six scientists who had relocated to Armidale from Canberra;
- 20 scientists who had been recruited in Armidale; and
- approximately 40 scientists working at the Canberra satellite office.⁴⁵

2.43 The scientists based in Canberra are expected to remain with the APVMA until the authority transitions to Armidale in mid-2019, after which time they would seek either redeployment or redundancy. In the meantime, the APVMA is conducting a recruitment process to fill the remaining positions. Dr Parker indicated that the authority expected to have 150 staff (including scientists and others) in Armidale when its permanent office opens in mid-2019.⁴⁶

2.44 A considerable amount of evidence to the Committee focused on the impact of the decision to relocate the authority to Armidale, particularly in relation to the loss of staff and scientific expertise, and its impact on the progress of chemical evaluations.⁴⁷ The point was also made that the APVMA has lost a number of support and other staff, many of whom were actively involved in the manufacturing and licencing aspects of the APVMA's work.

2.45 CropLife Australia submitted:

The APVMA's staff separation rate increased from 11.8 per cent in the 2014–15 financial year to 23.7 per cent in 2016–17. During the 2016–17 financial year, the APVMA lost more than 270 years of experience with the Regulator. The disruption of the relocation of the APVMA is likely to be felt for some years after implementation. Consequently, substantial reform is still urgently required to assist the APVMA during this very challenging period.⁴⁸

2.46 In its *Annual Report 2017–18*, the APVMA acknowledged its staff separation rate for ongoing staff in 2017–18 had increased to 36 per cent.⁴⁹

45 Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority; Ms Lisa Croft, Deputy Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 20 November 2018, pp. 4, 7.

46 Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, Opening Statement (tabled at a Supplementary Budget Estimates hearing on 23 October 2018), p. 3.

47 CropLife Australia, *Submission 10*, p. 12; Grain Producers Australia, *Submission 11*, p. 2; AUSVEG, *Submission 12*, p. [3]; GrainGrowers, *Submission 23*, p. [7]; Victorian Farmers Federation, *Submission 33*, p. [4]; Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, answers to questions on notice, 7 December 2018 (received 20 December 2018).

48 CropLife Australia, *Submission 10*, p. 16.

49 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, p. 15.

2.47 The Victorian Farmers Federation also noted that during the relocation process, 'at least 110 of a total 198 staff members departed the APVMA, including 33 regulatory scientists'.⁵⁰

2.48 In a 2017 report on the APVMA's cost recovery arrangements, PricewaterhouseCoopers (PWC) identified a further staffing complication. The largely demand-driven nature of the APVMA's work (that is, the volume, type and mix of applications for assessment, and consequent post-market activities), made predicting the volume and type of work the authority received difficult. Without the means to reliably forecast the nature of applications, the APVMA could not accurately monitor and adjust its staffing profile to ensure it retained staff with the required skills to process the range of applications submitted to the authority.⁵¹

2.49 Further, PWC stated that as a consequence of the period of organisational change, management level staff were spending increasing amounts of time on non-registration related activities; and an increased proportion of time was being spent on general application processing, which external stakeholders attributed to staff turnover and loss of technical knowledge.⁵²

2.50 Evidence received by the Committee also raised particular concern about the period of time it would take the authority to rebuild its scientific and technical expertise. Grain Producers Australia stated 'companies expect it is likely to take up to 5 years for the APVMA to recover from the current lack of technical staff resources, with all companies noting there is a global shortage of regulatory experts'.⁵³ Other submissions concurred with this assessment.⁵⁴

2.51 There was, however, some confidence expressed that expertise would be rebuilt. The Australian Glyphosate Sustainability Working Group suggested:

It remains to be seen how long it takes for them to get back up to speed after the move. Certainly they have lost a lot of staff, and it's not always easy to attract staff of the right calibre to this particular area. It is a very specialist area, and you don't have lots of people available for it. But I certainly would expect that, in time, they'll get back to what they were.⁵⁵

50 Victorian Farmers Federation, *Submission 33*, p. [4].

51 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, p. 8.

52 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, p. 13.

53 Grain Producers Australia, *Submission 11*, p. 12.

54 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, Answers to Questions on Notice, 7 December 2018 (received 20 December 2018), p. 2; Victorian Farmers Federation, *Submission 33*, p. [4].

55 Dr Christopher Preston, Chair, Australian Glyphosate Sustainability Working Group, *Committee Hansard*, 7 December 2018, p. 9.

Delayed assessments

2.52 The ANAO found in 2017 that there had been issues with the APVMA's efficiency for many years. It noted there had been improved reported performance in the period 2014–2016, followed by a decline in the six months to March 2017. These fluctuations in the timeliness of assessments took place while a backlog of overdue assessments grew during 2016.⁵⁶

2.53 The APVMA has more recently reported improved regulatory performance, with on-time assessment of agricultural chemical product, permit and active applications increasing from 60 per cent in 2016–17 to 73 per cent in 2017–18, leaving 27 per cent uncompleted within established timeframes.⁵⁷

2.54 Evidence presented to the Committee suggested that the authority was meeting deadlines for simpler assessments, but it was not making significant progress in meeting deadlines for more complex assessments, and the finalisation of reconsiderations was being delayed.⁵⁸ The Veterinary Manufacturers and Distributors Association stated:

The move to Armidale has quite clearly been disruptive to the work of the APVMA. They've lost a lot of scientists and it hasn't always been easy to replace them. We, as an association, are members of the APVMA Relocation Advisory Committee. Essentially that's an informative body that lets us know what's going on in respect of the move. It's become quite clear to us and our members that the lack of experienced scientists will continue into the future and in the next two or three years things will probably only get worse...Almost all of the actual product applications, whether they be for brand-new products or for generics, are not completed within time frame. About 80 per cent of the applications that the APVMA receives are for those simpler assessments, so you would expect them to be completed within time frame. The rest regrettably are not.⁵⁹

2.55 The inability of the APVMA to meet its targets over an extended period of time led one submitter to question the targets themselves and the broader effect that efforts to meet them might have, particularly in the light of reduced scientific expertise. The NSW Farmers' Association stated:

The consistent failure to meet targets is a sign that the performance indicators poorly reflect the time needed for chemical review and assessment within the APVMA's current operating budget. Increased pressure to complete reviews against current indicators could reduce the

56 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Audit Report No. 56, 2016–2017, pp. 9, 34.

57 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 5.

58 CropLife Australia, *Submission 10*, p. 12; Grain Producers Australia, *Submission 11*, p. 12.

59 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Association, *Committee Hansard*, 7 December 2018, pp. 32–33.

quality of the APVMA's assessment and erode community and industry trust.⁶⁰

Impact of delayed assessments on farmers

2.56 The Committee received concerning evidence that suggested staff turnover and delayed assessments by the APVMA were impacting the ability of farmers to incorporate agvet products into business management and integrated pest management strategies.⁶¹ AUSVEG confirmed this was particularly a concern for Australian growers operating in a global market, where 'timely access to safe, environmentally sustainable and productivity enhancing products is absolutely crucial to ensure the countries [sic] ongoing global competitiveness in food production'.⁶²

2.57 The Chair of the Australian Glyphosate Sustainability Working Group, Dr Christopher Preston, noted the impact of the delays, stating:

We don't necessarily want fast decisions on everything, because some things are complex. However...it has certainly been my impression that the disruption caused by the move to Armidale has really slowed down the potential introduction of products. I'm now told that products that I was hearing about that we might have in time for sowing in 2019 are going to be in 2020. I had a meeting with UPL [UPL Australia Limited] earlier this week about a product...The case manager for that product has now left the APVMA. They were hoping for a release in time for sowing in 2019. It's unlikely that will happen now.⁶³

2.58 Grain Producers Australia submitted that it had conducted a survey of chemical companies on the effects of current regulatory delays, which found that companies had experienced at least a 12 month delay over and above the statutory timeframes on several new chemical products. It continued:

All companies had examples of at least one or more new product applications that had missed the 2017 season for growers as a consequence of the delays. The 2017 survey found that the grains industry had a delay in registration of at least 3 major new herbicide/fungicide actives resulting in a collective minimum direct loss through lack of the technology benefits these products deliver to grain growers of at least \$200 million and up to \$500 million, potentially compounding if pesticide resistance evolution that these new products resolve tracks faster than expected. Assessments had significantly slowed since November, particularly OH&S/Health and Environment.⁶⁴

60 NSW Farmers' Association, *Submission 8*, pp. 13–14.

61 NSW Farmers' Association, *Submission 8*, p. 12; Victorian Farmers Federation, *Submission 33*, p. [3]; Mr Ben Stapley, Executive Director, Animal Medicines Australia, *Committee Hansard*, 7 December 2018, pp. 37–38.

62 AUSVEG, *Submission 12*, p. [3].

63 Dr Christopher Preston, Chair, Australian Glyphosate Sustainability Working Group, *Committee Hansard*, 7 December 2018, p. 9.

64 Grain Producers Australia, *Submission 11*, p. 11.

2.59 Grain Producers Australia estimated that if the delays in new chemical mode of action products continue for another two years with a delay of 12 months on major projects, particularly new mode of action herbicide and fungicide products, 'the minimum impact through lost productivity and accelerated pesticide resistance evolution to the grains industry would be well over \$1 billion'.⁶⁵

2.60 The NSW Farmers' Association warned that gaps in chemistry not only led to decreased productivity, but could also incentivise off-label use. With improved timeframes for product registration, the association argued that demand on minor use products would likely reduce and access to new chemistry would be improved.⁶⁶

2.61 The Australian Dairy Industry Council and Dairy Australia identified that broader activities undertaken by the APVMA had also been affected by the reduced availability of staff. They stated:

We have observed that APVMA staff have little capacity to spend time on some of the more strategic projects initiated with the dairy industry. For example, amending the teat sanitiser efficacy guidelines or regulating dairy sanitisers via a Standard.⁶⁷

Global regulator trends: increasing workloads, complexity and failure to meet timeframes

2.62 The disruption to the regulator caused by the relocation to Armidale has been exacerbated by issues being experienced globally; specifically, increasing scientific and regulatory complexity. The Committee heard, for example, that several international regulators are also failing to meet some timeframes for assessments.

2.63 According to the Productivity Commission, in recent years the scope of products that the APVMA regulates had expanded for reasons including advances in technology, increases in generic products, and changes to farming practices, amongst other factors.⁶⁸

2.64 A trend towards increasing regulatory complexity has also impacted the timeliness of assessments globally. An independent report found there was growing complexity in the type of residue assessments now being undertaken by the APVMA, requiring more time and expertise than previously.⁶⁹ Similarly, the European Union reported increases in evaluation times for efficacy assessments due to increasing numbers of crop/uses covered in each application and increasing complexity of

65 Grain Producers Australia, *Submission 11*, p. 11.

66 NSW Farmers' Association, *Submission 8*, p. 11.

67 Australian Dairy Industry Council and Dairy Australia, *Submission 25*, p. 3.

68 Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 296.

69 The APVMA uses a residues complexity measure called 'ROCI' to prioritise assessments, support work forecasting and report on performance. This index almost doubled between 2009 and 2016. Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, pp. 11, 13.

environmental fate evaluations. In the United Kingdom, the evaluation time for assessments increased by 70 per cent between 2007 and 2015.⁷⁰

2.65 In addition to addressing the growing complexities, the APVMA provided some context in relation to the extent of its current workload:

We regulate over 11,500 agvet chemical products, managed by over 900 registrants...APVMA email correspondence exceeds a million sent and received in an average year. We respond to more than 6,300 phone calls to our general inquiries line and answer and respond to feedback through our online systems and website. It is not unusual to have a few hundred emails, largely on administrative matters, be sent between one agency and any one industry body.⁷¹

2.66 An independent review of the APVMA's performance in 2017 assessed its performance against comparable international agencies. The review showed agencies around the world were not meeting statutory or policy timeframes, though timeframes and assessment processes varied significantly.⁷²

2.67 For instance, reviews by the European Commission of active substances intended for use in plant protection products were scheduled to be completed within a statutory timeframe of 2.5 to 3.5 years. The Commission achieved a 75 per cent completion rate within statutory timeframes in 2016. The Canadian Pest Management Regulatory Agency (PMRA) had a policy timeframe of between 80 and 737 days for completing assessments. It met this time frame for between 87 and 95 per cent of cases in 2015–16.⁷³

2.68 Many international regulatory agencies have the ability to 'stop the clock' on assessment timeframes while awaiting information from applicants. They also have the ability to assess the technical completeness of data prior to the acceptance of the application (when the regulatory clock starts). It has been suggested that the APVMA's limited ability to do this puts extra pressure on its capacity to meet timeframes.⁷⁴

Training regulatory scientists

2.69 In 2017, an independent assessment of Australia's regulatory science workforce needs, commissioned by the Department of Health's Environmental Health

70 Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, pp. 5, 19.

71 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, pp. 8–9; Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 20 November 2018, p. 2.

72 Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, pp. 11, 37.

73 Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, pp. 11, 37.

74 Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, pp. 11, 37.

Standing Committee (enHealth), found there was no single type of qualification required by the regulatory scientists who were dispersed in Australia across a number of sectoral and organisational settings. These included the APVMA, the Therapeutic Goods Administration (TGA), the Department of Environment and Energy, the OGTR, and FSANZ.⁷⁵

2.70 The report, *Assessment of Australia's Regulatory Science Workforce Needs*, found that much of the training for regulatory scientists was in the form of job-specific experience and mentoring.⁷⁶ This finding was supported by the APVMA's 2016 *Regulatory Science Strategy*, which stated:

While regulatory science incorporates a variety of scientific disciplines, it is a specialised field of science. Most regulatory scientists have trained and worked in scientific research and have experienced a process of on-the-job training, mentoring and ongoing peer support to transition into regulatory science. Regulatory scientists are trained in risk analysis—comprising risk assessment, risk management and risk communication—as well as being trained in public administration and regulatory decision-making.⁷⁷

2.71 The Committee heard evidence about the very significant difficulties the APVMA faces in recruiting and training new staff, particularly as staff need to have experience as a regulatory scientist, as well as strong scientific knowledge. AgForce Queensland noted that the regulatory scientists for pesticides have considerable experience and that it is often people 'later in their career lives who are doing that type of work'.⁷⁸

2.72 The Veterinary Manufacturers and Distributors Association noted:

By the APVMA's own admission, it takes three years to train a scientific regulator, and there's a hell of a difference between scientific assessments and regulatory processes and procedures that require a knowledge of the law and all sorts of other legislative aspects of the APVMA's operations.⁷⁹

2.73 The particular skills needed by regulatory scientists was further detailed by Chemistry Australia who suggested the establishment of a university-based regulatory science centre to educate and train regulatory scientists to meet current APVMA shortages:

75 Human Capital Alliance, *Assessment of Australia's Regulatory Science Workforce Needs: Final Report*, July 2017, p. 15; Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, answers to questions on notice, 7 December 2018 (received 20 December 2018), p. 2.

76 Human Capital Alliance, *Assessment of Australia's Regulatory Science Workforce Needs: Final Report*, July 2017, pp. 10, 36, 38, 43.

77 Australian Pesticides and Veterinary Medicines Authority, *Regulatory Science Strategy*, August 2016, p. 5.

78 Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland Farmers Limited, *Committee Hansard*, 7 December 2018, p. 60.

79 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Association, *Committee Hansard*, 7 December 2018, p. 33.

We've got lots of science schools in Australia. But the APVMA...noted that scientists aren't regulatory scientists, and that for a scientist to become a regulatory scientist takes some time—between three and five years...The concept of this centre is that you'd have a broad based university with schools of law and schools of science that you could bring together to create a program that focuses on the key differences in regulatory science, those being the application of legal principles, the law, to decision-making; and the application of science in a legal framework—not just an investigative activity or a knowledge-building activity but a distinctly regulatory activity that is applying science to decision-making. We don't think that that is what's taught, and we'd like to see something like that.⁸⁰

2.74 Animal Medicines Australia spoke of the impact that an assessor's regulatory experience can have on the nature and quality of assessments:

From our perspective, the key risk associated with that relocation [to Armidale] has been the impact on assessments, the impact on confidence and the ability of the APVMA to provide high-quality assessments. From our members' perspectives, we can always quite clearly identify when a particular application is going to be challenged by the experience of particular staff associated with the APVMA—the particular assessor associated with the APVMA. The APVMA itself has recognised that three to five years experience is necessary to get a high-quality and capable regulatory assessor...

The experience our members often have is that the assessor that they receive on the application...can have a significant impact on the predictability of the outcome of that assessment process...That can go to questions which are asked on a particular assessment...You might get questions which are already answered in a dossier of information provided. You might get questions which are not relevant or misunderstand the application which has been provided by the applicant at the time...

The experience of our members is: the more experienced assessors provide more timely and predictable outcomes.⁸¹

2.75 The issue of building industry-specific expertise, in addition to scientific and regulatory expertise was also raised. The Australian Dairy Industry Council and Dairy Australia stated:

Many of the decisions made by the APVMA are based on assessing the risks of chemical use in particular circumstances, so having a thorough knowledge of the farming systems where chemicals are used would be useful for their evaluators. However many have no background or experience in agriculture. Dairy Australia has delivered presentations to

80 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 48.

81 Mr Ben Stapley, Executive Director, Animal Medicines Australia, *Committee Hansard*, 7 December 2018, pp. 37–38.

[the] APVMA's evaluation staff in the past to help skill them up, and these type of continuing education programs should be encouraged.⁸²

2.76 The Committee heard that a factor compounding the difficulty of the situation was the global shortage of regulatory scientists and a lack of 'competent well qualified graduates to undertake critical roles in the APVMA, such as performing risk assessments'.⁸³

2.77 It is worth noting that the work of enHealth in assessing Australia's regulatory science workforce is ongoing.⁸⁴ The independent report commissioned by enHealth, *Assessment of Australia's Regulatory Science Workforce Needs*, highlighted the APVMA's need for regulatory scientists, and APVMA staff have presented to enHealth on the regulator's staff training program.⁸⁵

2.78 In its *Annual Report 2017–18*, the APVMA stated its intention to be at 'the forefront of regulatory science training', through its 10-month Accelerated Regulatory Science Training Program from which participants graduate with a Diploma of Government (Regulatory Science). The program is intended to develop the skills of the authority's regulatory science staff. There have been three intakes: two in Canberra and one in Armidale. Forty-six staff members have either finished or are undertaking the training.⁸⁶

2.79 The authority also noted it had provided assistance to develop the curriculum for the Graduate Certificate and Graduate Diploma in Science (Regulatory Science) at the University of New England (UNE), both offered for the first time in 2017. Through consultation with UNE, the APVMA had recommended the inclusion of certain core competencies in these courses that were relevant to the needs of the APVMA.⁸⁷

82 Australian Dairy Industry Council and Dairy Australia, *Submission 25*, p. 2.

83 Associate Professor Susan Wilson and Professor Brian Sindel, *Submission 42*, p. [2]. See also: Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, answers to questions on notice, 7 December 2018 (received 20 December 2018), p. 2; Victorian Farmers Federation, *Submission 33*, p. [4]; Human Capital Alliance, *Assessment of Australia's Regulatory Science Workforce Needs: Final Report*, July 2017, p. 6.

84 Department of Health, *Environmental Health Publications: Assessment of Australia's Regulatory Science Workforce Needs (2017)*, <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-environ.htm> (accessed 11 January 2019).

85 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, p. 38; Human Capital Alliance, *Assessment of Australia's Regulatory Science Workforce Needs: Final Report*, July 2017.

86 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, pp. 2, 43.

87 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, pp. 36–37.