

The Senate

Rural and Regional Affairs
and Transport
References Committee

Independence of regulatory decisions made
by the Australian Pesticides and Veterinary
Medicines Authority (APVMA)

February 2019

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Membership of the committee

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Senator Slade Brockman

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Senator Malarndirri McCarthy

Senator Janet Rice

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Queensland, NATS

Western Australia, LP

Queensland, ALP

Northern Territory, ALP

Victoria, AG

Secretariat

Dr Jane Thomson, Secretary
Ms Sarah Redden, Principal Research Officer
Ms Trish Carling, Senior Research Officer
Dr Fiona Allen, Senior Research Officer
Mr Michael Fisher, Research Officer
Mr Max Stenstrom, Administrative Officer

PO Box 6100
Parliament House
Canberra ACT 2600
Ph: 02 6277 3511
Fax: 02 6277 5811
E-mail: rrat.sen@aph.gov.au
Internet: www.aph.gov.au/senate_rrat

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Abbreviations and acronyms

AGMIN	Agriculture Ministers' Forum
Agvet	agricultural and veterinary
Agvet Code	Agricultural and Veterinary Chemicals Code (a schedule in the Agvet Code Act)
Agvet Code Act	<i>Agricultural and Veterinary Chemicals Code Act 1994</i>
Amendment Act	<i>Agricultural and Veterinary Chemicals Legislation Amendment Act 2013</i>
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
COAG	Council of Australian Governments
DAFF	Department of Agriculture, Fisheries and Forestry
DAWR	Department of Agriculture and Water Resources
enHealth	Environmental Health Standing Committee, Department of Health
EPA	United States Environmental Protection Agency
FSANZ	Food Standards Australia New Zealand
GRDC	Grains Research and Development Corporation
IARC	International Agency for Research on Cancer
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
OCS	Office of Chemical Safety, Department of Health
OGTR	Office of the Gene Technology Regulator
PMRA	Canadian Pest Management Regulatory Agency

PPDC	EPA Pesticide Program Dialogue Committee
PWC	PricewaterhouseCoopers
TGA	Therapeutic Goods Administration
UNE	University of New England
White paper	Agricultural Competitiveness White Paper (2015)

List of recommendations

Recommendation 1

6.21 The Committee recommends that the Australian Government undertakes a comprehensive scoping study on the need for regulatory scientists across Australian Government agencies. The scoping study should consider:

- (a) the current educational, training and work experience environment for regulatory scientists;**
- (b) the likely future demand for regulatory scientists and the skills and competencies they will require; and**
- (c) the findings of the Environmental Health Standing Committee (enHealth) on the need for regulatory scientists.**

6.22 In undertaking this study, relevant educational and training bodies, and Australian Government agencies, should be consulted as required.

Recommendation 2

6.23 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority works closely with the Australian education sector to identify and expand integrated learning opportunities that would provide science graduates with experience in regulatory environments.

Recommendation 3

6.29 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority progresses, as a matter of priority, the development and implementation of a robust quality control framework and a fit for purpose workflow management system.

Recommendation 4

6.30 The Committee recommends that the Australian Government takes into consideration the disruption caused by the forced relocation of the Australian Pesticides and Veterinary Medicines Authority (including the ongoing impact on staff capability and capacity), and prioritises a fit-for-purpose and stable workforce over any decentralisation policy.

Recommendation 5

6.39 The Committee recommends that the Australian Government confirms its ongoing support for the Improved Access to Agricultural and Veterinary Chemicals Initiative and provides sufficient funding for the initiative over the forward estimates to ensure its continued operation.

Recommendation 6

6.40 The Committee recommends that the Australian Government commissions an independent assessment of the impact of regulatory costs on the registration of minor use chemicals, with a view to obtaining evidence that would inform policy and consider the availability of minor use chemicals in Australia.

Recommendation 7

6.50 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority consults with key stakeholders to establish a formal mechanism for ongoing liaison and discussion. The forum should develop clear terms of reference which set out its working arrangements, and the minutes of each meeting should be recorded and made public in a timely manner.

Recommendation 8

6.65 The Committee recommends that the Australian Government develops and implements a national strategic plan for agricultural and veterinary pest-control innovation, which addresses Australian specific environmental conditions and pests.

Recommendation 9

6.76 The Committee recommends that the Department of Agriculture and Water Resources and the Australian Pesticides and Veterinary Medicines Authority undertake a formal study of the United Kingdom Pesticides Forum and the United States Environmental Protection Agency Pesticide Program Dialogue Committee with the aim of establishing a similar forum for the Australian regulatory environment.

Chapter 1

Introduction

Referral of the inquiry

1.1 On 16 October 2018, the Senate moved that the following matters be referred to the Rural and Regional Affairs and Transport References Committee (the Committee) for inquiry and report by 1 February 2019:

The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA), with particular reference to:

- (a) the responsiveness and effectiveness of the APVMA's process for reviewing and reassessing the safety of agricultural chemicals in Australia, including glyphosate, and how this compares with equivalent international regulators;
- (b) the funding arrangements of the APVMA, comparisons with equivalent agricultural chemical regulators internationally and any impact these arrangements have on independent evidence-based decision making;
- (c) the roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals;
- (d) the need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products;
- (e) the impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner; and
- (f) any other related matters.¹

Conduct of the inquiry

1.2 Information about the inquiry was made available on the Committee's webpage. The Committee wrote to government departments, industry stakeholder groups, community groups and individuals to invite submissions. The Committee received 110 public submissions. A list of organisations and individuals that made public submissions, together with additional information authorised for publication, is at Appendix 1.

1.3 The Committee also received a large number of form letter submissions. Approximately 110 such submissions raised concerns about pesticides and their impact on bees. Approximately 237 raised concerns about the safety of chemicals in general, the safety of glyphosate more specifically, and the need to ban the use of neonicotinoid-based pesticides. The Committee also received approximately 200 emailed form letters, addressed to the inquiry, but which contained no content.

1 *Journals of the Senate*, No. 123, 16 October 2018, p. 3927.

1.4 The Committee held public hearings on 20 November 2018 and 7 December 2018 in Canberra.

1.5 A list of witnesses who appeared at the hearings is at Appendix 2. Submissions and Hansard transcripts of evidence may be accessed through the Committee's website.²

Acknowledgment

1.6 The Committee thanks all the organisations and individuals who made submissions to the inquiry and appeared before the Committee to give evidence.

Note on references

1.7 References to Hansard are to the proof transcript. Page numbers may vary between the proof and the official (final) Hansard transcript.

Structure and scope of the report

1.8 The report is divided into five chapters. Chapter 1 states the inquiry's terms of reference and provides an overview of the use of pesticides and veterinary medicines in Australia. It concludes by describing the role of the APVMA.

1.9 Chapter 2 discusses previous reviews of the APVMA's performance, the decision to relocate the APVMA to Armidale and its consequences, and how the APVMA's performance compares globally.

1.10 Chapter 3 sets out a brief history of government charging for services and the charging practices of other regulatory agencies in Australia and internationally. It examines the APVMA's funding model and perceptions of the authority's independence. The chapter discusses the impact of the charging framework on the registration of chemicals in Australia, and the use of international data for assessment.

1.11 Chapter 4 details the APVMA's processes for chemical reconsideration and the reconsideration practices of regulators internationally. It examines the process for reconsideration as it applied to glyphosate, and discusses the APVMA's chemical risk approach. It also explores the issue of innovation in the development of products and practices for Australian pests and Australian conditions.

1.12 Chapter 5 broadly examines some of the community concerns raised in evidence about decisions made by the regulator. It discusses social licence; perceptions of a conflict in the mandate of the APVMA; the comprehensiveness of the regulator's assessments; the public availability of data; and the regulator's responsiveness to community concerns. The chapter also examines options to formalise contact between industry and the APVMA, and international models for community consultation forums.

1.13 Chapter 6 provides the Committee's views and recommendations.

2 Senate Rural and Regional Affairs and Transport References Committee, *The Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)*, https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Rural_and_Regional_Affairs_and_Transport

Issues not addressed by the report

1.14 The Committee received several submissions that raised concerns with the lack of uniformity in the way states and territories manage their control-of-use responsibilities for agricultural and veterinary (agvet) chemicals, particularly off-label use.

1.15 This matter was raised by the Productivity Commission in 2016 when it recommended that the Australian, state and territory governments implement a national control-of-use regime (including harmonisation of off-label use provisions) for agvet chemicals by the end of 2018.³

1.16 The Australian Government responded to this report in January 2019. It stated that harmonised models for training and licensing of fee-for-service operators and users of restricted chemical products and schedule seven poisons, and record keeping for agricultural chemicals were finalised in 2017–18. It further noted that full national implementation is required by 2022.⁴

1.17 The Government also noted that it had been working with state and territory governments to implement a Council of Australian Governments (COAG) 2010 direction to harmonise agricultural and veterinary chemical regulation. It further explained that while it has continued to work with state and territory governments, a proposal for harmonising agricultural off-label use is expected to be considered by the Agriculture Ministers' Forum (AGMIN) this year.⁵

1.18 Given that these matters are subject to ongoing discussions at AGMIN at the direction of COAG, the Committee did not investigate them. The Committee did, however, receive a volume of evidence that highlighted significant impediments caused by the lack of a nationally consistent regime. For these reasons, a number of submitters encouraged reform in this area.⁶

3 This recommended followed from an earlier 2008 recommendation of the Productivity Commission. Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 305.

4 Australian Government, *Productivity Commission Inquiry into the Regulation of Australian Agriculture: Australian Government Response*, January 2019, pp. 11–12.

5 Australian Government, *Productivity Commission Inquiry into the Regulation of Australian Agriculture: Australian Government Response*, January 2019, pp. 11–12.

6 See the following submissions for further detail: NSW Farmers' Association, *Submission 8*, p. 11; CropLife Australia, *Submission 10*, p. 16; Western Australian Farmers Federation, *Submission 15*, p. 3; Chemistry Australia, *Submission 17*, p. 2; Associate Professor Christopher Preston, *Submission 19*, p. [2]; Pastoralists & Graziers Association of Western Australia, *Submission 22*, p. 5; Australian Dairy Industry Council and Dairy Australia, *Submission 25*, pp. 1, 3; National Farmers' Federation, *Submission 27*, pp. 2–3; AgForce Queensland Farmers Limited, *Submission 34*, p. [4]; Government of South Australia Primary Industries and Regions SA, *Submission 72*, p. 3. See also: Department of Agriculture and Water Resources, *Proposal to Harmonise Off-Label Use of Agricultural Chemicals*, <http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/domestic-policy/off-label-use-harmonisation-proposal> (accessed 3 January 2019).

Use of pesticides and veterinary medicines in Australia

1.19 Australia's agricultural industry is worth an estimated \$60 billion annually and an effective and trusted pesticides and veterinary medicines regulator is central to its integrity and ongoing viability.⁷

1.20 Each year, over \$3 billion is spent on agvet chemicals in Australia.⁸ According to the Department of Agriculture and Water Resources (DAWR), agvet chemicals have:

...brought long-term benefits to Australian agriculture by supporting increased productivity, better quality produce, and agricultural industries that are more competitive.⁹

1.21 It was put to the Committee that agvet chemicals are an integral component of sustainable production systems, providing primary producers with the means to manage pests and maintain biosecurity whilst contributing to the productivity and viability of Australia's agricultural industries.¹⁰

1.22 More than 11,480 pesticide and veterinary medicine products, managed by over 900 registrants, are currently registered in Australia. These range from products to treat crop and garden diseases and pests, to medicines to treat agricultural and companion animals.¹¹ The APVMA receives around 5,000 applications annually for various assessments.¹²

Role of the Australian Pesticides and Veterinary Medicines Authority

1.23 The Minister for Agriculture and Water Resources has overall policy responsibility for agvet chemicals. DAWR manages the legislation that relates to agvet chemicals, including the legislation under which the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) operates. The Department's responsibilities include amending current legislation or introducing new bills in

7 Australian Bureau of Agricultural and Resource Economics, *Farm Production Value Forecast to Rise in Mixed Agricultural Outlook*, 19 June 2018, <http://www.agriculture.gov.au/abares/news/media-releases/2018/farm-prod-value-forecast-rise-mixed-ag-outlook> (accessed 3 January 2019); GrainGrowers, *Submission 23*, p. 3; Victorian Farmers Federation, *Submission 33*, p. [3].

8 Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, No. 56, June 2017, p. 7.

9 Department of Agriculture and Water Resources, *Submission 9*, p. 3; Mr David Mailler, Chair, Agricultural Science Committee, NSW Farmers' Association, *Committee Hansard*, 20 November 2018, p. 16.

10 Cotton Australia, *Submission 6*, p. [1]; GrainGrowers, *Submission 23*, p. [6].

11 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.

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

circumstances where Australian, state and territory governments have agreed there is a need.

1.24 The APVMA sits within the DAWR portfolio as an independent statutory authority. In its submission to the inquiry, the APVMA stated its 'primary purpose is to protect the health and safety of people, animals and the environment' by ensuring chemical products are safe. It noted that:

In many cases, the products we regulate are intrinsically hazardous. Pesticides, herbicides, fungicides and parasiticides protect the environment, animals and agricultural crops from pests and diseases. We regulate agvet chemical products using a structured process combining scientific methodology, legislation and risk assessment to ensure products are safe to use and do not adversely impact trade.¹³

1.25 The APVMA is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) to administer the NRS in partnership with state and territory governments, and the scheme's legislation.¹⁴

1.26 In Australia, agvet chemicals are regulated under a cooperative statutory scheme. The APVMA is the independent statutory authority responsible for assessing, registering, and regulating agvet chemicals in Australia. The APVMA's regulatory responsibilities extend from registration and manufacturing through to the point of sale. The APVMA must evaluate and register all agvet chemicals prior to their legal sale, supply or use in Australia. It is the responsibility of state and territory governments to regulate and monitor how chemicals are used after they are sold.¹⁵

1.27 The APVMA administers the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code Act), and related supporting legislation and regulations.¹⁶

1.28 The APVMA regulates agvet chemicals by:

- approving active constituents and registering agvet chemical products;
- reconsidering active constituents and agvet chemical products when new scientific information emerges that suggests a change in the risks to human health, the environment, animal or crop safety, or trade;
- administering a permit scheme for the legal use of chemicals in ways contrary to the label instructions, or for the limited use of unregistered chemicals (permits are subject to the same safety, efficacy and trade criteria as active constituents and chemical products);
- licensing the manufacture of chemical products (currently restricted to veterinary chemical products);

13 Australian Pesticides and Veterinary Medicines Authority, *Submission 7*, p. 1.

14 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, pp. 8–9.

15 Australian Pesticides and Veterinary Medicines Authority, *Submission 7*, p. 1; Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, pp. 8–9.

16 Australian Pesticides and Veterinary Medicines Authority, *Submission 7*, p. 1.

- conducting compliance and enforcement activities associated with the sale, supply, import, export, manufacture, labelling, packaging, storage and advertising of agvet products and active constituents; and
- enforcing compliance with the Agvet Code (as set out in the Schedule to the Agvet Code Act) in partnership with law enforcement, the judiciary, and Australian, state and territory government agencies.¹⁷

1.29 The APVMA can call upon other specialist government agencies and researchers to conduct aspects of evaluation, approval, registration, reconsideration and permit issuances. Specialist expertise can be sought from:

- the Department of the Environment and Energy—for the environmental impact of agvet chemicals;
- the Department of Health—for human health, including the Poisons Scheduling Committee, Food Standards Australia New Zealand (FSANZ), and the Office of the Gene Technology Regulator (OGTR); and
- state and territory departments with responsibility for agriculture or primary industries—for the quality, efficacy and safety of agvet chemical use.¹⁸

1.30 Under the APVMA's compliance and monitoring powers, the authority also undertakes post market surveillance and testing with regard to the continued safety and effectiveness of registered products.¹⁹

1.31 A number of submissions highlighted the importance of the APVMA's role in the protection of Australian agriculture, forestry, horticulture and aquaculture. Submitters noted that the APVMA responds to biosecurity threats, protects farm workers and the community, and supports Australian trade. The APVMA's role in supporting trade was considered to be of particular importance given that more than two thirds of agricultural commodities produced on farms are exported each year. Submitters also commented that the authority was recognised globally as a world-leading independent, science-based regulator with a proven track record of scientific and evidence-based assessments.²⁰

1.32 Submitters emphasised the point that the APVMA must retain the necessary scientific and administrative resources to perform its important role efficiently. The point was also made that the authority must retain the trust of the community in the decisions it makes.

17 Department of Agriculture and Water Resources, *Submission 9*, p. 7.

18 Department of Agriculture and Water Resources, *Submission 9*, p. 7.

19 Australian Pesticides and Veterinary Medicines Authority, *Submission 7*, p. 1.

20 Cotton Australia, *Submission 6*, p. [1]; CropLife Australia, *Submission 10*, p. 1; Associate Professor Christopher Preston, *Submission 19*, p. [2]; National Farmers' Federation, *Submission 27*, pp. [1, 2]; Agribusiness Australia, *Submission 30*, p. 3; AgForce Queensland Farmers Limited, *Submission 34*, p. [1].

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.aph.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.

Chapter 3

The APVMA charging framework

3.1 The APVMA is funded largely through fees, levies and charges imposed on registrants on a cost recovery basis. However, the sustainability of the current model in providing sufficient resources for the authority was questioned during the inquiry.

3.2 Although this type of funding model is used by other regulatory agencies in Australia and around the world, there were differing opinions as to whether a cost recovery model could lead to actual, or perceived, undue influence on the decisions of the regulator.

3.3 While many stakeholders recognised the cost recovery model as appropriate, some expressed concern that certain fees could act as an impediment to registering certain chemicals, particularly those for minor uses. This situation was made more complex to resolve by the small size of the Australian market.

3.4 This chapter considers the APVMA's charging framework and explores the views of submitters in relation to it.

History of the government charging framework

3.5 A 2001 Productivity Commission review of Commonwealth cost recovery arrangements found almost all Australian government agencies recovered some of their costs, and that the proportion was increasing. At that time, more than \$3 billion was raised annually by agencies through cost recovery. The review recommended that the Government adopt a formal cost recovery policy for agencies undertaking regulatory and information activities.¹

3.6 In December 2005, the Australian Government established a formal cost recovery policy, administered by the Department of Finance and Deregulation. The central principal of the policy was that:

Agencies should set charges to recover all the costs of products or services where it is efficient and effective to do so, where the beneficiaries are a narrow and identifiable group, and where charging is consistent with Australian Government policy objectives.²

3.7 In April 2015, the Australian Government agreed to implement a whole-of-government charging framework to apply across the general government sector. The framework consists of:

- a charging policy statement, providing the rationale for charging activities;

1 Productivity Commission, *Cost recovery by Government Agencies*, No. 15, August 2001, pp. XXVIII, LIV.

2 Australian Pesticides and Veterinary Medicines Authority, *Cost Recovery Impact Statement: Covering the Period 1 July 2013 – 30 June 2015*, 2012, pp. 7–8.

- charging considerations to guide decision-making on appropriate charging; and
- charging principles to guide design, implementation and review of charging activities.³

3.8 The Australian Government charging policy states:

Where specific demand for a government activity is created by identifiable individuals or groups, they should be charged for it unless the Government has decided to fund that activity. Where appropriate for the Australian Government to participate in an activity, it should fully utilise and maintain public resources, through appropriate charging. The application of charging should not, however, adversely impact disadvantaged Australians.⁴

Charging by other agencies

3.9 In addition to the APVMA, other regulatory agencies, including the TGA, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and FSANZ, charge registrants for the cost of evaluation and other regulatory services.⁵

3.10 The Committee received evidence that all comparable international regulators charge 'the regulated entity for access to [the] chemicals market in that country', though the exact charging mechanism varies. For instance, the Committee heard that in the United States the entire evaluation fee is charged up-front rather than being partly recovered through levies on sales.⁶

3.11 The New Zealand Government expects its Environmental Protection Authority to 'set fees that recover a fair and reasonable proportion of the costs' of providing its services. It is funded through a combination of fees and charges, and crown funding.⁷ The New Zealand Ministry for Primary Industries similarly receives crown funding and revenue from levies and application fees.⁸

3 Department of Finance, *Australian Government Charging Framework*, Resource Management Guide No. 302, July 2015, p. 4.

4 Department of Finance, *Australian Government Charging Framework*, Resource Management Guide No. 302, July 2015, p. 7.

5 Department of Agriculture and Water Resources, *Submission 9*, p. 4; Pastoralists & Graziers Association of Western Australia, *Submission 22*, p. 4.

6 Department of Agriculture and Water Resources, *Submission 9*, p. 4; CropLife Australia, *Submission 10*, p. 5; United States Environmental Protection Agency, *Submission 109*, p. 2; Dr Brian Richards, Executive Director, Office of Chemical Safety; Director, National Industrial Chemicals Notification and Assessment Scheme, *Committee Hansard*, 20 November 2018, p. 34.

7 New Zealand Environmental Protection Authority, *Annual Report for the Year Ended 30 June 2018*, pp. 26–31; New Zealand Environmental Protection Authority, *Fees, Charges and Cost Recovery*, <https://www.epa.govt.nz/applications-and-permits/fees-and-charges/> (accessed 3 January 2019).

8 New Zealand Ministry for Primary Industries, *Annual Report 2017–2018*, p. 78.

3.12 The Canadian PMRA charges fees for the review of applications to register pesticides, and an annual charge for every registered pesticide. It also receives government funding.⁹ The Canadian Veterinary Drug Directorate, part of Health Canada's Health Products and Food Branch, similarly charges a number of fees including for evaluation, licencing and authority to sell.¹⁰

3.13 Before an active substance can be used in a plant protection product within the European Union, it must be approved by the European Commission following scientific and technical evaluation by a rapporteur member state. Most rapporteur member states charge a fee for the evaluation of a new active substance.¹¹ Countries within the European Union authorise plant protection products within their borders and ensure compliance with EU rules. Member states are permitted to cost recover through fees and charges. These vary between countries.¹²

APVMA funding

3.14 The APVMA is funded through fees, levies and other charges imposed under legislation, with the exception of specific government-funded projects to improve or enhance the authority's ability to perform its legislated functions. The relocation to Armidale and reforms stemming from the 2015 white paper were funded by government.¹³

3.15 DAWR told the Committee that APVMA funding arrangements complied with the charging framework. The department also confirmed that the authority's regulatory activities were subject to the Australian Government Cost Recovery Guidelines, which establish the overarching framework for the design, implementation and review of regulatory charging activities.¹⁴

3.16 The APVMA's current cost recovery arrangements were implemented on 1 July 2013 for a period to 30 June 2015, during which time a first-principles review

9 Government of Canada, *Pesticide Registration Cost Recovery*, <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/product-application/cost-recovery.html> (accessed 3 January 2019).

10 Government of Canada, *Fees for Veterinary Drugs*, <https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/veterinary-drugs.html> (accessed 3 January 2019).

11 Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, p. 47; European Commission, *Approval of Active Substances: Application, Fees, Data*, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/application_report_en (accessed 3 January 2019).

12 Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, p. 47; European Commission, *Procedure to Apply for Authorisation of a PPP*, https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/application_procedure_en (accessed 3 January 2019).

13 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 104.

14 Department of Agriculture and Water Resources, *Submission 9*, p. 4.

of the APVMA's cost recovery arrangements was to have been completed.¹⁵ The 2013 cost changes were intended to address identified shortfalls in the authority's funding in preparation for a subsequent 2015 cost recovery impact statement. However, neither the first-principles review nor the 2015 cost recovery statement were completed within the established timeframe. The cost recovery statement is now scheduled for 2019–20 and the authority continues to operate on the cost recovery arrangements introduced in 2013.¹⁶

3.17 The authority incurs costs through registration assessments, renewals of existing product registrations, and by undertaking a variety of post-market compliance, monitoring and enforcement activities.¹⁷

3.18 The APVMA recovers the costs of registrations and approvals through application fees and levies. The costs of assessing an application are collected in two parts: 40 per cent of the assessment charge is recovered upfront through an application fee; the balance is recovered through a levy on the annual value of sales.¹⁸

3.19 The cost to assess an application for registration is split to ensure application fees are not a disincentive to bring new and innovative products to market. This is particularly the case for small businesses, niche products, and chemical products with low value of sales. It also aims to encourage competition and ensure equitable access to the chemicals market for the producers of generic variants.¹⁹

3.20 Post-market compliance activities conducted by the APVMA, including good manufacturing practice assessments, licencing, export certificates and other investigation and enforcement activities are subject to fees.²⁰

3.21 The APVMA's fees, levies and charges are credited to a special appropriation, created under s. 58(6) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, held and managed by DAWR, for and on behalf of, the APVMA.²¹

3.22 The following table (Table 3.1) details the APVMA's income sources during 2017–2018, showing the breakdown and proportion of fees and levies.

15 Australian Pesticides and Veterinary Medicines Authority, *Cost Recovery Impact Statement: Covering the Period 1 July 2013 – 30 June 2015*, 2012, p. 7.

16 Australian Pesticides and Veterinary Medicines Authority, *Cost Recovery Impact Statement: Covering the Period 1 July 2013 – 30 June 2015*, 2012, p. 52; Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 34.

17 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, pp. 3–4.

18 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, p. 6.

19 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, p. 6; Department of Agriculture and Water Resources, *Submission 9*, p. 4.

20 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, p. 6.

21 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 104.

Table 3.1—APVMA income sources 2017–18

Income source	Income (\$'000)	%
Receipts from industry		
<i>Levies</i>	18,802	47.97
<i>Application fees</i>	6,246	15.94
<i>Annual fees (renewal fees)</i>	5,604	14.30
<i>Other receipts from industry</i>	2,272	5.80
Parliamentary appropriation	6,056	15.45
Other revenue	215	0.54
Total Income	39,195	100.00

*APVMA Annual Report – total income 2017–18*²²

3.23 DAWR explained to the Committee the benefits of a cost recovery arrangement, stating:

Cost recovery measures improve the transparency of the costs of sound management of chemicals and preserve the integrity of those management systems thereby ensuring they maintain adequate resourcing to protect human, animal and environmental health and Australia's interests as an agricultural exporter.²³

3.24 An independent review of the APVMA's cost recovery arrangements in 2017 conducted by PWC did, however, raise some concerns about the sustainability of the authority's funding. PWC found that:

- the fees charged by the APVMA were not based on the workload of individual applications;
- there was no annual indexation of charges;
- the prices set were not consistent or reflective of the true costs of undertaking activities;
- revenue forecasts were optimistic and not representative of actual results; and
- budget allocations for the authority are aligned to a forecast activity level that may not have been achievable due to reduced volumes and decreased revenue.

22 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 78.

23 Department of Agriculture and Water Resources, *Submission 9*, p. 4.

In particular, the price structure for applications did not result in a sustained 40 per cent cost recovery.²⁴

3.25 In terms of its financial position, the APVMA recorded a deficit for 2017–18 of \$880,000; and has run an operating loss since 2014–15. The authority's equity balance of \$6.418 million was more than \$500,000 below the targeted equity position of \$7 million, and lower than the 2016–17 total equity balance of \$6.798 million. The APVMA's target equity balance of \$7 million is equivalent to three months operating expenses, regarded as sufficient to cover periods of variations between revenue and expenses as a consequence of movement in activity volume. PWC noted a downward trend in the level of equity reserves at the end of reporting years once normalised for equity injections.²⁵

3.26 The APVMA observed that the structure of payments affected the cash flow of the authority. The authority's primary income was derived from levy payments which come due in December and June; it also received registration payments in May and June—meaning the majority of revenue was paid at three points during the year. Although cash holdings could exceed \$7 million at points during the year, the authority had to operate to keep cash levels above \$2 million as an operating reserve to ensure sufficient cash was available to pay creditor expenses.²⁶

3.27 DAWR acknowledged the APVMA's financial position was deteriorating and could not be sustained if expenditure and cost recovery pressures remained unaddressed.²⁷ However, the APVMA's *Annual Report 2017–18* indicated the planned 2019–20 cost recovery impact statement was expected to address some of these issues in the context of a new business operating model.²⁸

3.28 DAWR informed the Committee that the APVMA was currently reassessing the entirety of its regulatory activities to ensure the fees and charges appropriately reflected the costs of the activities and the administrative infrastructure supporting them. The APVMA announced it would implement a renewed cost recovery implementation statement in 2019–20; with interim measures to retain positive cash flows.²⁹

24 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, pp. 3–4, 7.

25 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 14, 80, 87; PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, pp. 9, 16.

26 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 14, 80, 87.

27 Department of Agriculture and Water Resources, *Submission 9*, p. 4.

28 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 4, 34.

29 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 34; Department of Agriculture and Water Resources, *Submission 9*, p. 4.

Views regarding the impact of the APVMA funding model

Evidence regarding APVMA's independence

3.29 The Committee received considerable evidence that supported the view that the authority is independent. Many witnesses acknowledged that whilst the APVMA was largely funded through fees and levies, this type of system reflected global best practice, was not an unusual arrangement, and did not allow for undue influence in practice.

3.30 Further, evidence suggested the alternative to cost recovery—full public funding—could make the authority subject to the general budgetary decisions of the government of the day and could result in insufficient funding for its regulatory functions.³⁰ It was also suggested that if there was no financial risk to registrants, 'there is a high probability of poorly conceived registration proposals being submitted. The large number of registrants of generic products in Australia make this a particular concern'.³¹

3.31 The National Farmers' Federation suggested it was a misunderstanding of cost recovery principles to suggest the APVMA could be unduly influenced.³² Rather, as suggested by a number of submitters, decisions by the APVMA were made within a robust regulatory and science-based framework governed by legislated processes and procedures.³³

3.32 The Australian Academy of Science explained that the regulator's activities were 'based on formal legislated requirements that provide for decisions informed by expert scientific review. The legislation and supporting administrative arrangements ensure that decisions are based on the best available information'.³⁴ Further, the Academy:

...considers the APVMA's analyses to be generally open and transparent, well informed and appropriate. Its regulatory decisions with respect to

30 Associate Professor Christopher Preston, *Submission 19*, p. [2]. There was some support from industry groups for public funding. See, for example: CropLife Australia, *Submission 10*, p. 1; Pastoralists & Graziers Association of Western Australia, *Submission 22*, pp. 4–5.

31 Associate Professor Christopher Preston, *Submission 19*, p. 2. See also: Chemistry Australia, *Submission 17*, p. 3.

32 National Farmers' Federation, *Submission 27*, p. [1].

33 Cotton Australia, *Submission 6*, p. [2]; NSW Farmers' Association, *Submission 8*, p. 10; CropLife Australia, *Submission 10*, p. 5; Grain Producers Australia, *Submission 11*, p. 5; AUSVEG, *Submission 12*, pp. [1–2]; Pastoralists & Graziers Association of Western Australia, *Submission 22*, pp. 3–4; GrainGrowers, *Submission 23*, pp. [1, 5]; National Farmers' Federation, *Submission 27*, p. [1]; Agribusiness Australia, *Submission 30*, p. 8; AgForce Queensland Farmers Limited, *Submission 34*, p. [3]; Primary Industries and Regions SA, *Submission 72*, p. 3; Mr Justin Crosby, Industry and Government Relations, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, p. 30.

34 Australian Academy of Science, *Submission 107*, p. [1].

agricultural chemicals are published on its website and are subject to public scrutiny. Such scrutiny is important for public trust in the agency.³⁵

3.33 Similar sentiments with regard to the independence of the regulator's processes were expressed by Bayer Crop Science:

I understand that people feel that, because we are funding the organisation, there might be some conflict there. I don't believe that to be the case whatsoever. There's a very straightforward process by which we deal with our applications and the APVMA deals with our applications.³⁶

3.34 Animal Medicines Australia's evidence reflected general industry agreement as to the strength and quality of the authority's work, stating:

We have no concern with the independence of the APVMA. We have concerns with respect to their efficiency and predictability from time to time, but the regulator on the whole is very scientifically based and makes rigorous decisions which are respected around the world.³⁷

3.35 Support for the APVMA's science was also expressed by AgForce Queensland who told the Committee:

We believe they are very good with their science. They have very rigorous methods. It is all above board...It is an independent regulator. Like a lot of services offered by regulators, by government, they've got to look at cost recovery.³⁸

3.36 The NSW Farmers' Association also voiced its support for the cost recovery model and argued that it ensured an appropriate distribution of the financial burden. It offered the following observations:

NSW Farmers has not seen any evidence to suggest that there is undue influence from chemical manufacturers on the decisions made by the APVMA. The cost-recovery model currently employed by the APVMA is appropriate for an agency undertaking work that is often for private benefit, notwithstanding the broader public benefit attached to agriculture, environmental stewardship, biosecurity and the prevention of disease. We also recognise the need for investment certainty in the agricultural sector to ensure that farmers have access to safe and reliable chemicals...

The current cost-recovery model used by the APVMA essentially ensures that the financial burden of chemical registration is not directly linked to the agricultural industry or taxpayers. Registration of chemicals by a private

35 Australian Academy of Science, *Submission 107*, p. [1].

36 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 3.

37 Mr Ben Stapley, Executive Director, Animal Medicines Australia, *Committee Hansard*, 7 December 2018, p. 39.

38 Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland, *Committee Hansard*, 7 December 2018, p. 57.

company represents a private good, and this cost should not be fully passed on to government.³⁹

3.37 Chemistry Australia acknowledged that whilst suggestions of undue influence were sometimes made, it was of the view:

There isn't corporate influence over the regulatory system...the facts are that we have full confidence that it's independent. Just because our members pay and participate in the scheme doesn't mean every regulatory decision that's made is one that's made in their favour... They're [regulatory scientists at the APVMA] professionals. They have training and education, and they have roles and responsibilities which are legal ones.⁴⁰

3.38 GrainGrowers pointed to the international reputation of the APVMA as evidence of its independence and scientific authority, and indicated:

The strength of the regulatory and compliance measures imposed by the APVMA are recognised internationally through the memorandum of understanding held with New Zealand, and the mutual recognition agreement for good manufacturing practice with nations such as Europe, the US and Canada. Furthermore, the practice of international collaboration to assess specific applications, and use of international assessments reports in work-sharing arrangements, supports independent national risk assessment.⁴¹

3.39 Submitters identified a number of decisions taken by the regulator—including suspensions of product registrations or changes to label use—which were strongly opposed by some parts of the industry. These included the recent review of 2,4-D label instructions; the 2011 suspension of insecticide products containing dimethoate and the issue of new label instructions that no longer allowed its use on specified food crops; the 2014 cancellation or variation to all registered uses of products containing fenthion, on the grounds the chemical posed unacceptable risks to human and environmental health; and regulatory measures in 2000 including label amendments with updated directions for use, first-aid and safety directions, and environmental warning statements for products containing chlorpyrifos.⁴²

3.40 With regard to these decisions, CropLife Australia stated:

While in some cases these decisions may have significant negative consequences for CropLife members or grower industries and attract considerable political and community opposition and media attention, the

39 NSW Farmers' Association, *Submission 8*, pp. 6, 9.

40 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 49.

41 GrainGrowers, *Submission 23*, p. [3].

42 CropLife Australia, *Submission 10*, pp. 11–12; Grain Producers Australia, *Submission 11*, pp. 2, 5; Pastoralists & Graziers Association of Western Australia, *Submission 22*, p. 2; GrainGrowers, *Submission 23*, p. [3].

APVMA consistently acts in the best interest of the Australian public by committing to science and evidence-based regulatory decisions.⁴³

3.41 The Pastoralists & Graziers Association of Western Australia summarised its members' perspectives with regard to the regulator's decisions, arguing:

Despite the not unexpected disagreements between industry and regulator over costs, timeliness, efficiency and access to agricultural chemicals, there is industry support of both the APVMA's independence and its primary role as a regulator.⁴⁴

3.42 There was also support for the impartiality of the funding model, which the Western Australian Farmers Federation argued did not create any incentive to favour the registration of certain chemicals.⁴⁵ The NSW Farmers' Association agreed, stating:

NSW Farmers does not consider that the funding model provides incentive for the APVMA to favour registration of certain chemicals; particularly in the case of glyphosate, were it to be removed from the market, the APVMA would receive income from other companies seeking to register chemicals to fill the gap in available herbicides.⁴⁶

3.43 Evidence provided by industry groups suggested there was little opposition from them to the fees and levies charged by the APVMA. Subject to some reservations about the impact of cost recovery on investment in innovation and minor use chemicals (discussed below), there was in fact general support for cost recovery from these industry stakeholders.

3.44 However, some stakeholders stressed the importance of industry being able to engage with the regulator and for timely service in response.⁴⁷ The Veterinary Manufacturers and Distributors Association stated:

We accept that, as with other government regulatory entities, the APVMA is virtually a fully cost recovered agency and, while we would be happy to not pay for it, the reality is that we do as required by the legislation. We do, however, wish that the APVMA's performance was more predictable and timely, and to that end we also engage with the regulator to help streamline procedures while accepting the robust assessment and review processes that protect not only the animal population of Australia but also the integrity of our industry...

43 CropLife Australia, *Submission 10*, p. 1.

44 Pastoralists & Graziers Association of Western Australia, *Submission 22*, p. 6.

45 Western Australian Farmers Federation, *Submission 15*, p. 3.

46 NSW Farmers' Association, *Submission 8*, p. 9.

47 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Australia, *Committee Hansard*, 7 December 2018, p. 33; Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 48; NSW Farmers' Association, *Submission 8*, p. 10; CropLife Australia, *Submission 10*, p. 1; National Farmers' Federation, *Submission 27*, p. [2]; Australian Dairy Industry Council and Dairy Australia, *Submission 25*, p. 3.

While we'd like to be able to say that we control the regulator, the daily battles of our members with the APVMA in respect of registration applications indicates otherwise. This is genuinely a case of he who pays the piper not calling the tune—and sometimes not even getting to hear the music.⁴⁸

Evidence regarding perceptions of undue influence

3.45 The Committee received some evidence that suggested the APVMA's funding arrangements and relationships with industry compromised the authority's independence. However, these submitters were not able to provide clear evidence of instances that showed undue influence or bias, or regulatory capture.⁴⁹

3.46 Gene Ethics held the view that:

All regulators have conflicts of interest when they depend on cost recovery from corporate customers to cover their operating costs...Of the APVMA's \$35 million annual budget glyphosate-based herbicides (GBH) contribute about \$1.5 million p.a. This may convey to the public the vivid impression that our regulator has an interest in keeping glyphosate on sale.⁵⁰

3.47 Gene Ethics went on to argue that there was a community expectation that the APVMA be an objective and impartial referee with regard to disputed health, safety and environmental issues. It made the point that the regulatory activities of the APVMA should be conducted at arm's length from industry. It continued:

But the main chemical industry lobby group, CropLife Australia, views the APVMA as a reliable service provider and, in our opinion, directly and indirectly exercises undue influence over both agvet chemical regulatory policy and APVMA practice...It [CropLife Australia] notes that 85 per cent of the chemicals that Australian farmers use are controlled by 16 of CropLife's corporate members, and seven member companies own 100 per cent of crop biotechnology products—that is GM cotton and canola.⁵¹

3.48 Friends of the Earth Australia similarly identified the funding arrangement as a problem that had 'effectively created a client relationship between the APVMA and industry, and that really needs to be decoupled'.⁵²

48 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Australia, *Committee Hansard*, 7 December 2018, p. 32.

49 For a selection of submitters who expressed concern, see the following: Friends of the Earth Australia, *Submission 35*, p. [4]; Mr Bob Gray, *Submission 47*; Ms Melissa Anderson, *Submission 56*; Mr John Harvey, *Submission 58*; Mr Richard Nankin, *Submission 77*, pp. 3–4; Mr Dean Mensinga, *Submission 79*; Ms Helena Martin, *Submission 86*; Mr John Beale, *Submission 88*; Australian Food Sovereignty Alliance, *Submission 90*, p. 20; Mr Peter Raftos, *Submission 96*.

50 Gene Ethics, *Submission 40*, pp. 2, 8.

51 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, pp. 19, 22.

52 Ms Louise Sales, Emerging Tech Project Coordinator, Friends of the Earth, *Committee Hansard*, 7 December 2018, p. 52.

3.49 The Australian Food Sovereignty Alliance suggested the cost recovery model provided an incentive for the APVMA to encourage industry to create more chemicals and had resulted in regulatory capture where the interests of industry were put above those of the community:

The APVMA's 2012 Cost Recovery Impact Statement (CRIS) shows APVMA are concerned with losing capital and, as a result of product evaluations falling below their 40% target through application fees, increased fees for industry. The logical operation of the APVMA in the current regulatory environment would be to encourage companies to create products for their registration in order to meet targets and increase capital...

A known outcome of regulatory capture is that regulation becomes lenient, putting industry interests above the interests of those the regulator should serve and protect, namely farmers, farmworkers, landscapers, gardeners, everyday consumers and any ordinary citizen who comes into contact with hazardous chemicals.⁵³

3.50 The National Toxics Network suggested the APVMA did not act on existing evidence, thus putting the community at risk. It argued that the agvet chemical lobby were 'extremely powerful' and that they were getting what they want while the 'community and the environment pay the price of continued registration and use of dangerous pesticides'.⁵⁴

3.51 Associate Professor Susan Wilson, amongst others, confirmed there was a perception in the wider community that because of the cost recovery strategy, and the actual need for industry to work closely with the APVMA, there was potential for industry to exert undue influence on the application process. Associate Professor Wilson contended that as the APVMA does not undertake any chemical research—the majority of data used for assessments is generated by the applicant or industry—this could also lead to a perception of bias.⁵⁵

3.52 However, Associate Professor Wilson also stated there had definitely been no loss of confidence in the independence of the APVMA and its ability to undertake its regulatory functions 'from the more-informed and academic part of the community'.⁵⁶

3.53 Some submitters called for either an arm's length separation between the regulator and industry or for public funding of the APVMA. Gene Ethics, for example, stated:

We would like the funding of the APVMA by the industry—and it is overwhelmingly funded by the industry—to be much more at arm's length

53 Australian Food Sovereignty Alliance, *Submission 90*, pp. 20–21.

54 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, p. 25.

55 Associate Professor Susan Wilson and Professor Brian Sindel, *Submission 42*, p. [1]; Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 16.

56 Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 16; CropLife Australia, *Submission 10*, p. 1.

than it is at the moment. Even though the money goes to Treasury, it comes back to the APVMA. We think that the APVMA and other regulators like the OGTR, for instance, should be funded from the public purse and that any revenues should be delinked from the regulator that 'benefits' from the industry's input.⁵⁷

3.54 This was a suggestion also raised by Associate Professor Wilson. While she did not believe that there was undue influence, she recognised the importance of creating trust within the community, stating:

It's a difficult problem to answer. Possibly by having some component that's publicly funded or having an arm's length entity to manage the fee payment rather than all of that being handled within that one grouping. There is a loss of trust, especially with everything that's in the media at the moment. Building community trust and building community understanding would help significantly.⁵⁸

Access to chemicals and veterinary medicines in Australia

3.55 The Committee was told that several factors discouraged some companies from applying to either register their products in Australia, or reduce the uses for which they applied. These factors included the small size of the Australian market (approximately 1.5 per cent of the global market), the fact Australia is no longer on the global priority list for pesticide and veterinary medicine investment in commercialisation, and the cost of registration.⁵⁹

3.56 Grain Producers Australia provided research comparing the first registered labels between Australia and the United States for several compounds. Although a direct comparison was not possible as the particular local conditions and regulations that led to the approvals was not clear, the results are summarised in Table 3.2.

3.57 Table 3.2 shows that in the larger market of the United States, in some cases applicants register a significantly larger number of uses.

57 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, p. 22.

58 Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 16.

59 Grain Producers Australia, *Submission 11*, p. 10; Associate Professor Christopher Preston, *Submission 19*, pp. 2–3; National Farmers' Federation, *Submission 27*, p. 3; Victorian Farmers Federation, *Submission 33*, pp. [4–5]; AgForce Queensland Farmers Limited, *Submission 34*, pp. [4–5]; Mr David Mailler, Chair, Agricultural Science Committee, NSW Farmers' Association, *Committee Hansard*, 20 November, p. 16; Mr Chris Groves, Chair, Farming Systems Committee, National Farmers' Federation, Vice President, NSW Farmers' Association, *Committee Hansard*, 20 November 2018, p. 17; Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, p. 30.

Table 3.2—Comparison of first registered labels between Australia and the United States

Compound	Number of initial registered uses	
	Australia	United States
Penflufen	2	10
Sedaxane	4*	4*
Penthiopyrad	10	22
Fluxapyroxad	1	21
Prosulfuron	1	3
Saflufenacil	1	13
Pyroxasulfone	2*	2*
Foramsulfuron	1	2

* registered uses differed; *Grain Producers Australia*.⁶⁰

3.58 GrainGrowers explained the problems caused by various factors in the Australian marketplace:

Given the small size of the Australia market, and the extent of global chemical development and manufacturing, Australian farmers are inherently disadvantaged in the range of chemicals they can access compared to growers in other countries. Put simply, the lower commercial return available in Australia compared to larger markets results in products never being submitted for registration or a delay in submitting for registration in Australia.⁶¹

3.59 Grain Producers Australia added its concerns over the negative impact of the small market in Australia, arguing:

Global multinational companies face a poor rate of return on commercialisation investment compared with major developing markets including Brazil and China...

Growers are impacted by the 'double whammy' of lack of new, more advanced pesticide options delivering productivity outcomes, plus accelerated selection pressure for pesticide resistance due to a narrow pool of products.⁶²

60 Grain Producers Australia, *Submission 11*, p. 10.

61 GrainGrowers, *Submission 23*, p. 6.

62 Grain Producers Australia, *Submission 11*, pp. 10–11.

3.60 From the perspective of chemical companies and in response to suggestions about raising the costs of registration in Australia, CropLife Australia suggested to the Committee:

...the Australian market is one-tenth the size of the US market, but the regulatory system costs the same, dollar for dollar. So we immediately have a serious hurdle in terms of ensuring that Australian farmers have access to products in the same timely manner as around the world. A new chemical product, from beginning to end, now costs more than US\$256 million and 11 years in R&D to bring to market, and a third of those costs are now directly related to regulatory systems. So the reason that we are cautious on adding any new costs to the regulatory system is that it has genuine, real consequences to farmers' access to innovation in the first place and what they pay. It's not this view that it would just be the chemical companies that pay for it. It builds into the whole of the costs that end up on farm for production.⁶³

3.61 The APVMA has recognised that registration and assessment costs can outweigh the benefits of commercialising new products for certain low-volume use chemicals, or in emergency situations. The minor use permit system allows chemicals that are not registered to be permitted for 'minor uses'. This permits the use of agvet chemicals without the full cost of registration.⁶⁴

3.62 The use of this system was explained by AgForce Queensland:

The APVMA has regulatory provisions for off-label use of agvet chemicals through emergency and minor use permits. This regulatory pathway must be retained to enable rapid response to new biosecurity pest, weed or disease incursion. For example, agvet chemical companies are reluctant to invest in changing product labels for emerging weeds that must be rapidly controlled. Often there is very little return on investment for agvet chemical companies to add certain weed species to labels for rangeland weeds in non-crop areas and certain application methods for roadsides, waterways. The APVMA minor use permit system can accommodate these niche situations.⁶⁵

3.63 Some submitters argued that both the fees and data requirements for minor use permits remain too onerous and undermined the intent of the program to protect consumers and prevent industry loss.⁶⁶ Associate Professor Christopher Preston also advised that the intent of the program was not always realised:

63 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, p. 59.

64 Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 306.

65 AgForce Queensland Farmers Limited, *Submission 34*, pp. [4–5].

66 Western Australian Farmers Federation, *Submission 15*, p. 3; Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland Farmers Limited, *Committee Hansard*, 7 December 2018, p. 60. See similar comments for off-label permits: South Australian Department of Primary Industries & Regions, *Submission 72*, p. 3.

Australia has a permit system that is regularly used to allow additional products to be used by growers of minor crops; however, that system has the intention that the permit uses will be moved onto labels. In practice this too often does not happen due to a lack of willingness by registrants to invest in minor crop use.⁶⁷

3.64 With regard to the costs of minor use permits, CropLife Australia stated:

In the case of minor and specialty crops, this cost of developing the necessary supporting data to meet due diligence and regulatory requirements far exceeds any potential return on investment. Similarly, the financial burden on grower groups to generate the necessary data to support an application for a minor use permit is often prohibitive. As a result, Australian producers of specialty food and minor crops are faced with numerous challenges in managing plant pests, weeds and diseases.⁶⁸

3.65 This view was supported by Cotton Australia, which argued the process to apply for permits was not efficient and had the potential to endanger safety through off-label use:

Cotton Australia applies for a number of permits on behalf of its growers to cover specialty use situations that are not covered by established approved chemical use patterns. The lengthy time frames (often over 12 months) for having these minor use permits approved, or amended, is prohibitive to productivity. This is especially the case when emergency permits for new pest outbreaks are required. The prohibitive cost and time frames results in producers having to use products 'off-label'. The use of products in an unregulated, off-label situation creates potential risks with product safety, efficacy and resistance management for the whole Australian community.⁶⁹

3.66 Submitters suggested a number of ways to deal with the issue of high costs. For example, Grain Producers Australia stated:

...the application fee should be set at a level that balances the ability for the APVMA to recover a portion of the cost of assessment upfront while not acting as a significant disincentive for users to seek a minor use permit for off-label use of an agvet chemical.⁷⁰

3.67 GrainGrowers argued that Australia's chemical assessment and registration processes should be made as efficient and rigorous as possible to allow farmers to access new chemistry in a timely manner to maintain competitive advantage. GrainGrowers further observed:

The APVMA does not rely on international registration of products to a sufficient extent, thus duplicating the assessment of the same product's

67 Associate Professor Christopher Preston, *Submission 19*, pp. 2–3.

68 CropLife Australia, *Submission 10*, p. 15. See also: Cotton Australia, *Submission 6*, p. 2; Agribusiness Australia, *Submission 30*, p. 7.

69 Cotton Australia, *Submission 6*, p. 2.

70 Grain Producers Australia, *Submission 11*, p. 7.

registration in Australia despite it being registered in many other countries.⁷¹

3.68 The Western Australian Farmers Federation encouraged the APVMA to refine the application process for minor use permits through the adoption of a digital application process and a more pragmatic approach to the detailed evidence required for the application.⁷²

3.69 Agribusiness Australia highlighted an existing DAWR program that assisted with the costs of registrations for minor uses: the Improved Access to Agvet Chemicals Initiative. Agribusiness Australia stated the program helped alleviate regulation-generated market failure. It was noted this type of market failure often resulted from the high costs associated with registering products for minor uses that could not be offset by volume of sales.⁷³

3.70 The Improved Access to Agricultural and Veterinary Chemicals Initiative, which was established in 2014 (with \$8 million in funding to the end of the 2017–18 financial year), had several purposes, including:

- establishing an agvet collaborative forum to allow stakeholders to share access needs with each other and chemical companies;
- creating an official Australian crop grouping list and associated APVMA guidelines;
- migrating some APVMA permits to product labels; and
- developing an assistance grants program to help fund the generation of sufficient data to support applications to the APVMA.⁷⁴

3.71 Some submitters presented an alternative to promoting the increased availability of chemicals, arguing for the adoption of alternative and smaller farming practices over seeking new chemical solutions.⁷⁵ The Australian Food Sovereignty Alliance, for example, argued:

Despite the glaring need for a transition to ecological agriculture, agvet chemical use is increasing. Governments and regulators continue to

71 GrainGrowers, *Submission 23*, p. [6]. See also: Victorian Farmers Federation, *Submission 30*, p. [5].

72 Western Australian Farmers Federation, *Submission 15*, p. 3.

73 Agribusiness Australia, *Submission 30*, p. 7.

74 Department of Agriculture and Water Resources, *Improved Access to Agricultural and Veterinary Chemicals – \$8 million initiative*, <http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/improved-access-agvet-chemicals#about-the-new-funding> (accessed 10 January 2019); Australian Pesticides and Veterinary Medicines Authority, *The Crop Groupings Project*, <https://apvma.gov.au/node/18851> (accessed 10 January 2019).

75 See, for example: Local Environment Action Forum, *Submission 14*, p. 5; Mr Duncan Mills, *Submission 20*, p. 2; Ms Jessica Harrison, *Submission 37: Attachment*, p. [1]; Gene Ethics, *Submission 40*, p. 16; Pesticide Action Group WA, *Submission 104*, p. 21; M and P Wilson, *Submission 108*, p. [3].

facilitate pesticide industry claims to dictate the future of our food system. The number of small farms in Australia is decreasing, with only 10% of farms producing over half of our agricultural output, and more large farms consolidating to respond to pressures on the agribusiness industry.⁷⁶

3.72 The Australian Food Sovereignty Alliance also called for government support for the development of:

...businesses that create, sell and use sustainable alternatives to agvet chemicals, including agroecology and regenerative agriculture, organic alternatives to weed, insect and other pest management, and traditional agricultural pesticides, herbicides, fungicides and potentially veterinary solutions.⁷⁷

Greater efficiency through the use of international data

3.73 A number of submitters argued that more efficient and faster processing of applications would occur if the APVMA made greater use of international data and assessments within a risk-based assessment framework.⁷⁸

3.74 However, in calling for greater acceptance of international data, submitters were not of the view that Australia should automatically recognise or abide by the decisions of regulators from other jurisdictions.⁷⁹

3.75 The NSW Farmers' Association emphasised the need for an Australian regulator to consider the unique circumstances of Australian agriculture and the applicability of particular chemicals or veterinary medicines to the Australian environment. The association stated there had to be:

...an appropriate balance between referencing the approval process that has been relied upon internationally and the science that has been used to underpin some of those things, but then to make sure that that doesn't mean that when, for example, a European regulator coughs, Australia necessarily catches a cold when it comes to the application of that chemistry in this market.⁸⁰

3.76 It was suggested by the NSW Farmers' Association that the automatic acceptance of decisions made in other jurisdictions could lead to less stable decision

76 Australian Food Sovereignty Alliance, *Submission 90*, p. 6.

77 Australian Food Sovereignty Alliance, *Submission 90*, p. 28.

78 Grain Producers Australia, *Submission 11*, pp. 12–14; Western Australian Farmers Federation, *Submission 15*, p. 2; GrainGrowers, *Submission 23*, pp. 3, 6; Australian Dairy Industry Council and Dairy Australia, *Submission 25*, p. 2.

79 See, for example: Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, pp. 60–61.

80 Mr Robert Hardie, Policy Director, Environment, Cropping and Horticulture, NSW Farmers' Association, *Committee Hansard*, 20 November 2018, p. 18.

making and increase the risk of the politicisation of the approval of chemicals for use by the farm sector.⁸¹

3.77 The trade implications of using international data were identified by the National Farmers' Federation, which stated:

The APVMA also does a trade assessment, a market assessment, when it assesses chemicals, and that's important to note, because, I think you would acknowledge, other regulators don't necessarily service the same markets that Australia does. There are certainly members within our remit that would like to see that trade assessment remain, even with the acknowledgement of international processes. And that's pretty important. You can imagine a scenario where a product is approved in one country but they may not export to the same markets we do, so that's important to be taken into account in that process.⁸²

3.78 The APVMA previously agreed it was necessary to consider Australian situations and circumstances, providing the example that conditions placed on herbicides used in the EU would probably not be automatically transposed to herbicide use in tropical Queensland, due to requirements of state legislation to protect the Great Barrier Reef.⁸³

3.79 The Committee was informed the APVMA already participated in a global joint registration program, which aimed to improve the efficiency and effectiveness of the registration process by sharing data amongst participants. It also had a mutual recognition agreement with some regulators from Europe, Canada, New Zealand and the United States with regard to manufacturing standards.⁸⁴

3.80 Over recent years, the APVMA has been moving towards making greater use of international data and assessments and has made provisions for international work sharing. The regulator is participating in an Organisation for Economic Cooperation and Development process to establish a framework for global joint reviews; and has undertaken collaborative regulatory assessments of veterinary medicines with Canadian and New Zealand authorities.⁸⁵

3.81 Further, APVMA CEO, Dr Parker, recently issued a direction that detailed the expectations of the APVMA in relation to the use of international data, standards and

81 NSW Farmers' Association, *Submission 8*, pp. 7–8.

82 Mr Mark Harvey-Sutton, General Manager Rural Affairs, National Farmers' Federation, *Committee Hansard*, 20 November 2018, p. 18.

83 Australian Pesticides and Veterinary Medicines Authority quoted in, Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 302.

84 Western Australia Department of Primary Industries and Regional Development, *Submission 16*, p. 2; AgForce Queensland Farmers Limited, *Submission 34*, p. [3]; Australian Pesticides and Veterinary Medicines Authority, *Recognition of Overseas GMP Authorities*, <https://apvma.gov.au/node/141> (accessed 4 January 2019).

85 Australian Pesticides and Veterinary Medicines Authority, *Collaborative and International Assessments Including Work-Sharing*, <https://apvma.gov.au/node/1053> (accessed 10 January 2019).

assessments.⁸⁶ This legal direction requires APVMA staff to maximise the use of international assessments supplied with an application in order to improve the efficiency and timeliness of the APVMA's assessments.⁸⁷

86 Australian Pesticides and Veterinary Medicines Authority, *CEO Expectations on Use of International Data, Standards and Assessments*, 20 June 2018, https://apvma.gov.au/sites/default/files/publication/26886-26886-revised_ceo_expectations_for_use_of_international_data_standards_assessment_ceo_approved_final_1.pdf (accessed 4 January 2019).

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

Chapter 4

Chemical reconsideration and innovation

4.1 The APVMA has a formalised process for chemical reconsideration and a program for chemicals subject to review that is based on assessment of risk, rather than a pre-determined schedule. The risk principle establishes a balance between protecting community safety and maintaining access to safe and effective chemicals.

4.2 The APVMA's reconsideration of glyphosate, a chemical that is commonly used and essential to current farming methods in Australia, has been subject to intense scrutiny, particularly in response to a perceived disagreement with the evaluation undertaken by the International Agency for Research on Cancer (IARC). While the APVMA's chemical risk and weight-of-evidence approach contrasts with the IARC's hazard-based assessment, perceptions of a disagreement between the two demonstrate the challenges for the APVMA in educating and informing the general public of its approach.

4.3 The case of glyphosate has also raised the issue of alternative chemical use and the barriers to innovation and investment for the Australian market for Australian-specific pests. This chapter explores the chemical review process and evidence provided to the committee in relation to it.

Reconsideration (chemical review)

4.4 The APVMA has a legislated process, through its Chemical Review Program, to undertake a formal chemical review (or reconsideration) of active constituents after they have been approved or registered in Australia. This allows the authority to take into consideration new and/or emerging scientific information that could change the approved chemical's risk to human health, the environment, animal or crop safety, or trade. Typically, an APVMA review might focus on one or more areas, including environmental safety, worker safety, public health, residues, trade or efficacy.¹

4.5 A formal reconsideration process, under the Chemical Review Program, is initiated when new scientific information raises concerns relating to the safety or effectiveness of a pesticide or veterinary medicine. It incorporates legislative, administrative and scientific elements, which inform a final decision to affirm, vary, suspend or cancel an approval or registration.²

4.6 The APVMA observed that the process could be complex, requiring significant organisational resources and time. During the assessment phase of a reconsideration, companies must submit a range of data, which might include

1 Australian Pesticides and Veterinary Medicines Authority, *Chemical Review*, 18 May 2016, <https://apvma.gov.au/node/10916> (accessed 19 December 2018); Australian Pesticides and Veterinary Medicines Authority, *Submission 7*, p. 2.

2 Australian Pesticides and Veterinary Medicines Authority, *Chemical Review*, 18 May 2016, <https://apvma.gov.au/node/10916> (accessed 19 December 2018).

laboratory studies, the results of field trials, target animal or crop studies and human studies. These are scientifically assessed. Under current legislation, reconsiderations must be completed within a maximum timeframe of 57 months.³

4.7 The Committee received evidence that this timeframe was not always met. For example, the National Toxics Network stated the chemical chlorpyrifos had been under review by the APVMA for 22 years.⁴

4.8 The Australian Food Sovereignty Alliance also raised concerns with reconsideration timeframes and processes, stating:

Despite there being hundreds of chemicals on the market, the APVMA has only prioritised five chemicals for reconsideration in the next 5 years. And of the 11,700 toxic pesticides registered, only 13 are being reviewed. In terms of timeliness...a review of Chlorpyrifos began in 2009, Diazinon in 2003, and Paraquat 1997, but all are incomplete. By contrast, APVMA has completed assessment of 757 new chemical applications since September 2018.⁵

4.9 The APVMA acknowledged its chemical review program was behind schedule, but told the Committee that the risks were being managed. Dr Parker, CEO of the APVMA, explained:

It is routine for the APVMA to take interim regulatory action in the early stages of a chemical review to suspend registration, remove uses or adjust label directions as a precaution. It is also common for us to reinstate uses once they've been assessed by additional data that is provided throughout the review process and that is finalised in our regulatory decision. We did this with dimethoate, diuron and [f]enthion. This is the system working as intended. It balances the spectrum of community, user and industry perspectives by applying the scientific evidence to what can only be at times an emotive debate over the safety of agriculture and veterinary chemicals.⁶

Chemicals subject to review

4.10 Over 5,000 agvet chemical products currently available in Australia were registered under prior legislative arrangements, often involving less rigorous assessments, some of which date back to the 1950s. These chemicals, previously approved by the states and territories, were grandfathered into the NRS in 1995. The development of the NRS came out of a 1991 agreement between the Commonwealth,

3 Australian Pesticides and Veterinary Medicines Authority, *Chemical Review*, 18 May 2016, <https://apvma.gov.au/node/10916> (accessed 19 December 2018); Australian Pesticides and Veterinary Medicines Authority, *The Reconsideration Process*, <https://apvma.gov.au/node/10966> (accessed 4 January 2018).

4 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, pp. 26, 28.

5 Australian Food Sovereignty Alliance, *Submission 90*, pp. 13–14

6 Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 20 November 2018, p. 2.

states and territories to place under one national umbrella the assessment and registration of all agvet chemical products, which had hitherto been undertaken independently by the Commonwealth and each of the states and territories.⁷

4.11 Initially over 300 chemicals on the NRS were nominated by stakeholders as potential candidates for review. Ultimately, a priority list of 80 was established. In the years since the Chemical Review Program has been operating, an additional 80 chemicals have been nominated and prioritised for inclusion on the review list with the original 80 chemicals. Of the chemicals on the review list, 75 had been completed by 2014.⁸

4.12 The APVMA's process to identify and nominate chemicals for review remains ongoing. In 2015, the APVMA consulted the public, industry and federal and state government agencies on the prioritisation of 19 chemicals (or types of chemicals) it had identified for review. Five chemicals were prioritised for detailed scoping with the remainder prioritised once the first five had been commenced.⁹

4.13 The Committee heard evidence that between 20 and 30 chemicals currently sold in Australia had been either banned by other jurisdictions or were under serious review in other jurisdictions—some of which were grandfathered into the NRS.¹⁰

4.14 Bayer Crop Science responded to these claims and suggested that for insecticides and herbicides, 'there may be a difference between Europe and Australia', though they were not aware of any differences in registrations between the United States and Australia.¹¹

4.15 Bayer Crop Science went on to suggest that the differences in registration could depend on the types of data requirements of regulators:

In the EU right now, there's a guidance document that makes it extremely difficult to conduct the study in a way that can satisfy the requirements, so it's almost impossible to get through. That can raise an issue, whereas, in the risk based system that you have here in Australia or in the US or Canada, there are ways to tier those studies to make sure your product is

7 Productivity Commission, *Chemicals and Plastics Regulation*, July 2008, p. 209; Australian Pesticides and Veterinary Medicines Authority, *Legislative Framework*, <https://apvma.gov.au/node/4131> (accessed 10 January 2019).

8 Australian Pesticides and Veterinary Medicines Authority, *History of the Chemical Review Program*, 1 July 2014, <https://apvma.gov.au/node/10971> (accessed 19 December 2018); Ms Kareena Arthy, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Estimates Hansard*, 29 May 2014, p. 104.

9 Australian Pesticides and Veterinary Medicines Authority, *Chemicals Nominated and Prioritised for Reconsideration*, <https://apvma.gov.au/node/10876> (accessed 4 January 2019).

10 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, p. 29.

11 Dr William Reeves, Health and Safety Issues Manager, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 7.

safe, can be used safely and won't harm the environment but also is going through a reasonable scientific assessment.¹²

Differences between jurisdictions—risk and scheduled review

4.16 International regulators may use periodic reviews to conduct a re-evaluation of chemicals from first principles against contemporary standards, or target re-evaluations based on new information that addresses regulatory standards introduced since initial registration.¹³

4.17 For chemical review, other national regulators often operate under either risk-based principles or legislated timeframes. For instance, the Canadian PMRA has a legislated 15-year re-evaluation cycle to ensure products meet the latest health and environmental risk assessment standards. The European Union combines a risk-based approach with a maximum review period of 15 years. The United States Environmental Protection Agency (EPA) has a 15-year review period. Brazil has a risk-based approach.¹⁴

4.18 The APVMA's review program is risk-based. A review is considered when new scientific information becomes available that suggests there may be a change in the risk posed by a product. In 2013 and 2014, the authority was briefly required to conduct automatic reviews of all registrations according to certain specified timeframes. The 2013 Amendment Act inserted into the Agvet Code Act a requirement that the existing approvals and registrations of active constituents and chemical products operate for a finite period; and when that period elapsed, a new application was to be lodged for re-approval or re-registration.¹⁵ The *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* repealed this provision.¹⁶

4.19 Many witnesses and submitters favoured a risk-based approach to re-evaluation.¹⁷ One consideration emphasised in submissions was the adverse consequences of the cost to industry of providing the information required by the

12 Dr William Reeves, Health and Safety Issues Manager, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 7.

13 Department of Agriculture and Water Resources, *Submission 9*, p. 3.

14 Reason Group, *Independent Review of Assessment Performance: Australian Pesticides and Veterinary Medicines Authority*, December 2017, pp. 37–55; Dr William Reeves, Health and Safety Issues Manager Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 6.

15 Paula Pyburne, *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014*, *Bills Digest No. 93*, 2013–14, Parliamentary Library, Canberra, 2014, p. 3.

16 Paula Pyburne, *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014*, *Bills Digest No. 93*, 2013–14, Parliamentary Library, Canberra, 2014, p. 3.

17 See, for example: AUSVEG, *Submission 12*, p. [2]; CropLife Australia, *Submission 10*, p. 13; Western Australian Farmers Federation, *Submission 15*, p. 2; National Farmers' Federation, *Submission 27*, p. [2].

regulator during the review process. These costs would be exacerbated if scheduled (rather than risk-based) reviews were enforced. DAWR stated the cost to industry in addressing a review had 'resulted in the withdrawal of some chemical products from the market in the absence of identifiable concerns for human, animal or environmental health'.¹⁸

4.20 This perspective, particularly in the case of chemicals with a small (yet important) market in Australia, was supported by the Australian Glyphosate Sustainability Working Group.¹⁹ Chemistry Australia also spoke in support of a risk-based approach, stating:

In the context of our economy and the size of our economy, a reconsideration process akin to what they have in the United States would be costly, cumbersome and probably not deliver a lot better outcome.²⁰

4.21 Mr Bernard Lee, Director of Policy and Regulation at Chemistry Australia further explained that in the United States, the fact that the chemistry is under constant review creates its own obstacle to market entry and can result in farmers potentially paying more for the chemical products. Mr Lee continued:

If you wanted to duplicate that in this country, the market size is not large enough to be having all of the companies involved generating data on an ad hoc basis for a chemical review program. It is far better that it be targeted at the risks associated. That's the beauty of the system we have—the regulator can respond. If it identifies concerns—if there are community concerns or if there are international developments that it becomes aware of—it can respond and place a chemical under review.²¹

4.22 The Australian Glyphosate Sustainability Working Group described the consequence of undertaking compulsory reviews of all products, and the impact these reviews would have on companies:

The APVMA is looking after hundreds of active ingredients and, if we were to have a review time frame that was too short, they'd be doing nothing but reviewing existing products, which would just waste everybody's time...One of the issues we have with reviews of agricultural products is that, once products are off-patent, companies are much less likely to do any work to protect those products in the marketplace because the return on the investment is going to be very small because you have a large number of generic players. So, part of the risk we would run in having a too tight or a too firm review process is that products which have been perfectly safe and with which we've had years and years of safe use would simply not be

18 Department of Agriculture and Water Resources, *Submission 9*, pp. 3–4.

19 Dr Christopher Preston, Chair, Australian Glyphosate Sustainability Working Group, *Committee Hansard*, 7 December 2018, pp. 13–14.

20 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 50.

21 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 50.

reregistered because nobody would present the data. They couldn't make any money out of doing so because of all the generic players in the marketplace. We have hundreds of generic players in the marketplace in Australia.²²

4.23 CropLife Australia also raised the workload associated with scheduled re-evaluation and drew upon the example of Canada, which has a 15-year re-evaluation for registered pesticides. It was noted that the re-evaluation workload was not sustainable, with the agency lacking resources to manage upcoming scheduled re-evaluations. The PMRA had almost double the staff of the APVMA. CropLife Australia also provided evidence of the regulatory burden of scheduled re-evaluations (and their delays) in the EU and the United States.²³

4.24 The APVMA, given the nature of the formal process, stated that it 'seeks to address regulatory issues pragmatically by exploring alternative regulatory and non-regulatory pathways before deciding to conduct a review'.²⁴

4.25 DAWR noted that although there were different triggers for regulatory reconsideration in other similar agencies located in international jurisdictions, once started, APVMA reconsiderations were 'comparable in their assessment rigour once evaluation has commenced'.²⁵

APVMA chemical risk approach

4.26 As with regulators in other countries, the APVMA undertakes a risk-based weight-of-evidence assessment to determining chemical risk.²⁶ A risk-based assessment includes a hazard assessment and an exposure assessment. It draws upon evidence reproduced independently by different researchers.²⁷

22 Dr Christopher Preston, Chair, Australian Glyphosate Sustainability Working Group, *Committee Hansard*, 7 December 2018, p. 13.

23 CropLife Australia, *Submission 10*, pp. 13–15.

24 Australian Pesticides and Veterinary Medicines Authority, *Chemical Review*, 18 May 2016, <https://apvma.gov.au/node/10916> (accessed 19 December 2018).

25 Department of Agriculture and Water Resources, *Submission 9*, pp. 3–4. See also: United States Environmental Protection Agency, *Submission 109*, pp. 1–2.

26 The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) also adopts a risk-based approach. The United States Environmental Protection Agency uses a standard risk assessment procedure and a weight-of-evidence approach. Dr Brian Richards, Executive Director, Office of Chemical Safety, and Director, National Industrial Chemicals Notification and Assessment Scheme, Department of Health, *Committee Hansard*, 20 November 2018, p. 34; United States Environmental Protection Agency, *Submission 109*, pp. 3–4.

27 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

Risk assessment: hazard assessment and exposure assessment

4.27 A hazard assessment examines the data related to the intrinsic toxicity potential of an active ingredient and/or formulated product, and is the first step in determining whether a chemical poses an undue risk.²⁸

4.28 An exposure assessment involves an examination of the likely exposure of humans and environmental organisms to a chemical, and considers how the chemical product is intended to be used, the type and formulation of the product, and the crops or animals to be treated.²⁹

4.29 By combining these two elements, the APVMA assesses the likelihood and extent to which an adverse outcome would occur if the product was used according to the instructions on the approved product label.³⁰

Weight-of-evidence assessment

4.30 In a weight-of-evidence assessment, data is considered validated when it is reproduced independently by different researchers. This type of assessment considers the number of studies reporting a particular conclusion and the quality of the study design and data evaluation.³¹

4.31 Although there was significant support for the APVMA's chemical risk approach, several submitters were critical of it (for both initial assessment and reconsideration), calling instead for the introduction of a system based on the precautionary principle.³² Gene Ethics explained that in the European re-approval and re-registration process, which is based on the precautionary principle, 'if registrants do not come up with the evidence to show their products are safe, they are deregistered'.³³ This issue is discussed further in chapter 5.

Glyphosate

4.32 The case of the glyphosate re-assessment is illustrative of the broad range of factors that bear upon the work of chemical regulators.

28 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

29 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

30 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

31 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

32 Ms Ruth Weston, *Submission 4*, p. [1]; Local Environmental Action Forum, *Submission 14*, p. 1; Mr Duncan Mills, *Submission 20*, p. [1]; Friends of the Earth Australia, *Submission 35*, p. [2]; Ms Janet Grogan, *Submission 36*, p. [2]; Ms Kali Moynihan, *Submission 43*, p. [1]; Sustainable Agriculture & Communities Alliance, *Submission 76*, p. 2; Australian Food Sovereignty Alliance, *Submission 90*, p. 10; Pesticide Action Group WA, *Submission 104*, p. 5.

33 Gene Ethics, *Submission 40*, p. 1.

4.33 In 2015, the World Health Organization's IARC evaluated glyphosate as 'probably carcinogenic to humans'.³⁴ In the same year, the APVMA proactively self-nominated glyphosate for reconsideration.³⁵

4.34 The Committee was told there had been considerable community concern raised by the IARC report. The Australian Glyphosate Sustainability Working Group spoke of reactions within the agricultural community:

They [were] concerned about how this has happened, because they'd been told for years and years that glyphosate was safe, and suddenly here it was as a probable carcinogen and did they have to worry about it and those sorts of things.³⁶

4.35 More broadly, the Committee was informed that some local councils were reviewing their use or had stopped using Roundup (glyphosate) for weed management.³⁷ Some submissions to the inquiry drew on the IARC report to call for further examination of glyphosate while others called for it to be restricted or phased out on the basis that there remained too many questions as to the chemical's safety.³⁸ Gene Ethics was of the view that:

Overall it is fair to say that IARC conclusions call into question the safety of GBHs [glyphosate-based herbicides] beyond 'reasonable certainty of no harm'...To improve GBH safety standards...the following [should] be urgently undertaken...:

- human biomonitoring for glyphosate and its metabolites;
- prioritisation of glyphosate and GBHs for hazard assessments, including toxicological studies that use state-of-the-art approaches;
- epidemiological studies, especially of occupationally exposed agricultural workers, pregnant women and their children; and evaluations of GBHs in commercially used formulations, recognising that herbicide mixtures likely have effects that are not predicted by studying glyphosate alone.³⁹

34 World Health Organization International Agency for Research on Cancer, *IARC Monographs Volume 112: Some Organophosphate Insecticides and Herbicides*, July 2015, p. 78.

35 CropLife Australia, *Submission 10*, p. 11.

36 Dr Christopher Preston, Chair, Australian Glyphosate Sustainability Working Group, *Committee Hansard*, 7 December 2018, p. 10.

37 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, p. 59.

38 See, for example: Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, p. 19; Local Environmental Action Forum, *Submission 14*, p. 5; Mr Chris Anderson, *Submission 38*, p. [1]; Mr Richard Nankin, *Submission 77*; Australian Food Sovereignty Alliance, *Submission 90*, p. 27; Pesticide Action Group WA, *Submission 104*, p. 2.

39 Gene Ethics, *Submission 40*, pp. 9–10.

APVMA assessment of glyphosate

4.36 The APVMA commissioned the Office of Chemical Safety (OCS) within the Department of Health to undertake a two-phase review of the IARC report:

- phase 1: a preliminary scoping review of the IARC report to determine the relevance of the glyphosate classification as 'probably carcinogenic to humans' and the implications for glyphosate approvals and registrations in Australia; and
- phase 2: detailed assessment of studies identified during the phase 1 assessment which required further evaluation.⁴⁰

4.37 The APVMA also evaluated the studies referenced in the IARC report, as well as other studies and data, including recent international assessments of glyphosate undertaken by other regulators.⁴¹

4.38 The APVMA received 197 submissions during a consultation period on the proposed regulatory position report and the OCS reports between 30 September 2016 and 30 December 2016. Submissions were received from:

- representatives of growers who use glyphosate (2);
- representatives of non-government organisations (8);
- private business (1); and
- members of the public (186).⁴²

4.39 The APVMA noted that the majority of submissions received were beyond the scientific scope of the APVMA's assessment; and no new scientific evidence relating to the possible carcinogenicity of glyphosate not already considered by the APVMA was received during the consultation period.⁴³

4.40 In March 2017, the APVMA released its final regulatory position on glyphosate, which stated:

Based on this nomination assessment, the APVMA concludes that the scientific weight-of-evidence indicates that:

- exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans

40 Australian Pesticides and Veterinary Medicines Authority, *Final regulatory position: Consideration of the evidence for a formal reconsideration of glyphosate*, March 2017, p. 8.

41 Australian Pesticides and Veterinary Medicines Authority, *Final regulatory position: Consideration of the evidence for a formal reconsideration of glyphosate*, March 2017, p. 8; Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 20 November 2018, p. 2.

42 172 of these were generated from an online petition campaign. Australian Pesticides and Veterinary Medicines Authority, *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate*, March 2017, pp. 9, 15.

43 Australian Pesticides and Veterinary Medicines Authority, *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate*, March 2017, p. 9.

- there is no scientific basis for revising the APVMA's satisfaction that glyphosate or products containing glyphosate:
 - would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
 - would not be likely to have an effect that is harmful to human beings
 - would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment
 - would be effective according to criteria determined by the APVMA by legislative instrument, and
 - would not unduly prejudice trade or commerce between Australia and places outside Australia.
- there are no scientific grounds for placing glyphosate and products containing glyphosate under formal reconsideration
- the APVMA will continue to maintain a close focus on any new assessment reports or studies that indicate that this position should be revised.⁴⁴

4.41 The APVMA responded to questions about the comprehensiveness of its re-evaluation of glyphosate during a public hearing. Dr Parker stated:

When the APVMA looked at the International Agency for Research on Cancer's report on glyphosate, we evaluated all 264 studies referenced in that report, plus further studies and data. We took the time to get the science right. We found that, on balance of scientific information, we did not have a need to change our stance on glyphosate.⁴⁵

4.42 Many submissions to the Committee supported the APVMA's assessment.⁴⁶ However, some interpreted it as contradicting the IARC findings (and other international evidence). A significant number of submitters argued there was

44 Australian Pesticides and Veterinary Medicines Authority, *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate*, March 2017, p. 9.

45 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.

46 See, for example: CropLife Australia, *Submission 10*, p. 1; Western Australian Farmers Federation, *Submission 15*, p. 2; GrainGrowers, *Submission 23*, pp. 4–5; CropLife Australia *Submission 108 (Response)*; pp. 3–4; Agribusiness Australia, *Submission 30*, p. 6.

sufficient publicly available evidence that demonstrated the dangers of glyphosate, and that this evidence had been ignored by the regulator.⁴⁷

4.43 Academic and research scientist, Dr Ian Musgrave, indicated that he had examined the process used by the APVMA in its review and advised the Committee:

I checked the APVMA review against the similar reviews produced by the EFSA, the ECHA and the US EPA and compared what they reviewed, how they reviewed it and the depth of the review. My conclusion was that the APVMA had done a comparable job to other regulators in coming to their conclusion.⁴⁸

4.44 Bayer Crop Science gave evidence to the Committee that there was no engagement by Monsanto Australia with the APVMA as part of APVMA's review 'on any matters of substance'. However, there had been limited communication at relevant times about the APVMA's intentions for the review with regard to process and timing, and to clarify the scope of the review. Bayer Crop Science stated 'the review undertaken by APVMA was independent of any input from Monsanto Australia'.⁴⁹

IARC assessment

4.45 The IARC report (referred to as a monograph) on glyphosate was an evaluation of cancer hazard—defined as 'an agent capable of causing cancer under some circumstances'. This differed to an evaluation of cancer risk—defined as 'an estimate of the carcinogenic effects expected from exposure to a cancer hazard'.⁵⁰

4.46 The IARC emphasised the distinction between hazard and risk, stating that its *Monograph* publications 'identify cancer hazards even when risks are very low at current exposure levels'.⁵¹

4.47 The classification given by the IARC to a chemical is based on the strength of the evidence that an agent causes cancer. It is a measure of how confident the scientists who undertook the evaluation are that an agent causes cancer in humans. As a consequence, elements with different potencies can be placed in the same classification. The IARC cites the case of tobacco, plutonium, diesel engine

47 See, for example: Dr Alison Bleaney, *Submission 3*, p. 3; Ms Rosemary Mason, *Submission 5 (Attachment)*, p. 1; Local Environmental Action Forum, *Submission 14*, pp. 4–5; National Toxics Network, *Submission 24*, p. 5; Ms Jessica Harrison, *Submission 37*, p. [1]; Mr Chris Anderson, *Submission 38*, p. 1; Mr Richard Nankin, *Submission 77*, pp. 2–3, 14; M Oliver, *Submission 91*, p. [1]; Ms Patsy Lisle, *Submission 92*, p. [1]; Ms Robin Thomas, *Submission 110*.

48 Dr Ian Musgrave, *Committee Hansard*, 7 December 2018, p. 41.

49 Mr Tony May, Commercial Operational Lead, Bayer Crop Science, answers to questions on notice, 7 December 2018 (received 21 December 2018), p. 2. See also: Dr Nina McCormick, Regulatory Affairs, Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 4.

50 World Health Organization International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble*, 2006, p. 2.

51 World Health Organization International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble*, 2006, p. 2.

emissions, hepatitis viruses and processed meat as having sufficiently strong evidence to classify them in the same group of cancer-causing agencies—group 1.⁵²

4.48 Given its stated purpose, the IARC report examined the intrinsic toxicity potential of glyphosate as a cancer-causing agent only. The IARC's evaluation consulted epidemiological studies that examined the circumstances under which human exposure occurs and at what levels. However, according to the APVMA, the assessment did not specifically consider risk management in actual use situations, nor did it examine the risk of cancer when glyphosate was used according to label instructions in a registered chemical product.⁵³

4.49 The IARC stated that identifying a carcinogenic hazard, based upon observable data, was a first step in risk assessment and management. It deferred risk assessment and risk management to national and international bodies; judging that risk assessment involved extrapolation beyond observed data, and risk management included social, economic and political considerations.⁵⁴

4.50 Dr Musgrave summarised the findings of the IARC report, observing:

The IARC concluded that glyphosate was a probable human carcinogen. They made that ruling independent of whether humans will be exposed to the levels of glyphosate that could potentially cause any form of cancer...it picks up hazards. Then it is up to the regulators...to make regulations based on their understanding of the data that the IARC brings forward.⁵⁵

Use of glyphosate in Australia

4.51 Bayer Crop Science estimated that around \$400 million of glyphosate-based products were sold in the Australian market each year—the largest selling agricultural chemical product on the Australian market.⁵⁶ The Committee was also told glyphosate had been crucial to growth in farming productivity in Australia's dry conditions.⁵⁷

52 World Health Organization International Agency for Research on Cancer, *IARC Response to Criticisms of the Monographs and the Glyphosate Evaluation*, January 2018, https://www-prod.iarc.fr/wp-content/uploads/2018/07/IARC_response_to_criticisms_of_the_Monographs_and_the_glyphosate_evaluation.pdf (accessed 12 December 2018), p. 8.

53 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018); World Health Organization International Agency for Research on Cancer, *IARC Response to Criticisms of the Monographs and the Glyphosate Evaluation*, January 2018, https://www-prod.iarc.fr/wp-content/uploads/2018/07/IARC_response_to_criticisms_of_the_Monographs_and_the_glyphosate_evaluation.pdf (accessed 12 December 2018), p. 7; Dr Ian Musgrave, *Submission 41*, p. [3].

54 World Health Organization International Agency for Research on Cancer, *IARC Response to Criticisms of the Monographs and the Glyphosate Evaluation*, January 2018, https://www-prod.iarc.fr/wp-content/uploads/2018/07/IARC_response_to_criticisms_of_the_Monographs_and_the_glyphosate_evaluation.pdf (accessed 12 December 2018), p. 9.

55 Dr Ian Musgrave, *Committee Hansard*, 7 December 2018, p. 43.

56 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 4.

57 GrainGrowers, *Submission 23*, p. [7]; Agribusiness Australia, *Submission 30*, p. 5.

4.52 The Committee was advised that herbicides, including glyphosate, contribute to the preservation of soil health and stored carbon through their ability to facilitate no-till (or minimum till) farming practices; and through reducing chemical use in genetically modified canola systems.⁵⁸

4.53 Bayer Crop Science elaborated on what it saw as the benefits of glyphosate:

It really has enabled the uptake of zero-till farming, and, without those sort of practices, we wouldn't be able to store moisture over summer and we wouldn't be able to have more reliable cropping systems, and I think we've also seen higher yields. But we've also seen some environmental benefits around the reduction in tillage, and the reduction in wind and water erosion.⁵⁹

4.54 Around 85 per cent of growers in Australia were estimated by Grain Producers Australia to have adopted no-till production systems, one of the highest rates in the world.⁶⁰ Chemistry Australia gave evidence that glyphosate:

...has led to more sustainable agriculture, particularly the practices of minimum till. Minimum till reduces agricultural CO₂ emissions and it aids in the retention of soil moisture. Without advances like this from chemistry, we might well be sitting here today discussing the loss of Australia's prime agricultural land due to soil erosion.⁶¹

4.55 Grain Producers Australia also observed that 'farmers today are growing a lot more on a lot less moisture with the technology that's available to us. One of those key parameters for us is the use of glyphosate in terms of that minimum tillage and stored water'.⁶²

4.56 Given its centrality to contemporary farming methods, the Committee received evidence regarding the impact that the loss of glyphosate would have. The Grains Research and Development Corporation stated that, 'if glyphosate, for some reason, were no longer available and herbicide resistance continues to spread, it will cause pain to our grain growers'.⁶³ This was confirmed by GrainGrowers, which pointed out:

58 NSW Farmers' Association, *Submission 8*, pp. 12–13; Mr David McKeon, Chief Executive Officer, GrainGrowers Limited, *Committee Hansard*, 20 November 2018, p. 38.

59 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 2.

60 Dr Rohan Rainbow, Consultant Adviser, Grain Producers Australia, *Committee Hansard*, 20 November 2018, p. 45.

61 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 46.

62 Mr Andrew Weidemann, Chairman, Grain Producers Australia, *Committee Hansard*, 20 November 2018, p. 44.

63 Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, p. 31.

When we consider Australian grain farmers, we're talking about a group of a bit over 20,000 farm businesses who sustainably manage over 20 million hectares of Australian agricultural land, so there is a very large area that they look after and manage. And, if we think about those growers, if there were an immediate ban on, or removal of, glyphosate from the system, that would have absolutely catastrophic short-term impacts on Australian production systems.⁶⁴

4.57 AgForce Queensland agreed with other stakeholders about the significant consequences should glyphosate become unavailable, stating:

If, from public pressure and lack of trust, social licence caused the loss of glyphosate, the farming sector—our grain areas, our cane areas and all those areas—would no longer be able to do minimal till and no till. They would have to go back to tilling the land, which is digging up the soil, because minimum till and no till require herbicides to suppress the weeds, and that organic layer is keeping those soils protected until you plant your crop.⁶⁵

4.58 The NSW Farmers' Association described the potential impacts of removing glyphosate from agricultural activities and estimated that without glyphosate:

There would be an annual environmental loss associated with a net increase in the use of herbicides of 8.2 million kg of herbicide active ingredient (+1.7%), and a larger net negative environmental impact, as measured by the environmental impact quotient indicator of a 12.4%. Also, there would be additional carbon emissions arising from increased fuel usage and decreased soil carbon sequestration, equal to the equivalent of adding 11.77 million cars to the roads.⁶⁶

4.59 Many submitters and witnesses identified the lack of viable alternatives to glyphosate and the consequences for farming and food production should it become unavailable or banned in other jurisdictions.⁶⁷

4.60 The National Farmers' Federation contended that this was a particular concern for an industry that was export exposed.⁶⁸ AUSVEG noted the lack of alternative products, saying it would be 'catastrophic' to the industry if glyphosate were taken off the market.⁶⁹ Grain Producers Australia agreed, pointing out:

64 Mr David McKeon, Chief Executive Officer, GrainGrowers Limited, *Committee Hansard*, 20 November 2018, p. 39.

65 Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland Farmers Limited, *Committee Hansard*, 7 December 2018, p. 57.

66 NSW Farmers' Association, *Submission 8*, pp. 12–13.

67 GrainGrowers, *Submission 23*, p. [7]. See also: Micro Survey Response—Glyphosate, attachment to GrainGrowers, *Submission 23*.

68 Mr Chris Groves, Chair, Farming Systems Committee, National Farmers' Federation, *Committee Hansard*, 20 November 2018, p. 15.

69 Mr Tyson Cattle, National Public Affairs Manager, AUSVEG, *Committee Hansard*, 20 November 2018, p. 53.

There are no other alternatives at the moment, which is a concern for industry. We don't have any other alternatives...The ability for us to produce as we do today will be reduced, because we won't have that alternative—we'll have to go back to tillage. Burning will become more of a consequence of that—that's one of the natural weed control methods that we still have today, but you will see a lot more concentration of that. You will also see us having to resort to using other products that we don't necessarily want to use, such as gramoxone and spray seed—those two particular products are S7 poisons. For farmers, they're products that we don't necessarily like to use...you would be going back to probably half of the current production area of cropping. So you take all those things into account, in a growing global climate of farmers right across the world having to do the same thing, and then we're in no-man's-land.⁷⁰

4.61 The trade impacts of glyphosate's removal were illustrated by Grain Producers Australia:

If consumers around the world banned glyphosate, particularly the European Union, that would have a big impact on our marketing of our grain into those particular markets...they're going to be asking us to do something that we cannot do in terms of our production system here in Australia. We will have no other alternative...⁷¹

4.62 The difficulty of finding viable alternatives to glyphosate was also made clear to the Committee. CropLife Australia remarked that 'even with US\$10 billion of research and development money each year, none of our members have come up with an alternative yet'.⁷²

4.63 However, some submitters contended that there were alternatives to glyphosate and other chemicals, and these could include: blade cultivation, rod and saturated steam weeding, swathng (for wet harvest), mechanical slashing, hand weeding, strategic plantings, and solarizing.⁷³

Innovation for Australian conditions

4.64 The glyphosate case raises concerns about the next generation of pesticides and veterinary medicines, particularly for a country like Australia that experiences specific conditions and represents a small market when compared globally.⁷⁴

70 Mr Andrew Weidemann, Chairman, Grain Producers Australia, *Committee Hansard*, 20 November 2018, p. 44.

71 Mr Andrew Weidemann, Chairman, Grain Producers Australia, *Committee Hansard*, 20 November 2018, p. 45.

72 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, p. 59.

73 Mr Duncan Mills, *Submission 20*, p. [2]; Ms Jessica Harrison, *Submission 37 (Attachment)*, p. [1]; M and P Wilson, *Submission 108*, p. [3].

74 Mr David Mailler, Chair, Agricultural Science Committee, NSW Farmers' Association, *Committee Hansard*, 20 November, p. 16.

4.65 The growth of resistance to pesticides in some areas adds urgency to the situation. Apple & Pear Australia, for example, noted that resistance was becoming a more serious issue for its industry.⁷⁵ AgForce Queensland stated:

An increasing concern for AgForce is resistance of parasitic ticks to most acaricides and limited products for goat parasites. There is no interest from agvet chemical registrants to develop new products for use in Australia and no catalyst from Australian Government innovation programs to overcome pesticide resistance.⁷⁶

4.66 Associate Professor Christopher Preston also put forward his views on the role of pesticides, pointing out:

This reliance on pesticides has come at some cost. Pests are evolving resistance to pesticides requiring the adoption of new strategies for pest management and the need for new pesticides. On the other side, Australia is a relatively small market for pesticides. Internationally, there has been tremendous consolidation in the agricultural chemical space as companies merge. This has dramatically reduced the number of companies doing research and development on new pesticide molecules and frequently these molecules are being developed for large markets in Europe and North and South America and the main commodity crops grown in those locations.⁷⁷

4.67 Bayer Crop Science, which completed its acquisition of Monsanto in 2018, indicated that it spent approximately \$2.6 billion each year on research and development, yet:

The ability to find products has become harder and harder. Success in finding new compounds takes a lot more investigation and a lot more time, and there is a much greater cost to bring them to market than ever before.⁷⁸

4.68 Bayer Crop Science also noted:

Bringing new chemical compounds to market is now much more difficult than ever. Thirty years ago, an average of one in every ten thousand compounds that was tested could be developed for commercial release. Now the rate is only one in every fifty thousand.⁷⁹

4.69 Evidence provided to the inquiry indicated that Australia remains a low priority for chemical producers. For example, Grain Producers Australia commented:

Australia is no longer on the global priority list for pesticide and veterinary medicine investment in commercialisation as it was 20 years ago. Australia

75 Apple & Pear Australia Ltd, *Submission 31*, p. [1]. See also: Australian Food Sovereignty Alliance, *Submission 90*, p. 31.

76 AgForce Queensland Farmers Limited, *Submission 34*, pp. [4–5].

77 Associate Professor Christopher Preston, *Submission 19*, pp. [2–3]. See also: Gene Ethics, *Submission 40*, p. 5.

78 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, pp. 2–3.

79 Bayer Crop Science, *Submission 21*, p. 3.

is also missing out from productivity improvement through commercial investment in a large number of potential emerging biological, biochemical and biotechnology based AgVet technologies.⁸⁰

4.70 This point was echoed by AgForce Queensland:

Australia is only a very small part of the marketplace for most pesticides—I think just over 1.25 per cent of agvet chemicals internationally are used here—and most of our ticks are more an Australian pest; they're not in every other country. So, for a lot of the large pesticide companies, there is insufficient return on investment for them to work on a new active constituent or a new pesticide that would overcome these issues we get of pesticide resistance. Because there are millions of dollars that go into finding a product and doing all the necessary testing to be able to get it registered, unless a company knows it can forecast sales in that area, it's not willing to do that work.⁸¹

Australian conditions

4.71 The Committee heard there have been some programs that aim to address Australian-specific pest-management issues. One program run by the Grains Research and Development Corporation (GRDC) in conjunction with Bayer Crop Science has funded 33 postdoctoral positions to explore molecules effective in Australian conditions on Australian weeds. Under the partnership, postdoctoral students studied in Germany with Bayer Crop Science. The intent of the program was to put extra capacity into discovery for herbicides.⁸²

4.72 The GRDC reported that it had been working more broadly with the Bayer herbicide innovation platform so Australian weeds were included in initial screenings in herbicide discovery, including some resistant species. The early molecules were then brought to Australia and tested under Australian conditions against Australian weeds. According to the GRDC, part of the intention of the work with Bayer was to try to discover new chemistries that had the potential to replace chemicals like glyphosate.⁸³

4.73 Further, the GRDC has worked with the University of Western Australia under the Australian Herbicide Resistance Initiative to implement harvest wheat seed

80 Grain Producers Australia, *Submission 11*, p. 9. See also: Victorian Farmers Federation, *Submission 30*, p. [5].

81 Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland Farmers Limited, *Committee Hansard*, 7 December 2018, pp. 59–60.

82 Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, p. 17; Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 3.

83 Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, pp. 30–31.

control. It was also investigating the use of microwaves and lasers, and the strategic use of tillage to control weeds.⁸⁴

4.74 Bayer Crop Science's Commercial Operations Lead, Mr Anthony May, argued that programs like the GRDC postdoctoral program had 'certainly elevated Australia and Australian weeds in that targeted area—where we might have been left behind—to larger markets, so I think it's been very effective in that way'.⁸⁵

4.75 The importance of understanding the operation of chemicals in specific conditions was highlighted by Associate Professor Susan Wilson. Noting that weed incursions into Antarctica and the sub-Antarctic are a considerable threat, she explained that there was a concern about the application of glyphosate in soils in that region when the research on it has been conducted with different soils and climatic conditions. Associate Professor Wilson continued:

There's been a little bit on cold climate in the Arctic, in the Northern Hemisphere. We've done a literature review in the first instance. As to how we test glyphosate in Macquarie Island soil, we bring back the actual soil and we specifically look at what would happen in the soil we're applying it to. We're subjecting it to the lower temperatures and where you might have higher persistence, a lot of rainfall and greater mobility. We're seeing whether that is the case or isn't the case for glyphosate in those systems so that, if a decision does need to be made regarding glyphosate use in weed management, the regulators have the science to make sound decisions.⁸⁶

84 Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, pp. 30–31.

85 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 8.

86 Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 17.

Chapter 5

Transparency and community consultation

5.1 The importance of transparency and the need to maintain the confidence of the communities they serve are fundamental to the operations of the APVMA and regulators across the world. This inquiry has identified a number of issues that the APVMA must address if it is to maintain a strong level of community confidence in its decisions.

5.2 Many submitters to the inquiry expressed concern about the operations of the APVMA, including the regulator's priorities, processes, independence and responsiveness. Concerns were also raised about the availability of data and evidence, and the dangers of glyphosate and a range of other chemicals.¹ The lack of confidence in the work of the regulator expressed in evidence to the committee was affirmed in a 2018 survey of the APVMA which found that only 62 per cent of respondents held the view that the regulator's decisions were underpinned by science.²

5.3 While considerable evidence to the committee raised concerns about the APVMA's decisions, the inquiry has revealed that it is the manner in which decisions are communicated, rather than the scientific soundness of the decisions themselves, that requires improvement. Furthermore, there would appear to be considerable scope for the APVMA to improve its community consultation processes in order to better understand and respond to community concerns. Implementation of a community consultation mechanism would also assist the regulator in combating some of the community's concerns about its independence and assist in demystifying its decisions for the general public.

Confidence in the regulator and industry social licence

5.4 It became clear to the Committee that stakeholders who had active and regular engagement with the APVMA were more likely to have confidence in its scientific rigour and independence; whilst organisations and individuals who did not have direct or regular contact with the authority tended to question its impartiality, processes and evaluations.

5.5 For instance, Cotton Australia, which regularly engages with the APVMA, stated:

1 See, for instance: H Ross, *Submission 28*; Mrs Lara Warwick, *Submission 29*; Ms Jessica Harrison, *Submission 37*; Mr Chris Anderson, *Submission 38*; Ms Alison Wylie, *Submission 39*; Gene Ethics, *Submission 40*; Ms Kali Moynihan, *Submission 43*; Mr Andrew Zimmerman, *Submission 66*; Ms Svyetlana Hadgraft, *Submission 69*; Mr Neal Salan, *Submission 74*; Sustainable Agriculture & Communities Alliance, *Submission 76*; Mr Richard Nankin, *Submission 77*; Ms Patsy Lisle, *Submission 92*; Ms Vanda Grabowski, *Submission 93*; Ms Sarah Toose, *Submission 98*; Joint Submission, *Submission 103*; Pesticide Action Group WA, *Submission 104*; Alliance for a Clean Environment, *Submission 105*.

2 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, p. 32.

The safety of agricultural chemicals for users, communities, consumers and the environment must be of the highest priority. Regulatory decisions must be made independently, using rigorous scientific methods, to ensure the safety of the community, animals and the environment. The APVMA is globally recognised as a world leading regulator that makes decisions based on science.³

5.6 As discussed in previous chapters, this view was widely held across the agricultural and veterinary medicines industries. At the same time there was recognition that this was not sufficient. It was agreed that the agriculture industry also required a social licence, particularly in the context of greater consumer advocacy and sometimes negative representations of farming and chemical use.⁴

5.7 A representative of both the National Farmers' Federation and NSW Farmers' Association informed the Committee:

We are now as organisations and as a farming community very aware of our...social licence to operate, because so many people are watching everything we do. We are covering everything, making sure that, as much as possible, it is acceptable. I also have a fair bit to do with agripolitics and animal welfare, and something we are looking at there is the fact that it has to be socially acceptable, and chemical usage definitely comes under that. We have to make sure that what we are doing is socially acceptable to the community.⁵

5.8 Those organisations and individuals who voiced a lack of confidence in the APVMA were equally suspicious of the chemical industry and raised concerns about the relationship between the two. As a case in point, Ms Immig from the National Toxics Network expressed the view that:

The ag and vet chemical lobby are extremely powerful and they are getting exactly what they want, while the community and the environment pay the price for continued registration and use of dangerous pesticides.⁶

5.9 Friends of the Earth Australia told the Committee that 'time and time again in history, there are chemicals that are regarded as safe and then, five or ten years later, scientists will find somewhere that they're not safe at all'.⁷

5.10 Focusing on the glyphosate matter, Dr Musgrave explained the lack of trust some within the broader community had in the APVMA:

3 Cotton Australia, *Submission 6*, p. [1].

4 See, for instance: NSW Farmers' Association, *Committee Hansard*, 20 November 2018, pp. 20–22.

5 Mr Chris Groves, Chair, Farming Systems Committee, National Farmers' Federation; Vice President, NSW Farmers' Association, *Committee Hansard*, 20 November 2018, p. 16.

6 Ms Joanna Immig, National Toxics Network Inc, *Committee Hansard*, 7 December 2018, p. 25.

7 Mr Anthony Amis, Pesticides and Drinking Water Campaigner, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 53.

The subject of glyphosate is particularly emotive, the potential for wide ranging entry of this chemical into the ecosystem (despite evidence that glyphosate residues on Australian crops are negligible), the emotive association glyphosate with Genetically Modified crops and Monsanto (despite glyphosate being off patent and being manufactured by many other companies now), misunderstanding of the amounts consumers are exposed to and the confusion of Australian versus US farming practices makes it difficult for consumers to feel they have trust in regulatory agencies. A similar emotive issue arose recently with the relatively safe insecticide pyriproxyfen. Issues such as lack of autonomy in decision making and perceived lack of transparency in information exchange contribute to this lack of trust.

Events such as the recent Californian court case suggest to consumers that their regulatory agencies are compromised, regardless of the actual facts... Regaining this trust will require substantial effort, and the lessons around vaccine hesitancy may be relevant here where public trust is eroded despite significant evidence of benefit and minimal harm.⁸

5.11 To address concerns about transparency and to meet legislative requirements, the APVMA publishes application summaries, and information on manufacturing licences and approval or variation of an active constituent or registration. It also makes available information about its regulatory processes.⁹

5.12 Nevertheless, many organisations including the National Toxics Network explained that they were unable to discuss matters of concern directly with the APVMA. The issue of consultation and communication is considered later in this chapter.

Concerns raised about the APVMA

A potential conflict in the role of the APVMA

5.13 A number of submitters raised concerns about what they saw as an inherent conflict in the ability of the APVMA to protect community wellbeing whilst also furthering trade and commerce, and the viability of Australia's primary industries.

5.14 This issue was previously recognised by the Productivity Commission, which identified the multiple considerations and potential need for tradeoffs in the Agvet Code Act. The Agvet Code Act recognises, amongst a range of other things:

- a) that the protection of the health and safety of human beings, animals and the environment is essential to the well-being of society and can be enhanced by putting in place a system to regulate agricultural chemical products and veterinary chemical products; and

8 Dr Ian Musgrave, *Submission 41*, p. [4].

9 Australian Pesticides and Veterinary Medicines Authority, *Transparency*, <https://apvma.gov.au/node/267> (accessed 10 January 2019).

- b) that the principle of ecologically sustainable development requires a regulatory system that is designed to ensure that the use of such products today will not impair the prospects of future generations; and
- c) that the furthering of trade and commerce between Australia and places outside Australia, and the present and future economic viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products, are essential for the well-being of the economy and require a system for regulating such products that is cost-effective, efficient, predictable, adaptive and responsive...¹⁰

5.15 Some stakeholder groups suggested the APVMA was not taking human health and impacts on the environment into account when making assessments or decisions. Gene Ethics criticised what it perceived as the APVMA's priority 'to get new active ingredients onto farms'.¹¹ The Local Environmental Action Forum stated the safety of human and environmental health should be the APVMA's top priority.¹²

5.16 The National Toxics Network was also of the view that a better balance was required within the APVMA, arguing:

It's all about efficiency at the front end to get the products on to the market quickly, which is fair enough, but it consistently fails to review chemicals in a timely way and get them off the market when it's needed...The balance between safeguarding community and environmental health and agricultural productivity has been out of kilter for decades.¹³

Comprehensiveness of APVMA assessments

5.17 Two key issues were raised in evidence regarding the comprehensiveness of the regulator's assessments: the product-specific focus of APVMA assessments; and perceived shortcomings with the regulatory science approach.

5.18 Friends of the Earth Australia suggested APVMA assessments were incomplete:

At the assessment stage, the APVMA assesses only individual chemicals and not the combined, synergistic, cumulative and long term impacts on human health and the environment. In assessing the safety of chemicals, the APVMA does not assess the safety of whole formulations but solely so-called 'active ingredients'—despite the evidence that many 'inactive'

10 *Agricultural and Veterinary Chemicals Code Act 1994* (long title). See also: Productivity Commission, *Chemicals and Plastics Regulation*, July 2008, p. 204.

11 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, p. 22.

12 Mr Marden Philip Hundley, Local Environmental Action Forum, *Committee Hansard*, 7 December 2018, p. 62.

13 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, p. 25.

ingredients can have significant impacts on the nature and scale of the chemical's impacts.¹⁴

5.19 This view was supported by an earlier review of the APVMA's risk-assessment processes undertaken by the Australian Academy of Technological Sciences and Engineering that found (as reported by the Productivity Commission):

APVMA hazard and risk assessments are product specific and do not consider the cumulative and synergistic environmental and health effects of multiple chemicals. There is no routine assessment of multiple exposures or of all likely workplace mix combinations of pesticides. Further, there is no assessment of the cumulative or synergistic effects of multiple pesticide residues on human health, or on the environment.¹⁵

5.20 Gene Ethics also voiced its concerns over the APVMA's assessment processes, suggesting:

The APVMA's assessments are not scientific or objective as only the so-called active components of chemical formulations are the primary focus of assessment and regulation, yet many other ingredients can also pose substantial but unassessed hazards. APVMA assessments are also blind to the cumulative and synergistic impacts of multiple chemicals all approved on the same crops. For instance, a carrot may have up to 14 different approved chemicals sprayed on it, yet each of those chemicals is assessed and approved in isolation from all the others. The interaction of their residues in human and animal food supplies is also ignored.¹⁶

5.21 DAWR challenged these views, noting that under the National Residue Survey Program, it undertook monitoring of agvet chemical and environmental contaminant residues in food commodities and published the results of the annual survey. The survey involved random, targeted and compliance monitoring of agvet chemical residues and environmental contaminants in selected animal and plant products. The survey helped to identify compliance issues that may require follow-up action by regulators.¹⁷

5.22 Concerns about the scientific basis of the APVMA's assessments were often tied to questions about the appropriateness of regulatory science in assessing chemicals, and calls for the adoption of the precautionary principle.

5.23 In making a case for the precautionary principle, some submissions drew upon the APVMA's 2015 *Regulatory Science Strategy: Consultation Draft* definition of regulatory science. The draft definition stated:

What differentiates regulatory science from conventional [research] science is that decisions are based on analysis and interpretation of existing

14 Friends of the Earth Australia, *Submission 35*, p. [4].

15 Productivity Commission, *Chemicals and Plastics Regulation*, July 2008, p. 207.

16 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, p. 19.

17 Department of Agriculture and Water Resources, *Submission 9*, p. 6.

scientific knowledge and, where necessary, assumptions to address data gaps or uncertainty. Regulatory scientists do not generate new lines of enquiry to answer questions, instead relying on available information (provided by applicants or in the literature) to make a decision one way or another.¹⁸

5.24 Gene Ethics, in particular, criticised this approach by suggesting it was 'passive and selective' and allowed applicants to submit unverified evidence in support of their claims of safety and efficacy and where gaps existed, allowed assumptions to be made.¹⁹

5.25 The APVMA pre-empted some of these criticisms in its consultation draft by confirming the broad expertise of regulatory scientists, stating:

While regulatory science incorporates a variety of scientific disciplines, it is in itself a specialised field of science. Most regulatory scientists have trained and worked in conventional scientific research, and additionally have gone through 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.²⁰

5.26 The APVMA released its final *Regulatory Science Strategy* in 2016, which detailed the scientific basis of the regulator's decisions and outlined six strategic initiatives to further strengthen its regulatory science expertise. The strategy also contained an updated definition of regulatory science:

Regulatory science differs from research science in that decisions are based on analysis and interpretation of existing scientific knowledge and—where necessary—use of conservative assumptions, based on a precautionary approach to deal with data gaps or uncertainty. It is uncommon for regulatory scientists to instigate new lines of enquiry by conducting their own scientific experiments or trials. They rely on information provided by applicants or generated by research scientists and published in the peer-reviewed scientific literature to make a decision.²¹

5.27 Many criticisms of the APVMA's assessment processes were accompanied by a call for the authority to adopt the precautionary principle (to be distinguished from

18 Australian Pesticides and Veterinary Medicines Authority, *APVMA Regulatory Science Strategy: Consultation Draft*, November 2015, p. 3.

19 Gene Ethics, *Submission 40*, p. 18.

20 Australian Pesticides and Veterinary Medicines Authority, *APVMA Regulatory Science Strategy: Consultation Draft*, November 2015, p. 3.

21 Australian Pesticides and Veterinary Medicines Authority, *APVMA Regulatory Science Strategy*, August 2016, p. 4.

the APVMA's precautionary approach), which requires evidence to prove a chemical is safe, rather than relying upon the absence of evidence it is unsafe.²²

5.28 The Australian Food Sovereignty Alliance drew upon an example of the precautionary principle in practice in the *Environment Protection and Biodiversity Conservation Act 1999*, which provides a 'legal framework to protect and manage nationally and internationally important flora, fauna, ecological communities and heritage places'.²³ The Act's definition of the precautionary principle provides that:

...[a] lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage.²⁴

5.29 Friends of Earth Australia also criticised the APVMA for not applying the precautionary principle:

In Europe, pesticides have to be proven safe to human health and the environment in order to be allowed onto the European market. It is the responsibility of industry to provide the data showing that a pesticide can be used safely. Australia does not have the same system as Europe and the APVMA does not apply the same precautionary approach.

The APVMA implicitly shifts from a safety first to a market first approach by conflating the notion that no evidence of harm is the same as evidence of safety...it means that intervention will only occur once 'sufficient' evidence is provided to justify intervention. This occurs rarely.²⁵

5.30 The Committee heard, however, that the APVMA can and does have the authority to request information from registrants where there are identified gaps in scientific information. It was suggested that in the reconsideration process, the APVMA constantly calls for new data.²⁶

Public availability of data and peer review

5.31 Several submissions were critical of the APVMA not making data publicly available for peer review and for relying upon industry funded science or

22 See, for example: Ms Ruth Weston, *Submission 4*, p. [1]; Local Environmental Action Forum, *Submission 14*, p. 1; Mr Duncan Mills, *Submission 20*, p. [1]; Ms Janet Grogan, *Submission 36*, p. [2]; Ms Kali Moynihan, *Submission 43*, p. [1]; Sustainable Agriculture & Communities Alliance, *Submission 76*, p. 2; Australian Food Sovereignty Alliance, *Submission 90*, p. 10; Pesticide Action Group WA, *Submission 104*, p. 5.

23 Australian Government Department of the Environment, *EPBC Act—Frequently Asked Questions*, http://www.environment.gov.au/system/files/resources/0de020d9-1c03-40d3-adb2-54710b97dbac/files/epbc-act-fact-sheet_2.pdf (accessed 4 January 2019).

24 *Environment Protection and Biodiversity Conservation Act 1999*, ss. 391(2).

25 Friends of the Earth Australia, *Submission 35*, p. [2].

26 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 49.

company-provided data as the basis for regulatory approval.²⁷ Friends of the Earth Australia, for example, commented:

The literature is now littered with examples of industry hiding data that shows evidence of harm and hiring compliant academics to produce evidence that suggests safety, such as with asbestos, tobacco and, we would argue, now, glyphosate as well.²⁸

5.32 However, it was put to the Committee that there was a conflict between making data publicly available for peer review, and protecting the proprietary information of companies. Bayer Crop Science contended:

I think the challenge there would be you have this problem that there's a reason a lot of the data and studies are held as proprietary. They can be used by anyone to register, and it's a considerable amount of resources to get those studies conducted.²⁹

5.33 However, Bayer Crop Science also acknowledged the need for publicly available peer reviewed studies; with the proviso there would be other studies not made publicly available for proprietary reasons, but they would be considered as part of risk assessments.³⁰

5.34 The Committee also heard support for current regulatory practices given that under such practices, companies were required to provide evidence that a substance was safe.³¹ Chemistry Australia stated:

The way the system works at the moment is that people who want to advance a position have to get independent research undertaken to prove and establish certain facts that prove that, when the product is used in accordance with the labelled directions, it doesn't present unacceptable risk to human health and to the environment.³²

Community consultations and responsiveness

5.35 Industry submitters and witnesses generally expressed satisfaction with the responsiveness of the authority, whereas other submitters and witnesses called for greater consultation and responsiveness to community concerns, including broader representation on the proposed APVMA board.

27 See, for example: Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 17; Mr Jeremy Tager, Campaigner, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 53.

28 Ms Louise Sales, Emerging Tech Project Coordinator, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 52.

29 Dr William Reeves, Health and Safety Issues Manager, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 5.

30 Dr William Reeves, Health and Safety Issues Manager, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 5.

31 Dr Ian Musgrave, *Committee Hansard*, 7 December 2018, p. 45.

32 Mr Bernard Lee, Director, Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 50.

5.36 The views of the Veterinary Manufacturers and Distributors Association in this regard were broadly representative of industry perceptions:

Since its inception as a national regulator in 1994, the NRA, now APVMA, has monitored and engaged with industry to ensure that our production processes and capabilities and the scientific data that we supply to justify product registrations remain at the forefront of international standards for animal health products. In return, we hope that our members can continue to engage with the regulator on a cooperative basis to ensure the ongoing development of our industry and the delivery of safe and effective animal health products to not only Australia but the world.³³

5.37 This view was not widely shared beyond industry representatives. A number of submitters and witnesses voiced concern about the regulator's lack of responsiveness to community concerns. For example, Gene Ethics advised:

We receive emails regularly from them [APVMA] about gazettals of changes to things like maximum residue levels and the introduction of new active ingredients. You can make comments; you get no feedback. Certainly an exchange of information and views is important. There are no forums for doing that...It appears that the advisory bodies do not include public interest representatives, and I think anybody who's advising regulators should necessarily have, as part of its membership, those interested and informed members of the community who have the expertise, the time and the energy to make input.³⁴

5.38 Friends of the Earth Australia gave evidence that the APVMA had previously been more responsive to community views. An APVMA advisory board and community consultative committees provided a means through which community concerns could be expressed and considered. However, both were abolished. According to Mr Anthony Amis of Friends of the Earth Australia, there was no explanation offered when the APVMA advisory board was abolished in 2015 and members of the APVMA community consultative committees were not provided any rationale when the committees were shut down in 2012. He concluded that the APVMA has moved backwards in terms of its engagement with the community and that the regulator demonstrated an unwillingness to disclose its work to a wide section of the community.³⁵

5.39 The National Toxics Network echoed this view and emphasised the importance of consultation:

When we had greater access to the APVMA and their staff, when they had advisory committees, we used to have a lot more robust discussions. But

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

34 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, pp. 21–22. See also: Ms Ruth Weston, *Submission 4*.

35 Mr Anthony Amis, Pesticides and Drinking Water Campaigner, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 53.

since those committees no longer exist, we actually find it much more difficult to raise our concerns in a productive way with the APVMA. However, on occasions, when we are discussing certain issues, there are certain members of staff who are willing to talk to us on the phone and to provide their perspective, which is helpful.³⁶

5.40 The Committee heard there appeared to be an imbalance between the APVMA's consultations with industry and its consultations with community groups. For instance, Friends of the Earth Australia referenced evidence from DAWR with regard to the proposed APVMA governance board and told the Committee:

It says that there were 13 meetings with industry—either CropLife or other representatives of the agrochemical industry—and I note that there were absolutely no meetings with any public health experts, any environmental groups or any risk assessment experts. In that document it talks about lowering the costs of doing business and reduced regulatory burden. We're really concerned that this seems to be a consistent emphasis, and I notice in the APVMA's reporting on its performance that it all seems to be about rushing as many chemicals through as quickly as possible. That's how they're recording their performance.³⁷

5.41 Some submitters called for community representation on the proposed governance board for the APVMA.³⁸ The legislation for the APVMA board was introduced in the Senate in September 2018 as an amendment to the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*. According to DAWR, the purpose of the board would be to:

- ensure the proper, efficient and effective performance of the APVMA's functions;
- determine the policies, objectives and strategies to be followed by the APVMA; and
- be the accountable authority under the *Public Governance, Performance and Accountability Act 2013*.³⁹

36 Ms Joanna Immig, National Coordinator, National Toxics Network Inc, *Committee Hansard*, 7 December 2018, p. 26.

37 Ms Louise Sales, Emerging Tech Coordinator, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 52. See also additional information: Department of Agriculture and Water Resources, Inquiry into the Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA): APVMA Governance Board, additional information received 22 November 2018.

38 For further information on the proposed governance board, see: Department of Agriculture and Water Resources, Inquiry into the Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA): APVMA Governance Board, additional information received 22 November 2018.

39 Department of Agriculture and Water Resources, Inquiry into the Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA): APVMA Governance Board, additional information received 22 November 2018.

5.42 The Government's intention was for the board to be skills-based, and to comprise five members: the chair, three board members, and the APVMA CEO as an *ex officio* member.⁴⁰

5.43 With regard to representation on the board, a number of environmental and community groups advocated for wide representation beyond the industry. Ms Immig from the National Toxics Network expressed the view that any proposed governance board should contain members outside of industries 'that want to sell or benefit from the use of those chemicals'. Noting that the core business of the APVMA is to protect health and the environment in relation to pesticides use, she argued in favour of appointing board members who represented those sectors.⁴¹

5.44 In terms of engaging with the community, the Committee found that the APVMA does, as part of its reconsideration powers under the Agvet Code within the Agvet Code Act, invite any person through a public invitation notice to propose active constituents, chemical products, or labels for chemical reconsideration. A person proposing a chemical/product or label for reconsideration must submit reasons (based on the statutory criteria of safety; efficacy; trade; labelling; or a subset determined by the APVMA) for the proposal.⁴²

5.45 Further, the APVMA is required to make efforts to ensure its process for reconsideration is transparent. When commencing a chemical reconsideration, the APVMA prepares and publishes on its website, a work plan that provides information on the specific process. This includes expected dates for information requests and opportunities for interested parties to contribute to the reconsideration.⁴³

5.46 When making a decision in a chemical reconsideration, the APVMA must have regard to:

- the information given to it in response to notices or invitation for comment;
- the results of trials it required holders to conduct;
- information it has received independent of the chemical reconsideration that would suggest one or more of the safety, efficacy, trade or labelling criteria may not be met; and
- any other information it deems necessary.⁴⁴

40 Department of Agriculture and Water Resources, Inquiry into the Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA): APVMA Governance Board, additional information received 22 November 2018.

41 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, pp. 29-30. See also: Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, pp. 21–22.

42 Department of Agriculture and Water Resources, *Submission 9*, p. 2.

43 Department of Agriculture and Water Resources, *Submission 9*, p. 2.

44 Department of Agriculture and Water Resources, *Submission 9*, p. 3.

Consultative forums

5.47 Regulators overseas have adopted various models to engage with and address community concerns. Two such models are the UK Pesticides Forum and the US EPA Pesticide Program Dialogue Committee (PPDC).

UK Pesticides Forum

5.48 In 1996, the UK Government established the Pesticides Forum to engage a range of organisations interested in how pesticides were used and the impact of their use. In 2013, under the European Union mandated *UK National Action Plan for the Sustainable Use of Pesticides*, its role was expanded to provide for stakeholder interaction and an annual report on developments in the action plan.⁴⁵

5.49 Other than maintaining stakeholder oversight of the UK National Action Plan, the Forum aims to monitor the effects of policies, laws and other initiatives that affect or are affected by the use of pesticides, and offer advice to ministers and stakeholders as appropriate. It is a forum for exchanging views, and wherever possible, allowing stakeholders (people with an interest in the work of the Forum) to come to a general agreement.⁴⁶

5.50 The Forum's terms of reference are to:

- bring together the views of those concerned with the use and effects of pesticides and identify their current interests;
- assist in the effective dissemination of best practice, advances in technology and research and development in results; and
- advise government on the development, promotion and implementation of its policy relating to the responsible use of pesticides.⁴⁷

5.51 The Forum also works to a series of objectives around communication, impact monitoring, and knowledge transfer. It has three groups, which examine specific sectoral issues: Grower Liaison; Amenity Use Liaison; and Amateur (home and garden) Liaison.⁴⁸

45 Health and Safety Executive, *Pesticides Forum*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/grouphome> (accessed 2 January 2019); Department for Environment, Food & Rural Affairs, *UK National Action Plan for the Sustainable Use of Pesticides (Plant Protection Products)*, February 2013.

46 Health and Safety Executive, *About the Forum: Pesticides Forum Aims, Objectives and Terms of Reference*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=36915&exp=e1> (accessed 2 January 2019).

47 Health and Safety Executive, *About the Forum: Pesticides Forum Aims, Objectives and Terms of Reference*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=36915&exp=e1> (accessed 2 January 2019).

48 Health and Safety Executive, *About the Forum: Pesticides Forum Aims, Objectives and Terms of Reference*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=36915&exp=e1> (accessed 2 January 2019).

5.52 The Forum intentionally includes stakeholders with differing views about pesticides and how the impacts of their use should be addressed. Member organisations, of which there are currently 26, include those who make, use or advise on pesticides as well as environmental, conservation and consumer interest groups. Membership covers the farming (conventional and organic production), farming equipment and pesticide industries; environmental and conservation groups; education and training; consumer interests and trades unions. Representatives from all UK government departments responsible for, or interested in, pesticides in the UK also participate in meetings.⁴⁹

5.53 The Forum provides a mechanism for exchanging ideas, encouraging joint initiatives to address particular issues and giving advice to Government on practical aspects of pesticide usage.⁵⁰ Minutes from the meetings of the Forum are publicly available, as are a range of papers and presentations.⁵¹

Environmental Protection Agency: Pesticide Program Dialogue Committee

5.54 The Pesticide Program Dialogue Committee (PPDC) was established in 1995 as a forum for stakeholders to provide policy advice, information and recommendations to the EPA on a range of pesticide regulatory, policy and program implementation issues, but specifically on:

- developing practical, protective approaches for addressing pesticide regulatory policy, program implementation, environmental, technical, economic and other policy issues; and
- reviewing proposed modifications to the EPA's Office of Pesticide Programs' current policies and procedures, including the technical and economic feasibility of any proposed regulatory changes to the current process of registering and re-evaluating pesticides.⁵²

5.55 The EPA selects members of the PPDC, of which there are currently 37, to represent a diverse group of stakeholders. Members are drawn from pesticide user, grower and commodity groups; consumer and environmental public interest groups; farm worker organisations; pesticide industry and trade associations; state, local and

49 Health and Safety Executive, *About the Forum*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=36915&exp=e1> (accessed 2 January 2019).

50 Health and Safety Executive, *Pesticides Forum*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/grouphome> (accessed 2 January 2019).

51 Health and Safety Executive, *Forum Meetings*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=37683&exp=e1> (accessed 2 January 2019).

52 United States Environmental Protection Agency, *Pesticide Program Dialogue Committee (PPDC)*, <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc#about> (accessed 11 January 2019); United States Environmental Protection Agency, *Pesticide Program Dialogue Committee Charter*, <https://www.epa.gov/sites/production/files/2018-04/documents/ppdc-2017-renewal-charter.pdf> (accessed 11 January 2019).

tribal governments; federal government; academia; the general public; and public health organisations.⁵³

5.56 Topics discussed at meetings vary, but have included the following:

- regulatory issues such as registration, reduced risk pesticides, labelling, fees, experimental use permits, environmental marketing claims, pollinator protection;
- science issues including toxicology, non-animal testing and ecological standards; and
- a range of other topics like integrated pest management, public health, spray drift, antimicrobial pesticides, engendered species, minor uses, and public engagement.

5.57 The PPDC is permitted, with the EPA's approval, to form subcommittees or workgroups for any purpose consistent with its charter. It currently has two active workgroups: pollinator protection plan metrics; and public health. Records from 16 previously active workgroups are available on the EPA's website.⁵⁴

5.58 The PPDC meets twice a year and its meetings are open to the public. Meeting papers are published on the EPA website. Members of the public are encouraged to contribute to each meeting during the comment session or by submitting comments prior to the meeting.⁵⁵

5.59 The EPA identified the PPDC as an important way to ensure the inclusion of stakeholders in its scientific and policy decisions.⁵⁶

Liaison between industry and APVMA

5.60 In addition to providing for more formal engagement between the APVMA and community groups, the Committee was provided with evidence about the importance of facilitating contact between industry and the regulator. A number of stakeholders expressed their strong support for organised interactions between industry and the APVMA, as had occurred previously on both a formal and informal basis.

53 United States Environmental Protection Agency, *Submission 109*, p. 2; United States Environmental Protection Agency, *Pesticide Program Dialogue Committee Charter*, <https://www.epa.gov/sites/production/files/2018-04/documents/ppdc-2017-renewal-charter.pdf> (accessed 11 January 2019); United States Environmental Protection Agency, *Pesticide Program Dialogue Committee—Roster 9/12/2018*, <https://www.epa.gov/sites/production/files/2018-09/documents/ppdc-roster-9-12-2018.pdf> (accessed 11 January 2019).

54 United States Environmental Protection Agency, *Pesticide Program Dialogue Committee (PPDC)*, <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc#about> (accessed 11 January 2019).

55 United States Environmental Protection Agency, *Pesticide Program Dialogue Committee (PPDC)*, <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc#about> (accessed 11 January 2019).

56 United States Environmental Protection Agency, *Submission 109*, p. 2.

5.61 Greater industry involvement, including in the development of policies on the responsibilities of the industry sector and national regulators, was suggested by Grain Producers Australia. The organisation stated such work was supported by the Strategic Approach to International Chemicals Management under the United Nations Environment Program, which aimed to promote chemical safety around the world.⁵⁷

5.62 The NSW Farmers' Association agreed industry engagement with the APVMA was appropriate to 'ground-test the agency's work' and to ensure safe chemical use, for instance, to test if there was a 'proper understanding of APVMA labelling'.⁵⁸

5.63 Veterinary Manufacturers and Distributors Australia identified the need for contact between the regulator and industry, particularly in understanding the organisation's procedures and requirements:

We are invited to become involved in situations where the regulator is trying to improve its processes, such as clarity around the top 20 project, which is a means of trying to set standards and/or procedures that will make it clearer and more certain as to what is required...it's a little bit like a maze where you run into a brick wall with an application and all you can do is back up and start again. There's no clear overview of where an application will go.

To be fair to the APVMA, they are working on developing such a thing. The industry—our body and others—are involved in that so that there will be some sort of clear critical path or Gantt chart that will show you, 'At this point you will need X information,' which at least would allow you to say, 'If we can't get that information, there's no point in proceeding with this application.' At the moment, the formal procedure is to just put it in and wait for a brick wall to be thrown up.⁵⁹

5.64 The benefits of industry and the APVMA working together were also identified by Horticulture Innovation, with Ms Jodie Pedrana remarking that the APVMA had offered considerable guidance, particularly about the data required to support an application for a permit. She explained that the APVMA had helped and guided Horticulture Innovation in order that it could undertake the required residue data, efficacy data or crop safety data required to make an application more successful and to protect industries and consumers in the process. Ms Pedrana also remarked of the APVMA:

They've communicated different areas to our growers continuously to inform them of decisions that might impact them with regard to reviews...It

57 Grain Producers Australia, *Submission 11*, p. 5.

58 NSW Farmers' Association, *Submission 8*, p. 12.

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

takes time to generate the data, and they've guided us through that process so we can be successful.⁶⁰

5.65 Industry stakeholders spoke highly of the broader assistance APVMA scientists provided to industry. For example, Cotton Australia stated:

On the resistance management plan...our scientists did a lot of work and set up some tactics that farmers have to carry out if they grow a genetically modified cotton crop, and those tactics were developed in consultation with the owners of the GM product, with our farmers in the industry and with the APVMA, so it's a process where we all work together with the best possible science to put these robust processes in place to stop resistance developing to the insects. You've got this situation where the protein or the chemical that's killing the insects is actually in the plant, so there is a high chance that you could get resistance unless you have these strategies. We work with the APVMA to do that. As Dr Taylor said, there are now published scientific papers out there that hold Australia up as the glowing example of how to do this, how to have these tactics that maintain the GM crop and stop resistance developing. So it is a really important role that the APVMA has played...a very important role in working with the proponents and with industry to get that right, because that is, if you like, on the label. This resistance management plan is something legally the farmers have to comply with.⁶¹

5.66 While there was general agreement that the formal consultation processes of the past were beneficial to a wide range of stakeholders, the Committee was cautioned that they should not be reintroduced without prior consultation and improvement. For example, the Veterinary Manufacturers and Distributors Association explained that the former formal industry liaison committee was not well designed. Mr Jim Adams, Executive Director noted that the APVMA had 'shoe-horned all of its technical people into the industry liaison committee'. He continued:

We had a table like this and quarterly meetings, and we tried to talk about policy with 20 different opinions in the room, some from organisations with a broad view and others from people...who have one single issue with one single product.⁶²

60 Ms Jodie Pedrana, Research and Development Manager, Horticulture Innovation Australia, *Committee Hansard*, 20 November 2018, p. 27.

61 Mr Adam Kay, Chief Executive Officer, Cotton Australia, *Committee Hansard*, 20 November 2018, pp. 50–51.

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

Chapter 6

Committee view and recommendations

6.1 The APVMA has a crucial role in assessing, registering and regulating agvet chemicals in Australia. An effective and efficient regulator is essential to protect the health and safety of people, animals and the environment, and to support trade and commerce in agricultural commodities. To carry out its legislated functions, the APVMA must make efficient decisions to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products, whilst at the same time maintaining the confidence of both industry and the community.

6.2 A number of issues have combined to create a situation where the APVMA will face significant challenges in maintaining its ability to effectively regulate agvet chemicals. The decision to relocate the APVMA to Armidale has hampered the regulator's ability to address a number of long-running issues with regard to its performance and funding. Without any prior strategic planning to address the inevitable upheaval that would come from relocating a specialist scientific agency, the regulator has lost important institutional knowledge and technical expertise and must now overcome numerous challenges to effectively and efficiently carry out its functions.

6.3 Evidence to the Committee has suggested that it will take the APVMA a number of years to regain its lost scientific, technical and management strength. The concern was raised that this will not only affect the APVMA's ability to effectively regulate agvet chemicals, but will also hinder the implementation of urgent organisational reforms required for its effective operation.

Consequences of relocation

6.4 The Committee is concerned about the manner in which the APVMA was relocated to Armidale and of its impact on the availability of staff expertise and assessment timeframes. It notes the flow-on effects for farmers across Australia who require timely and certain access to pesticides and veterinary medicines. Further, the relocation has the potential to undermine, or at least set back, the benefits that were to have come from reforms within the authority.

6.5 The Committee was informed that the satellite office in Canberra was retained in order for the APVMA to maintain its performance and fulfil its statutory responsibilities. Despite the best efforts of the APVMA in exploring a range of mechanisms to fulfil these functions from Armidale, including that of drawing on the private sector, the APVMA had no other option than to retain a satellite office in Canberra.

6.6 Whilst the Committee appreciates the rationale for retaining a Canberra satellite office, the evidence is clear that the relocation of the APVMA to Armidale has undermined the authority's ability to retain scientific and other experienced staff that would allow it to undertake its regulatory functions in a timely manner.

6.7 The Committee notes that staff shortages have resulted in management-level staff undertaking non-registration-related activities, with increasing amounts of time being spent on general application processing at the expense of other activities. That the APVMA is currently reviewing several aspects of its own operations, and is the subject of proposed legislative change, adds to the non-regulation-related workload of the authority.

6.8 The Committee regrets that the relocation has also brought into question the independence of the authority and has delayed the implementation of essential reforms within the authority, which would have improved its performance as well as public confidence in its operations.

6.9 The Committee believes the importance of having a regulator that is able to conduct robust, scientifically based regulatory activities cannot be underestimated and should not be jeopardised.

6.10 It is vital that the regulator maintains the necessary expertise to assess all applications it receives, and is able to oversight and control the assessment process. The Committee upholds the view that sufficient staff should be retained so as to ensure the authority is able to fulfil its regulatory responsibilities in a timely and efficient manner. The Committee also appreciates the considerable efforts underway by the APVMA to attract and secure staff, and in particular regulatory scientists.

Use of international data to improve regulator efficiency

6.11 The Committee heard suggestions that within a risk-based framework, a greater use of international data and assessments would improve the regulator's efficiency.

6.12 The Committee welcomes the direction issued by APVMA CEO, Dr Parker, to APVMA staff detailing expectations with regard to the use of international data, standards and assessments. Whilst the Committee is of the view that the APVMA must make decisions based on Australian legislative requirements, the regulator should incorporate the findings of international assessments as appropriate.

6.13 The Committee notes that whilst the authority has made significant effort in the area, some industry stakeholders remain concerned about the APVMA's processes for accepting international data in support of registering products in Australia. The Committee therefore encourages the APVMA to continue to liaise with industry to provide clarity to applicants.¹

Training regulatory scientists

6.14 The Committee recognises the particular specialist skills required by regulatory scientists and the difficulties the APVMA faces in recruiting and training

1 See: Australian Dairy Industry Council and Dairy Australia, *Submission 25*, p. 2; Australian Pesticides and Veterinary Medicines Authority, *Guidance for Applicants—Submission of International Data, Standards and Assessments*, <https://apvma.gov.au/node/14186> (accessed 4 January 2019).

new scientific staff, which itself can take three to five years. The reported global shortage of regulatory scientists adds a complicating factor.

6.15 The Committee acknowledges the work of the APVMA to train its newly recruited regulatory scientists through the Accelerated Regulatory Science Training Program. However, it believes a 10-month training program, however intensive, cannot compensate for the lost experience and expertise that was caused by the decision to relocate the authority.

6.16 Having considered the evidence presented, the Committee believes that over the next five years, there is a risk that the quality of the authority's assessments will be affected by a lack of expertise and experience. The absence of a robust quality control framework exacerbates this problem.

6.17 Having regard to evidence of a shortage of regulatory scientists, and the need for regulatory scientists across a number of government agencies, the Committee believes there is merit in investigating the education, training, and future supply of regulatory scientists in Australia. The Committee is of the view the sector would benefit from the establishment of more graduate courses in regulatory science, and consideration of a dedicated school of regulatory science.

6.18 The Committee acknowledges the current work being undertaken by enHealth in relation to the regulatory science workforce (both in the private and public sector), and encourages the APVMA to continue its participation in this study. The Committee considers, however, that the Australian Government should be treating this issue as a matter of priority.

6.19 The Committee also believes there is much to be gained from the regulator working with existing educational institutions to provide practical experience for science students in a regulatory environment, with the long-term outcome of ensuring Australian agencies are able to attract suitably qualified staff.

6.20 In light of these views, the Committee makes the following recommendations for a scoping study on the Government's need for regulatory scientists, and the expansion of integrated learning opportunities in regulatory environments for science graduates.

Recommendation 1

6.21 The Committee recommends that the Australian Government undertakes a comprehensive scoping study on the need for regulatory scientists across Australian Government agencies. The scoping study should consider:

- (a) the current educational, training and work experience environment for regulatory scientists;**
- (b) the likely future demand for regulatory scientists and the skills and competencies they will require; and**
- (c) the findings of the Environmental Health Standing Committee (enHealth) on the need for regulatory scientists.**

6.22 In undertaking this study, relevant educational and training bodies, and Australian Government agencies, should be consulted as required.

Recommendation 2

6.23 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority works closely with the Australian education sector to identify and expand integrated learning opportunities that would provide science graduates with experience in regulatory environments.

Regulator performance and efficiency

6.24 The Committee acknowledges there is a longer history of performance and efficiency concerns in relation to the APVMA, and that the regulator has been subject to significant administrative, legislative and regulatory change.

6.25 The additional pressure created by the relocation to Armidale, not the least of which has been caused by the loss of a significant proportion of the regulator's experienced staff, has exacerbated a number of underlying problems. The relocation has caused considerable disruption to staff and severely weakened the authority's ability to operate effectively and efficiently. Based on the evidence before it, the Committee recognises that the Government must prioritise the authority's ability to perform its regulatory functions over imposing an overarching policy of decentralisation.

6.26 The Committee expresses concern that reforms such as a robust quality control framework and a fit-for-purpose workflow management system remain unfulfilled at a time of significant disruption. Indications from the regulator are that these reforms remain years from completion.²

2 The implementation of the authority's digital strategy was funded over three years from mid-2018; and the internal quality framework remains in the planning stages and will not be implemented until after the regulator's relocation to Armidale has been completed. Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 5, 23, 53; Australian Pesticides and Veterinary Medicines Authority, *Digital Strategy 2018–2022*, p. 17.

6.27 The absence of these measures has the potential to affect the quality and efficiency of the regulator's work, endanger its ability to fulfil legislative requirements, and undermine trust in the authority.

6.28 The Committee therefore recommends that the APVMA progresses, as a matter of priority, a robust quality control framework and a fit-for-purpose workflow management system.

Recommendation 3

6.29 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority progresses, as a matter of priority, the development and implementation of a robust quality control framework and a fit-for-purpose workflow management system.

Recommendation 4

6.30 The Committee recommends that the Australian Government takes into consideration the disruption caused by the forced relocation of the Australian Pesticides and Veterinary Medicines Authority (including the ongoing impact on staff capability and capacity), and prioritises a fit-for-purpose and stable workforce over any decentralisation policy.

APVMA funding model and its implications

APVMA cost recovery funding model

6.31 The Committee shares the concern of a number of submitters that the APVMA is not operating on a sound financial footing, particularly at a time of organisational upheaval, and encourages the timely completion and implementation of the current funding review.

6.32 The Committee does appreciate the challenge, as highlighted by Dr Parker, of ensuring sufficient staff expertise remains within the APVMA to carry out the authority's regulatory functions upon which the cost recovery funding model is dependent. The departure of staff has impacted on productivity and will continue to do so.

6.33 Notwithstanding this point, the Committee believes the cost recovery funding model is comparable to the funding models of other national and international regulators.

Access to chemicals and veterinary medicines in Australia

6.34 The Committee acknowledges that the combination of small market size and regulatory cost has an impact on access to agvet chemicals for minor uses in Australia. That applications for registration contain fewer label usages has negative consequences for farmers in general, and for those who farm specialty crops or animals in particular.

6.35 The APVMA's new cost recovery implementation statement, scheduled for release in 2019–20, may result in increases in some costs. In light of this, some submitters suggested that a reduction in fees for the registration of minor use

chemicals would provide a way to compensate for the low commercial return on investment.

6.36 The Committee recognises the Government's efforts to address the problem of access to minor-use chemicals through the Improved Access to Agricultural and Veterinary Chemicals Initiative, which provided some funding for the registration of agricultural chemical products for minor uses and specialty crops. However, the Committee also recognises that the allocated \$8 million of funding was committed for 2014–2018. The Committee takes the view that funding for this initiative should be continued.

6.37 The Committee recognises that a thorough assessment of the actual impact of regulatory costs on the registration of chemicals for minor uses is necessary to inform policymaking into the future. Understanding the impact will allow for effective and targeted policymaking to address chemical availability in Australia.

6.38 Accordingly, the Committee makes recommendations with regard to funding the Improved Access to Agricultural and Veterinary Chemicals Initiative, and to assessing the impact of regulatory costs on the registration of minor use chemicals in Australia.

Recommendation 5

6.39 The Committee recommends that the Australian Government confirms its ongoing support for the Improved Access to Agricultural and Veterinary Chemicals Initiative and provides sufficient funding for the initiative over the forward estimates to ensure its continued operation.

Recommendation 6

6.40 The Committee recommends that the Australian Government commissions an independent assessment of the impact of regulatory costs on the registration of minor use chemicals, with a view to obtaining evidence that would inform policy and consider the availability of minor use chemicals in Australia.

Perceptions of independence

6.41 The Committee received significant evidence with regard to the cost recovery funding model and its relationship to the perceived independence of the regulator.

6.42 Regardless of whether the authority does recover the full cost of its activities, because the regulator is funded by those whose products it regulates, its cost recovery funding arrangement is perceived by some as a conflict of interest. This funding model, however, is not a unique arrangement for regulatory agencies in Australia or internationally; and it complies with the Australian Government Charging Framework.

6.43 The Committee is confident that the authority's clearly legislated regulatory responsibilities do not allow for industry to unduly influence the decisions of the regulator, by the fact that it is industry funded. Furthermore, the Committee does not share the view, held by some submitters, that the APVMA has an incentive to approve chemicals to gain funding through levies or that companies might be encouraged by the APVMA to create products for their registration so the APVMA can meet funding targets and increase capital.

6.44 The Committee agrees with those who argue that the current funding model provides adequate checks and balances to prevent preferential treatment, such as the acceleration of any particular chemical application from any particular manufacturer.

6.45 The Committee considers the current funding arrangement to be adequate and appropriate. Further, it believes application fees provide an incentive for the submission of quality applications.

6.46 The Committee acknowledges the industry is united in the view that the funding model does not allow for undue influence over the decisions of the regulator, which are robust and based on sound scientific principles. The Committee does see value, though, in looking to formalise some of the contact between the regulator and industry so as to discuss, in a transparent manner, a range of issues with regard to agvet chemical regulation in Australia.

Liaison between industry and the APVMA

6.47 The Committee accepts that it is important the APVMA has direct contact with industry groups and applicants, and responds to broad industry concerns. While the Committee acknowledges the efforts of the APVMA to make assessment requirements clear to applicants, there is considerable scope for a more formalised and ongoing engagement.

6.48 The Committee recognises merit in re-establishing an industry advisory committee or establishing a similar liaison forum. The purpose of the communication mechanism would be to discuss the needs of those who use and rely upon the APVMA's services. While it is not the role of the Committee to prescribe the nature and form of any such forum, as this is a matter for the APVMA and involved industry stakeholders to develop, consideration should be given to ensure that there are adequate opportunities to discuss specific issues, for instance plant, pests or veterinary medicines. Furthermore, any such forum should provide for broad, representative membership and develop clear terms of reference which set out the working arrangements. To provide for greater transparency, the minutes of meetings of the liaison forum or committees should be recorded and published in a timely manner.

6.49 The Committee therefore recommends that the APVMA, in cooperation with industry, develop a liaison committee or forum to facilitate open and transparent communication between industry and the APVMA.

Recommendation 7

6.50 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority consults with key stakeholders to establish a formal mechanism for ongoing liaison and discussion. The forum should develop clear terms of reference which set out its working arrangements, and the minutes of each meeting should be recorded and made public in a timely manner.

Chemical reconsideration

APVMA's process for chemical reconsideration

6.51 The Committee acknowledges the significant concern expressed by some submitters as to the APVMA's process and schedule for the review of agvet

chemicals, some of which were grandfathered into the NRS, having been assessed under previous standards.

6.52 The Committee received evidence of the APVMA's Chemical Review Program and examined its chemical risk process, which combines hazard and exposure assessments through a weight-of-evidence approach.

6.53 As to the timing of reviews, the Committee acknowledges the diverse views with regard to risk-based versus scheduled review of agvet chemicals. The Committee supports the APVMA's current risk-based approach to chemical reconsideration, believing it strikes an appropriate balance between community safety and access to chemicals. This approach allows the regulator to reconsider a chemical whenever it identifies evidence that would support reconsideration.

6.54 The Committee is concerned, however, about the delay in the current schedule of reconsiderations and encourages the APVMA to ensure sufficient resourcing is dedicated to this task.

Reconsideration of glyphosate, and its use in Australia

6.55 The Committee considered the approach taken by the APVMA in its reconsideration of glyphosate following the IARC classification of the chemical as 'probably carcinogenic to humans'.

6.56 The Committee acknowledges the range of strongly-held views about the APVMA's decision on glyphosate. However, it considers the APVMA's scientific processes to be robust, noting that all 264 of the studies referenced in the IARC report were independently evaluated by the OCS, in addition to other studies and data.

6.57 Further, the Committee was informed that the regulator did not receive any new scientific evidence during the consultation period relating to the possible carcinogenicity of glyphosate that it had not already considered.

6.58 The Committee points out that many of the concerns raised about the APVMA assessment are addressed in the APVMA's *Final Regulatory Position* report on glyphosate and in other APVMA material about the decision.

6.59 The Committee recognises the centrality of glyphosate to the sustainability and productivity of Australian farming. It is concerned, however, that neither the government nor industry has contemplated a loss of access to glyphosate or the impact in Australia of a ban on glyphosate overseas.

6.60 While the Committee does not hold a view on alternative methods of pest control to glyphosate, it recognises the need to consider alternative techniques and methods that can be used to manage pests when glyphosate is not accessible. However, the Committee also appreciates that concerns regarding viable alternatives to glyphosate stem from a broader problem of limited investment in innovation and research.

Chemical innovation

6.61 The Committee was very concerned by evidence that international chemical companies are reluctant to contribute resources towards research, development and

innovation to address Australian-specific pests and circumstances, particularly at a time of growing pest resistance. The Committee appreciates that Australia's small market has placed it at a competitive disadvantage globally and that research and development to discover new products is an expensive undertaking.

6.62 Nevertheless, the Committee is of the view the lack of research and development for Australian-specific conditions—whether for chemicals or other weed control strategies—has the potential to endanger the productivity and sustainability of Australia's agricultural industries.

6.63 The Committee supports the innovative programs run by the GRDC and other research organisations, to develop pest solutions for Australian-specific conditions. However, it believes these programs are not sufficient to address the current situation.

6.64 The Committee is of the view that the Australian Government cannot wait for clear market failure or the development of uncontrollable pests before taking stronger action. Accordingly, the Committee recommends the development of a coordinated national approach to agvet innovation, by way of a national strategic plan. The plan should be underpinned by an audit of areas where alternative chemicals or practices are not available to the Australian market and an evaluation of existing and developing pesticide and herbicide resistance. The Committee further suggests that sufficient funding be made available to implement the strategic plan.

Recommendation 8

6.65 The Committee recommends that the Australian Government develops and implements a national strategic plan for agricultural and veterinary pest-control innovation, which addresses Australian-specific environmental conditions and pests.

Transparency and community confidence

6.66 Whilst stakeholders with active and regular engagement with the APVMA spoke of their confidence in the regulator's scientific rigour, others questioned its impartiality, processes and evaluations. The Committee recognises there are concerns in some areas about the quality of decisions made by the regulator, particularly from organisations and individuals who do not have direct or regular contact with the authority.

6.67 The Committee heard concerns about a potential conflict in the role of the APVMA to protect the community, promote ecologically sound development, and further trade. It considered evidence that a product-specific focus to assessments failed to take into consideration cumulative exposure to agvet chemicals and that regulatory science was not sufficiently precautionary. The Committee also considered concerns raised during the inquiry that the evidence upon which the APVMA relies to make assessments is not publicly available for peer review; and that the APVMA did not consult the community.

6.68 The Committee recognises the concerns expressed by a number of stakeholders about the APVMA's processes. The Committee did not receive evidence that would lead it at this time to question the scientific basis of the regulator's assessments. The Committee believes the APVMA, through its regulatory approach to

the evaluation of data, balances the need to ensure community safety whilst also supporting the viability of Australian agriculture. The Committee received several examples of the APVMA's independence in the face of strong industry resistance and of the APVMA's efforts to promote transparency by regularly publishing material, including its decisions.

6.69 Nevertheless, the Committee believes that the industry and the regulator both need to consider the industry's social licence to operate—not in terms of compromising the scientific basis of the decisions made by the regulator, but in communicating more effectively with the community about decisions, processes and procedures.

6.70 The Committee acknowledges the reservations some stakeholders have expressed about the responsiveness of the APVMA to community concerns and the absence of general community consultation processes. It is concerning to hear of the lack of confidence some in the community have in the scientific basis of the regulator's decisions.

6.71 The Committee notes the authority has no proactive means to engage with consumers and others concerned about its procedures and assessments. This absence of engagement can lead to a perception that the regulator's assessments are flawed, despite the regulator's international reputation for robust, scientifically-based assessments.

6.72 As detailed in this report, there are other regulators that have established robust, community-focused communication mechanisms. The Committee encourages the APVMA to draw on the experience of these regulators, in particular the UK Pesticides Forum and the United States EPA Pesticide Program Dialogue Committee (PPDC) and develop its own communication mechanism accordingly.

6.73 Drawing upon the cases of other regulators, the Committee believes there would be much benefit in the establishment of a pesticides forum, based on the UK or PPDC model that would bring stakeholders from all sectors together to discuss issues of mutual concern and to express these concerns to the appropriate government agencies.

6.74 The Committee believes an appropriately constituted forum could go some way to allowing the APVMA to communicate its complex processes and procedures more effectively. It would also enable the regulator to detail the extent of its scientific assessment of applications, including supporting data. Furthermore, through such a forum, the APVMA and industry could more directly address community concerns. Conversely, such a forum would permit the public to question the APVMA, to raise concerns and develop a more informed understanding of the APVMA's regulation.

6.75 The Committee therefore recommends that a study of the UK Pesticides Forum and the EPA's PPDC be undertaken with a view to establishing a similar forum in Australia. The forum should have established aims, terms of reference, and objectives; include diverse and representative membership; make publically available its discussions and deliberations; and have its operating costs funded by government.

Recommendation 9

6.76 The Committee recommends that the Department of Agriculture and Water Resources and the Australian Pesticides and Veterinary Medicines Authority undertake a formal study of the United Kingdom Pesticides Forum and the United States Environmental Protection Agency Pesticide Program Dialogue Committee with the aim of establishing a similar forum for the Australian regulatory environment.

Senator Glenn Sterle

Chair

Coalition Senators' Dissenting Report

1.1 Coalition Senators of the Committee cannot agree with the recommendations of the majority report which attempts to disrupt and politicise a longstanding pillar of the government's policy agenda, namely the decentralisation of Government jobs outside of Canberra, central Sydney and central Melbourne.

1.2 The relocation of Australian Public Service (APS) agencies and jobs has been a consistent and unapologetic part of the Federal Government's commitment to ensuring the benefits of national economic growth is not restricted to our major cities through our decentralisation agenda.

1.3 This policy provides proven benefits to regional communities through the creation of local jobs, local economic diversification, and stimulation of regional economic growth.

1.4 Recommendation 4 of the majority report calls for government to prioritise a stable workforce for the Australian public service. It is our argument that decentralisation improves regional access to stable government jobs and related business opportunities.

1.5 Decentralisation is also about equity. Rural and regional Australians deserve government careers just as much as city people. Regional economies deserve government agencies just as much as capital cities do.

1.6 By locating government services and jobs in the regions, public servants are close to the people and industries they serve. The benefits go beyond service delivery.

1.7 Closer proximity to rural and regional communities and stakeholders supports greater understanding of the views, needs and experiences of citizens living and working in rural Australia. It reinforces the Government's strong connection with regional communities and the land.

1.8 The Liberal National Government is leading by example and delivering for rural, regional and remote Australia to create long term careers and confidence to build sustainable local communities.

1.9 The decentralisation strategy enacted by the Liberal National Government will create more career opportunities for young people and enable them to stay in the communities they grew up in.

1.10 We know the flow on effect from relocating agencies will contribute to a region's economic prosperity in the form of new employment opportunities, both direct and indirect.

1.11 In a recent recruitment round, APVMA received almost 300 applications for between 15 and 40 jobs. There were 79 applications from scientists all over Australia for 19 science jobs.

1.12 In addition, APVMA announced in July 2018 that they would have a unit of specialist scientists and decision makers who will work from Canberra. This will

ensure that APVMA fulfils its statutory obligations under the Agricultural and Veterinary Chemicals Code and maintain access to highly skilled scientific staff.

APVMA Performance

1.13 The latest available performance statistics (September 2018 quarter) released in November 2018, shows that the APVMA has significantly improved its performance, with 86 per cent of applications finalised within the legislated timeframes. This is the fifth straight quarter of timeframe performance improvement.

1.14 In the September 2018 quarter, APVMA commenced the assessment of 757 product, permit and active applications; and finalised 996 applications for products, permits and actives.

1.15 Results from the September 2018 quarter also show:

- Pesticide product applications at 80 per cent completed on time, up from 77 per cent last quarter.
- Veterinary product applications at 88 per cent completed on time, up from 84 per cent last quarter.
- Active constituent applications at 96 per cent completed on time, up from 95 percent in the June quarter and 82 per cent in the March quarter.

1.16 APVMA's latest performance statistics show the authority's performance continues to move in the right direction.

1.17 APVMA is also investing \$10.1 million over three years to modernise their information and communications technology (ICT), which will further enable it to deliver improved regulatory services from Armidale.

Glyphosate

1.18 Australia has a robust system for regulating the use of agricultural chemicals, including glyphosate. We have confidence that the APVMA will continue to regulate agricultural chemicals using a scientific and evidence-based approach.

Senator Barry O'Sullivan
Deputy Chair

Senator Slade Brockman
Senator for Western Australia

Greens Dissenting Report

1.1 The Greens support aspects of the committee's majority report, in particular relating to the impacts of the APVMA relocation to Armidale and the need for our chemical regulator to have the appropriate resourcing to ensure that our agricultural and veterinary chemicals are safe for use as directed. Protecting the health of people and the environment is one of the most important roles for Government.

1.2 However the Greens do not agree with the committee views in relation to both glyphosate specifically or to chemical safety overall.

1.3 Despite the statement by the committee that the process undertaken to be 'robust', we find that the contradictions of the APVMA's statements warrant a different finding.

1.4 Under questions during the 2018 Supplementary Budget Estimates, the CEO of the APVMA, Dr Parker, admitted that he agreed with the IARC finding that glyphosate was 'probably carcinogenic'.

Senator Rice: Not talking about whether it is a risk but in terms of it being a hazard—this is that risk assessment being a hazard, timed exposure, essentially—do you accept the IARC findings that glyphosate is probably carcinogenic?

Dr Parker: Yes.¹

1.5 This was confirmed by the Executive Director of the Scientific Assessment and Chemical Review Division, Dr Lutze, who agreed with Dr Parker:

Senator Rice: Yes. But what I'm trying to get to is whether in APVMA—and in that assessment—there was acceptance of that IARC finding, which was essentially a change in the understanding of the hazard of glyphosate?

Dr Lutze: I've already answered yes.²

1.6 The APVMA's statement in relation to glyphosate on their website makes it clear that the risk of any particular chemical is a product of the hazard of that chemical and the exposure risk of that chemical.³ By admitting that the IARC findings may have bearing on the hazard of glyphosate, it is impossible to conclude that this would then not impact on the chemical risk of glyphosate.

1.7 Given the magnitude of the claims of the impact of glyphosate on human health, such a shift in one component of the chemical risk formula warrants a much more comprehensive review than the APVMA has conducted. Anything less than a

1 Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Rural and Regional Affairs and Transport Legislation Committee*, 23 October 2018, p. 97.

2 Dr Jason Lutze, Acting Executive Director, Scientific Assessment and Chemical Review, Australian Pesticides and Veterinary Medicines Authority, *Rural and Regional Affairs and Transport Legislation Committee*, 23 October 2018, p. 98.

3 *Glyphosate*, Australian Pesticides and Veterinary Medicines Authority, <https://apvma.gov.au/node/13891>.

full and thorough independent review of glyphosate in light of the IARC findings is entirely insufficient.

Recommendation 1

1.8 That the Commonwealth Government order the conduct of a full and independent review of the chemical risk of glyphosate immediately.

1.9 The ad-hoc nature of our current regime for chemical review, as demonstrated by the approach of the APVMA to community concerns about glyphosate, is clearly not up to the task of keeping our community and environment safe.

1.10 The irony is that a mandatory scheme for re-approval and re-registration of registered products was introduced in the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*, but this was repealed before coming into effect by the Coalition Government with the support of the Labor Opposition in 2014.

1.11 The need for such a system is overwhelming. As identified by Ms Joanna Immig from the National Toxics Network, many chemicals currently approved and in use in Australia have not been reviewed since the *Agricultural and Veterinary Chemicals Act 1994* began. Even more concerning, there are products that have been under continuous review for decades, including numerous chemicals that are already banned in many overseas constituencies.⁴

1.12 There were genuine concerns voiced in the inquiry about the independence of the decisions of the APVMA and the Ministers who influence them.⁵ Multiple witnesses pointed to the relationship between political parties and the agricultural chemical sector, singling out the role of both corporate donations to political parties and the influence of lobbyists with high level connections to political elites.

1.13 A legislated mandatory requirement to conduct appropriate reviews and re-registrations would remove much of the discretionary latitude available to the APVMA and help improve confidence in the independence of its decision making.

Recommendation 2

1.14 That the Government introduce legislation to reinstate the APVMA re-approval and re-registration scheme that was repealed in 2014.

Senator Janet Rice
Australian Greens

4 National Toxics Network, *Submission 24*, p. 3.

5 Friends of the Earth Australia, *Submission 35*; Gene Ethics, *Submission 40*.

Appendix 1

Submissions received

Submission Number	Submitter
1	R Underwood
2	Ms Carol Dehm
3	Dr Alison Bleaney OBE
4	Ms Ruth Weston
5	Dr Rosemary Mason
6	Cotton Australia
7	Australian Pesticides and Veterinary Medicines Authority
8	SNW Farmers
9	Department of Agriculture and Water Resources
10	CropLife Australia
11	Grain Producers Australia
12	AUSVEG
13	Maurice Blackburn Lawyers
14	Local Environmental Action Forum
15	Western Australian Farmers Federation
16	Department of Primary Industries and Regional Development
17	Chemistry Australia
18	Veterinary Manufacturers and Distributors Association
19	Dr Christopher Preston
20	Mr Duncan Mills
21	Bayer
22	Pastoralists & Graziers Assn of WA (Inc.)
23	Grain Growers Limited
24	National Toxics Network
25	Dairy Australia
26	Animal Medicines Australia
27	National Farmers Federation
28	H Ross
29	Mrs Lara Warwick
30	Agribusiness Australia
31	Apple and Pear Australia Ltd
32	Ms Bianca Wrecht
33	Victorian Farmers Federation
34	AgForce Queensland
35	Friends of the Earth Australia
36	Janet Grogan
37	Ms Jessica Harrison
38	Ms Christine Anderson
39	Ms Alison Wylie
40	Gene Ethics
41	Dr Ian Musgrave

42	Associate Professor Susan Wilson & Professor Brian Sindel
43	Ms Kali Moynihan
44	Ms Dörte Planert
45	Ms Caryl Highton
46	Mr Krush Deepak
47	Mr Bob Gray
48	Ms Gabrielle Richardson
49	Ms Esther Gallant
50	Mr Mark Hansel
51	Ms Robin Bayvel
52	Mr Ted Mitchell
53	Mr Robert Mahoney
54	Ms Jacqueline Dossor
55	Ms Suzie St George
56	Ms Melissa Anderson
57	Mr Brendan Lewis
58	Mr John Harvey
59	Ms Tracey Davis
60	Ms Emily Wallis
61	Ms Julia Deasley
62	Mr Brian Bucktin
63	Ms Lowana Chapman
64	S Liddell
65	Ms Diane Potter
66	Mr Andrew Zimmerman
67	H Psaila
68	Ms Alison Bremer
69	Ms Svyetlana Hadgraft
70	Mr William Moore
71	Mr Roger Corben
72	Department of Primary Industries and Regions South Australia
73	Ms Margo Rutledge
74	Mr Neal Salan
75	Mr Gerry Gillespie
76	Sustainable Agriculture and Communities Alliance
77	Mr Richard Nankin
78	Ms Suzanne Whiting
79	Mr Dean Mensinga
80	Ms Shelley Davies
81	Ms Belinda Esperson
82	Mr Roger Vanamois
83	Mr Clive Newland
84	Ms Tracey Mietzke
85	Ms Hanni Corbett
86	Ms Helena Martin
87	Mr Andrew Faulkner
88	Mr John Beale
89	Ms Julie Reid
90	Australian Food Sovereignty Alliance
91	M Oliver

92	Ms Patsy Lisle
93	Ms Wanda Grabowski
94	Ms Diane Turner
95	Mr Anthony Meehan
96	Mr Peter Raftos
97	J Baker
98	Ms Sarah Toose
99	Ms Annette Haridan
100	Brynn Mathews
101	Mr Steve Dunn
102	Ms Ann Phillis
103	Mr Peter Curtin, Lord Howe Island Residents
104	Pesticide Action Group WA
105	Alliance for a Clean Environment
106	Ms Elizabeth Hobson
107	Australian Academy of Science
108	M and P Wilson
109	U.S. Environmental Protection Agency
110	Ms Robin Thomas

Additional information received

Tabled documents

- Document tabled by Dr Chris Parker at a public hearing in Canberra on 20 November 2018. 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".

Additional information

- Additional information provided by GrainGrowers. Report into the Grains Non-Tariff Measures Project. Received on 22 November 2018.
- Additional information provided by the Department of Agriculture and Water Resources. Received on 22 November 2018.
- Additional information provided by the Department of Agriculture and Water Resources. Received on 4 December 2018.

Answers to questions on notice

- Questions taken on notice by the Department of Agriculture and Water Resources at a public hearing in Canberra on 20 November 2018. Answers received on 4 December 2018.
- Questions taken on notice by Animal Medicines Australia at a public hearing in Canberra on 7 December 2018. Answers received on 11 December 2018.
- Question taken on notice by the Australian Glyphosate Sustainability Working Group at a public hearing in Canberra on 7 December 2018. Answer received on 17 December 2018.
- Questions taken on notice by Gene Ethics at a public hearing in Canberra on 7 December 2018. Answers received on 17 December 2018.
- Questions taken on notice by Chemistry Australia at a public hearing in Canberra on 7 December 2018. Answers received on 20 December 2018.
- Questions taken on notice by Bayer at a public hearing in Canberra on 7 December 2018. Answers received on 21 December 2018.

Appendix 2

Public hearings and witnesses

Tuesday 20 November 2018

- BEER, Mr Michael, General Manager, Research and Innovation, AgriFutures Australia
- CATTLE, Mr Tyson, National Public Affairs Manager, AUSVEG
- COSSEY, Mr Matthew, Chief Executive Officer, CropLife Australia
- CRERAR, Dr Scott, General Manager, Science and Risk Assessment Branch
Food Standards Australia New Zealand
- CROFT, Ms Lisa, Deputy Chief Executive Officer,
Australian Pesticides and Veterinary Medicines Authority
- CROSBY, Mr Justin, Industry and Government Relations,
Grains Research and Development Corporation
- DELBRIDGE, Ms Katherine, Director of Corporate Affairs, CropLife Australia
- DUNSTAN, Ms Kylie Dunstan, Corporate Affairs,
Grains Research and Development Corporation
- GAGLIA, Ms Julie, Assistant Secretary, Vet Chemicals Branch,
Department of Agriculture and Water Resources
- GROVES, Mr Chris, Chair, Farming Systems Committee,
National Farmers' Federation; and Vice President, NSW Farmers Association
- HARDIE, Mr Robert, Policy Director, Environment, Cropping and Horticulture,
NSW Farmers Association
- HARVEY-SUTTON, Mr Mark, General Manager, Rural Affairs, National Farmers'
Federation
- HOLMES, Ms Sally, Company Secretary and General Counsel; and Executive
Manager,
Governance and Risk, Horticulture Innovation Australia
- JAMES, Mr Alastair, Director of Agricultural Chemical Policy, CropLife Australia
- KARLOV, Mr Tim, Director, Agvet Chemical Regulation Reform, Agvet Chemicals,
Fisheries and Forestry Division, Department of Agriculture and Water Resources
- KAY, Mr Adam, Chief Executive Officer, Cotton Australia
- LUCAS, Mr Jason, Director, Industry Support Branch, Finance and Business Support
Division, Department of Agriculture and Water Resources
- LUTZE, Dr Jason, Executive Director, Scientific Assessment and Chemical Review,
Australian Pesticides and Veterinary Medicines Authority
- MAILLER, Mr David, Chair, Agricultural Science Committee, NSW Farmers
Association
- MANEN, Ms Rebecca, General Manager, Business Facilitation and Food Branch,
Industry Growth Division, Department of Industry, Innovation and Science
- McCREIDIE, Ms Fiona, National Policy Manager, Grain Growers Limited
- McKEON, Mr David, Chief Executive Officer, Grain Growers Limited
- MORRALL, Mr Joseph, Assistant Director, Agvet Chemicals, Fisheries and Forestry
Division, Department of Agriculture and Water Resources

- PARKER, Dr Chris, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority
- PEDRANA, Ms Jodie, Research and Development Manager, Horticulture Innovation Australia
- PETERS, Dr Kirrily, Manager, Business Facilitation Section, Department of Industry, Innovation and Science
- RAINBOW, Dr Rohan, Consultant adviser, Grain Producers Australia
- RICHARDS, Dr Brian, Executive Director, Office of Chemical Safety, and Director, National Industrial Chemicals Notification and Assessment Scheme, Department of Health
- TAYLOR, Dr Ian, General Manager, Research and Development, Investment and Impact, Cotton Research and Development Corporation
- THOMPSON, Mr Ian, Chief Environmental Biosecurity Officer, Environmental Biosecurity Office, Department of Agriculture and Water Resources
- WEIDEMANN, Mr Andrew, Chairman, Grain Producers Australia
- YOUNG, Dr Ken, Crop Protection, Applied Research and Development, Grains Research and Development Corporation

Friday, 7 December 2018

- ADAMS, Mr Jim, Executive Director, Veterinary Manufacturers and Distributors Association
- AMIS, Mr Anthony, Pesticides and Drinking Water Campaigner, Friends of the Earth Australia
- BOWKETT, Ms Vivien, Member, Local Environmental Action Forum
- BREMMER, Ms Jane, Secretary, National Toxics Network Inc.
- HUNDLEY, Mr Marden Philip, Local Environmental Action Forum
- IMMIG, Ms Joanna, National Coordinator, National Toxics Network Inc.
- LEE, Mr Bernard, Director, Policy and Regulation, Chemistry Australia
- MAY, Mr Anthony (Tony), Commercial Operations Lead, Bayer Crop Science
- McCORMICK, Dr Nina, Regulatory Affairs Lead, Bayer Crop Science
- MUSGRAVE, Dr Ian, Private capacity
- PHELPS, Mr Robert (Bob), Executive Director, Gene Ethics
- PRESTON, Dr Christopher, Chair, Australian Glyphosate Sustainability Working Group
- REEVES, Dr William (Bill), Health and Safety Issues Manager, Bayer Crop Science
- SALES, Ms Louise, Emerging Tech Project Coordinator, Friends of the Earth
- SINDEL, Professor Brian, Private capacity
- STAPLEY, Mr Ben, Executive Director, Animal Medicines Australia
- TAGER, Mr Jeremy, Campaigner, Friends of the Earth
- VITELLI, Mrs Marie, Biosecurity Policy Officer, AgForce Queensland
- WILSON, Associate Professor Susan, Private capacity