

# 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.<sup>1</sup>

### 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.

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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.<sup>2</sup>

### **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.

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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](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.<sup>3</sup>

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.<sup>4</sup>

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.<sup>5</sup>

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.<sup>6</sup>

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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.<sup>7</sup>

1.20 Each year, over \$3 billion is spent on agvet chemicals in Australia.<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup>

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.<sup>11</sup> The APVMA receives around 5,000 applications annually for various assessments.<sup>12</sup>

## 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

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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.<sup>13</sup>

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.<sup>14</sup>

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.<sup>15</sup>

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

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);

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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.<sup>17</sup>

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.<sup>18</sup>

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.<sup>19</sup>

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.<sup>20</sup>

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.

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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].