

# Chapter 1

## Referral of inquiry

1.1 The Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (the bill) was introduced in the House of Representatives on 19 March 2014. On 20 March 2014, the Senate referred the provisions of the bill to the Senate Rural and Regional Affairs and Transport Legislation Committee (the committee) for inquiry and report by 16 June 2014.

1.2 The Selection of Bills Committee noted the reasons for referral and principal issues for consideration were to 'Investigate thoroughly the impact of this legislation on the health and safety of human beings, animals and the environment as a priority of the regulatory system.'<sup>1</sup>

## Purpose of the bill

1.3 A key objective of the bill is to wind back the re-registration process for agricultural chemicals and veterinary medicines (together referred to as 'agvet chemicals').

1.4 In particular, the purpose of this bill is to:

- amend the *Agricultural and Veterinary Chemicals Code Act 1994* to:
  - prevent the expiry of active constituent approvals and prevent the application of dates after which a registration cannot be renewed;
  - remove the requirement for applications to be made to re-approve active constituents or re-register chemical products;
  - enable the Australian Pesticides and Veterinary Medicines Authority (APVMA) to require information to be provided about substances supplied as a chemical product;
  - simplify how variations to approvals and registrations are processed by APVMA; and
  - enable APVMA to charge a fee when it provides copies of documents in its possession; and
- amend the *Agricultural and Veterinary Chemicals Code Act 1994*, *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*, *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* and the *Food Standards Australia New Zealand Act 1991* to make consequential amendments.<sup>2</sup>

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1 Selection of Bills Committee, *Report no. 3 of 2014*, 20 March 2014, Appendix 1.

2 Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014, *Summary*, <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fbillhome%2Fr5196%22>, (accessed 14 April 2014).

## **Conduct of the inquiry**

1.5 The committee wrote to a number of stakeholder groups seeking submissions on the provisions of the bill. Twenty two submissions were received. Given the non-controversial nature of the bill, the committee agreed not to hold a public hearing in relation to this inquiry.

## **Background**

### ***The regulatory environment***

1.6 Agricultural chemicals and veterinary medicines are regulated through a cooperative National Registration Scheme (NRS) for Agricultural and Veterinary Chemicals. The NRS was first agreed to by the Australian Agriculture Council (subsequently the Standing Council on Primary Industries) in 1991 and is described in a ministerial level intergovernmental agreement that was signed in September 1995.<sup>3</sup>

1.7 The NRS is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities. Assessment and registration of agvet chemicals, as well as the control of supply activities up to the point of retail sale are undertaken on behalf of the states by the Australian Pesticides and Veterinary Medicines Authority (APVMA), a Commonwealth authority. Control of the use of agvet chemicals after sale is the responsibility of the states and territories.<sup>4</sup>

1.8 In 2006 an audit by the Australian National Audit Office (ANAO) examined the APVMA's arrangements for planning and overseeing the delivery of its regulatory functions and for administering its cost recovery framework.<sup>5</sup> The ANAO noted:

Since the ANAO's previous audit in 1997–98, and particularly in recent years, the APVMA has introduced various initiatives to improve the effectiveness of its operations. However, key programs to monitor the quality of pesticides and veterinary medicines, such as the Manufacturers' Licensing Scheme and the Chemical Review Program, could be better administered. Greater emphasis needs to be given to compliance programs and to completing chemical reviews in order for the APVMA to provide assurance that manufacturers of pesticides and veterinary medicines are meeting the required standards, and that products approved for sale in Australia are safe and effective. The APVMA is also not meeting its obligation to finalise all Applications within statutory timeframes. This increases the cost of regulation, for both the APVMA and applicants, and impacts on users' access to pesticides and veterinary medicines.<sup>6</sup>

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3 Explanatory Memorandum, p. 4.

4 Explanatory Memorandum, p. 4.

5 Australian National Audit Office, *Regulation of pesticides and veterinary chemicals*, Audit report no. 14, 2006–07, December 2006, p. 14.

6 Australian National Audit Office, *Regulation of pesticides and veterinary chemicals*, Audit report no. 14, 2006–07, December 2006, p. 19.

1.9 In 2006, the Council for Australian Governments (COAG) identified the need for regulatory reform in relation to chemicals and established a Ministerial Taskforce, to 'develop a streamlined and harmonised national system of chemicals and plastics regulation'.<sup>7</sup> COAG also referred the matter to the Productivity Commission for advice. In 2008, the Commission published a report, *Chemicals and Plastics Regulation*, which found that:

...the current institutional and regulatory arrangements are broadly effective in managing the risks to health and safety, but are less effective in managing risks to the environment and national security. Efficiency could be enhanced by: national uniformity in some regulatory areas; reducing costs and delays in obtaining regulatory approvals; and attaining economies of scale in regulatory administration.<sup>8</sup>

1.10 In 2009, COAG announced that a Memorandum of Understanding for Chemicals and Plastics Regulatory Reform had been agreed to, and established the Standing Committee on Chemicals to co-ordinate, monitor and advise governments on the implementation of reforms identified by the Productivity Commission.<sup>9</sup> In mid-2013 ministers confirmed their commitment to a new NRS agreement.<sup>10</sup>

1.11 The APVMA's operations are described in the Explanatory Memorandum as follows:

The APVMA is responsible for administering and managing the parts of the NRS that oversee registration, quality assurance and compliance of agvet chemicals up to and including the point of retail sale.

Australia currently has around 11 700 separate agvet chemical products registered (approximately 8 350 agricultural and 3 350 veterinary), each of which contains one or more of around 2 230 approved active constituents, of which around 782 are unique.<sup>11</sup>

### ***Recent changes – the Amendment Act***

1.12 The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013 (the amendment bill) was passed by Parliament in June 2013. The amendment bill made changes to: approvals, registrations, permits and licences, re-approval and re-registration, enforcement, data protection, and levy collection.<sup>12</sup> The amendment bill

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7 Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne, p. III.

8 Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne, p. XXV.

9 Memorandum of Understanding for Chemicals and Plastics Regulatory Reform, Council of Australian Governments, [www.coag.gov.au/node/93](http://www.coag.gov.au/node/93), (accessed 15 April 2014).

10 Explanatory Memorandum, p. 4.

11 Explanatory Memorandum, p. 4.

12 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, pp 2–8.

also included other amendments to remove redundant provisions and amend outdated provisions.<sup>13</sup>

1.13 Prior passing of the amendment bill, there was no mandatory requirement for agvet chemicals, once approved or registered, to be reviewed. Some of the amendments in the amendment bill provided for such a scheme as follows:

The Act [as it became] reformed the approval, registration and reconsideration (review) of agvet chemicals to improve the effectiveness of the regulatory system and reduce inefficiency at the APVMA, while making processes more predictable, clearer and less unwieldy for industry. The reforms were intended to improve community's confidence that chemicals approved for use in Australia are safe.

The reforms of the Amendment Act (including provisions for re-approval of active constituents and re-registration of chemical products, or re-registration) commence on 1 July 2014.<sup>14</sup>

1.14 The amendment bill was examined by four Parliamentary committees, including the Senate Standing Committee for the Scrutiny of Bills and the Parliamentary Joint Committee on Human Rights. The Senate Rural and Regional Affairs and Transport Legislation Committee tabled its report on 27 February 2013, recommending that the amendment bill be passed.<sup>15</sup> The Coalition Senators' Dissenting Report indicated that Coalition Senators did not support its passage on account of the mandatory requirement for re-registration of agricultural and veterinary chemicals, which was described as 'expensive and developed without a compelling cost/benefit analysis'.<sup>16</sup>

## **The bill**

1.15 The Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (the bill) amends:

- the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act);
- the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act);
- the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act); and
- the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).<sup>17</sup>

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13 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, p. 2.

14 Explanatory Memorandum, pp 3–5.

15 *Journals of the Senate No. 135*, 27 February 2013, p. 3684; Rural and Regional Affairs and Transport Legislation Committee, *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 [Provisions]*, p. 26.

16 Rural and Regional Affairs and Transport Legislation Committee, *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 [Provisions]*, Dissenting Report, pp 27–30.

17 Explanatory Memorandum, p. 1.

1.16 The explanatory memorandum indicates that the bill implements an election commitment to remove the requirement to re-register agvet chemicals:

The Bill implements the Australian Government's 2013 election commitment to remove the requirement for agricultural chemicals and veterinary medicines...re-registration by removing end dates for approvals and last renewal dates for registrations so that approvals will no longer end after a particular period and registrations may be renewed perpetually, and removing redundant provisions that allow applications to re-approve and re-register active constituents and chemical products.<sup>18</sup>

The government considers that, prior to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*, existing chemical review mechanisms provided sufficient basis for the examination of newly discovered risks about the safety, efficacy or trade impact of a chemical. New mechanisms (the re-registration scheme) duplicating the existing system and impose additional costs on industry are not required.<sup>19</sup>

1.17 Schedule 1 of the Bill would amend the Agvet Code to prevent the expiry of active constituent approvals and prevent the application of dates after which a registration cannot be renewed. Active constituent approvals are to continue in force so long as they are not cancelled. Registrations would continue in force so long as they are not cancelled, subject to renewal of the registration. The bill would also remove provision for applications to be made to re-approve active constituents or re-register chemical products.<sup>20</sup>

1.18 While the bill would remove re-registration, other provisions strengthened by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* would be retained. The existing comprehensive powers held by APVMA ensure that any newly identified risks about the safety, efficacy or trade impact of a chemical are examined, would be retained. The APVMA would also retain powers to recall unsafe chemical products or suspend or cancel the registration of a chemical product if they no longer meet criteria for registration.<sup>21</sup> The bill would also introduce reforms that aim to:

- reduce red tape by providing for less frequent registration renewals;
- improve the APVMA's ability to secure information about the safety of chemicals supplied in the market;
- introduce further simple reforms to the regulation of agvet chemicals to reduce red tape and improve efficiency;
- oblige the APVMA to provide access to information about approvals and registrations in its files to persons eligible to receive it; and

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18 Explanatory Memorandum, p. 1.

19 Explanatory Memorandum, p. 5.

20 Explanatory Memorandum, p. 10.

21 Explanatory Memorandum, p. 10.

- address some minor implementation issues identified in existing reform legislation.<sup>22</sup>

### **Consultation**

1.19 A consultation paper and an exposure draft of the bill were released, with submissions sought between 18 December 2013 and 7 March 2014. The Explanatory Memorandum notes that 42 submissions were received and meetings were held with stakeholders over January and February 2014. The bill was revised to address some issues raised during the consultation.<sup>23</sup>

### **Acknowledgements**

1.20 The committee thanks those organisations and individuals who made submissions.

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22 Explanatory Memorandum, p. 1.

23 Explanatory Memorandum, p. 3.