Chapter 1

Introduction

Referral of inquiry

1.1 On 29 November 2018, the Senate referred the provisions of the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (bill) to the Senate Rural and Regional Affairs and Transport Legislation Committee (committee) for inquiry and report by 11 February 2019.

1.2 The Selection of Bills Committee noted that the reason for the referral was to 'investigate the impact of the bill on the regulation of agricultural and veterinary medicines products in Australia'. It also explained that the purpose of the referral was to investigate the impact of the bill on agricultural industries and other relevant stakeholders while also scrutinising amendments to the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; *Agricultural and Veterinary Chemicals Code Act 1994*; and *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.[1]

Conduct of the inquiry

1.3 The committee advertised the inquiry on its webpage calling for submissions by 21 December 2018. The committee also wrote to a range of organisations and individuals likely to have an interest in the matters covered by the bill, drawing their attention to the inquiry and inviting them to make written submissions.

1.4 The committee received 13 public submissions, as listed in Appendix 1. Submissions were published on the committee's inquiry webpage.

Acknowledgement

1.5 The committee thanks the organisations and individuals that made submissions to the inquiry. This work has informed the committee's deliberations.

Structure of the report

1.6 The report consists of three chapters. This chapter provides an overview of the bill and background information on the regulatory context. Chapter 2 discusses the key provisions of the bill. Chapter 3 considers the concerns raised in evidence regarding some of the bill's provisions and sets out the committee's conclusions and recommendation.

Purpose of the bill

1.7 The bill seeks to amend various Acts relating to the regulation of agricultural and veterinary chemicals. The proposed amendments seek to improve the

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1 Selection of Bills Committee, *Report 14 of 2018,* 29 November 2018, Appendix 1.

effectiveness and efficiency of the national system for agricultural and veterinary (agvet) chemical regulation.

1.8 The legislative changes proposed under the bill will amend the:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act);
- *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act); and
- *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act).

1.9 The bill will also repeal the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* (Removing Re-approval and Re-registration Act).

1.10 The purpose of the bill is to:

- enable the use of new, simpler regulatory processes for low risk chemical products (to simplify the approval of active constituents and labels, and the registration of certain products);
- provide the Australian Pesticides and Veterinary Medicines Authority (APVMA) and industry with more flexibility to deal with certain types of new information provided when the APVMA is considering an application;
- provide for extensions to limitation periods and protection periods as an incentive for chemical companies to register certain new uses of chemical products;
- enable computerised decision-making by the APVMA;
- provide for a legislative instrument made by the APVMA to prescribe a scheme in the future that would allow applicants and the APVMA to use accredited third party providers to undertake assessment services;
- provide for greater transparency regarding voluntary recalls of chemical products;
- harmonise the need to inform the APVMA of new information relating to safety criteria so that the same obligations apply to all holders and applicants;
- amend the procedure when dealing with minor variations in the constituents in a product;
- provide the APVMA with more options when dealing with false or misleading information, and clarify what information must be included on a label;
- allow the holder of a suspended product to address the reason for the suspension;
- correct anomalies in the regulation-making powers for the labelling criteria;
- amend the APVMA's corporate reporting requirements; and

- repeal the Removing Re-approval and Re-registration Act in its entirety.[2]

1.11 In October 2018, when introducing the bill, the Minister for Agriculture and Water Resources, the Hon David Littleproud MP, explained:

> The bill specifically provides for new, simpler processes for chemical product assessment based on risk. These changes support improved access to safe and effective chemical products and reduce costs associated with their registration. They do this by better aligning regulatory effort with risk and reducing red tape.
>
> The bill specifically provides for new prescribed approval and registration processes that will be quicker and less costly than those currently available, while also ensuring these products remain safe and effective. These new processes will apply for those active constituents, chemical products and products that require minimal or no assessment of technical information.[3]

Consideration of the bill by other committees

1.12 The Parliamentary Joint Committee on Human Rights considered the bill and determined it does not raise human rights concerns.[4]

1.13 On 14 November 2018, the Standing Committee for the Scrutiny of Bills (Scrutiny Committee) raised a number of concerns in relation to the bill.[5] Of primary concern to the Scrutiny Committee was that significant matters would be left to delegated legislation, rather than being included in the primary legislation.[6]

Significant matters in delegated legislation

1.14 The Scrutiny Committee raised concerns with proposed amendments that would provide for the APVMA to make a disallowable legislative instrument that prescribes the accreditation scheme for third party assessors.

1.15 The Scrutiny Committee focused its attentions on item 43 of Part 5 of Schedule 1 of the bill, which seeks to insert a new section 6G(1) into the Code Act to allow the APVMA to prescribe, by legislative instrument, matters relating to the accreditation of persons by the APVMA for the purposes of the Agricultural and

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2 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 1.

3 The Hon David Littleproud MP, Minister for Agriculture and Water Resources, Second Reading Speech, *House of Representatives Hansard*, 18 October 2018, p. 4.

4 Parliamentary Joint Committee on Human Rights, *Report 12 of 2018*, 27 November 2018, p. 50.

5 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 1.

6 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 2.

Veterinary Chemicals Code (Code).[7] Proposed subsection 6G(2) sets out examples of matters a legislative instrument made under proposed subsection 6G(1) may deal with.

1.16 In addition, the Scrutiny Committee noted that the enactment of proposed subsection 6G(4) would allow the regulations to prescribe penalties for offences against the regulations, or declare provisions of the regulation to be civil penalty provisions, in relation to an accredited person contravening a condition of accreditation or any other requirement set out under a legislative instrument made under proposed subsection 6G(1).[8]

1.17 The Scrutiny Committee expressed the view that significant matters, such as a scheme to accredit persons to perform functions in relation to the Code, should be included in primary legislation 'unless a sound justification for the use of delegated legislation is provided'. It noted that the Explanatory Memorandum (EM) does not provide any justification for leaving all of the content of the proposed accreditation scheme to be set out in a legislative instrument rather than in primary legislation. Furthermore, the committee noted that a legislative instrument, made by the executive is not subject to the 'full range of parliamentary scrutiny inherent in bringing proposed change in the form of an amending bill'.[9]

1.18 The Scrutiny Committee continued that where the Parliament delegates its legislative power to significant regulatory schemes, it is appropriate that specific consultation obligations, beyond those in section 17 of the *Legislation Act 2003*, are included in the bill and that compliance with these obligations is a condition of the validity of the legislative instrument.[10]

1.19 The Scrutiny Committee requested from the minister detailed advice as to why it was considered necessary to leave all of the content of the proposed accreditation scheme to delegated legislation and indicated that it may be appropriate to amend the bill so as to include at least high-level guidance as to the requirements of the proposed accreditation scheme. It also sought information from the minister as to whether specific consultation obligations, beyond those in section 17 of the *Legislation Act 2003*, could be included in the legislation.[11]

Incorporation of external material into the law

1.20 The Scrutiny Committee raised concerns with proposed subsection 6G(3):

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7 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 2.

8 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 2.

9 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 2.

10 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 3.

11 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, pp. 3–4.

> Proposed subsection 6G(3) provides that, despite subsection 14(2) of the *Legislation Act 2003*, a legislative instrument made under proposed subsection 6G(1) may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in any other instrument or writing as in force or existing from time to time.[12]

1.21 In general terms, the Scrutiny Committee has concerns where provisions in a bill allow the incorporation of legislative provisions by reference to other documents. Such an approach raises the prospect of changes being made to the law in the absence of parliamentary scrutiny, can create uncertainty in the law, and may create difficulties for those seeking to access the terms of the law in order to obey them.[13]

1.22 The Scrutiny Committee acknowledged the justification in the EM as to why material may need to be incorporated from time to time. It also noted that the EM states that incorporated material would be available without a fee and published on the APVMA website 'where possible'.

1.23 The Scrutiny Committee left the matter of the appropriateness of incorporating material that may not be freely and readily available to all those interested in the law, to the Senate as a whole.[14]

Minister's response to Scrutiny Committee

1.24 Minister Littleproud responded to the Scrutiny Committee's concerns on 27 November 2018.

1.25 In his reply to concerns raised about the proposed third party accreditation scheme, Minister Littleproud explained that the use of such schemes by Commonwealth regulators was not unusual. Drawing on examples such as the Australian Maritime Safety Authority, the Minister further noted that it was not unusual for the content of such schemes to be set out in delegated legislation.[15]

1.26 By leaving much of the content of the proposed accreditation scheme to delegated legislation, the APVMA would be given the flexibility to determine how it might efficiently obtain a robust assessment of an applicant's data to assist it in determining whether an agvet chemical met the necessary criteria for registration. This flexibility would allow the APVMA to tailor the accreditation scheme as appropriate,

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12 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 4.

13 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 4.

14 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 13 of 2018*, 14 November 2018, p. 5.

15 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 14 of 2018*, 28 November 2018, p. 8.

for instance, to the different requirements of assessments of toxicology, environmental safety, residues or chemistry.[16]

1.27 The Minister suggested that placing detailed content of the proposed accreditation scheme in primary legislation could also inhibit the APVMA from making timely adjustments to assessor accreditation and operational requirements.[17]

1.28 The Minister also addressed the Scrutiny Committee's suggestion to amend the bill to include at least high-level guidance as to the requirements of the proposed accreditation scheme. He stated that proposed subsection 6G(2) would provide sufficient guidance as to matters that should be considered in the design of the proposed accreditation scheme. Further, he noted that there was precedent in other legislation for this approach and level of guidance.[18]

1.29 In response to the Scrutiny Committee's suggestion to include specific consultation obligations within the legislation, the Minister responded that because the APVMA was currently empowered to make legislative instruments in relation to various matters, it was practiced in undertaking broad consultation with industry and other stakeholders.[19]

1.30 Moreover, mandating consultation in primary legislation could limit the APVMA's ability to respond to urgent situations where the integrity of the agvet chemical regulation framework could be compromised or where the pace of relevant science was outstripping the speed at which consultation could be conducted.[20]

Scrutiny Committee's commentary on ministerial response

1.31 The Scrutiny Committee noted Minister Littleproud's response and considered that it may be appropriate for the bill to be amended to include at least high-level guidance as to the requirements of the proposed accreditation scheme. The Scrutiny Committee also suggested that it would be appropriate to amend the bill to include specific consultation obligations, with compliance with such obligations a condition of the validity of the legislative instrument.

1.32 The Scrutiny Committee drew its concerns to the attention of senators and left to the Senate as a whole the appropriateness of the bill's provisions with regard to

16 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 14 of 2018*, 28 November 2018, p. 7.

17 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 14 of 2018*, 28 November 2018, p. 8.

18 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 14 of 2018*, 28 November 2018, p. 8.

19 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 14 of 2018*, 28 November 2018, p. 9.

20 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 14 of 2018*, 28 November 2018, p. 9.

allowing all the content of the accreditation scheme to be placed in delegated legislation.[21]

Background

1.33 The regulatory framework for managing pesticides and veterinary medicines in Australia is referred to as the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). First agreed to by the Australian Agricultural Council in 1991, the NRS is described in a ministerial level intergovernmental agreement signed in September 2015.

1.34 As a partnership between the Commonwealth and the states and territories, the NRS was established to ensure that pesticides and veterinary products are effective on target species, safe when exposed to humans and non-target species, not a risk to the environment, and are labelled and packaged correctly.

1.35 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. The states and territories are responsible for control of use.[22]

1.36 The Code is a schedule contained in the Code Act. The Code provides for the APVMA to evaluate, approve or register and review active constituents and agricultural and veterinary chemical products, to issue permits, and licence the manufacture of chemical products. It also contains provisions for controls to regulate the supply of chemical products, and provisions ensuring compliance with, and for the enforcement of, the Code.[23]

Public consultation on the exposure draft of the bill

1.37 Public consultation on the exposure draft of the bill took place between 11 July and 22 August 2018. The Department of Agriculture and Water Resources (DAWR) received 17 submissions on the exposure draft.

1.38 In response to the submissions received during the consultation period, DAWR made a number of changes to the bill. These changes included:

- omitting a proposal for provisional registration;
- simplifying the proposed legislation for accrediting persons and removing the aggravated offence for contravening conditions of accreditation;
- aligning voluntary recalls more closely with the Australian Consumer Law;

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21 Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 14 of 2018*, 28 November 2018, pp. 10–11.

22 Department of Agriculture and Water Resources, *The National Registration Scheme*, http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/regulation (accessed 7 December 2018).

23 Australian Pesticides and Veterinary Medicines Authority, *Legislative Framework*, https://apvma.gov.au/node/4131 (accessed 7 December 2018).

- providing internal review of an APVMA decision that is substituted for a computer-based decision; and
- simplifying the provisions for extending 'data protection' periods.[24]

24 Department of Agriculture and Water Resources, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/streamlining/public-consultation (accessed 7 December 2018).