The Senate

Rural and Regional Affairs and Transport Legislation Committee

Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 [Provisions]

February 2019

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Recommendation 1

3.73 The committee recommends the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 be passed.

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).

Chapter 2

Key provisions

2.1 The bill comprises two schedules, with the first containing 14 parts and the second, two parts.

2.2 A key feature of the bill is that it transfers several aspects of APVMA responsibility to regulations. Section 6 of the Code Act contains broad regulation-making powers. This section allows the Governor-General to make regulations in relation to any matter required or permitted by the Code Act to be so prescribed.

2.3 The following summarises the bill's key provisions.

Schedule 1—Main amendments

Part 1—Approval and registration for prescribed active constituents, chemical products or labels

2.4 Part 1 proposes amendments to the Code Act Schedule (primarily to subsections 9A(2) to (5); and by inserting new sections 14C, 14D and 14E) that would create a streamlined assessment process for a new category of applications: prescribed applications for active constituents, chemical products and container labels. It is anticipated this process will be quicker and less costly than the current approval and registration processes.[1]

2.5 Under the proposed streamlined process, there would be no preliminary assessment procedure. The APVMA would be required to approve an application if:

- it meets application requirements (including safety, efficacy, trade and labelling criteria);
- it is a 'prescribed' application; and
- no disqualifying criteria apply.

2.6 The types of applications that would be prescribed applications are to be determined in regulations. The EM anticipates that they would be applications of 'sufficiently low associated risk as to warrant reduced supporting information requirements'.[2] These would be cases where minimal or no assessment of technical information occurs. The EM states that as it is conceivable no technical information may be required, the prescribed process could support the introduction of a means of self-approval or self-registration.[3] The EM provides the following examples:

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1 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 8.

2 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 8.

3 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 7–8.

- applications involving well-characterised chemistry or existing pharmacopoeial active constituents;
- products with a history of safe use; and
- applications with assessments conducted by accredited third party providers.[4]

2.7 Although prescribed applications would be subject to less scrutiny, the APVMA could consider the trustworthiness of an applicant as a 'disqualifying criteria'. However, if an applicant is disqualified on the basis of this criterion, they would still be eligible to submit an application under the standard process. According to the EM, an applicant may be disqualified on the basis of trustworthiness if they have:

- been convicted of an offence;
- been ordered to pay a civil pecuniary penalty; or
- had a registration or approval cancelled or suspended for breaching a condition or providing false or misleading information.[5]

Part 2—Information to be taken into account in determining applications

2.8 Under section 8C of the Code, the APVMA is restricted from considering new information provided by, or on behalf of, an applicant during the assessment period for an application.

2.9 The proposed amendments in Part 2 of Schedule 1 of the bill would amend section 8C to provide the APVMA with greater flexibility in dealing with certain types of information when determining an application. Under the proposal, the types of information to be taken into account would be prescribed in regulation, but may include the provision of an updated good manufacturing practice certificate.[6]

2.10 These changes would allow applicants to provide information during the application process without having to face delays, or having to make a variation application after the initial application has been assessed, approved and the product registered.

Part 3—Limits on use of information

2.11 There are currently two forms of data protection recognised under the Code. The first is that of limits on the use of information. Under this category, information that is provided to the APVMA as part of an application under the Code and relied on by the APVMA in making a decision receives a 'limitation period'. During this limitation period, the APVMA may not use the information to assess or make a

4 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 7–8.

5 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 9.

6 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 12.

decision on another application or a reconsideration unless an exemption applies. The current limitation period for this information as prescribed by the Code ranges from three years to 10 years.

2.12 The second form of data protection is for 'protected information'. This information relates to either an active constituent that has been approved or a chemical product that has been registered and then provided as part of a reconsideration. A protection period of eight years applies to this information.

2.13 Part 3 of Schedule 1 of the bill (proposing new sections 34KA and 34MA, and other consequential amendments to the Code Act Schedule), aims to extend the period of time that information used to assess an application or reconsideration for a chemical product or active constituent, is protected from use by other applicants for a period of up to five years.[7]

2.14 The EM describes the purpose of the proposed provisions:

> An innovator funds the production of information to support a new active constituent (or improved characteristics for an existing active constituent) or a new use of a chemical product. Limiting the use of information prevents competitors from using innovators' data or allows innovators to seek compensation from the competitors for use of the innovators' information. This benefits the innovator, who has incurred the cost of generating this information, and promotes innovation.[8]

2.15 The proposed provision is expected to be of particular benefit in situations of minor use, where only a low economic return is expected. In addition, the proposed amendments aim to increase the number of applications made to the APVMA for certain kinds of active constituents with new, desirable features (such as new modes of action to manage resistance) or to register certain uses (priority uses) of chemical products.[9]

Part 4—Computerised decision making

2.16 Part 4 of Schedule 1 of the bill (proposing a new section 5F; various amendments to sections 166(1), 166(1A) and 167(2A); and other consequential amendments to the Code Act Schedule), seeks to amend the Code to enable the APVMA to use computerised decision-making as part of its processes.

2.17 The bill contains a number of amendments to align the treatment of computer-made decisions with existing procedures and to provide for a review of computerised decisions.

2.18 Safeguards include proposed provisions to:

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7 This provision would extend both the 'limitation period' of three to 10 years, and the protected information period of eight years, up to a further five years.

8 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 13.

9 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 13.

- allow the APVMA to substitute a decision for a computerised decision if it is satisfied that the computerised decision is incorrect;
- ensure that a computerised decision is subject to the same reconsideration process as a decision made by an APVMA staff member; and
- provide that a substituted decision may be reviewed by the Administrative Appeals Tribunal.[10]

2.19 The EM states the intent of the amendments is to increase the efficiency of the APVMA by establishing a 'flexible legislative regime that will support future developments in information technology and business processes'.[11]

2.20 According to the EM, the APVMA will develop procedures and guidance for the implementation of computerised decision-making in accordance with the best practice principles developed by the Administrative Review Council in its report No. 46 of 2004, *Automated Decision Making*.[12]

Part 5—Accreditation of third party assessors

2.21 The proposed amendments under Part 5 of Schedule 1 of the bill (a new section 6G and other consequential amendments to the Code Act Schedule), would allow the APVMA to recognise assessments from accredited third party providers. Through a disallowable legislative instrument, the APVMA would be able to prescribe matters relating to the accreditation of persons, and the roles such accredited persons might perform. Proposed subsection 6G(2) details some of the matters that the disallowable legislative instrument might consider, including:

- criteria to be met by persons seeking accreditation;
- how accreditation is to be recognised, and for how long;
- the certificates, assessments or reports accredited persons may or must provide and the circumstances in which they must be provided;
- standards and other obligations persons must continue to meet to remain accredited;
- monitoring of compliance with conditions of accreditation;
- circumstances in which an accredited person may have the person's accreditation varied, suspended or revoked, and the review process; and
- who may deliver training to accredited persons.

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10 However, if the initial decision was not reviewable by the Administrative Appeals Tribunal (AAT), then the proposed amendment in item 35 has the result that the substituted decision is also not reviewable by the AAT. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 18.

11 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 17.

12 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 17.

2.22 The proposed amendments also allow for regulations to prescribe a method of calculating fees, with the intention the accreditation scheme will run on a cost recovery model in the future.[13]

2.23 The EM explains that the proposed accreditation scheme would have broad application to support the APVMA to accredit persons for a range of purposes.

2.24 An accredited person might prepare assessment reports either directly with or for industry for inclusion in applications made to the APVMA. Alternatively, an accredited person might undertake work that the APVMA currently undertakes, such as conducting assessments of information in applications made to the APVMA.[14]

2.25 Under the proposed amendments, accredited assessors need not be persons, and can include a 'body politic or corporate as well as an individual'. Neither do they need to be Australian citizens or located in Australia.[15] Further, accreditation would not be mandatory—the requirements only relate to particular persons who voluntarily apply to be accredited under the scheme.[16]

2.26 The EM suggests that there are a number of potential benefits that will flow from the proposed accreditation scheme. These include:

- providing applicants with greater flexibility over data assessment timeframes and cost;
- simplifying administration processes within the APVMA;
- increasing the efficiency of application processing; and
- opening data assessment to greater competition.[17]

Part 6—Voluntary recalls of chemical product

2.27 Part 6 of Schedule 1 of the bill (primarily a substitution of section 106 of the Code Act Schedule), intends to improve the voluntary recalls process by introducing specific provisions that require persons to inform the APVMA when undertaking certain voluntary recalls and requires the APVMA to publish information about such recalls.

2.28 Item 50 of the bill replaces section 106 of the Code to specify the requirements for a voluntary recall. It states that a voluntary recall applies if a person

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13 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 23.

14 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 19.

15 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 19, 21.

16 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 22.

17 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 19.

(who does not need to be a holder of the registration) voluntarily proposes to take action to recall a chemical product because it appears to the person that:

- the chemical product does not meet the safety, trade or efficacy criteria, or the label does not meet the labelling criteria; or
- the chemical product is not a registered chemical product (for example, where the concentration, composition or purity of constituents in a batch of the chemical product vary by more than the prescribed extent set out in the Register of Chemical Products).[18]

2.29 Under the proposed amendments, a person who recalls a chemical product must notify the APVMA within two days of the recall. In turn, the APVMA must publish a copy of the notice about the voluntary recall on its website within three working days and in the APVMA Gazette within 14 days. The APVMA may also publish the recall in any other manner it deems appropriate.

2.30 In its submission to the exposure draft of the bill, the Australian Competition and Consumer Commission (ACCC) had raised concerns about the duplication of notification requirements with regard to the recall of an avget product. It noted that in instances where an agvet product also met the definition of a consumer good, a supplier would have to meet the requirements of both the bill and section 128 of the Australian Consumer Law when conducting a voluntary recall.

2.31 Following the consultation period, DAWR amended the bill to ensure that voluntary recalls were aligned more closely with the Australian Consumer Law.[19]

Part 7—Notification of new information

2.32 Part 7 of Schedule 1 of the bill (various amendments to paragraphs and subparagraphs of sections 160A and 161 of the Code Act Schedule), seeks to amend the Code to provide consistency with regard to the notification of new information.

2.33 This will be achieved by provisions which oblige holders of label approvals, and applicants for both label approvals and variations to approvals or registrations, to provide 'relevant information' to the APVMA. These obligations already apply to holders of active constituent approvals and product registrations under sections 160A and 161 of the Code.[20]

2.34 Relevant information is defined as information that contradicts any information that was given in an application; and information that shows the

18 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 24.

19 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).

20 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 28.

constituent or product may not meet the safety criteria, trade criteria, efficacy criteria, or labelling criteria.[21]

2.35 The proposed amendments are intended to ensure the regulator is aware of the latest available information and provide safeguards to protect public, animal and plant health, and the environment from potential damage, where new information about an agvet chemical comes to light.[22]

Part 8—Definition of registered chemical product

2.36 Part 8 of Schedule 1 of the bill (inserting a new section 5AA to the Code Act Schedule), seeks to amend the Code's definition of a registered chemical product to provide prescribed standards for the:

- concentration range of constituents of a chemical product; and
- composition and purity of constituents of a chemical product.

2.37 These amendments seek to address an anomaly in the Code whereby the regulations can provide concentration ranges for constituents in chemical products to allow for the routine variation in constituent concentration arising in manufacturing. However, offences and civil penalty provisions in Part 4 of the Code operate in a way that prohibits the supply of a product if it is formulated differently to the registered formulation.[23]

2.38 According to the EM, this inconsistency places an unreasonable burden on the APVMA and industry because the only recourse available is for a holder to make an application to the APVMA to include more detail about a product's composition in the register. The regulatory effort associated with this task is considered inconsistent with the risks, particularly given that some provisions of the Code already provide for reasonable variations in a product's composition.[24]

2.39 The EM notes that the proposed amendments are intended to allow reasonable variations in the composition of a product and that any fundamental changes would still require the holder to submit a variation application to the APVMA.[25]

Part 9—Suspension or cancellation of approval or registration

2.40 Part 9 of Schedule 1 of the bill (substitution of section 38A of the Code Act Schedule), proposes to expand the grounds upon which the APVMA may suspend or

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21 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 28.

22 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 28.

23 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 31.

24 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 31.

25 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 31–32.

cancel approvals or registrations where information is provided that is false or misleading.

2.41 Under current provisions in the Code, the APVMA has the power to suspend or cancel an active constituent approval or product registration where false or misleading information has been provided. The proposed amendments would enable the APVMA to suspend or cancel an approval or registration if any person (not just the holder of the registration) has given false or misleading information in relation to any of the following:

- an application for approval or registration;
- an application for a variation of approval or registration;
- in response to a notice to provide information under subsection 32(1) or section 33 or 159 of the Code; or
- in the event that new information has come to light, either before or after, the APVMA has made an approval or registration decision.[26]

Part 10—Supply of registered chemical products with unapproved label

2.42 Part 10 of Schedule 1 of the bill (primarily a substitution of paragraphs 81(3)(a), (b) and (c) of the Code Act Schedule), proposes to address an inconsistency in the Code by clarifying what information must be included in a product label. The proposed amendments will specify the minimum information requirements for inclusion on a label to reduce the need for unnecessary information.

2.43 In recognition of the fact that the information on labels will change in accordance with the proposed provisions, the bill provides for a period of two years (or as determined by the APVMA) to trade out a product with previously required information on the label. Amendments in the bill will allow the APVMA to manage this transition by allowing a product (with the previously required information on the label) to be supplied, where considered appropriate.[27]

Part 11—Variation of approval or registration during suspension

2.44 Part 11 of the bill (various amendments to sections 42, 43 and 45 of the Code Act Schedule), proposes to introduce measures into the Code to deal with suspended registrations and to address the reason for a suspension. It would also allow holders to request a suspension of an approval or registration, in addition to the current option of requesting a cancellation of an approval or registration.

2.45 The bill provides that whilst a registration or approval is suspended, a person would be allowed to lodge a notice, make an application or seek a variation of the relevant particulars or conditions, provided it is relevant to the reasons for the suspension. These proposed changes would ensure that the matters with a registration

26 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 33.

27 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 35.

or approval that led to its suspension could be rectified prior to the revocation of the suspension.[28]

2.46 Under the Code, the APVMA may suspend an approval or registration. However, the APVMA does not have the power to amend a product registration to address the problem that led to the suspension of the product registration without first revoking the suspension. According to the EM, the proposed amendments correct an unintended administrative barrier which prevents the holder of a registration from dealing with the suspension matter and putting the chemical product back on the market.

2.47 Furthermore, the bill proposes to amend the Code to provide that a holder can request suspension of an approval or registration, in addition to the current option of requesting cancellation of an approval or registration. This will enable the holder to have their approval or registration suspended while they deal with any issues with it. It will ensure that the holder will not have to cancel their registration or approval to deal with administrative matters before having to re-apply for registration or approval at a later time.[29]

2.48 Part 11 of Schedule 1 is drafted on the basis that Part 4 of Schedule 1 to the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 would have commenced to provide for the variation of relevant particulars and conditions of a label approval that is suspended.[30]

Part 12—Safety, efficacy, trade and labelling criteria

2.49 Part 12 of Schedule 1 to the bill (amendments to section 5D and a new section 5E of the Code Act Schedule), contains two related measures. Item 85 of the bill amends section 5D of the Code to allow the APVMA to make regulations to prescribe matters the APVMA must consider when determining whether a label meets the labelling criteria. As it currently stands, regulation-making powers are only permitted for safety criteria, efficacy criteria and trade criteria.

2.50 Secondly, the amendments will rectify an existing anomaly, and will allow the APVMA the discretion to consider the following when making a decision as to whether an application meets the criteria with regard to safety, efficacy, trade and labelling:

- the results of any trials or experiments already carried out in a foreign country in relation to an active constituent for a proposed or existing chemical product, or in relation to a chemical product or any of its constituents;

28 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 38.

29 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 37–38.

30 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 37.

- any decisions or evaluations made by regulators of agricultural or veterinary chemicals in a foreign country; and
- any information on which a decision or evaluation mentioned in the dot point above is based.[31]

Part 13—Annual operational plans

2.51 Part 13 (amendments to Part 6, a repeal of sections 55, 56, 57 and substitution of a new paragraph 61(b) to the Administration Act), seeks to remove the need for the APVMA to develop and seek approval for an annual operational plan in addition to the corporate plan.

2.52 Under the Administration Act, the APVMA is required to prepare an annual operational plan. The plan sets out the actions that the APVMA intends to take to comply with the objectives in the corporate plan in the coming year. It provides any performance indicators considered appropriate and any information prescribed by regulations. The plan requires ministerial approval.[32]

2.53 Section 35 of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and Part 6 of the Administration Act both require the APVMA's Chief Executive Officer to prepare a corporate plan. The corporate plan is prepared annually, covering a period of four years, and requires ministerial approval. The corporate plan is also presented to the Minister for Finance, and under the PGPA Act must include the following information:

- how the entity will achieve its purposes;
- how the entity's performance will be measured and assessed, including for the purposes of preparing its annual performance statements;
- the key strategies and plans that the entity will implement in each year covered by the plan to achieve its purposes; and
- a summary of the risk oversight and management systems in place for each year of the plan.[33]

2.54 The EM notes that removing the requirement for the APVMA to prepare an annual operational plan would remove a duplication in reporting.

Schedule 2—Other amendments

Part 1—Amendments

2.55 Parts 1 and 2 of Schedule 2 include agvet chemical-related matters from the Agriculture and Water Resources Legislation Amendment Bill 2016. The matters included in the bill include amendments to the Code Act Schedule (subparagraph

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31 *Agricultural and Veterinary Chemicals Code Act 1994*, section 160(2).

32 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 40.

33 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 40.

8E(2)(b)(i) and paragraph 117A(1)(a)) to simplify notices provided by the APVMA to Food Standards Australia New Zealand under section 8E of the Code.[34]

Part 2—Repeals

2.56 Item 4 repeals the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*, as all transitional provisions for this Act are no longer required.

34 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 45.

Chapter 3

Issues raised in evidence

3.1 Most submitters to the inquiry were generally supportive of the purpose and intent of the bill.[1] However, there were a number of issues and concerns raised in relation to key provisions of the bill. This chapter explores these issues and considers the evidence provided during the inquiry.

Part 1—Approval and registration

3.2 The proposed amendments under Part 1 would insert sections 14C, 14D and 14E to the Code to provide for a streamlined assessment process for 'prescribed applications' that is faster, simpler and less costly. Prescribed applications would be for products considered to be of low- and medium-risk.[2]

3.3 Some submitters questioned the proposed changes on the basis that prescribed applications would receive minimal or no technical assessment. Grain Producers Australia (GPA) offered only partial support for the provision. While it argued in favour of reforms that accelerated the evaluation process and avoided unnecessary delays for new chemical approvals, it expressed concern that potentially minor variations requiring minimal technical assessment could in fact have significant consequences. To highlight its concerns, GPA explained that under the existing prescribed variation process, formulation changes with some chemical herbicide products had 'resulted in major changes to efficacy, particularly where lower manufacturing cost formulations have been used'.[3]

3.4 Similarly, the Grains Research and Development Corporation (GRDC) offered conditional support to the amendments on the basis that the details of what comprises 'minimal technical risk' were yet to be described in the regulations. GRDC referenced the GPA's concerns with the existing prescribed variation process, and suggested that the APVMA would need a legislative mechanism to withdraw prescribed approvals and registrations where there were adverse experiences.[4]

3.5 Dr Ian Musgrave questioned the utility of the amendments on the basis that 'it is hard to imagine a circumstance where minimal or no assessment of technical

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1 As a case in point, there was broad support for the proposed measures in Part 6 of the bill to formalise the voluntary recall process on the basis that it would improve transparency. Grain Producers Australia, *Submission 3*, p. 3; National Farmers' Federation, *Submission 4*, p. [10]; Animal Medicines Australia, *Submission 5*, pp. 3–4; Herbicide Consortium, *Submission 7*, p. [3]; Grains Research and Development Corporation, *Submission 10*, p. 1.

2 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 7–9.

3 Grain Producers Australia, *Submission 3*, p. 3.

4 Grains Research and Development Corporation, *Submission 10*, pp. 1, 5.

information is required for a new approval'.[5] Similarly, Gene Ethics argued that there was a 'lack of objective measures and a general paucity of good data to establish that certain chemicals are of low enough risk to justify simpler regulatory processes'. It questioned how a chemical could be classed as low risk without any supporting information or technical evidence being presented to the regulator.[6]

3.6 However, according to DAWR, the process for prescribed applications will be similar to that which already exists for notifiable and prescribed variations, which can be submitted once a product has been approved and registered. Further, it made the point that safeguards will remain in place to ensure that only safe and effective products continue to be available.[7]

3.7 A number of submitters voiced their support for the proposed amendments for reasons of efficiency. The National Farmers' Federation (NFF) and Animal Medicines Australia (AMA) argued in favour of the proposed amendments on the basis that they would lead to faster and less costly approval and registration processes, and would better align regulatory effort with risk.[8]

Part 2—Information to be taken into account in determining applications

3.8 Part 2 contains amendments to allow the APVMA to consider, during the assessment period, 'certain types of new information' not included in an original application.

3.9 Some submitters including Dr Ian Musgrave raised questions about the amendments. He suggested that the changes would make the application process more complex and piecemeal rather than providing flexibility.[9]

3.10 Gene Ethics also opposed the amendments. It argued that the bill and EM had failed to define the scope of 'certain types of new information' and that the public had the right to know what was envisaged.[10]

3.11 However, in its submission, DAWR clarified the purpose of the amendments. It explained that prior to the 2013 Amendment Act, applicants were able to provide information to the APVMA while an assessment was underway. This led to the provision of sub-standard or incomplete applications and additional work for the APVMA in undertaking additional assessments not foreseen when applications were first made. The 2013 amendments aimed to encourage the submission of complete and high-quality applications as the APVMA was prevented from considering new

5 Dr Ian Musgrave, *Submission 8*, p. [3].

6 Gene Ethics, *Submission 9*, pp. 4, 8.

7 Department of Agriculture and Water Resources, *Submission 11*, p. 3.

8 National Farmers' Federation, *Submission 4*, p. [8]; Animal Medicines Australia, *Submission 5*, p. 2; Herbicide Consortium, *Submission 7*, p. [1].

9 Dr Ian Musgrave, *Submission 8*, p. [3].

10 Gene Ethics, *Submission 9*, p. 4.

information after an application had been made, with one exception. The APVMA could specifically request information under a section 159 notice.

3.12 DAWR noted that the proposed amendments in the bill would provide for a more efficient system as certain types of (limited) information could be provided and considered by the APVMA during the assessment period for an application without the need for a section 159 notice.[11]

3.13 The AMA voiced its support for this measure on the basis that it would remove the need for the APVMA to issue section 159 notices to request simple, clarifying information that required no technical assessment. It also made the point that the changes would address the current need for applicants to submit a variation application immediately after an original application had been finalised in order to submit additional information.[12] The AMA further explained:

> Given the long timeframes for some application types, it is reasonable that applicants will often have more, or updated, information available while the original information is being assessed. Simple clarifying information, such as updated Good Manufacturing Practice certificates or clearer copies of a document already provided, is primarily administrative and does not require technical assessment. This simple clarifying information should not be associated with additional assessment timeframe and associated fees, like those imposed with the issue of a S159 notice or submission of a variation application.[13]

3.14 Similarly, the Herbicide Consortium, GPA, NFF and GRDC supported the proposed changes on the basis they would speed up the evaluation process and avoid unnecessary delays for new chemical approvals.[14]

Part 3—Limits on the use of information

3.15 Part 3 provides for extensions to existing limitation and protection periods for information used to assesses or reconsider certain chemical products. This amendment aims to encourage chemical companies to register certain new uses of chemical products, specifically for minor uses.[15]

3.16 The amendments provide that an extension would be automatically triggered if a certain type of application (prescribed by regulation) was lodged at least three years prior to the end of the existing limitation or protection period. It was

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11 Department of Agriculture and Water Resources, *Submission 11*, pp. 3–4.

12 Animal Medicines Australia, *Submission 5*, p. 2.

13 Animal Medicines Australia, *Submission 5*, p. 2.

14 Grain Producers Australia, *Submission 3*, p. 3; National Farmers' Federation, *Submission 4*, p. [9]; Herbicide Consortium, *Submission 7*, p. [2]; Grains Research and Development Corporation, *Submission 10*, p. 1.

15 Department of Agriculture and Water Resources, *Submission 11*, p. 2.

foreshadowed by DAWR that the regulations defining eligible applications would include technical detail and priority uses that would change over time.[16]

3.17 The proposed provisions were supported by some submitters including the NFF.[17] Others offered conditional support whilst raising a number of concerns. A few submitters including Gene Ethics opposed the measures outright on the basis that they place a 'restraint on public access to information and data submitted in support of applications and chemical reviews'.[18] GPA also suggested that the measures would not provide the tools for industry to remain internationally competitive and that greater investment was required.[19]

3.18 GRDC supported the intent of the proposed reforms, but warned the method for determining the additional protection periods was not balanced across crop groupings and could, in fact, serve as a disincentive for some minor use crops.[20]

3.19 Whilst the AMA supported the amendments in principle, it held the view that the provisions would have limited application to veterinary medicines. The AMA stated:

> Unlike crops, animal species are rarely grouped together. Simple groupings of animal species, or generalisations between animal species, cannot be made because the differences in drug pharmacokinetics and pharmacodynamics between species are numerous and often unpredictable. Veterinary applications will continue to need to be assessed on a case-by-case basis to ensure the safety and efficacy of use in each animal species.[21]

3.20 The Herbicide Consortium did not oppose the measures but warned of the negative consequences for growers. It accepted that the measures would provide incentives for chemical companies to develop and register new chemistry that would aid growers and negate the need for minor use permits. At the same time, it raised concern that the measures would likely keep prices higher for longer because of reduced competition from generics.[22]

3.21 In its submission, DAWR explained some chemical uses that are available overseas are not registered in Australia because they are not expected to produce sufficient economic return to offset the cost of approval or registration (including data generation), despite farmers (and other users) needing these chemical uses. It noted that the proposed measures will encourage more uses to be included on product labels and could reduce the need for permits.[23] DAWR also made the point that encouraging

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16 Department of Agriculture and Water Resources, *Submission 11*, p. 4.

17 National Farmers' Federation, *Submission 4*, Attachment 1, pp. [8–9].

18 Gene Ethics, *Submission 9*, p. 4.

19 Grain Producers Australia, *Submission 3*, pp. 4, 9.

20 Grains Research and Development Corporation, *Submission 10*, pp. 1, 5–6.

21 Animal Medicines Australia, *Submission 5*, p. 3.

22 Herbicide Consortium, *Submission 7*, pp. 2–3.

23 Department of Agriculture and Water Resources, *Submission 11*, p. 4.

more priority uses to be added to product labels could also reduce the regulatory burden on product users who may otherwise seek permits. [24]

Part 4—Computerised decision-making

3.22 Amendments proposed under Part 4 of the bill provide for the APVMA to use a computer program to make a decision, exercise any power or comply with any obligation.

3.23 The proposed amendments allow for the APVMA to substitute a computerised decision within 60 days if it believes that the decision made by the computer program is incorrect. By introducing computerised decision-making, the measures are designed to contribute to greater efficiency in decision-making.[25]

3.24 In its submission to the inquiry, DAWR stated that similar provisions were already contained in the *Therapeutic Goods Act 1989*, and proposed in the Industrial Chemicals Bill 2017.[26]

3.25 There was support for the introduction of computerised decision-making from a number of submitters. The GPA supported the reform to the extent it would promote a move from paper-based to digital systems.[27] Similarly, GRDC recognised the potential for the APVMA to integrate the regulatory system into the digital age and the fast approaching autonomous machine age.[28]

3.26 The NFF supported computerised decision-making for largely administrative processes and noted the importance of allowing the APVMA to substitute an incorrect computerised decision.[29] The Herbicide Consortium supported the reform on the basis it would benefit small users by simplifying the regulatory process.[30]

3.27 Other submissions qualified their support. For instance, whilst supportive of the measure in principle, the AMA cautioned that any computerised decision-making system would need to be routinely validated to ensure that the correct decisions were made to reduce the need for additional human verification. Otherwise, the efficiency gains brought about by the introduction of the automated decision-making system may be undermined.[31]

3.28 Dr Musgrave acknowledged that computerised decision-making could accelerate certain administrative processes but also raised concern that the bill did not

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24 Department of Agriculture and Water Resources, *Submission 11*, p. 4.

25 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 17.

26 Department of Agriculture and Water Resources, *Submission 11*, p. 5.

27 Grain Producers Australia, *Submission 3*, p. 3.

28 Grains Research and Development Corporation, *Submission 10*, pp. 1, 6.

29 National Farmers' Federation, *Submission 4*, p. 9.

30 Herbicide Consortium, *Submission 7*, p. [3].

31 Animal Medicines Australia, *Submission 5*, p. 3.

provide any detail about how it would be administered. Noting the failures of several high profile computerised systems, he suggested that the provisions be reconsidered.[32]

3.29 Gene Ethics opposed the measure on the basis it was the first step in delegating substantial decision-making powers to algorithms.[33]

3.30 However, DAWR confirmed that a cautious approach was to be taken whereby computerised decision-making would be used where the APVMA considered it appropriate. While highlighting the safeguards in place to review and substitute a computerised decision, DAWR suggested that computerised decision-making would be particularly suitable for decisions of a largely administrative nature.[34]

Part 5—Accreditation of assessors

3.31 Part 5 provides for the accreditation of third party assessors. Under the proposal, assessors would be accredited for two main purposes:

- to undertake assessments on behalf of the APVMA, as currently occurs when the APVMA outsources some elements of technical assessments to third party external assessors who have particular expertise in certain areas; and
- to undertake assessments on behalf of industry for inclusion in applications made to the APVMA.

3.32 Most submitters acknowledged the need for industry to have access to a timely and effective regulatory system.[35] A substantial number supported the proposed scheme or offered in principle support, subject to certain concerns being addressed. It was recognised that many of these concerns may be addressed when the details of the scheme are prescribed in regulation. One submission opposed the scheme outright on public interest and accountability grounds.[36]

3.33 Amongst the concerns raised in submissions were issues relating to regulatory risk and the potential for conflicts of interest that are inherent in third party assessment models. The Western Australia Department of Primary Industries and Regional Development (DPIRD) acknowledged the APVMA had used independent assessors under contract for a number of years, most often for a particular assessment or task. However, along with the GRDC, DPIRD identified the proposed system as fundamentally different in one key respect—assessors would be selected by a registrant.[37]

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

33 Gene Ethics, *Submission 9*, p. 5.

34 Department of Agriculture and Water Resources, *Submission 11*, p. 5.

35 See, for instance: Herbicide Consortium, *Submission 7*, p. [3]; Community and Public Sector Union, *Submission 12*, p. [1].

36 Gene Ethics, *Submission 9*, pp. 5–6.

37 Department of Primary Industries and Regional Development, Western Australia, *Submission 2*, p. 2; Grains Research and Development Corporation, *Submission 10*, p. 5.

3.34 These submitters cautioned that allowing chemical companies to pay accredited third party providers to undertake assessment services directly on their behalf could risk the integrity, credibility and reputation of the regulatory process. For instance, GRDC suggested that the system had the potential to put undue pressure on assessors to approve data packages that were marginal to meeting the regulatory requirements.[38] The Community and Public Sector Union (CPSU) added its concerns:

> Chemical companies invest significant resources in product development and delays in regulatory approval can carry significant costs. It is foreseeable that they may prioritise their financial interests ahead of the public interest. Independent assessors would also have a financial interest in attracting and retaining assessment work. This increases the risk of decisions being influenced by financial concerns or pressures.[39]

3.35 As to the potential for a real or perceived conflict of interest, the concerns raised by the DPIRD and GRDC were echoed by Dr Musgrave who stated:

> The AVMPA not only must be independent, but must been seen to be independent for there to be public trust in the registration process. The evaluation process must be at arm's length from the sponsors…and they should not be paid by the sponsors…the perceived conflict of interest in the case will be substantial (even though the assessors are professionals of the highest integrity, it is the perceived conflict of interest that is the issue).[40]

3.36 The suggested mitigation measures for regulatory risk and conflict of interest concerns varied. The DPIRD called for robust management mechanisms.[41] GRDC suggested accredited external assessors should only assess low-risk applications and further, could be allocated to registrants by the APVMA. It argued that these measures would allow the assessor to maintain independence from the registrant and uphold the integrity of the registration system.[42] Dr Musgrave emphasised the importance of establishing formal processes and requirements for accreditation, data handling and conflicts of interest.[43]

3.37 Concerns with regard to the administration, cost and governance of the accreditation scheme were raised by the AMA, which offered in principle support for the proposal. The AMA recommended consultation with industry to ensure any arrangement put in place provided a net benefit for the community.[44] DAWR confirmed in its submission that any decision about penalties, fees or other aspects of

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38 Grains Research and Development Corporation, *Submission 10*, p. 5.

39 Community and Public Sector Union, *Submission 12*, p. [1].

40 Dr Ian Musgrave, *Submission 8*, p. [3].

41 Department of Primary Industries and Regional Development, Western Australia, *Submission 2*, p. 2.

42 Grains Research and Development Corporation, *Submission 10*, p. 5.

43 Dr Ian Musgrave, *Submission 8*, p. [3].

44 Animal Medicines Australia, *Submission 5*, p. 3.

the scheme, would be subject to consultation when the legislative instrument setting out the scheme was developed.[45]

3.38 Concerns about liability were raised by the GPA, which partly supported the reforms, citing the potential of the scheme to break the current APVMA 'monopoly'. The GPA stated there would need to be provisions in the regulations to protect the liability of assessors, with final decisions and liability risk being held by the APVMA. It warned that failure to put in place limitations on liability from negligence would raise the cost of insurance premiums and could make the program unworkable.[46]

3.39 In response to some of the concerns raised about the proposal, DAWR highlighted the point that the APVMA was already working with industry on a pilot project in which third party external assessors were engaged directly by applicants (from a list of APVMA-approved assessors) to conduct pre-application assessment of efficacy and target animal and crop safety.[47]

3.40 Furthermore, by opening data assessment to competition, DAWR made the point that applicants would get more control over data assessment timeframes and costs; processes within the APVMA could be simplified; and efficiency would be improved. It further clarified that while the bill provides for the accreditation of assessors, the particulars will be determined in the regulations.[48]

Part 7—Notification of new information

3.41 Under this proposed amendment, obligations will be placed on holders of label approvals, and applicants for label approvals and variations to approvals or registrations, to provide relevant information to the APVMA. Relevant information is information that shows an active constituent or product may not meet statutory criteria or contradicts the information in the application or information the APVMA has recorded in the Record of Approved Active Constituents for Chemical Products kept under section 17 of the Code or in the Register of Agricultural and Veterinary Chemical Products (Register) kept under section 18 of the Code.[49]

3.42 In its submission, DAWR noted that the obligations already apply to holders of active constituent approvals and product registrations, and the proposed amendments would address a gap in the current requirements in the Code. DAWR explained that the measures would ensure that the regulator is aware of the latest information available while also providing safeguards to protect public, animal and

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45 Department of Agriculture and Water Resources, *Submission 11*, p. 7. See also: Department of Agriculture and Water Resources, *Consultation on Streamlining Regulation of Agricultural and Veterinary Chemicals*, http://www.agriculture.gov.au/SiteCollectionDocuments/ag-food/agvet/reforms/consultation-streamlining-reg-agvet.pdf (accessed 14 December 2018), pp. 12–14.

46 Grain Producers Australia, *Submission 3*, pp. 3, 7.

47 Department of Agriculture and Water Resources, *Submission 11*, p. 5.

48 Department of Agriculture and Water Resources, *Submission 11*, p. 5.

49 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 3, 28.

plant health from potential damage when new information about an agvet chemical comes to light.[50]

3.43 There was general support for these reforms in submissions to the inquiry. The GPA and GRDC voiced their support, as did the NFF, which encouraged more consistency in agvet chemical labelling. Similarly, the Herbicide Consortium supported the change and encouraged the APVMA to communicate the changes with permit holders.[51]

3.44 Gene Ethics also supported the proposal so long as any changes did not compromise existing strict reporting rules. Raising a related matter, Gene Ethics highlighted the importance of interested public and advocacy groups having a clear role in, and path to, notifying the APVMA of new evidence and information as it became available. It further noted that the regulator should be required to review and respond to such advice, in consultation with those who submitted it.[52]

Part 8—Definition of registered chemical product

3.45 Part 8 of the bill proposes to amend the Code to allow for variations, within certain prescribed limits, of the concentration of constituents, the kinds of constituents, and the composition and purity of constituents in chemical products—as might occur, for example, during standard manufacturing processes.

3.46 Many submitters supported the proposed reform, including the NFF and the GPA, however others raised concerns.[53] The AMA recognised the measure as a more efficient way to accommodate routine (safe) variations in constituent concentrations that arise during manufacture, but which do not represent fundamental changes in the composition of that product, or affect the quality, efficacy or safety of that product.[54] However, it argued that veterinary chemical products should be considered differently to agricultural chemical products. The AMA stated the majority of veterinary products were manufactured in compliance with the Australian Code of Good Manufacturing Practice (the GMP Code), or equivalent overseas GMP codes, which included strict requirements for quality assurance and batch consistency.[55]

3.47 Other submitters questioned whether small variations would always be safe. GRDC offered its conditional support on the proviso that there was an appropriate

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50 Department of Agriculture and Water Resources, *Submission 11*, p. 8.

51 Grain Producers Australia, *Submission 3*, p. 3; National Farmers' Federation, *Submission 4*, p. [10]; Animal Medicines Australia, *Submission 5*, p. 4; Herbicide Consortium, *Submission 7*, p. [4]; Grains Research and Development Corporation, *Submission 10*, p. 1.

52 Gene Ethics, *Submission 9*, pp. 6–7, 9.

53 Grain Producers Australia, *Submission 3*, p. 3; National Farmers' Federation, *Submission 4*, p. [11].

54 Animal Medicines Australia, *Submission to consultation on Streamlining Regulation Bill*, August 2018, p. 8, http://www.agriculture.gov.au/SiteCollectionDocuments/ag-food/agvet/exp-draft-submissions/ama.pdf (accessed 12 December 2018).

55 Animal Medicines Australia, *Submission 5*, p. 4.

legislative mechanism to withdraw approvals where small changes resulted in adverse experience reports. It explained:

> While the proposed changes are deemed low risk, certain combined changes across the other constituents could result in decreased efficacy or product stability. If such unintended consequences occur the APVMA needs to have the legislative mechanisms to withdraw the approvals or change the standards.[56]

3.48 This point was expanded by Dr Musgrave who stated:

> While the idea that there can be some degree of variation in the chemical constituents of a product (with in manufacturing tolerances) is attractive, this section needs more clarity. While a ± 5% concentration of an active ingredient is not problematic, these tolerances should be carefully defined…Non active ingredients might be assumed to be less of a problem, but the human health literature is replete with examples where supposed non-active excipient substitution caused severe health issues. The current proposal lacks appropriate detail.[57]

3.49 Gene Ethics opposed the proposal and urged the APVMA to develop a scientific framework for measuring variations in agvet chemical products, to provide a means of measuring whether any deviation from the standard formula approved by the APVMA was minor or major.[58]

3.50 However, in its submission, DAWR emphasised the point that the measure would not allow for fundamental changes in a product's composition—such changes would continue to require a variation application.[59] It further clarified that under the current legislation, the concentration of each constituent in a chemical product had to be the same as the concentration recorded in the Register. It noted that this did not allow for routine, safe variations in constituent concentration arising in manufacturing. Although regulations currently allowed for the regulator to prescribe concentration ranges, offences and civil penalty provisions in Part 4 of the Code meant a product could not be supplied if it was formulated differently to the 'registered' formulation. The consequence of this inconsistency was that holders had to make an application to the APVMA to include more detail about a product's composition to the Register. This regulatory effort was considered to be inconsistent with the risks.[60]

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56 Grains Research and Development Corporation, *Submission 10*, pp. 1, 6.

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

58 Gene Ethics, *Submission 9*, p. 7.

59 Department of Agriculture and Water Resources, *Submission 11*, p. 9.

60 Department of Agriculture and Water Resources, *Submission 11*, p. 9.

Part 9—Suspension or cancellation of approval or registration for provision of false or misleading information

3.51 The proposed amendments in Part 9 of the bill aim to address existing anomalies to provide more comprehensive grounds for suspending or cancelling approvals or registrations where false or misleading information is given in connection with an application.[61]

3.52 Most submitters, including the GPA, NFF, AMA and GRDC supported the reform, noting the importance of having uniform provisions for suspension or cancellation when false or misleading information had been provided to the regulator.[62]

3.53 Gene Ethics also supported the proposed reforms on the grounds that it was appropriate to broaden the circumstances where a more proportionate APVMA response was available to sanction instances where false or misleading information had been supplied. It did, however, question whether the grounds for suspension or cancellation went far enough to include claims and information in advertising, promotions and advice.[63]

Part 10—Supply of registered chemical products with unapproved label

3.54 Proposed amendments under Part 10 of the bill aim to clarify what information must be included in a label; and to allow for trade out of a product which contains a label previously approved but where the label is subject to new required information.

3.55 The GPA supported the reform to make the requirements for minimum information on labels clearer, noting the amendment would clarify the need for the label to contain information like the nominated agent, the holder of approval and the marketer of the product.[64] Similarly, GRDC supported the proposal while the AMA stated it did not oppose the amendments.[65] The NFF was supportive, but also noted that more work was required to make labels consistent and more user-friendly.[66]

Part 11 —Variation of approval or registration during suspension

3.56 Part 11 amendments provide for two issues:

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61 Department of Agriculture and Water Resources, *Submission 11*, p. 9.

62 Grain Producers Australia, *Submission 3*, p. 3; National Farmers' Federation, *Submission 4*, pp. [8, 11]; Animal Medicines Australia, *Submission 5*, p. 4; Grains Research and Development Corporation, *Submission 10*, p. 1.

63 Gene Ethics, *Submission 9*, p. 7.

64 Grain Producers Australia, *Submission 3*, p. 3.

65 Animal Medicines Australia, *Submission 5*, p. 4; Grains Research and Development Corporation, *Submission 10*, p. 1.

66 National Farmers' Federation, *Submission 4*, p. [11].

- to allow the holder of a suspended registration to address the reasons for the suspension whilst it is suspended; and
- to allow for a holder to request a suspension (rather than requiring the holder to request a cancellation), to deal with administrative matters.

3.57 The NFF, GRDC and AMA supported the amendment on the grounds of efficiency. The AMA stated that it would deliver small efficiency improvements for the regulator, and significant improvements for the applicant to return a product to the market.[67]

3.58 The GPA partly supported the changes. It agreed on the need for a more pragmatic mechanism to vary a suspended chemical product registration in some cases. However, it warned that making the process too easy might result in registrants failing to take timely responsibility for the registration of their products, preferring to manage situations after the effect. It suggested that a penalty may be required in instances of a continued suspension.[68]

Part 12—Safety, efficacy, trade and labelling criteria

3.59 The measures proposed in Part 12 would permit regulations to be made with regard to labelling criteria; and allow for a regulation to direct the APVMA to have regard to international data when determining whether an active constituent or chemical product meets safety criteria, efficacy criteria, trade criteria and labelling criteria.

3.60 GRDC supported the proposed reform, as did the AMA, though it noted the APVMA had already taken administrative action that had substantively the same effect as this regulatory reform measure.[69] The GPA also noted that the APVMA had already taken administrative action to maximise the use of international data in its assessments. The GPA was concerned that this requirement might become compulsory. The GPA also argued that:

- the change would unnecessarily increase the operational demands of the APVMA, requiring unsolicited review assessment under their normal assessment process; and
- there were sovereignty risks to creating legislative review triggers in Australia based on overseas information.[70]

3.61 The NFF agreed that the APVMA had to retain discretion over how it used international data, and its decision-making role in registrations and approvals had to

67 National Farmers' Federation, *Submission 4*, p. [12]; Animal Medicines Australia, *Submission 5*, p. 4; Grains Research and Development Corporation, *Submission 10*, pp. 2, 6.

68 Grain Producers Australia, *Submission 3*, pp. 3, 7.

69 Animal Medicines Australia, *Submission 5*, p. 4; Grains Research and Development Corporation, *Submission 10*, p. 2.

70 Grain Producers Australia, *Submission 3*, pp. 3, 8.

be preserved. Nevertheless, it did not oppose the measures, acknowledging that it was important for the APVMA to continue considering international data.[71]

3.62 DAWR acknowledged the concerns raised in evidence about sovereignty risks. It explained if a supporting regulation was made in the future that required the APVMA to take account of international data, the APVMA would retain discretion over how it used the material and its decision-making role in registrations and approvals would be preserved. DAWR continued:

> The potential benefit of such a regulation, if the government ever considered it necessary, would be to support the APVMA's current approach to using international assessments and data, and to provide greater predictability for stakeholders about the APVMA's ongoing use of international data and assessments.[72]

Part 13—Annual operational plan

3.63 The proposed amendments in Part 13 of the bill aim to eliminate the duplication caused by the APVMA being required to develop and seek approval for an annual operational plan and a corporate plan, reducing this requirement to preparing a corporate plan only.

3.64 Many submitters supported the reform provided it removed duplication and inefficiencies; ensured the APVMA's resources were better dedicated to its core business of providing high quality, rigorous and timely product approvals and registrations; and provided transparency on operational activities.[73]

3.65 Both the GPA and Gene Ethics, however, opposed the amendment on the grounds that it would reduce the transparency and accountability of the APVMA.[74]

Part 14—Other amendments

3.66 Under subsection 4(4) of the Amendment Act, the minister is required to provide a report to parliament on the amendments made by that Act within 15 sitting days after 1 July 2019. Separately, the minister must also ensure, at least every 10 years, that a review is made of the agvet chemical regulatory framework under section 72 of the Administration Act.

3.67 Several submitters supported the amendment with regard to reporting requirements, including the AMA, NFF and GRDC. These submitters agreed that alignment would avoid duplication and administrative costs.[75]

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71 National Farmers' Federation, *Submission 4*, p. [12].

72 Department of Agriculture and Water Resources, *Submission 11*, p. 11.

73 See: National Farmers' Federation, *Submission 4*, p. [12]; Animal Medicines Australia, *Submission 5*, p. 5; Grains Research and Development Corporation, *Submission 10*, p. 2.

74 Grain Producers Australia, *Submission 3*, pp. 4, 8; Gene Ethics, *Submission 9*, p. 8.

75 National Farmers' Federation, *Submission 4*, p. [13]; Animal Medicines Australia, *Submission 5*, p. 5; Grains Research and Development Corporation, *Submission 10*, p. 2.

3.68 However, the GPA opposed the amendment on the basis that the review of two different measures may result in an incomplete assessment. It suggested that:

> The 10 year review of the AgVet chemical regulatory framework under section 72 of the Administration Act should be conducted separately and consider the broader strategic issues of future legislative reforms including digital data, labels and systems, autonomy in application and use in legislative label consideration and reforms…allowing consideration of new science of chemical, biological and biochemical technology.[76]

3.69 The point was made in evidence that it is inefficient to conduct two parallel reviews when the issues in section 4 of the Amendment Act would be better aligned with the review required by section 72 of the Administration Act. For this reason, the bill proposes to align the timing of the review required under section 4 of the Amendment Act and that of the review required under section 72 of the Administration Act. As noted by DAWR, this would consolidate the timing of the two reviews and avoid the need for separate reviews of agvet legislation.[77]

Committee view

3.70 Evidence to the committee indicated broad support for the provisions of the bill and its intent to improve the effectiveness of the regulation of agvet chemicals in Australia.

3.71 The committee notes that many of the concerns raised in relation the bill arise from the fact that much of the detail as to how the amendments will operate in practice will be specified in regulations. However, the committee recognises that DAWR has committed to consulting with industry and other stakeholders as it prepares the regulations. To inform this process, the committee encourages DAWR to draw on the evidence provided throughout this inquiry and during the consultation period.

3.72 The committee is satisfied the bill will improve the efficiency and effectiveness of the national system for regulating agvet chemical products in Australia. Therefore, the committee recommends that the bill be passed.

Recommendation 1

3.73 The committee recommends the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 be passed.

Senator Barry O'Sullivan

Chair

76 Grain Producers Australia, *Submission 3*, pp. 3, 8.

77 Department of Agriculture and Water Resources, *Submission 11*, p. 11.

Australian Labor Party Dissenting Report

1.1 Labor acknowledges that the Committee received broad support for the provisions of the bill and its intent to improve the effectiveness of the regulation of agvet chemicals in Australia.

1.2 However, Labor shares the real concerns raised by stakeholders in relation to various measures in the bill, particularly to the lack of detail as to how the amendments will operate in practice via regulations.

1.3 Labor currently does not support Part 5—Accreditation of assessors, without the concerns raised by the Western Australian Department of Primary Industries and Regional Development, Grains Research and Development Corporation, and Community and Public Sector Union being properly addressed.

1.4 Whilst the Department of Agriculture and Water Resources (DAWR) has committed to consulting with industry and other stakeholders, Labor is of the opinion that these consultations should be undertaken prior to the passing of the bill as whole.

1.5 Labor recommends that the Government remove the Part 5—Accreditation of assessors measure before full support for the bill can be provided.

1.6 If the Government refuses to amend its own bill, Labor will not support the bill as a whole.

Recommendation 1

1.7 The Australian Labor Party recommends that the Government remove the Part 5—Accreditation of Assessors measure.

Senator Glenn Sterle
Deputy Chair

Australian Greens Dissenting Report

1.1 Evidence presented in submissions to both this inquiry and others relating to the APVMA have demonstrated that due to the relocation to Armidale, the APVMA has lost capacity and is unable to meet its core functioning.

1.2 However, the Greens do not believe that this loss of functioning should be rectified by relying on third party assessments.

1.3 The potential conflict of interest that will be created by registrants being able to select their own third party providers to conduct assessments is galling. The CPSU sums this up well:

> Chemical companies invest significant resources in product development and delays in regulatory approval can carry significant costs. It is foreseeable that they may prioritise their financial interests ahead of the public interest. Independent assessors would also have a financial interest in attracting and retaining assessment work. This increases the risk of decisions being influenced by financial concerns or pressures.[1]

1.4 While accreditation may provide some degree of restraint, the Bill would delegate the specifics of the accreditation of third party assessors to the APVMA itself, without parliamentary oversight.

1.5 Collectively these changes not only risk exacerbating the existing perceptions of a lack of independence and good process within the APVMA, but could be interpreted as the privatisation of our chemical assessment regime.

1.6 It is hard to interpret this shift to needing outside support from third parties as anything other than an admission that the relocation strategy has failed.

1.7 Other measures contained in the Bill are equally problematic. Multiple submitters raised concerns with the intent to streamline assessment of 'prescribed applications', pointing to the lack of clarity in the Bill around how the APVMA will identify risk and what the appropriate thresholds for determining 'low' or 'medium' risk would be.

1.8 Further concerns were raised about the Bill's changes to the limitation and protection periods for private information, which would further erode the public's access to timely information and could negatively impact input costs for growers.

1.9 Given the ongoing crisis in the legitimacy and perceptions of independence of the APVMA, a Bill which reduces regulatory oversight, reduces public oversight and outsources the core functioning of the body is a Bill that is going in the entirely wrong direction.

1.10 While the Greens acknowledge the problems created for the APVMA by the relocation, alternative solutions to 'streamlining regulation' must be found if the APVMA is to maintain public confidence.

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1 Community and Public Sector Union, *Submission 12*, p. [1].

Recommendation 1

1.11 The Australian Greens recommend that the Bill be opposed.

Senator Janet Rice
Australian Greens

Appendix 1

Submissions received

Submission Number	Submitter
1	CropLife
2	Department of Primary Industries and Regional Development WA
3	Grain Producers Australia
4	National Farmers' Federation
5	Animal Medicines Australia
6	Pesticide Action Group of Western Australia
7	Herbicide Consortium - Forest Industries Research Centre
8	Dr Ian Musgrave
9	Gene Ethics
10	Grains Research and Development Corporation
11	Department of Agriculture and Water Resources
12	Community and Public Sector Union
13	Ms Corinne Coombs