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.